

6180



*Health Care in Transition: Technology
Assessment in the Private Sector*

Richard Reffig

DRU-1443-DHHS/ASPE/AHCPR

July 1996

Prepared for the Department of Health and Human Services, the Assistant Secretary for Planning and Evaluation, and the Agency for Health Care Policy and Research



The RAND unrestricted draft series is intended to transmit preliminary results of RAND research. Unrestricted drafts have not been formally reviewed or edited. The views and conclusions expressed are tentative. A draft should not be cited or quoted without permission of the author, unless the preface grants such permission.

RAND is a **nonprofit** institution that helps improve **public** policy through research and analysis. RAND's publications and drafts do **not** necessarily **reflect the** opinions or policies of its research sponsors.

PREFACE

Medical technology, broadly construed, embraces innovations in medicine--new drugs, **biologics**, medical devices, and procedures--as well as existing therapeutic and diagnostic capabilities. The evaluation of the clinical and cost-effectiveness of medical technology, therefore, is a matter of substantial interest to many parties. Technology *assessment* (**TA**) is the term most often applied to such evaluation.

Much attention has been given in the past two decades to the exercise of a strong federal government role in technology assessment, most notably with the creation of the National Center for Health Care Technology (NCHCT) within the Public Health Service in the late 1970s. NCHCT was discontinued in 1982 and succeeded by a smaller Office of Health Technology Assessment (OHTA). When NCHCT met its demise, policy makers turned to non-government or **public-private** alternatives. One of these was the Council on Health Care Technology of the Institute of Medicine, which existed from 1985 through 1989. Another alternative was proposed by the Physician Payment Review Commission in 1994, namely, a new government agency for national coverage decisions. Both of these entities, one actual and one proposed, however, were national or centralized organizations.

A strong national TA organization has not developed, however, either at the federal government level or in the private sector and it appears very unlikely that the situation will change any time in the near future. From the perspective of the 1993-94 failure of health care reform legislation, the forceful emergence of managed care, and the continuing rapid change in all aspects of the health care system, then, questions arise about the extent of TA activity in the private health care sector, especially in managed care, whether this activity fulfills the functions that were once expected of the federal government, and the implications of these developments for the federal government's role in TA. These questions are the subject of this report.

PREFACE

This report is addressed to all those concerned with the institutions and processes by which medical technology is evaluated, both in the public and private sectors of the health care system. In addition, those concerned with clinical practice guidelines will also find the report of interest, as both TA and guidelines share a commitment to evidence-based analyses. The audiences for this report include not just those having focused responsibilities in technology assessment, but all those policy makers and managers who are actual or prospective users of TA. In the federal government, the audiences include Members of Congress and their staff, and officials in the Department of Health and Human Services, the Department of Veterans Affairs, the Department of Defense, among others. In state governments, Medicaid programs and health insurance commissioners should also find it useful. The private sector audiences include managed care organizations, indemnity insurers, corporate purchasers of health care services, health insurance purchasing cooperatives, hospitals, physicians, and manufacturers of drugs, **biologics**, and medical devices.

This research was sponsored by the Office of the Assistant Secretary for Planning and Evaluation/Health (ASPE) and the Agency for Health Care Policy and Research (AHCPR), both of the Department of Health and Human Services. I was very fortunate to have as project officers two veterans of TA discussions, Cheryl Austein, Director of the Division of Public Health Policy of ASPE and Peter Bouxsein, then Assistant to the Administrator of AHCPR. They supplied a continuing reality test throughout the project.

SUMMARY

The policy discussion of technology assessment (**TA**) in medicine has focused most of its attention historically on the role of the federal government. This report focuses on TA in the private health care system. Although some attention is given to TA in the hospital and physician sectors, the report is concerned primarily with TA in the managed care sector.

Innovation in medical technology (drugs, medical devices, and clinical procedures) has been identified by many analysts as a major factor driving the relentless increase in national expenditures for health care services. At the same time, innovation in medicine is regarded by many as a primary guarantor of quality health care and the only pathway to finding new solutions to both old and new clinical problems.

The efforts, largely unsuccessful, to establish a national technology assessment capability in the federal government or in the non-profit sector reveal this deeply-rooted societal ambivalence toward medical technology -- we wish to control health care costs but not at the expense of innovation, quality and clinical progress. Society, however, is not a decision maker and societal ambivalence toward TA is seldom found at the level of the interested parties. Indeed, political opposition to TA by those developing new health and medical care products and bringing them to the market has been expressed strongly and with great effectiveness over two decades.

However, the health system environment affecting TA has changed profoundly in the past five years compared to the period that began in the mid-1970s. The failure to enact federal health care reform legislation in 1994 both diminished the role of the federal government and released substantial private sector energies. Large corporate purchasers of health care have become more active in seeking to rein in the growth of health care expenditures. Managed care organizations have responded to market opportunities by enrolling an increasing proportion of

patients, reducing excess hospital capacity, and shifting care away from physician specialists to primary care-givers.

In this context, the evaluation of clinical practice for its clinical and cost-effectiveness has assumed greater market value. In short, the demand for TA and other forms of evaluation has increased. Traditional forms of evaluation of medical technology, which occur at the beginning of the innovation process, include Food and Drug Administration evaluation of drugs and medical devices for safety and efficacy and clinical trials for the evaluation of medical procedures. Among more recent means of evaluation, technology assessment takes place mainly at the boundary between innovation in medical technology and clinical practice. Clinical practice guidelines come into play more with respect to widely accepted, though not always well evaluated, clinical practices. Both TA and practice guidelines draw heavily on health services research pertaining to efficacy, effectiveness, outcomes, and appropriateness.

This report briefly describes a number of private health sector organizations that are engaged today in technology assessment. This information is not a comprehensive enumeration of all such organizations but a selective picture of the major ones. There are several national TA subscription services. Some national insurers/managed care organizations conduct centralized TA efforts that serve member plans. Several membership organizations have **constituency-**oriented TA programs. And some individual managed care organizations have significant TA capability. In short, the private sector TA "system" is a mix of distributed centralization (national subscription, plan, and constituency efforts) and decentralized (regional and local health plans) efforts.

The report emphasizes managed care organizations for two reasons. First, managed care constitutes the most visible and rapidly changing element in a changing health care system and it deserves attention for that reason alone. And second, it is an appropriate time to move beyond undifferentiated studies of all those engaged in TA to consider sector analyses -- of hospitals, physicians, insurers/managed care, the therapeutic products industries (drugs,

bioinformatics, medical devices), and research and consulting. Each sector differs regarding the incentives to develop and use medical technology and, thus, the incentives to support or conduct technology assessment differs in similar fashion. It appears from the evidence presented in this report that managed care has strong incentives to support and conduct TA in the current environment.

The conduct of TA is examined with respect to its changing scope (e.g., more attention is being given to the evaluation of new drugs than before and sole reliance upon FDA approval is less frequent). Most important, a strong conceptual and methodological development within TA has been the movement toward evidence-based medicine. This movement seeks to develop a strong scientific base for what is known about effective clinical practice. Although consensus processes are used to interpret and apply the results of **TAs**, the evidence-based movement discounts very heavily the use of consensus to assess the scientific bases of clinical practice. In methodological terms, priority-setting processes are well developed, cost-effectiveness analysis is on the verge of being used in operational decision-making, TA and clinical practice guidelines show substantial convergence (though the former focuses more on specific technologies and procedures and the latter on the management of clinical problems or disease conditions), and the need for greater attention to improved design and conduct of clinical trials becomes increasingly clear.

The use of TA in the managed care sector is primarily to support coverage **decision-**making. However, a number of innovative developments go beyond this narrow range of issues. These include benchmarking for member organizations of evaluative activities believed to be needed for survival in the current marketplace and the provision of a forum for reviewing the evidence related to competing technologies. They also include educational efforts in some plans directed to changing physician behavior toward evidence-based medicine.

Finally, an examination of private sector TA activity leads back to questions about the appropriate role of the federal government in TA and the appropriate division of labor between

the public and private sectors. One strong implication is that the federal government as purchaser of health care services should be no less competent and effective than the private sector in the support and conduct of TA. However, this does not necessarily imply a centralized federal government leadership role, which does not appear feasible at present. Another implication is that both public and private sectors should emphasize evidence-based assessments and the development of cost-effectiveness as an operational tool. In addition, as evidence-based TA organizations encounter the weaknesses of the clinical literature, the need becomes clearer for a feedback loop to the organizations that sponsor and perform clinical trials. Both sectors should also promote the convergence of technology assessment and clinical practice guidelines. These activities have some differences but share a commitment to evidence-based medicine and have common methodologies. The effective use of TA beyond coverage decision-making should also be promoted. Finally, among the various forms of public-private cooperation, a distinct role for the federal government remains the sponsorship of TA-related research. Such research generates benefits available to all to use and is extremely modest in cost relative to the benefits received.

CHAPTER 1. INTRODUCTION

A. Health Care in Transition

The United States health care system is undergoing substantial change in practically all dimensions. Change is occurring at the level of the nation's health system, within all major elements of the system, and in the established *relationships* between elements of the system. Elements that were once loosely-coupled are now being drawn into more tightly-coupled relationships. Important changes include:

- Large corporate purchasers of health care have become increasingly aggressive in seeking to reduce their health care costs and, concurrently, are forcing explicit attention to the measurement of and accountability for the quality of delivered services.
- Traditional indemnity health insurance is shrinking as a source of payment for health care and indemnity insurers are either abandoning health insurance entirely, providing both indemnity insurance and managed care, or shifting to managed care entirely.
- Managed care organizations--ranging from traditional group and staff model health maintenance organizations (**HMOs**) to preferred provider organizations (**PPOs**) and independent practice associations (**IPAs**) to network and mixed models-- have become the most visible manifestation of change in the delivery system.
- A number of managed care entities are now evolving into integrated delivery systems, which combine aspects of managed care with hospital-based delivery systems (Shortell, et al., 1994).
- Simultaneously, however, the hospital is being displaced as the center of the health care system and the hospital sector is engaged in downsizing (both by reductions in the number of beds and by the closing of hospitals), consolidation into multi-hospital chains,

CHAPTER 1. INTRODUCTION

and evolution toward integrated delivery systems (Robinson, 1994; Stoeckle, 1995; **Shortell**, et al., 1995).

Physician practice is changing from traditional solo fee-for-service to single- and **multi-**specialty group practices that are contracting with managed care plans and, increasingly, are **capitated** or involve other risk-sharing arrangements, or involve physicians organizing health plans themselves.

What is motivating the rate and direction of change? There are two primary concerns: first, the growth of health care expenditures has imposed increasing burdens on federal and state governments, private employers, and individuals in recent years and this has stimulated a search for ways to control costs. The second concern is to ensure that the quality of health care is not impaired by cost containment, a quest often referred to as seeking value for the health care dollar.

In this context, medical technology is of substantial interest to many parties. The Office of Technology Assessment defined medical technology as “the drugs, devices, and medical and surgical procedures used in medical care, and the organizational and supportive systems within which such care is provided” (Banta, Behney, Sisk, 1981). This definition, which has been adopted by most analysts, embraces innovations in medicine--new drugs, **biologics**, medical devices, and procedures--as well as existing therapeutic and diagnostic capabilities.

There are at least three reasons for the interest in medical technology. First, it is believed by many to be a major driver of increased health expenditures (**Weisbrod**, 1991; Newhouse, 1993; Rettig, 1994; Cutler, **1995**), thus an object of cost containment. Second, medical technology is also regarded as a primary guarantor of quality in U.S. health care. Third, both elite attitudes and mass public opinion strongly support innovation in medicine as the **hoped-for-**source of tomorrow’s solutions to many of today’s intractable medical problems. These attitudes

CHAPTER 1. INTRODUCTION

toward medical technology create great ambivalence among both public and private health policy makers--they wish to control the cost impacts of medical technology, but without sacrificing the benefits of innovation. This ambivalence has often complicated efforts, especially in the public sector, to establish effective institutions and processes for evaluating the benefits and costs of medical technology.

B. The Changing Context of Technology Assessment

The evaluation of the clinical and cost-effectiveness of medical technology, then, is a matter of great concern to a diverse array of institutions--purchasers, insurers, managed care organizations, hospitals, physicians, other health care personnel, and patients. *Technology assessment* (TA), the term most often applied to such evaluation, was defined by an Institute of Medicine report (IOM-Mosteller, 1985) as "any process of examining and reporting properties of a medical technology used in health care, such as safety, efficacy, feasibility, and indications for use, cost, and cost-effectiveness, as well as social, economic, and ethical consequences, whether intended or unintended." Although not included in the definition, the distinction between efficacy, or "what a method [technology] can accomplish in expert hands when correctly applied to an appropriate patient" and effectiveness, or a technology's "performance in more general routine applications" is discussed in the report.

The historical experience with TA, however, has been mixed. Since the **mid-1970s**, a strong federal government leadership role in TA has been envisioned. This view was embodied historically in the National Center for Health Care Technology (NCHCT), which existed within the U.S. Public Health Service from 1978 through 1982 (Perry, 1982; Blumenthal, 1983; Rettig, 1991). When NCHCT ceased to function in 1982 because no funds had been appropriated for it,

CHAPTER 1. INTRODUCTION

a national, nongovernmental, public-private entity was advocated (Bunker et al, 1982; Barondess, **1983**). In response, a Council on Health Care Technology was established within the Institute of Medicine following legislation in 1984 and 1985. This council existed from 1985 to 1989, when Congress withdrew the statutory authority for its public funding and the IOM decided to discontinue it.

Notwithstanding this history, the idea of a national TA entity continues to receive support. Had federal health care reform legislation proposed in 1993 become law, a strong federal government TA organization might have been established. In fact, the Physician Payment Review Commission recommended in early 1994 that a single national organization be established to conduct assessments supporting coverage decision-making (PPRC, 1994). In the wake of the collapse of reform legislation in 1994, however, and the election in November of that year of a Republican-controlled Congress, political support for such an approach to TA has all but vanished. A two-decade history of failed efforts to establish a strong federal or national TA organization reflect the ambivalence with which TA is regarded at the national level as well as the limited political feasibility of such proposals.

During this complicated history, several reports have assessed the status of TA in medicine. In 1985, the Institute of Medicine (IOM) published Assessing Medical Technologies (IOM-Mosteller, **1985**), which surveyed the field of TA. This included profiles of 20 organizations that conducted TA programs. These programs fell in the following categories: professional medical societies; the hospital sector; third-party insurers; health maintenance organizations; therapeutic products firms and industries (drugs, **biologics**, medical devices); TA consulting and research organizations; and federal government (biomedical research, health services research, technology assessment, information resources, health policy analysis, and **reimbursement**-related policy analysis).

CHAPTER 1. INTRODUCTION

The IOM also published a Medical Technology Ass-, in 1988, which greatly expanded the number of TA organizational profiles and added information on specific medical technologies, TA information resources, and TA organizational resources. Its Directory used the same organizational categories as the 1985 report, but added federal government regulatory and payment agencies and many international organizations. (IOM-Goodman, 1988).

A 1994 Office of Technology Assessment report, Identifying Health Technologies that Work: Searching for Evidence, which with 954 references is undoubtedly the most extensive survey of the literature, is the most recent review. This report focused mainly on federal government agencies involved in TA and clinical practice guidelines development. However, the report did observe that the private sector market for technology assessment was “small but explosive,” thus raising the question that motivated this study.

A comprehensive analysis of private sector TA would consider four sectors of the health care system: insurance/managed care; hospitals; professional medical societies; and firms in the therapeutic product industries (pharmaceuticals, biotechnology, and medical devices). These sectors differ in the incentives they have to use medical technology and thus in their reasons for supporting or using technology assessments. In this report, attention is given primarily, but not exclusively, to the managed care sector. Time and resource constraints made it necessary to limit the scope of the study and managed care constitutes the most significant change in the financing, organization, and delivery of health care.’

Managed care organizations have strong incentives to hold down the costs of care and one way to do so is to avoid providing unnecessary, inappropriate, or inadequately tested

‘Managed care organizations include traditional group and staff model health maintenance organizations (HMOs), preferred provider organizations (PPOs), independent practice associations (IPAs), and hybrid or mixed models. Unlike indemnity insurance-based fee-for-service, managed care organizations negotiate physician fee discounts or capitate payments.

CHAPTER 1. INTRODUCTION

medical technologies and procedures. Managed care has had and is having a strong but *indirect* effect on shrinking the demand for medical technology by reducing hospital bed capacity and reducing the demand for physician specialists. Presumably it is also having a *direct* effect by damping the incentives to purchase medical technology. It was assumed, therefore, that managed care had a strong interest in evaluating medical technology for clinical and **cost-effectiveness**.

Limited consideration is given in this study to the hospital sector and to professional medical societies and none to the therapeutic products industries. The hospital sector has a complicated orientation toward technology and TA. A typical hospital views technology mainly in terms of capital equipment, but also includes supplies and disposable items used in inpatient care. It is concerned with the effect of acquisition of technology on assets and liabilities, on revenues and expenses (Teplensky, et al., 1995). It values technology in relation to its competitors and its share of the local health care market, its ability to recruit physicians to its staff, and its ability to attract patients. Hospitals have generally seen medical technology as revenue-generating, thus damping interest in TA. In the contemporary environment, however, hospitals are increasingly seen as cost centers, not revenue centers, and technology is regarded in a similar way. This shift in perception creates greater incentives in the hospital sector to engage in and use TA (Anderson and Steinberg, 1994). In this study, attention has been limited to the American Hospital Association (**AHA**) and the University Health System Consortium (UHC). A more detailed examination of the changing role of TA in the hospital sector is warranted.

Physician specialty societies accounted for a number of the entries in the 1988 Institute of Medicine Directory. In this study, we have included only the American Medical Association (AMA) and the American College of Physicians (ACP). We limited the research in this sector on the assumption that, in 1995, physician specialty societies are more likely to be engaged in the

CHAPTER 1. INTRODUCTION

development of clinical practice guidelines than in technology assessment. Indeed, both the AMA's Diagnostic and Therapeutic Technology Assessment Program and the **ACP's** Clinical Efficacy Assessment Program could be characterized as guidelines development programs rather than as TA programs.

The firms and associations in the therapeutic products industries (drugs, **biologics**, and medical devices) respond quite differently to TA as a function of the structure of their respective industries, their products, and the relative importance they attach to Food and Drug Administration (FDA) regulatory issues and payment issues. The pharmaceutical industry has a more-or-less settled, even if fractious, relationship with FDA and is engaged actively in responding to the implications of pricing and marketing its products for a managed care world. The therapeutic biotechnology firms are preoccupied mainly with the **drug/biologics** review and approval process of FDA and with demonstrating via randomized controlled clinical trials the safety and efficacy of their products.

The medical device industry stands in a somewhat different position than the prescription drug industry, being actively concerned with **FDA reform** of device evaluation, issues of product liability, and how to pay for clinical trials. The "TA issues" of coverage and reimbursement that engage the device industry deal mainly with Medicare coverage decision-making, less so with the TA efforts of decentralized managed care organizations. No attention has been given in this report to the firms in these industries, but a thorough treatment of their views of TA is warranted (HIMA, HI, 1995).

C. The Research Questions

CHAPTER 1. INTRODUCTION

The five research questions of this study are: what is the demand for TA? who are the performers of TA? what characterizes the conduct of TA? how are the results of TA used? and what are the unmet needs of TA that might be met by cooperation between the public and private sectors of health care?

1. What is the Demand for Technology Assessment?

As noted above, the 1994 OTA report argued that the private sector market for technology assessment was “small but explosive.” However, this report provided **little** evidence to support this claim. In this study, we examined whether the private sector demand for TA was increasing--either steadily or explosively? If so, why, how, and for what reasons? What organizations were driving the change and why? What were the implications of changed demand on the conduct of **TAs**, especially on their rigor? Was increased demand resulting in TA being incorporated into operational decision-making policies and procedures of health care organizations? Was TA being integrated with other evaluative activities such as guidelines development? What expectations about the future demand for TA were reasonable in **1995**? These issues are considered in Chapter 2 and in later chapters.

2. Who Are the Performers of Technology Assessment?

Relatively speaking, the focus of much discussion of TA has been on federal government agencies responsible for this function. But there have been private sector organizations engaged in TA for some time, as two Institute of Medicine documents (1985, 1988) made clear. However, the question asked by the OTA regarding their rapid growth casts the discussion in a

CHAPTER 1. INTRODUCTION

new light. In this study we consider the organizations in the private health care sector that are engaged in the conduct technology assessment. What do they do? For whom? At what level of effort in terms of professional staff and volume of output? Are their **TAs** available freely to the public, available only to organization members, or available on a subscription basis? What coordination, if any, exists among these TA performers? These questions are examined in Chapter 3.

3. What Characterizes the Conduct of Technology Assessment?

The concern for performers of TA leads naturally to an examination of the conduct of assessments. What are the characteristics of **TAs**? How is TA defined operationally? Are **TAs** typically evidence-based or consensus-based? What is the scope of TA and how has it changed in the decade? How are priorities for assessments established? What analytical techniques, including cost-effectiveness analysis, are used? What are the products (reports, papers, guidelines, coverage policies) of **TAs**? What TA resources are used? How is TA related to other evaluative activities, such as appropriateness, effectiveness, and outcomes research, and especially clinical practice guidelines development? Chapter 4 addresses these questions.

4. What Use is Made of the Results of Technology Assessment?

The emphasis in the TA literature has been on the performance of assessments, much less on their use. In Chapter 5, consideration is given to who uses **TAs** and for what purposes? What policies and procedures exist that pertain to the implementation of **TAs**? Who is involved in decisions about the use of **TAs**? How are **TAs** evaluated for their clinical and financial utility?

CHAPTER 1. INTRODUCTION

CHAPTER 1. INTRODUCTION

5. What is the Role of the Government?

Both the public and private sectors of health care have a large stake in the effective conduct and use of technology assessments. The question arises about the appropriate roles of each sector. This leads in turn to the issue of opportunities for constructive TA-related relationships-cooperation, collaboration, coordination, contracting, technical **assistance**--between the federal government and the private, nongovernmental health sector. A discussion of these issues concludes the study and is found in Chapter 6.

D. Research Methods

The scope of this study, initially very broad, was narrowed to a focus on managed care in the study's early stages. Data collection relied on several methods--site visits; semi-structured interviews, both face-to-face and telephone; attendance at meetings; document review; and follow-up of referrals to others.

Since Blue Cross Blue Shield Association (BCBSA) and **ECRI**² had been involved in TA for a long period of time, contacts with these organizations were established early in the study. These contacts resulted in visits to both organizations. The initial visit to BCBSA, involved a one-hour interview with the principals of the Technology Evaluation Center (**TEC**). This initial contact established the basis for later interviews with officials, usually the medical directors, of Blue Shield of California, Blue Cross Blue Shield of Illinois, Blue Cross Blue Shield of Minnesota, and Blue Cross Blue Shield of Oregon. Later, an invitation was accepted to attend the two-day

²**ECRI** was once known as the Emergency Care Research Institute, but has long since given up that name for the acronym.

CHAPTER 1. INTRODUCTION

June 1995 meeting of the **TEC's** Medical Advisory Panel as an observer. In the case of **ECRI**, the visit resulted in a six-hour detailed discussion of that organization's TA effort.

Site visits were made to Philadelphia (ECRI, the American College of Physicians, University of Pennsylvania, Jefferson University); Chicago (BCBSA, the American Medical Association, the American Hospital Association, the University Health System Consortium; and Blue Cross Blue Shield of Illinois); San Francisco (Blue Shield of California; Kaiser Permanente of Northern California); Minneapolis-St. Paul (University of Minnesota, Health Partners, Institute for Clinical Systems Integration, Blue Cross Blue Shield of Minnesota, Allina Health System, Minnesota Business Health Care Action Group, and Medical Alley); Seattle (Group Health Cooperative of Puget Sound); Portland (Blue Cross Blue Shield of Oregon); Los Angeles (Kaiser Permanente of Southern California); and Hartford (Aetna).

All site visits involved face-to-face interviews of at least one hour; many resulted in extended discussions, as in the cases of **ECRI** and the University Health System Consortium; and several included multiple interviews, as in the case of Group Health Cooperative of Puget Sound. Some visits were preceded by telephone interviews, and some led to follow-up discussions on the telephone or on visits of key individuals to Washington, DC. Toward the end of the project, a number of interviews were conducted by telephone; these typically lasted **45** minutes to one hour in length. In total, 46 interviews were conducted with 56 individuals in 29 different organizations (The list of organizations interviewed for this study appears in the appendix to this chapter.)

The study director also attended a meeting of the American College of Physicians' Subcommittee on Clinical Efficacy Assessment and a meeting of the Medical Policy Committee on Quality and Technology of Blue Shield of California.

CHAPTER 1. INTRODUCTION

Chapter 3 was written when it became clear that it was necessary to separate the discussion of performers of TA from that of the conduct of TA (Chapter 4). The brief snapshots that are presented were sent to the individual organizations to review for accuracy.

The data provided by the organizations interviewed for the study, in our judgment, support the conclusion that substantial private sector activity in TA is occurring. In addition, we believe that they provide hypotheses that could be tested in a more comprehensive examination of private sector activity in TA and the management of medical technology.

CHAPTER 1. INTRODUCTION

REFERENCES

- Anderson, G.F. and Steinberg, E.P., 1994. "Role of the Hospital in the Acquisition of Technology," pp. 61-70 in Gelijns, A.C. and Dawkins, H.V., eds., 1994. Adopting New Medical Technology: Medical Innovation at the Crossroads, Vol. IV., Washington, D.C., National Academy Press.
- Banta, H.D., Behney, C.J., and Sisk, J.S., 1981. Toward Rational Technology in Medicine, New York, NY, Springer Publishing Company.
- Blumenthal, D., 1983. "Federal policy toward health care technology: the case of the National Center," Milbank Memorial Fund Quarterly/Health and Society, Vol 61, pp. 584-613.
- Brook, R.H., Park, R.E., Chassin, M.R., Solomon, D.H., Keesey, J., Kosecoff, J., 1990. "Predicting the appropriate use of carotid endarterectomy, upper gastrointestinal endoscopy, and coronary angiography," New England Journal of Medicine, Vol. 323, pp. 1173-1177.
- Bunker, J.P., Fowles, J., Schaffarzick, R., 1982. "Evaluation of medical technology strategies: effects of coverage and reimbursement," New England Journal of Medicine, Vol 306, pp. 620-624.
- Bunker, J.P., Fowles, J., Schaffarzick, R., 1982. "Evaluation of medical technology strategies: proposal for an institute of health care evaluation," New England Journal of Medicine, Vol 306, pp. 687-692.
- Cutler, D.M., 1995. "Technology, health costs, and the NIH," paper prepared for the National Institutes of Health Economics Roundtable on Biomedical Research.
- Fryback, D.G., ed., 1995. Introduction to Technology Assessment for Radiologists: Vision Beyond Tomorrow, Vols. 1 and 2, Milwaukee, Wisconsin, GE Medical Systems-Association of University Radiologists Radiology Research Academic Fellowship (GERRAF) Program.
- Health Industry Manufacturers Association, 1995. Report on Public Policy Reform and the U.S. Health Care Technology Industry. Part I: Reforms at the Food and Drug Administration, Washington, D.C., February 9.
- Health Industry Manufacturers Association, 1995. Report on Public Policy Reform and the U.S. Health Care Technology Industry. Part II: Reforming Product Liability Laws, Washington, D.C., March 2.
- Health Industry Manufacturers Association, 1995. Report on Public Policy Reform and the U.S. Health Care Technology Industry. Part III: Strengthening the Climate for Health Care Financing and Delivery, Washington, D.C., May 5.
- Institute of Medicine (Barondess, J., ed.), 1983. A Consortium for Assessing Medical Technology, Washington, D.C., National Academy Press.

CHAPTER 1.. INTRODUCTION

Institute of Medicine (Mosteller, F., ed.), 1985. Assessing Medical Technologies, Washington, D.C., National Academy Press.

Institute of Medicine (Goodman, C., ed.), 1988. Medical Technology Assessment Directory, Washington, D.C., National Academy Press.

Mendelson, D.N., Abramson, R.G., and Rubin, R.J., 1995. "State involvement in medical technology assessment," Health Affairs, Vol. 14, No. 2 (Summer), pp. 83-98.

Newhouse, J.P., 1993. "An iconoclastic view of health cost containment," Health Affairs, Vol. 12 (Suppl.), pp.1 52-l 71.

Office of Technology Assessment, U.S. Congress, 1994. Identifying Health Technologies that W - Searching for Evidence, Washington, D.C., Government Printing Office.

Perry, S., 1982, "The brief life of the National Center for Health Care Technology," New England Journal of Medicine, Vol. 307, pp. 1095-l 100.

Physician Payment Review Commission, 1994. Annual Report to Congress 1994, Washington, D.C., pp. 219-236.

Rettig, R.A., 1991. "Technology assessment: an update," Investigative Radiology, Vol. 26, pp. 165-l 73.

Rettig, R.A., 1994. "Medical innovation duels cost containment," Health Affairs, Vol 13, No.3 (Summer), pp.7-27.

Robinson, J.C., 1994. "The Changing Boundaries of the American Hospital," Milbank Quarterly, Vol. 72, No. 2, pp. 259-275.

Shortell, S.M., Gillies, R.R., and Anderson, D.A., 1994. "The New World of Managed Care: Creating Organized Delivery Systems," Health Affairs, Vol. 13, No. 5, Winter, pp.46-64.

Shortell, S.M., Gillies, R.R., and Devers, K.J., 1995. "Reinventing the American Hospital," Milbank Quarterly, Vol. 73, No. 2., pp. 131-160.

Stoeckle, J.D., 1995. "The Citadel Cannot Hold: Technologies Go Outside the Hospital, Patients and Doctors Too," Milbank Quarterly, Vol. 73, No. 1, pp. 3-17.

Teplensky, J.D., Pauly, M.V., Kimberly, J.R., Hillman, A.L., and Schwartz, J.S., 1995. "Hospital Adoption of Medical Technology: An Empirical Test of Alternative Models," HSR: Health Services Research, Vol. 30, No. 3 (August), pp. 437-465.

Weisbrod, B.A., 1991. "The health care quadrilemma: an essay on technological change, insurance, quality of care, and cost containment," Journal of Economic Literature, Vol. 29, pp. 523-552.

CHAPTER 1. INTRODUCTION

APPENDIX: INTERVIEWS FOR THE TA STATUS PROJECT

(* indicates telephone interview)

Third-party insurers and managed care organizations:

- . Aetna: William T. **McGivney**
- . Allina: Gordon M. Sprenger; John H. Kleinman'
- . Blue Cross Blue Shield Association: Susan **Gleeson**; Naomi Aronson; Ellen Pearson; also attended June **29, 1995** meeting of Medical Advisory Panel
- . Blue Cross Blue Shield of Minnesota: Del Ohrt; Jack Alexander; Julie Carr
- . Blue Cross & Blue Shield of Illinois: Arnold L. Widen
- . Blue Cross & Blue Shield of Oregon: John Santa
- . Blue Shield of California: Wade M. Aubry; also attended June **7, 1995** meeting of Medical Policy Committee on Quality and Technology
- . Cigna: Edward J. Smith*; Jadwiga Gocłowski'
- . Group Health Cooperative of Puget Sound, **Seattle**, Washington: Hugh Straley; Terri **Calnan**; Simeon Rubenstein; Michael E. Stuart*; Jeff K. Shornick; Timothy **McAfee**; Edward H. Wagner*
- . Harvard Community Health Plan, Boston, Massachusetts: Melinda **Karp***
- . Health Partners, Minneapolis, Minnesota: George J. Isham
- . The HMO Group, New Brunswick, NJ & Teminex, Buffalo, New York: Daniel Wolfson*; John **Reinhard***
- . Institute for Clinical Systems Integration, Minneapolis, Minnesota: Gordon Mosser; James C. Smith
- . Kaiser Permanente Program: Ian Leverton*
- . Kaiser Permanente Medical Group of Northern California: D. Blair Beebe*; Joseph Selby
- . Kaiser Permanente Medical Group of Southern California: Les **Zendle**; Robin Cisneros; David Eddy*
- . Prudential: Art L. Levin'; William L. Roper*
- . United Health Care: Lee N. Newcomer*; Joseph A. Barry*; Sylvia Giebler Robinson*

Other organizations:

- . American College of Physicians: Linda J. White; also attended May 31, 1995 meeting of Clinical Efficacy Assessment Subcommittee
- . American Hospital Association: Sutanna Hoppszallern
- . American Medical Association: **Sona** Kalousdian; Andrea Schneider
- . ECRI: Jeffrey Lerner; Vivian Coates
- . Medical Alley (Tom Meskan)
- . Minnesota Business Health Care Action Group: Steve Wetzel
- . National Committee on Quality Assurance: Margaret E. **O'Kane**; Cary **Sennet***
- . Thomas Jefferson (David Nash)
- . University Hospital Consortium (now University Health Systems Consortium): David A. Burnett; Karl A. Matuszewski; Jean Livingston; Richard A. Bankowitz
- . University of Pennsylvania (Alan **Hillman**, J. Sanford **Schwarz**)
- . Xerox: Helen Darling*

CHAPTER 2. THE CHANGING DEMAND FOR TA

B. Sources of Increased Demand for TA.

Currently, the priority of the health care marketplace, especially that of the private sector, lies in controlling the costs of health care. At the same time, however, many purchasers and providers are also giving substantial attention to quality of care, or to the value of the health care **received for** the resources expended. This dual concern for costs and value provides the basis for the increased demand for TA. (IOM-Field and Shapiro, eds., **pp.223-27**).

In this context, there are two main sources of increased demand for TA. The first is the major corporate purchasers of health care, especially self-insured corporations, which have pressed for both cost containment and performance evaluation (Darling, 1991). The second source of demand is from major health care insurers and managed care plans that have found TA useful in responding to the changing health care marketplace--to health care purchasers, to increasingly severe economic constraints, and prospectively to patients.

1. The role of purchasers.

In general, large corporations, especially the self-insured, have become a major force in the health care sector in encouraging the containment of costs and raising the issue of value received for funds spent (Freudenheim, 1995). An Institute of Medicine report (IOM-Field and Shapiro, eds. 1993) found the evidence that employer cost containment strategies had limited the growth of health care costs was "at best, quite modest, although certain techniques appear to have reduced some unnecessary or inappropriate spending and some have shifted a portion of the cost burden from employers to employees" (**p216**). However, limited data, lack of control

CHAPTER 2. THE CHANGING DEMAND FOR TECHNOLOGY ASSESSMENT

A. Introduction.

In Identifying Health Technologies that Work, the Office of Technology Assessment (1994) argued that “the explosive growth in the private sector market for the assessment of specific medical technologies” is one of the most significant developments in TA. Although some payers and providers have had long-standing TA programs, the report noted, “**What** is new is the degree to which technology assessments are becoming a standard ingredient in private-sector decisionmaking.” (p9) And while the assessment of specific technologies by the federal government has been stable, “the private market in health technology assessments has become a full-fledged economic activity in its own right.”

Whether the growth in private sector TA has been “explosive” or not is less important than the basic questions that the OTA report raises. First, has the demand for TA increased in recent years? Second, if so, what accounts for this increased demand? Third, what are the effects of this increased demand? This chapter considers these questions.

Demand, for purposes of this analysis, is defined as the perception of an unmet need of sufficient importance that it calls forth the resources enabling that need to be met. The expression of demand is necessary to elicit an intellectual and institutional response from the supply side. In the case of TA, demand is usually expressed in the context of other evaluative activities, which may include outcomes research, appropriateness research, clinical practice guidelines, and report cards. Although TA may sometimes be requested alone, more often it is “nested” in an array of complementary evaluative efforts that are usually linked to utilization management and quality assurance or improvement.

CHAPTER 2. THE CHANGING DEMAND FOR TA

B. Sources of Increased Demand for TA.

Currently, the priority of the health care marketplace, especially that of the private sector, lies in controlling the costs of health care. At the same time, however, many purchasers and providers are also giving substantial attention to quality of care, or to the value of the health care received for the resources expended. This dual concern for costs and value provides the basis for the increased demand for TA. (IOM-Field and Shapiro, eds., pp.223-27).

In this context, there are two main sources of increased demand for TA. The first is the major corporate purchasers of health care, especially self-insured corporations, which have pressed for both cost containment and performance evaluation (Darling, 1991). The second source of demand is from major health care insurers and managed care plans that have found TA useful in responding to the changing health care marketplace--to health care purchasers, to increasingly severe economic constraints, and prospectively to patients,

1. The role of purchasers.

In general, large corporations, especially the self-insured, have become a major force in the health care sector in encouraging the containment of costs and raising the issue of value received for funds spent (Freudenheim, 1995). An Institute of Medicine report (IOM-Field and Shapiro, eds. 1993) found the evidence that employer cost containment strategies had limited the growth of health care costs was 'at best, quite modest, although certain techniques appear to have reduced some unnecessary or inappropriate spending and some have shifted a portion of the cost burden from employers to employees" (p216). However, limited data, lack of control

CHAPTER 2. THE CHANGING DEMAND FOR TA

over key variables, and multiple causal factors complicate the analytic task. It may also be the case that the effects of aggressive cost containment are only now beginning to be manifest.

Utilization management strategies have been the principal means for cost containment. The table on the following page indicates the percentages of employers surveyed by A. Foster Higgins & Co., from 1987 to 1991, that are using selected utilization management features.

Table 1 about here

CHAPTER 2. THE CHANGING DEMAND FOR TA

Notwithstanding the absence of strong evidence supporting cost containment effects of self-insured corporations, Patricelli (1994) has argued that self-insured employers have driven much of the innovation in the financing and delivery of care:

Any practitioner of managed care knows that large, self-insured employers have driven the development of most of the advances in managed care technology in this country. The reasons are simple. These employers have sophisticated staffs who can challenge and work with managed care vendors, and they do so because they are self-insured and get the economic benefit of any savings they generate. ... Moreover, innovations including claims data analysis, utilization review, high-cost case management, **point-of-service** options, flex plans, carve-out specialty managed care plans, centers of excellence, and quality measurement in health care all have originated from vendor interactions with self-insured employers.

Self-insured employers, to take a notable example, have been instrumental in the development of the National Committee on Quality Assurance (NCQA), the primary accrediting body for health maintenance organizations (O'Kane, personal communication, 1995; Darling, 1995). In particular, performance evaluation, as reflected in the Health Plan and Employer Data and Information Set (HEDIS) report cards, is a clear instance of purchaser-driven demand for information about quality (Allen, et al., 1994; Roper, 1995). In mid-1995, for example, the New York Times reported that a meeting in Jackson Hole, Wyoming, of representatives of some of the largest employers and purchasers of health insurance had agreed to pursue a fundamental shift in emphasis in the nation's managed care systems: "They want the primary focus to be placed on measuring the quality of care now that costs have begun to be controlled" (Noble, 1995).

CHAPTER 2. THE CHANGING DEMAND FOR TA

Perhaps the most significant development regarding the demand for TA has been the addition by NCQA of a utilization management requirement for TA to its accreditation standards (NCQA, 1995). Requirement U.M. 7.0, which became effective on April 1, 1995, states that:

The managed care organization has policies and procedures in place to evaluate the appropriate use of new medical technologies, or new applications of established technologies, including medical procedures, drugs, and devices.

Although sparing of details about precise organization of the TA effort, this requirement specifies that “appropriate professionals” be involved in the development of evaluation criteria, that such criteria include “review of information from appropriate government regulatory bodies and published scientific evidence,” and that these criteria be used “effectively” to assess both new technologies and new applications of existing technologies. Therefore, to the extent that managed care plans seek NCQA accreditation, and major corporate purchasers are encouraging them to do so, this requirement is a strong indication of private sector demand for TA.

Regional groups of purchasers also have exerted strong influence on providers in local health care markets. Prominent among these are the Washington Business Group on Health, the Midwest Business Group on Health, the Pacific Business Group on Health, and the Minnesota Business Health Care Action Group (BHCAG). The BHCAG, whose members include the major self-insured corporations in the state, has played a very active role in health care organization and delivery.

The BHCAG, in 1992, issued a Request for Proposals to the major provider organizations in Minnesota requiring that acceptable responses include provision for clinical practice guidelines and technology assessment. The winning proposal from Health Partners resulted in the establishment of the Institute for Clinical Systems Integration (ICSI), a separate organization that develops guidelines and conducts **TAs** for use in coverage and reimbursement by Health

CHAPTER 2. THE CHANGING DEMAND FOR TA

Partners and some twenty other participating plans. (ICSI is described in greater detail in the following chapter.)

2. Changes in financing and delivery of health services.

The second source of increased demand for TA comes from the organizations that finance and provide health care services. These organizations are responding to several forces, primarily to the purchasers of care, but also to the immediate economic constraints under which they operate and to their own strategic planning for long-term survival. They have established an array of evaluative activities, among which TA is an element.

The major change in the provision of health care services has been the rapid growth of managed care in this decade, following a long history during which its philosophic and institutional foundations were established. Managed care organizations include: major health insurers that have converted, or are converting, wholly or in large part, from indemnity insurance to managed care, such as Prudential, Aetna, and CIGNA; Blue Cross and Blue Shield Plans making a similar transition, usually remaining not-for-profit but in some notable cases (such as Wellpoint in California) converting to for-profit status; as well as staff and group model HMOs, such as Kaiser-Permanente and Group Health Cooperative of Puget Sound, preferred provider organizations (PPOs), independent practice associations (IPAs), and networks and mixed models. The step beyond managed care is occurring as some of these plans affiliate with hospitals and hospital systems, or vice versa, and transform themselves into integrated delivery systems.

Managed care organizations (MCOs) have cost containment as a primary objective, but increasingly are addressing quality issues as well. These dual concerns manifest themselves in the emergence of formal TA and clinical practice guidelines programs. These organizations are

CHAPTER 2. THE CHANGING DEMAND FOR TA

a source of demand for TA on the health care system, making possible, for example, the growth of the TA subscription services of Blue Cross and Blue Shield Association and ECRI. The demand by managed care for TA, however, is a derivative of purchasers' demand and, consequently, we discuss their effort in the next chapter on the performers of TA.

The hospital sector has lagged behind managed care as a source of demand for TA. The reason is straightforward. Although medical technology may be seen as a factor driving increasing costs of health care, or may be recognized as under-evaluated relative to patient outcomes, hospitals have often confronted countervailing pressures regarding the use of medical technology. Medical technology has often been seen as a way to attract and retain physicians, to attract patients, and for a given hospital in a local market to differentiate itself from its competitors. Mainly, however, hospitals have seen technology as a revenue source. As managed care has increased in importance, this has led to a conceptual shift in hospital thinking wherein former revenue centers have now come to be seen as cost centers. Thus, the interest of hospitals in TA has become more active. Thus, the hospital sector has historically brought a complex set of motives into play regarding the use of medical technology and thus the priority attached to TA has been ambivalent. The hospital sector has not been a strong source of demand for TA. (Greer, 1985; Greer, 1987; Anderson and Steinberg, 1994; Teplensky, et al., 1995).

Professional medical societies are not driving change in medicine. They are reacting to change. In this study, we have assumed that they are more engaged in developing clinical practice guidelines than in conducting **TAs**, and not a major source of demand for the latter. Practice guidelines, after all, constitute one domain where the medical profession has a high likelihood of asserting, or reasserting, professional control over its own activities.

CHAPTER 2. THE CHANGING DEMAND FOR TA

The therapeutic products industries are, to some extent, a source of demand for TA. In particular, the drug industry has been a strong customer for pharmacoeconomics and for the inclusion of cost-effectiveness and quality-of-life analyses into clinical trials. These activities are believed to help in product development decisions, marketing of products relative to competitors, and defensive preparation for a time when such tools are more widely used by public and private purchasers of care.

3. The role of the federal government.

In the period from the mid-1970s through end of the **1980s**, a weak form of “demand” for TA was expressed in an ambivalent way through the Congress. This period began with the establishment in 1974 of a Health Program within the Office of Technology Assessment of the U.S. Congress, but it also included the adoption of the Medical Device Amendments of 1976, which expanded the role of the FDA, the creation in 1977 of the National Institutes of Health’s Office of Medical Applications of Research in response to clearly expressed dissatisfaction by the Senate with the report of the President’s Commission on Biomedical Research the year before, and the creation of the National Center for Health Care Technology in 1978 (Rettig, 1991).

This expansion of federal government activity was abruptly halted in 1982, after the inauguration of President Ronald Reagan, when Congress reauthorized the National Center for Health Care Technology but failed to appropriate any funds for it in the following fiscal year. The Council on Health Care Technology, established within the Institute of Medicine after Congressional authorization in 1984 and 1985, did not become an effective assessment agency. The entire period that began in the mid-1970s might be said to have ended in 1989 with the termination of the IOM’s Council, the creation of the Agency for Health Care Policy and Research

CHAPTER 2. THE CHANGING DEMAND FOR TA

(AHCPR), and the assumption by AHCPR of responsibility for the Office of Health Technology Assessment (OHTA).

One continuing aspect of the federal government's role in TA has been the efforts over an extended period by the Health Care Financing Administration (HCFA) to strengthen the evaluative rigor of its coverage decision processes. **HCFA's** source of advice within the federal government historically has been the Public Health Service. This Medicaredelegated PHS function has been exercised by the National Center for Health Care Technology (1978-82) and then the Office of Health Technology Assessment (from 1982 to the present). One notable feature of the HCFA experience has been the issuance in 1989 of a proposed rule that would add a **cost-effectiveness** element to the analyses supporting coverage and payment decisions (54 FR 4302, January 30, 1989). A final rule has been described as "imminent" for several years.

Given the prominence of HCFA as a purchaser of health care services through Medicare and Medicaid, and given the contribution those programs make to federal and state government budgets, it might be assumed that HCFA-as-purchaser would have developed a strong TA capability. In economic terms, the more fully informed all parties to market transactions are, the more efficiently markets perform. TA, at bottom, is one way of increasing the information available to purchasers of care about what works in medicine. In addition, there are beneficial spillover effects to the private health care sector from government generated information about effectiveness. Such information is in the public domain and thus available for the use of all other purchasers.

Historically, however, strong political opposition has existed, and will continue to exist, to the exercise by the federal government of a strong TA role. In the opinion of the therapeutic products industries, especially the medical devices industry (**HIMA, 1995**), government TA is seen as biased against innovation and in favor of cost containment. Thus, the substantial

CHAPTER 2. THE CHANGING DEMAND FOR TA

market power of HCFA that is exercised through Medicare is feared and a stronger Medicare TA capability is steadfastly resisted. Critics of a strong HCFA TA effort display relatively little concern about the theoretical efficiency of markets as a function of **better information when the potential exists** for challenging their economic self-interest.

In the case of the Department of Veterans Affairs (DVA), that department has been shielded in many respects from the intensity of the budgetary pressures that are acting on almost all other government agencies. Its hospital system has not been subjected to the same forces that are at work in the private sector. Consequently, it is only now beginning to develop a TA system. Interestingly enough, part of the **DVA's** efforts include subscribing to the TA efforts of University Hospital Consortium. In the case of **CHAMPUS**, the insurance program for the dependents of military personnel, that organization recently contracted with the Blue Cross & Blue Shield Association for a TA program.

The contribution of the federal government from the mid-1970s to the present has been to raise consciousness about TA and to enable key researchers work out the analytical methods of TA. However, a strong federal government leadership role in TA has not emerged. Federal government agencies have failed to develop a political constituency for TA and have actually developed some residual political enemies. The economic rationale for TA that stems from **HCFA's** role as a major purchaser of health care services has not been politically persuasive. Nor has the argument that federal government TA generates a spillover contribution to the entire U.S. health care system. Until political support for TA conducted or supported by the federal government has been established, the effort will remain in jeopardy. This factor should be kept in mind in all thinking about the role of the private health care sector in TA.

CHAPTER 2. THE CHANGING DEMAND FOR TA

REFERENCES

- Allen, H.M., Darling, H., McNeill, D.N., Bastien, F., 1994. "The Employee Health Care Value Survey: Round One," Health Affairs, Vol. 13, No. 4 (Fall), pp.2541.
- Anderson GF and Steinberg EP, 1994. "Role of the Hospital in the Acquisition of Technology," pp.61-70 in Gelijns AC and Dawkins HV, eds., Adopting New Medical Technology. Medical Innovation at the Crossroads. Vol. IV, Washington, D.C., National Academy Press.
- Darling, H., 1991. "Employers And Managed Care: What Are The Early Returns," Health Affairs, Vol. 10, No. 4 (Winter), pp.147-160.
- Darling, H., 1995. "Market Reform: Large Corporations Lead The Way," Health Affairs, Vol. 14, No. 1, (Spring), pp.1 122-124.
- Freudenheim, M., 1995. "10 Companies Join in Effort to Lower Bids by HMOs," New York Times, May 23.
- Greer AL, 1985. "Adoption of Medical Technology: The Hospital's Three Decision Systems," International Journal of Technoloav Assessment in Health Care 1(5):669-80.
- Greer AL, 1987. "Rationing Medical Technology: Hospital Decision-Making in the United States," International Journal of Technoloav Assessment in Health Care 3(2):199-222.
- Health Industry Manufacturers Association (HIMA), 1995. Report on Public Policy Reform and the U.S. Care Technology Industry: Part III: Strengthening the Climate for Health Care Financing and Delivery , Washington, D.C. (May 5).
- Institute of Medicine (Field, M.J., and Shapiro, H.T., eds), 1993. Employment and Health Benefits: A Connection at Risk, Washington, D.C., National Academy Press.
- National Committee for Quality Assurance, 1995. Standards for Accreditation, Washington, DC.
- Noble, H.B., 1995. "Quality Is Focus For Health Plans," New York Times, July 3.
- Office of Technology Assessment, U.S. Congress, 1994. Identifying Health Technologies That Work, Washington, D.C., Government Printing Office.
- Patricelli, R.E., 1994. "Why Do We Need Health Alliances," Health Affairs, Vol. 13, No. 1 (Spring), pp.239-242.
- Rettig, R.A., 1991. "Technology Assessment--An Update," Investigative Radiology, Vol. 26 (February), pp. 165-1 73.
- Roper, W.L., 1995. "Quality Assurance In The Competitive Marketplace," Health Affairs, Vol. 14, No. 1 (Spring), pp.120-121.

CHAPTER 2. THE CHANGING DEMAND FOR TA

Teplensky JD, Pauly MV, Kimberly JR, Hillman AL, and Schwartz JS, 1995. "Hospital Adoption of Medical Technology: An Empirical Test of Alternative Models," HSR: Health Services Research **30:3** (Spring), pp.437-465.

CHAPTER 3. THE PERFORMERS OF TECHNOLOGY ASSESSMENT

Technology assessment (TA) has long been regarded by many policy makers and interested parties as a federal government activity conducted by the Public Health Service and advisory to Medicare on coverage decisions for new technologies and procedures. The organizational reality of TA in the **mid-1990s**, however, is far more complex than a decade earlier. It is quite decentralized, becoming more so, and is now located mainly in the private sector. In this chapter, we examine this reality with respect to the performers of TA.

A. Prior Studies.

Two efforts by the Institute of Medicine (IOM) in the 1980s developed information about TA programs, and thus about the organizations that perform assessments. A 1985 IOM report (IOM-Mosteller, 1985) listed the following twenty technology assessment programs: five executive branch federal government agencies (National Center for Health Services Research [NCHSR] and Health Care Technology Assessment; National Institutes of Health [NIH]: Office of Medical Applications of Research [OMAR], National Heart, Lung, and Blood Institute [NHLBI], and National Library of Medicine [NLM]; and the Veterans Administration [VA]); two Congressional staff agencies (Office of Technology Assessment [OTA]; and Prospective Payment Assessment Commission [**ProPAC**]); one national association of not-for-profit insurers (Blue Cross and Blue Shield Association [BCBSA] with two programs); three medical societies (American Medical Association [AMA]; American College of Cardiology [ACC]; and American College of Physicians [ACP]); one national hospital organization (American Hospital Association [**AHA**]); two therapeutic products firms (Smith Kline & French Laboratories; and Medtronic); four research and consulting organizations (Battelle Memorial Institute; ECRI; the Permanente

CHAPTER 3. THE PERFORMERS OF TA

Medical Group; and the University of California San Francisco [UCSF]; and one bioethics center, the Institute of Society, Ethics, and the Life Sciences.

The 1988 institute of Medicine Medical Technology Assessment Directory (IOM-Goodman) presented far more information than did the 1985 report. It was organized as follows: Part 1: Assessment Program Profiles and Report Citations; Part 2: Assessment Report Citations Listed by Technology; Part 3: Information and Data Resources; Part 4: Organizational Resources; and Part 5: Index to Organizations. Part 1 listed 68 technology assessment programs of 55 organizations; under the American Medical Association, for example, three entries were included for the Council on Scientific Affairs, the Diagnostic and Therapeutic Technology Assessment Program, and the Drug Evaluations program. The 55 organizations included 14 U.S. medical societies, 14 U.S. research and consulting organizations, 14 international organizations, 10 federal government agencies, 2 hospital organizations, and one national organization serving **third-party** payers.

Looking at these two IOM documents from the perspective of 1995, several features are noteworthy. First, the sampling strategy for both efforts was to include as many organizations as could plausibly be said to have a TA program. Neither organizations nor TA programs were grouped by health care sector for purposes of examining the incentives these organizations had to both use and to evaluate medical technology. Second, the list was heavily weighted toward federal government agencies. Third, the inclusion of Blue Cross & Blue Shield Association reflected its position as a TA pioneer in the 1970s and '80s. But the fact that it was the only insurer listed is evidence of the generally weak demand for TA among third-party payers in the mid-1 980s. Fourth, medical societies were prominent on the IOM lists. Today they are engaged as much, if not more, in developing clinical practice guidelines as in technology assessment.

CHAPTER 3. THE PERFORMERS OF TA

In this chapter, we describe briefly those organizational performers of TA from whom information was obtained in this study. This effort does not attempt to be comprehensive. It does attempt, however, to characterize a number of private sector TA organizations, and the nature and diversity of their efforts. These snapshots suggest that change that is occurring in TA in the private health care sector, especially in the area of managed care.

For exposition, we have found it convenient in this chapter to discuss performers in three categories: private sector TA organizations or programs that were dearly established a decade ago; new private sector TA entrants in the decade; and government agencies. Consideration was given to a tabular summary of these organizations, especially for full-time equivalent personnel and number of assessments conducted each year. It became apparent, however, that the diversity of organizations, programs, and products was such that a tabular presentation would be misleading. Moreover, such a presentation ran the risk of being widely cited, thus compounding the effect of misleading information.

B. Previously Established TA Organizations.

In 1995, the organization of TA performers appears quite different than a decade earlier. Several organizations with TA roots in the 1970s have prospered in recent years. The two most prominent are the Blue Cross and Blue Shield Association's (BCBSA) Technology Evaluation Center and ECRI's technology assessment program. Several others that have had TA activities for a long time have undergone transitions that reflect external market changes, internal organizational changes, and strategic decisions about the priorities of the parent organizations.

CHAPTER 3. THE PERFORMERS OF TA

In this section, we discuss the American College of Physicians, the American Hospital Association, the American Medical Association, the Blue Cross & Blue Shield Association, Blue Shield of California, and ECRI.

American College of Physicians (ACP).

The Clinical Efficacy Assessment Project (CEAP) of the ACP began in 1981. CEAP evolved from ACP participation in the Medical Necessity Program of the BCBSA (see below), from which it had received financial support for Common Diagnostic Tests (Sox, 1987 and 1990) and Common Screening Tests (Eddy, 1991). The CEAP program received a three-year grant from the Hartford Foundation in its initial years (1981-84). Since that time, it has been funded from internal ACP funds and has relied heavily on the voluntary contribution of time by its members to conduct its assessments.

CEAP assessments involve a detailed examination of a technology or procedure. Over time, the focus has expanded from concern for evaluating the safety, efficacy, and effectiveness of diagnostic tests and medical technologies to the assessment of procedures and treatments used in clinical practice. The process involves a literature review and synthesis conducted by one or more college members, compilation of evidence tables, and the preparation of a manuscript by the analysts. The manuscript is subject to extensive review before its publication as a report authored by the analysts. A second product is generated by the CEAP committee, which prepares a draft statement about the appropriate conclusions and recommendations to be **drawn** from the review and synthesis manuscript. This draft guideline is also subject to extensive review and, when approved by the College's Board of Regents, becomes the official position of the ACP.

CHAPTER 3. THE PERFORMERS OF TA

Both the guideline and background paper are submitted for publication to the Annals of Internal Medicine. Many assessments have been highly controversial because they have intruded on the domains of various medical specialities. This is not surprising, as internal medicine intersects strongly with many specialty groups.

The ACP issues about ten assessments each year, a figure that has been stable for most of the past decade. The challenge to the ACP is whether to continue CEAP as a modest subsidized effort, whose products are “free” to the world, or transform it in some other way.

American Hospital Association (AHA).

The **AHA**, in 1982, initiated a Hospital Technology Series program, which was built around a set of publications and educational programs. The purpose of the effort was to help health care managers keep abreast of innovations in health technology and clinical hospital services and the implications that these innovations had for capital budgeting, staffing, training, maintenance, and the provision of clinical services. Financing came from internal **AHA** funds, from educational programs, and from publication revenues.

In the early **1990s**, the **AHA** underwent a major reorganization when a new president moved the main office was moved from Chicago to Washington, D.C. Policy functions previously located in Chicago were moved to D.C. as the organizational focused on health care reform legislation. Concurrently, all **AHA** products and services were reviewed. The Hospital Technology Series program lost its internal **AHA** funding, the educational programs were cancelled, but the publications program was continued.

The Health Technology Series now includes: Hospital Technology Scanner, reports containing evaluations of current and emerging management strategies, clinical practices, and

CHAPTER 3. THE PERFORMERS OF TA

medical technologies, and special reports that focus on current technology issues and trends. These publications are oriented mainly to hospital services--cardiology, clinical laboratory, diagnostic imaging, neurology, oncology, orthopedic services, rehabilitation, surgery, and to "big ticket" technologies such as information systems, lasers, lithotripters, magnetic resonance imaging (**MRI**), and positron emission tomography (PET). Even this scaled back effort reflects the continuing need of **AHA** members for technology assistance and the need of the organization to-maintain a presence in this field. Recently, the **AHA** has signed an agreement with the University Health System Consortium to market the latter's TA reports to **AHA** members.

American Medical Association (AMA).

The AMA has long issued reports on the scientific bases of various clinical procedures. It initiated its Diagnostic and Therapeutic Technology Assessment Program (DATTA) in 1982, publishing its first report in the Journal of the American Medical Association (JAMA) in 1983. The number of **DATTA** assessments has varied over time. This is indicated in the following table.

Table 3.1. AMA DATTA Technology Assessments, 1985 - 1994

Year	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994
Initial Assessment	6	6	4	3	8	9	8	5	3	5
Reassessment		1	1	1	2	2	1			

The breakpoint in this period is 1991, when general financial pressures on the AMA led to retrenchment in a number of activities. This time was marked by a two-year absence of a vice president for science and technology, the elimination of a long-standing drug evaluation program,

CHAPTER 3. THE PERFORMERS OF TA

and the loss of many science and technology staff. The **DATTA** program was continued but its staff was reduced and the number of assessments was scaled back.

CHAPTER 3. THE PERFORMERS OF TA

The process by which **DATTA** assessments are conducted has changed over time. Previously, **DATTA** staff prepared questions about a technology and distributed these to a panel of physicians, usually about 20 in number, drawn from a pool of several thousand experts. The questionnaire was not accompanied by a literature review. The result was an opinion poll of a large number of experts, which subjected the **DATTA** process to external criticism regarding the validity of expert consensus as a means to evaluate the science reported in the literature.

Under the new regime, questions are sent to a panel of expert physicians as before, but a literature review on which the questions are based is now sent to all panelists. The literature review is more systematic and structured than before, although it does not involve meta-analysis. It is a staff product and is reviewed by 2-3 peer reviewers from different specialties and points of view. In addition, a simple analysis of the data pertaining to the technology accompanies the questionnaire. Panel respondents rate the safety and effectiveness of each technology on an ordinal scale from +2 to -2 for each of five categories--established, promising, investigational, doubtful, or unacceptable. The size of the panels has been increased from about 20 individuals to about 50 at minimum, often over 100, and sometimes as high as 250. Finally, if there are not enough experts in the pool, the **DATTA** program will go outside the pool to the needed specialists or will go to the appropriate specialty societies.

The **DATTA** program employs 2.5 - 3.0 full-time equivalent (**FTE**) employees. Assessments today run 12-15 pages, compared to about three pages previously. Many are published in the Journal of the American Medical Association; all are available on a subscription service basis. A subscription, which costs \$325 for one year and \$485 for two years, brings back issues of **TAs**, current assessments, current Tech Briefs, the **DATTA** newsletter, Technology News, and access to the **DATTA** clearinghouse. There are 800-900 subscribers, of whom 80 percent are **M.D.s**, most of whom are engaged in managed care and utilization review.

CHAPTER 3. THE PERFORMERS OF TA

Blue Cross and Blue Shield Association.

BCBSA began its TA effort in 1977 with its Medical Necessity Program, which was designed to identify obsolete medical procedures as an aid to member plans regarding continued coverage of such procedures. The results of this program were made publically available by periodic press releases. BCBSA then added a Technology Evaluation and Coverage Program in the early 1980s to assist member plans in making coverage decisions about new medical technologies. The results of this program, however, were available only to member plans.

BCBSA also actively supported the TA efforts of other organizations. Notable was the financing of Common Diagnostic Tests: Use and Interpretation (Sox, ed.: 1st edition, 1987; 2nd edition, 1990) and Common Screening Tests (Eddy, ed., 1991), both prepared and published by the American College of Physicians (as noted above). It also provided financial support to the Institute of Medicine's Council on Health Care Technology during the 1985-89 period.

BCBSA Medical Necessity reports had always been in the public domain, while its Technology Evaluation reports had been for member plans only. Over time, these two efforts converged analytically. As they did, a business decision was made to make the reports of both programs publicly available--on a subscription basis--and not to seek a proprietary position regarding scientific information. In late 1993, BCBSA went public with an expanded technology assessment effort. Three "products" are now available: at the low end, Tecnologica, a newsletter published ten times a year, costs \$400 per year and provides summary information on at least one assessment per issue; in the middle, a standard subscription of \$13,500 buys all TA reports, which number approximately 40 per year, plus the newsletter; and at the high end, an additional customized package of services is available, including TA training of the subscriber's personnel and rights of observation at the BCBSA Medical Advisory Panel (MAP) meetings.

CHAPTER 3. THE PERFORMERS OF TA

Concurrent with going public, BCBSA entered into a collaborative relationship with Kaiser Permanente (KP), an arrangement regarded favorably by both parties. Both organizations are not-for-profit; both have invested substantial resources over time in quality-related efforts; BCBSA has a strong analytic staff; and KP has the largest HMO patient enrollment in the country. In this collaboration, both organizations share the services of Dr. David Eddy, a leading expert in TA; KP has access to the deliberations of the MAP through two members of the panel; and KP physicians are used in reviewing draft **TAs**, giving the end products a clinical reality test . At the same time as these changes were occurring, the MAP was changed to reduce the representation of Blue Cross members, add the two KP representatives, and appoint several unaffiliated national experts on TA and clinical research. Today, these unaffiliated members constitute a majority of the MAP.

The BCBSA TA program had grown to about 20 assessments a year by the time the 1993 change occurred, From 1993 to 1994, however, the capacity and output doubled and about **40** reports are now being produced each year. These reports are prepared by a full-time staff of approximately 10 professionals. Draft reports are reviewed by the MAP, which meets for four one-day meetings each year. The MAP considers the specific technologies on which staff have prepared reports and discusses and votes on a staff recommendation that a given technology “does meet” or “does not **meet**” the BCBSA technology evaluation criteria (listed on the following page.) These reports are advisory to member plans and subscribers as a decision-making input, usually for coverage decisions. BCBSA represents its work strictly as **TAs**, not as clinical practice guidelines.

Table 3.2. Blue Cross & Blue Shield Association Technology Evaluation Criteria

“1. The technology must have final approval from the appropriate government regulatory bodies.

- This criterion applies to drugs, biological products, devices and diagnostics.
- A drug or biological product must have final approval from the Food and Drug Administration.
- A device must have final approval from the Food and Drug Administration for those specific indications and methods of use that the Blue Cross and Blue Shield is evaluating.
- Any approval that is granted as an interim step in the Food and Drug Administration regulatory process is not sufficient.

“2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

- The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence.
- The evidence should demonstrate that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence or a convincing argument based on established medical facts that such measurement or alteration affects health outcomes.
- Opinions and evaluations by national medical associations, consensus panels, or other technology evaluation bodies are evaluated according to the scientific quality of the supporting evidence and rationale.

“3. The technology must improve the net health outcome.

- The technology’s beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.

“4. The technology must be as beneficial as any established alternative.

- The technology should improve the net health outcome as much as, or more than, established alternatives.

“5. The improvement must be attainable outside the investigational settings.

- When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy TEC Criteria #3 and #4.”

CHAPTER 3. THE PERFORMERS OF TA

Blue Shield of California (BSC).

Among the individual plans of the Blue Cross Blue Shield Association, Blue Shield of California stands out as having a long-established, well-developed independent TA program. The program, which is under the aegis of the Blue Shield Medical Director, focuses on a committee of the BSC Board of Directors, the Medical Policy Committee on Quality and Technology. Most of the 18-20 committee members are BSC board members, but some **non-board** members are added for their expertise. Of the committee members, roughly two-thirds are **M.D.s**, one is an ethicist, another a lawyer.

The Medical Policy Committee meets three times each year and considers a list of **half-a-dozen** or so “medical policy topics” at each meeting. Topics include new procedures or technologies for which a Blue Shield policy does not exist, or new indications for existing technologies for which a review and modification of a current policy is required. At the March 1995 meeting, for example, the agenda items were: laser uterine nerve ablation (LUNA); stereotactic radiosurgery for multiple brain metastases and gliomas; positron emission tomography (PET) for oncology indications; **sleep apnea testing**; sleep apnea surgeries; prolotherapy; and obsolete medical policies. The agenda for the June 1995 meeting included the following subjects: cryosurgery of liver tumors; arthroscopy and arthroscopic surgery of the hip; stereotactic pallidotomy for Parkinson’s Disease; external insulin pump therapy; and intravenous immunoglobulin (IVIG) indications. The October 1995 agenda included: stereotactic pallidotomy for Parkinson’s disease (discussed and tabled in June); PET for oncology and cardiology indications (oncology indications were discussed and tabled in March pending a BCBSA technology assessment; the BCBSA TA added cardiology indications); lung volume reduction surgery (LVRS); **meniscal** allograft transplantation; plasmapheresis indications; and hyperbaric oxygen therapy.

CHAPTER 3. THE PERFORMERS OF TA

For each of the medical technologies selected for consideration at any given meeting, the Blue Shield of California process involves a staff-generated literature review. This review becomes the basis for a policy recommendation by the Medical Director to the Medical Policy Committee, accompanied by supporting documentation. The committee receives two notebooks before each meeting. The first contains the staff analyses of the medical technologies or procedures under consideration. These analyses discuss the issue before the committee, background and current Blue Shield medical policy, the procedure itself, a review of the scientific literature in reference to the five BCBSA criteria (see above), views of pertinent medical societies, conclusions, and the Medical Director's recommendation. The form of the recommendation is that the given technology or procedure is either "eligible for coverage" or is "investigational." Eligibility for coverage may be restricted to particular indications for use or by certain requirements for the qualifications or experience of providers, or a procedure may require **preauthorization**. The second notebook includes approximately six to ten of the most important scientific papers on each of the specific medical procedures being considered.

The Medical Policy Committee meets for three half-day meetings each year, once each in San Francisco and Los Angeles, and rotating the third meeting among Sacramento, Orange County, and San Diego. Meetings are open to the public, including representatives of the print and electronic media, and involve open and often vigorous discussion of the Medical Director's recommendation by the committee members. The committee may also hear oral testimony by experts on a given procedure of technology. Using a majority rule, it then votes, usually to adopt, often to modify, and sometimes to table the recommendation of the Medical Director.

ECRI.

CHAPTER 3. THE PERFORMERS OF TA

ECRI, a nonprofit research organization, was established in 1955 as the Emergency Care Research Institute. It refocused its attention on medical technology in 1969 and, in 1971, established its Health Devices Program, essentially an equipment and device evaluation service. The primary clientele for this effort was hospitals, which were interested in procurement, safety, operation and maintenance, and general technology management. In **1981**, the organization established the Technology Assessment Program and sought to broaden its evaluations and expand the clientele group. The foundation of this effort, however, remained the evaluation of medical devices and hospital equipment to support hospital procurement. In the late 1980s and early '90s, **ECRI** surveyed the medical directors of third-party insurers, concluded that a market existed for technology assessment directed to these individuals, and initiated its current program, the Health Technology Assessment Information Service.

Currently, **ECRI** provides services in three areas: health care technology; health care risk and quality management; and health care environmental management. In health care technology, the **ECRI** catalogue lists various online data services (e.g., **ECRI**net, **Health Devices Sourcebook**, **Health Devices Alerts**), publications (e.g., **Health Devices**, **Health Devices Ale&**, **Health Devices Sourcebook**, **Health Technology Management**), and services to hospitals (e.g., health devices inspection and preventive maintenance system, equipment management software, health product comparison system, capital equipment procurement advisory service). The Health Technology Assessment Information Service constitutes the main TA effort of **ECRI**, described in its catalogue as “a comprehensive service that offers in-depth Custom Reports, database searches, regular newsletters, online services, published summaries, educational seminars, and a telephone hotline.”

The entire **ECRI** organization has slightly more than 225 **FTE** employees, many of whom hold doctorates in science. Of these, 3540 analysts and information specialists work in TA. The

CHAPTER 3. THE PERFORMERS OF TA

organization has strict conflict of interest policies that are consistently enforced: **it** accepts no advertising or financial support from medical product manufacturers and **no employee may own** stock in or consult for a medical equipment or pharmaceutical company. Staff members working in the Health Technology Assessment Information Service are prohibited from holding investments in managed care organizations and health insurers.

In the past five years, **ECRI** has increased the number and comprehensiveness of its **TAs** and now produces about 20-25 annually. Recent custom reports in oncology have included: assessment of the use of autologous bone marrow transplantation (ABMT) in the treatment of breast cancer, lung cancer, multiple myeloma, and ovarian cancer; and the use of interleukin-2 (IL-2) for the treatment of malignant melanoma and renal cell carcinoma. Cardiovascular assessments have included **tPA** versus Streptokinase for treating Acute Myocardial Infarction and an evaluation of left ventricular assist devices (**LVADs**). A large number of assessments of general medical devices, e.g., continuous lumbar passive motion devices for postoperative back surgery, and of imaging devices, e.g., ionic versus non-ionic radiographic contrast media, are performed.

The customers for **ECRI's** TA service include hospitals, physician organizations, and the medical directors of corporate health plans, **HMOs**, other managed care organizations, and health insurers, as well as **CHAMPUS**, HCFA, and some state governments, such as Tennessee. In addition, there is also a market for health care executives for summaries of longer reports. There are a variety of arrangements available for purchasing **ECRI** technology assessment reports and other services. Under one of these arrangements, a subscription to **ECRI's** technology assessment service costs \$15,000 per year, for which a subscriber gets six off-the-shelf reports and may request two new reports to suit its own needs. This ability of subscribers to specify customized **TAs** makes **ECRI** attractive to some parties.

CHAPTER 3. THE PERFORMERS OF TA

In its work for public and private payers, **ECRI** stresses the separation of technology assessment from coverage decision making. It believes that the former process is an objective evaluation of clinical and scientific evidence, while the latter is embedded in business, contractual, or regulatory considerations. In this way, **ECRI** seeks to ensure that its TA services bear scrutiny for technical merit and avoid financial and intellectual conflicts of interest. The organization's reports and processes are reviewed by an external audit committee of experts from the public and private sector who are committed to independent technology assessment and serve in an unpaid capacity.

C. New for Newly Visible) TA Organizations.

Evidence of increased demand for technology assessment is apparent with the emergence in the past decade of new organizational performers of **TAs**. These newer entrants may be established organizations with a new TA effort, or they may be new TA organizations. They constitute an organizational response to the changing health care marketplace.

In this section, we consider Aetna, Group Health Cooperative of Puget Sound, Harvard Community Health Plan, Hayes, the Institute for Clinical Systems Integration, Kaiser Permanente Medical Group, Kaiser Permanente Southern California, Kaiser Permanent Northern California, Prudential, TEMINEX, United Health Care, and University **HealthSystem** Consortium.

Aetna.¹

¹This information was obtained in 1995 before the purchase by Aetna of U.S. **HealthCare**.

CHAPTER 3. THE PERFORMERS OF TA

Aetna has 21,000 employees and about 18 million covered lives, 15 million of whom are in health plans. Its products include traditional indemnity insurance (2 -2.5 million), point of service (3.5 million and growing rapidly), **HMOs** (2 million), and **PPOs** (4 million). Twenty-four **HMOs** are covered by Aetna national policy.

Technology assessment is housed organizationally under Clinical and Coverage Policy (CCP), which also includes practice guidelines, **clinical** decision support, and the Institutes of Excellence network for organ and bone marrow transplantation. In addition, CCP has developed a cardiac care network. The TA unit consists of four physicians, one Ph.D., and three **R.N.s** who develop outcomes-based evaluations and precertification protocols for high-volume procedures that have a potential for high cost and controversy. The clinical decision support group includes two medical librarians, who respond to 8,000 queries each year, and a nurse who responds to field inquiries on a full-time basis.

Technology assessment provides direct support for coverage decisions. Assessments include, for example, peripheral endovascular interventions (peripheral laser (assisted) angioplasty; peripheral atherectomy; peripheral intraluminal stent placement), ambulatory event (transtelephonic) monitoring, and use of high dose chemotherapy and bone marrow/peripheral stem cell transplant for Hodgkin's disease. As of April 1998, Aetna has 315 assessments and policies that are on-line (through Med Query) for immediate access by its employees and health plan medical directors. Assessments also provide the precertification criteria for utilization management for **HMOs** and **PPOs**, including the patient selection criteria.

An assessment focuses on the indications for use of a technology and the data in the literature that support those indications. Assessments include sections on clinical policy, the disease or disorder, and outcome data. Evidence tables containing patient outcome data are included in major assessments, but not in the 2-3 page smaller assessments. A draft TA is

CHAPTER 3. THE PERFORMERS OF TA

reviewed by the Medical Directors' Advisory Committee, the Policy Review group (for business, legal, and actuarial aspects), and the director of TA prepares it in final form. An assessment then becomes the basis for translation into a coverage policy document. Coverage policies take federal and state coverage mandates into account, as well as provisions stipulated by the customer

TA is entirely internal to Aetna, which does not subscribe to BCBSA or ECRI. Turn-around time for an assessment is eight weeks. Volume is as follows: **1993, 45 major TAs**, 55 smaller assessments; **1994, 30-35** and 40-50; and **1995, 40-45** and **40-50**.

The scope is limited to devices and procedures. Emphasis is on new technologies, although policies for existing technologies are reviewed and updated, and some widely accepted procedures for which no data exist to support their effectiveness are occasionally reviewed. Drugs are handled by Aetna Pharmacy Management, a separate subsidiary, although the head of CCP chairs the Aetna P&T committee. This organization reviews FDA-approved drugs, which usually involves automatic approval for indemnity and PPO plans; reviews off-label use; and manages the drug formulary for the Aetna **HMOs**. The latter function involves analysis of relative effectiveness of a drug and cost, and sometimes cost-effectiveness, the only place in the Aetna system where cost is examined in direct relation to clinical outcomes for purposes of coverage.

Aetna established a terminal illness procedure five years ago, providing the stimulus to the Medical Care Ombudsman Program (MCOP) in Bethesda, Maryland. MCOP deals mostly with cancer. Its creation was driven by the controversy over the use of high-dose chemotherapy with autologous bone marrow transplantation. Aetna does not deny Phase III bone marrow transplant cases, but sends such cases to MCOP. A three-physician review team reviews the case for appropriateness of treatment for the particular patient. A definitive yes vote about effectiveness by one of the three reviewers results in an Aetna decision to cover. If the three

CHAPTER 3. THE PERFORMERS OF TA

physicians agree that treatment is not appropriate, they are prepared to go to court to defend their review. One hundred corporate firms now use MCOP, described below **in Chapter 4.**

Group Health Cooperative of Puget Sound (GHC).

Group Health Cooperative of Puget Sound is one of the country's oldest group model health maintenance organizations; physicians are salaried employees of the organization. It serves approximately 480,000 members in Western Washington and provides services in three geographic regions. Under the aegis of GHC Clinical Planning and Improvement are three long-standing committees that, broadly speaking, manage the GHC technology assessment and practice guidelines efforts. These are: the Committee on Medically Emerging Technologies (COMET); the Pharmacy and Therapeutics Committee (P&T); and the Committee on Prevention (COP).

COMET, established in 1981, deals with new medical procedures, devices, and practices. The committee conducts secondary **TAs** based on available data and on the credibility of the data source. The evaluation criteria are reliability and safety, health outcomes, satisfaction and desirability, and cost. Health outcomes are either primary endpoints or secondary endpoints that have a defined relationship to primary endpoints. Costs are assessed in relation to existing options, if any, but reportedly are rarely used as other criteria dominate decisions. The results of an assessment, then, are that a technology is clearly effective, clearly ineffective, or of indeterminate effectiveness.

When existing data are unclear or inadequate, resulting in an indeterminate judgment, GHC often institutes an internal clinical trial, in which data are collected by its physicians in accordance with a protocol and results are reported back to the committee on a periodic basis. For example, visually-assisted laser prostatectomy, an outpatient procedure, was considered by

CHAPTER 3. THE PERFORMERS OF TA

COMET. GHC urologists, strongly supported by device manufacturers, were promoting the procedure's use, but the data about outcomes were poor or nonexistent. A trial was designed, with assistance from the Center for Health Studies (GHC's health services research unit), and data were collected at 3, 6, 9, and 12 months. At 12 months, 100 patients had received the treatment: when matched against the controls, who had received transurethral prostatectomy, the outcomes were the same. The costs of the new procedure were substantially less than surgical prostatectomy, but in the period after the procedure treated patients reported more burning, bleeding, and pain. GHC decided that these data should be shared with patients, even though it was not in its immediate financial interest to do so.

The P&T Committee is more than 20 years old and has primary responsibility for managing the GHC formulary. In recent years, it has shifted from consensus-based to **evidence-**based assessments of new drugs in support of formulary decisions. One procedural change is that the P&T committee no longer allows requests for adding a new drug to come from an individual physician but requires that requests come from GHC divisions and be supported by data from the pertinent scientific literature. If an assessment of a new drug is favorable on effectiveness grounds, and the drug's financial impact on GHC is estimated at less than \$50,000 a year, the committee has authority to make a decision for the organization; if the impact is greater, the committee forwards its recommendation to the GHC Executive Council for decision. A form of cost-effectiveness analysis--cost-minimization--is done to the extent that the costs of comparable therapeutic agents are compared. Increasingly, the P&T Committee examines costs in terms of the drug versus no drug and the associated sequelae, such as hospitalization.

The P&T committee confronts several challenges. It follows the FDA docket closely for drug approvals, especially for those with a big political or financial impact. But pressure on FDA to review more drugs on a fast-track basis makes evidence-based assessment of patient benefit

CHAPTER 3. THE PERFORMERS OF TA

more difficult, to the extent that fast-track approvals are based on non-clinical surrogate endpoints. Another challenge to the committee is to shift the balance of its efforts from formulary management, a continuing responsibility, to influencing physician prescribing behavior. This objective is being helped by the installation of a computerized prescription order entry system, which will allow the integration of prescription data with the diagnosis of a patient's disease condition and eventually with a protocol for disease management.

The Committee on Prevention (COP) is oriented to primary and secondary prevention. Priorities for COP topic selection are based on the criteria that: (1) a clinical condition has a significant mortality, morbidity, or cost; (2) is pre-symptomatic; (3) is detectable; (4) an effective intervention exists; (5) GHC has the capacity to address the problem; and (6) resource use is justified on cost-effectiveness grounds. There are eleven key GH prevention areas, including tobacco use, cervical cancer, breast cancer, and HIV.

Until this past year, a fourth committee was involved, the Committee on Practice Efficacy (COPE), which was the clinical practice guidelines committee. COPE addressed the management of a disease-entity or clinical condition, often with respect to a defined patient population, in contrast to the COMET and P&T focus on specific technologies. It based its priorities on the identification of a gap between high quality literature and internal GHC data; i.e., if the data in the literature or within GHC were good, no guideline was developed; if the data were inadequate and the problem was important, a guideline would be developed. COPE has now been absorbed into a corporate oversight committee that helps divisions within GHC by providing them with a model of the criteria and processes for guidelines development.

Two characteristics of GHC guidelines are notable. First, the guideline is based on a careful assessment of the data in the scientific literature. And second, a good deal of attention is given to implementation of the guideline (Handley, et al., 1994). For example, in April 1991, a

CHAPTER 3. THE PERFORMERS OF TA

paper appeared in the New England Journal of Medicine (Catalona et al., 1991) that stated that prostate specific antigen (PSA) testing “identifies patients at high risk for prostate cancer.” Test ordering at GHC increased from 250 tests per month to 700 tests per month. This prompted concern, in part because GHC physicians were uneasy about using the test for screening purposes. A quick literature review led to the conclusion that PSA testing did not meet standard criteria for an acceptable screening test and may increase mortality and morbidity as a result of the clinical decisions taken in response to test results (Stuart, et al., 1992).

In response to this assessment, a guideline, “Prostate Specific Antigen (PSA) as a Screening Test for Prostate Cancer,” was prepared in early 1995 for GHC physicians and patients (GHCPs, 1995). The “Evidence Summary” for physicians included: background information about prostate cancer; data on PSA test characteristics (low sensitivity, ~70-80%; low specificity, ~38-59%; and low positive predictive value, ~10-50%). A discussion of benefits noted the absence of randomized clinical trial data showing that early detection of prostate cancer results in a decrease in cancer-specific mortality. The summary discussed the risks of the “cascade of interventions” that often were triggered by a positive PSA test result, including those associated with radical prostatectomy and radiation therapy. It concluded that “insufficient evidence” existed to support the use of PSA as a beneficial screening test for prostate cancer but that the test was of “known usefulness in monitoring the response to treatment of patients with known prostate cancer.” The two-sided single sheet of patient information reviewed the facts about prostate cancer, the two ways of detection (digital rectal examination, PSA test), some facts about the PSA test, and the implications of a positive PSA test result for treatment options (watchful waiting, radiation treatment, surgery, male hormone therapy), including the risks of each treatment (impotence, incontinence, death). The GHC guideline was preceded by two papers, one in HMO Practice (Stuart, et al., 1992) and the other in the Journal of Urology

CHAPTER 3. THE PERFORMERS OF TA

(Handley & Stuart, 1994). The latter reported a marked reduction in PSA tests in the feedback period following the assessment.

Several observations about GHC are pertinent to this discussion. First, the commitment to evidence-based **TAs**, P&T decisions, guidelines, and prevention guidelines appears to be genuine and deep. Dr. Michael Stuart, the COPE chairman, and Dr. Matthew Handley, have developed an instructional manual, An Evidence-Based Approach to Changing Clinical Practice (Stuart & Handley, n.d.), that has been widely used in **GHC's** own continuing education program. Second, the Division of Clinical Planning and Improvement is now seeking to build an integrated approach that links these four historically independent committees together at points of commonality; e.g., all groups now use the same format for evidence tables. Third, the Center for Health Studies, the health services research arm of GHC, supports clinical planning and improvement efforts in a number of ways, for example, participating in design of studies undertaken by the several committees. Fourth, substantial data system investments augur for an even stronger GHC capability to generate internal data bearing on clinical effectiveness, patient outcomes, patient satisfaction, and cost than currently exist.

Harvard Community Health Plan (HCHP).²

The Harvard Community Health Plan is an HMO with 570,000 enrolled members. Its Clinical Quality Management Department has a measurement effort oriented to health outcomes and a clinical planning and improvement element. The latter oversees both technology assessments and clinical practice guidelines, which are developed through their own distinct

*This discussion is based on information that was obtained before the merger of HCHP and Pilgrim Health System, now Harvard Pilgrim **HealthCare**.

CHAPTER 3. THE PERFORMERS OF TA

process. **TAs** and guidelines both use many of the same evidence-based processes, but the latter are concerned with processes of care and managing clinical conditions. (**TA** is sometimes referred to as a single-mode guideline.)

TAs are the province of the Committee for Appropriate Technology (CAT), which was organized in June 1992. The CAT consists of senior clinical leaders of HCHP (the Associate Medical Director for Clinical Quality, the medical directors of **HCHP's** three divisions, the Chief of Surgical Specialties, the Associate Medical Director for Practice Systems), the director of benefits and contracts for the Health Centers Division, the TA program manager, and a representative of the Fertility Review Board. The CAT meets every other month.

The CAT is a policy-making board for HCHP. As a general matter, it does not deal with specific case-by-case situations, often contracting with the Medical Care Management Corporation for external expert review on specific cases. It considers safety and efficacy, legal, marketing, adverse selection, and ethical aspects of the technologies it reviews, which are mainly new technologies but also include new indications and appropriate uses for existing technologies. An example of a technology assessment is pallidotomy for the treatment of Parkinson's disease. The TA process is as follows: for a given topic, an expert panel of physicians, mainly its own but including outside experts if necessary, is established to conduct the assessment; an evidence-based literature review is conducted by members of the expert panel and evidence tables are prepared; the entire panel reviews the evidence and makes recommendations to the CAT about the safety, efficacy, effectiveness, and cost-effectiveness of the technology; these recommendations are presented to the CAT at its meeting by a clinician from the expert panel, whenever possible, and the TA manager. The CAT then writes draft policies based on the evidence and rationale derived from the assessments. These draft policies are sent to approximately 120 clinical managers for review and may go through several revisions

CHAPTER 3. THE PERFORMERS OF TA

based on the comments received. The synthesis of comments is done by the **TA** manager; if major clinical issues are raised, however, the literature will be reexamined and the matter may be referred again to the expert panel. On completion of this process, policies are issued by the CAT.

The HCHP assessment effort is modest in scope, with one to 1 .0 **-1.5 FTE** staff support. It relies mainly on its own physicians for conducting assessments, but often brings in specialists affiliated with contract or partner hospitals, such as Brigham and Women's Hospital and Massachusetts General Hospital. In addition to doing its own **TAs**, HCHP uses **TEMINEX** assessments, often on a short-turn around basis. HCHP also subscribes to **ECRI's** service, partly for the customized reports. As a member of the HMO Group, HCHP has informal access to the medical directors of the other member organizations through the (non-TEMINEX) Quick Query service.

HAYES, Inc.

HAYES, Inc. was incorporated in 1989 as a consulting services organization with both a managed care and workers' compensation focus. It recognized that coverage decisions were often arbitrary and concluded that a market need existed in the payer community for TA support of such decisions. **ECRI** had not yet entered the payer market and **BCBSA's** assessments were still limited to member plans. Significant TA capability within the insurance industry was limited mainly to large insurers, such as Aetna and Prudential. The federal government's TA activity through OHTA and OTA did not meet private sector needs in terms of the number and timeliness of assessments produced. HAYES expected its initial market to be senior claims analysts in small to mid-sized insurance companies and **HMOs**. In actuality, most users are , physicians, nurses, attorneys, and senior managers dealing with claims and contract issues. Customers

CHAPTER 3. THE PERFORMERS OF TA

include a number of large HMOs, insurance carriers, PPOs, and the states of Minnesota and Tennessee.

HAYES published its first TA report in March 1991 and now markets two related services. It produces *The Hayes Directory of New Medical Technologies' Status*, a series of assessment reports on drugs, biologicals, devices, on diagnostic tests and medical and surgical procedures. As of December 1995, this directory consisted of eight volumes and about 450 reports. Existing reports are updated periodically and new reports are added on a quarterly basis. At present, 20-30 reports are issued each quarter, two-thirds or more being updates of existing reports. HAYES reports are based on information available in the published scientific literature, along with data from federal agencies and professional societies. These sources include NIH consensus conference statements, HCFA coverage decisions, FDA decisions, and position statements and guidelines developed by medical specialty societies and associations such as the American College of Physicians, the American College of Obstetrics and Gynecology, and the American Medical Association. Reports deal with safety, efficacy, patient selection criteria, impact on health outcome, comparisons to alternative technologies, and cost.

In addition to its TA reports, HAYES recently introduced *The HAYES Directory of Legal Precedent Reports* as its second product line. These reports deal with medical technologies that involve controversial legal issues pertaining to both medical malpractice and claims coverage litigation. About ten reports are produced quarterly, which discuss and review the emergence of case precedent, regulations, and statutes germane to applicable technologies and issues. **The organization has also begun to enter the hospital market, with** reports that focus on the acquisition of new technology; the emphasis here, however, is on risk management, quality assurance, utilization review, and the impact of technology on health outcomes; it is not on

CHAPTER 3. THE PERFORMERS OF TA

device performance. HAYES reports are available online through West Publishing (Westlaw) and, in early 1996, through Reed Elsevier (Lexis-Nexis).

In its medical technology assessments, HAYES does not use unpublished research data (sometimes called “the gray literature”) except on a customized basis for a specific client. In general, it relies on the peer-reviewed journal literature. Also, HAYES does not use specialty panels of experts to routinely review its products, viewing this as a way to control expert bias. A panel of physician-generalists with specialist training is used, however, for advice on coverage decisions and practice guidelines, incorporating both evidence-based **TAs** and expert opinion in their review and recommendations regarding the care of specific patients, policy development, and practice guideline development.

The HAYES staff consist of 7 full-time and 7 part-time employees, and 20 individual contractors, some of whom work for HAYES 20-30 hours per week. These people are mostly medical writers and editors, with varied medical backgrounds. The Philadelphia area, because of the large number of pharmaceutical firms, is rich with free-lance medical writers. No **MDs** are currently used as a primary writer, but physicians with research training are used as medical editors, reading for content accuracy, completeness, and relevancy, with an emphasis on evaluating the evidence.

Detailed information about pricing of the HAYES service--the Directory and the quarterly updates--is proprietary. In general, the organization wishes its customers to use the entire service, not just single reports. Pricing for a health plan, for example, is a function of the number of employees covered under the plan, the number of locations at which the service will be used, and the way in which the information is provided. For a small Taft-Hartley plan with 5,000 members, the initial cost may be \$2,000 and the annual fee an additional \$1,000. For a large multi-plan managed care organization, the cost may exceed \$100,000.

CHAPTER 3. THE PERFORMERS OF TA

Institute for Clinical Systems Integration (ICSI).

The Institute for Clinical Systems Integration originated in response to a Request for Proposals (RFP) issued in February 1992 to health care providers by the Business Health Care Action Group (see Chapter 2), a coalition of major Minneapolis-St. Paul employers. Among other things, the RFP called for a quality, technology assessment, and outcome measurement capability. The award-winning response to the RFP came from **GroupCare** Consortium, which consisted of Group Health, Inc., and its affiliated clinics, **MedCenters** Health Plan, Mayo Clinic, and Park Nicollet Medical Center. (Group Health and **MedCenters** merged in 1992 to form **HealthPartners**, which absorbed Ramsey Hospital and Clinic in 1993). The winning proposal led to the creation of **ICSI** as an entity to develop clinical practice guidelines and technology assessments.

ICSI, established in 1993, is a 501 (c)(3) non-profit organization whose founding members are **HealthPartners**, Mayo and Park Nicollet. Other participating organizations include 17 smaller Minnesota medical groups. The **ICSI** board includes three representatives from Health Partners, two from Mayo, three from Park Nicollet, two physicians from other medical groups, and three purchasers, including one from the BHCAG. **HealthPartners** makes a \$1.8 million payment to **ICSI** each year, which has a staff of twelve, eight of whom are professionals. The participating medical groups contribute services (basically physician time) on an in-kind basis to guidelines development and TA efforts; the total annual contribution is estimated at \$34 million from all groups, with Mayo and Park Nicollet each providing approximately \$800,000 per year of this amount.

The above arrangement means that **ICSI** is controlled by physicians from the medical groups and is funded by HealthPartners-the HMO. The basic objective in this design is to separate the preparation of guidelines and the conduct of **TAs** from decisions that the health plan

CHAPTER 3. THE PERFORMERS OF TA

must make on benefits and benefits design issues. **ICSI** reports go to the HMO as inputs to plan decision-making,

ICSI identifies six areas of long-term effort: population health--the general health status and health risk behaviors of specific populations; guidelines development (see below); measurement-of the effectiveness and appropriateness of practices in relation to guidelines and outcomes; technology assessment (see below); automation of clinical information; and continuous quality improvement. Guidelines development is described as follows:

“the process of analyzing all possible ways of treating a particular health condition to discover the current best practice. A guideline for care is then established in the participating medical groups so that all patients will receive the same high quality of care with little variation regardless of the individual physician’s practice style or geographic location.”

The process of guidelines development involves, first, the selection of a topic on the basis of health conditions common to a population, the potential impact of guidelines on that condition, the feasibility of developing and implementing guidelines, and the cost and frequency of treatment for these conditions. Next, a guideline work group is established of **cross-**disciplinary experts, who examine various treatment approaches and the associated outcomes data, identify the treatment that “yields the best, most consistent outcomes,” draft a guideline, with rationale and references, and measurement specifications for implementation. The draft guideline is then distributed for system-wide review, redrafted in response to comments, pilot tested, and then implemented on a system-wide basis. Once implemented, a guideline is periodically reviewed and monitored. Guidelines are the primary **ICSI** activity.

TA is important but has a slightly different focus and is at a somewhat earlier stage of development. **ICSI** describes technology assessment as:

CHAPTER 3. THE PERFORMERS OF TA

When the evaluation of new medical technology for its effectiveness. The results of technology assessment are incorporated into health care guidelines so that purchasers and patients will have the prompt benefit of new and effective technology and will not be subject to unnecessary costs due to the use of ineffective technology.”

TAs are supported by one full-time **ICSI** staff member and are organized under a Technology Assessment Committee (Stecher, et al., 1995). Committee members are appointed by **ICSI** and represent the various research, primary and specialty care medical departments from the participating medical groups; the chair of the **HealthPartners** benefits committee and a representative of BHCAG are also members. When a specific TA is undertaken, a Workgroup is formed of clinical experts as well as those with epidemiology and study design competence. A given assessment focuses narrowly on a specific new technology or procedure and is intended to aid clinicians in participating medical groups and support coverage decisions of Health Partners. The same evidence-based criteria that are used for guidelines are used for **TAs**, but there are seldom good data for review and the process is more dependent on the expert knowledge of the work group members. The evaluation criteria are essentially borrowed from BCBSA. Reports from groups such as TEMINEX, the Agency for Health Care Policy and Research, ECRI, and **DATTA** may be used in the TA process.

The TA process, however, does not yet have the same structure as the guidelines process. A formal process designed early in **ICSI's** existence was judged too complicated and the organization is currently designing a simpler process.

Kaiser-Permanente Medical Care Program.

Kaiser Permanente is the country's largest and oldest health maintenance organization with 6.5 million members. It is organized into 12 regions, which by design have a relatively high

CHAPTER 3. THE PERFORMERS OF TA

degree of autonomy from the corporate center. Two regions--Northern California and Southern California--account for 2.5 million and 2.2 million members, respectively, or 38% and 34% of total members.

At the corporate level, an Inter-regional New Technologies Committee has existed since the mid-1980s. This committee, whose members are drawn from the regions, meets four times a year. It reviews three-to-six technologies or procedures at each meeting, and has conducted over 450 during its decade-long existence. Following a review, the committee advises the regions of the views of clinical expert groups concerning experimental technologies. This allows for coordination of information among the Kaiser regions, while leaving coverage policy **decision-making** authority and responsibility at the regional level.

The new technologies committee is supported by one FTE professional and **relies heavily** on contributed time from regional medical directors and expert physicians on an ad hoc basis for a given assessment. Kaiser Permanente subscribes to ECRI, receives BCBSA assessments as a result of its recent relationship with that organization, and also obtains **TEMINEX** reports. It is prepared to use assessments from any legitimate source.

The scope of the committee's work began with medical devices but was expanded to include drugs when AIDS emerged. The primary review of drugs is at the level of the P&T committees of the regions. Coordination is served by the presence on the new technologies committee of a Regional Pharmacy Director. Although the emphasis of the committee's work is mainly on the new, it also re-reviews prior assessments as new information becomes available. Over one hundred technologies previously judged "experimental" have been reevaluated.

The concept of "experimental" as a basis for coverage decision-making is losing its usefulness within health care generally and specifically within Kaiser. As Dr. Ian Leverton, Director of Permanente Inter-regional Services, put it: "'Experimental' doesn't help in court. **Any**

CHAPTER 3. THE PERFORMERS OF TA

definition is problematic. A roomful of lawyers working for a week cannot write a definition.” The emerging alternative is to push the coverage decision down to the level of the individual physician and individual patient where the focus becomes the medical appropriateness of care.

On the other hand, committee deliberations and judgments rely heavily on the clinical literature for data about efficacy. Concern was expressed, therefore, that randomized clinical trials were becoming more difficult to conduct. In particular, the ethical constraints to **double-blind** clinical trials, the soundest methodological approach for determining medical efficacy, have become more constraining. Patient preferences, physician advocacy, and manufacturers’ interests in shorter trials are all factors limiting the ability to perform good trials. Given the dependence of TA on the published literature, this issue is seen as troublesome and becoming more so.

A Kaiser Permanente spokesman indicated the new technologies committee had not conducted cost-effectiveness analyses of procedures; it was “pure and virginal” in that regard (Telephone interview with Ian Leverton, M.D., October 4, 1995). Although expressing the view that CEA was an appropriate direction to move, he noted that existing Kaiser data systems did not permit such analyses to be done at the present time.

In general, the significant technology assessments are done by the regions, which strongly influence the work of the inter-regional committee. We focus below on the two largest regions, each of which has a representative on the BCBSA Medical Advisory Panel.

Kaiser-Permanente of Southern California (KPSC).

Kaiser-Permanente of Southern California is organized in 11 areas, has 3,000 physicians, owns 10 hospitals, and has 2.2 million members. In mid-1995, it merged its existing technology assessment and clinical practice guidelines development efforts within a new Department of

CHAPTER 3. THE PERFORMERS OF TA

Clinical Analysis. This marked the end of an evolutionary stage within KPSC relative to an array of TA activities.

A long-standing Medical Technology Committee has existed within KPSC, concerned with the acquisition of capital equipment and its associated logistics, which is now supported by the Department of Clinical Analysis. Assessments address appropriate utilization, clinical needs of provider and patient, equitable distribution within the region, and economics of procurement. Similarly, a P&T committee has existed for a long time to maintain the formulary at KPSC hospitals. It examines the merit of a drug for a selected group of patients; e.g., the use of Tacrine for the treatment of Alzheimer's disease.

In 1992, a separate biologicals committee was established to track and evaluate biotechnology products before they are approved by FDA. The special attention to biotechnology is based on the dramatic health benefits that are claimed for them before release and their high cost. (For example, when beta interferon was released, no cure existed for multiple sclerosis. Yet the press reported the biologic as a potential cure, generating intense interest among patients.) The biotechnology committee appoints a working group of physicians, pharmacists, and analysts for each biotechnology product as FDA approval approaches and as clinical data becomes available. After consensus building within relevant specialty groups, the **evidence-**based assessments of the biotechnology committee then go as recommendations to the P&T committee for a formulary decision.

Currently, attention is being given to the implications for KPSC of genetic technology research. Genetics poses a challenge for evaluation because there are a number of genetic tests on the market for conditions for which no treatment exists. Thus an array of ethical issues surrounds the use of such tests. Some of the KPSC effort in this area is directed to the education of the primary care physician. The biologicals committee initiated interest in this area,

CHAPTER 3. THE PERFORMERS OF TA

but interest has now migrated to an independent inter-regional project team examining **BrCa-1** in an effort to develop a clinical practice guideline.

Clinical practice guidelines lie at the heart of the KPSC technology assessment of procedures. Efforts focus on key areas of medical practice identified by KP physicians in which best practice can be defined and implemented. Assessments are conducted by relevant M.D. groups and technology assessment analysts through existing groups of specialty chiefs, regional committees, ad hoc task forces, and existing transplant committees. Evidence-based assessments involve extensive review of the efficacy of clinical interventions. Health policies result from these assessments and their implementation is monitored on an ongoing basis for health outcomes and utilization. Policies are reviewed periodically as new scientific evidence and monitoring data becomes available.

Kaiser-Permanente of Northern California (KPNC).

Kaiser-Permanente of Northern California, the largest of the 12 Kaiser regions, has 3,500 physicians, owns 15 hospitals, and has 2.5 million enrollees. Regarding TA activity, KPNC relies heavily on BCBSA for determinations about when, on the basis of the published scientific literature, a technology is no longer investigational. It also subscribes to ECRI. Infrequently, it will conduct an assessment itself, typically where none has been done by another organization. For example, it reviewed 4-5 procedures in 1994 that no one else had assessed to its knowledge, including 3-marker screening for genetic defects, small bowel nutrition (for taking small bowel patients off total parenteral nutrition), and cryoprostectomy (where a specific case required an evaluation).

KPNC's emphasis in the evaluation of medical technology, however, is on providing medically appropriate treatment to its enrollees. Consequently, most of its activity focuses on the

CHAPTER 3. THE PERFORMERS OF TA

review of cases of individual patients who, with their physician, are considering a treatment for which inadequate evidence of safety and efficacy exists. Such situations occur when a disease is very rare or when the difference in benefit between two treatments is so small that a definitive **clinical** trial would require large numbers of patients and many years of data collection. In contrast to the few formal assessments it conducts, KPNC reviews many individual patient cases. For example, in 1994, the estimates of case reviews of transplantation were 80 bone marrow transplants, 50 liver transplants, and about 40 heart transplants.

Case reviews are conducted by Permanente Medical Group physicians who are expert in a particular clinical area. KPNC has about fifteen standing clinical groups, or councils, which are built around a medical specialty or several related specialties. These councils meet regularly and may have a technology subgroup. For example, a bone marrow transplant council exists that consists of adult and pediatric oncologists and hematologists and has a subgroup for technologies. These councils have the primary responsibility for reviewing individual patient with respect to whether a particular treatment should be offered to a given patient. The process is described as consensus-based judgment of experts about cases involving treatments for which no evidence of efficacy or effectiveness yet exists.

If a KPNC clinical group decides that treatment for a given patient is medically appropriate, referral of the patient for enrollment in a clinical trial is provided. These referrals are based on standing agreements with major medical centers, such as Stanford. If the decision is to deny treatment, however, a three-level appeals process exists for the patient who disagrees with the judgment. The first level is to the advisory council; the second level is to two Kaiser physicians not involved with the case; and the third level is to the Medical Care Ombudsman Program of Bethesda, Maryland, which maintains a national roster of physicians for responding to such appeals (see Chapter 4 for more detail).

CHAPTER 3. THE PERFORMERS OF TA

KPNC has moved away from denial of coverage of experimental treatments. Currently, it allows patients to receive experimental treatments if they enroll in a clinical trial. In 1996, it plans to remove the experimental exclusion language from its contracts. The critical issue for KPNC is no longer exclusionary contract language but one of medical appropriateness as determined by expert physician review.

Other evaluative tasks are performed by different groups. P&T committees exist at each medical center and are overseen by a regional group; their job is to maintain the formulary. Medical device acquisition is handled by some 25 groups, e.g., for patient monitoring, imaging, nuclear medicine, intensive care nursery, etc, which consist of clinicians, biomedical engineers, and others. These groups review devices, visit manufacturers, review internal data, and then enter into an exclusive contract with a single manufacturer for all Northern California units. On the basis of this work, interregional contracts are now being developed for many products within the overall Kaiser system.

KPNC does not conduct cost-effectiveness analyses of new technologies. It does a large number of management-oriented cost analyses with respect to whether a given capability should be provided directly by Kaiser Permanente or should be obtained on a contract basis (the “make or buy” decision), but this is distinctly different from CEA. A spokesman noted that there exists a widespread public impression and frequent criticism of **HMOs** that they have incentives to undertreat for financial reasons. This criticism constitutes a disincentive to do formal **cost-effectiveness** analysis, which would only reinforce a negative public image, a decidedly different view than the data limitation view expressed by the corporate spokesman.

KPNC differs substantially at present from KPSC. The contrast between these two regions, which together include more than 80 percent of all Kaiser members, suggests some of the limits of TA as well as one strategy for dealing with new technology.

CHAPTER 3. THE PERFORMERS OF TA

Prudential.

Prudential is a national insurance company with **50-55** local health plans, defined geographically by cities and grouped in five regions. Local plans have a relatively high degree of autonomy. The company business includes both traditional indemnity health insurance and managed care products.

The Prudential home office in Roseland, New Jersey, provides technology assessment support to the member plans to ensure uniformity and efficiency through a formal TA program that has existed since 1985. **TAs** support two types of organizational decisions: corporate policies on coverage to guide local plans; and case-by-case decisions by local plan medical directors on **preauthorization**, and sometimes after-the-fact authorization, of treatments.

The Prudential TA effort is staffed by approximately ten professionals, primarily nurses and individuals with insurance experience, who conduct about 40-45 **TAs** each year. The criteria for assessing a technology include the following: it involves a new method of preventing, diagnosing, or treating a health problem; it involves a service that is frequently utilized, or costly, or controversial, or subject to rapid change, or subject to fraudulent and abuse practices; or new data have become available; or a given M-TECS has not been reviewed in the past three years.

Assessments involve review of the peer-reviewed literature, official statements of professional medical specialty societies, consensus statements from government agencies, **TAs** performed by public and private agencies, review of policies of federal agencies (e.g., FDA, NIH, AHCPR, HCFA). Staff select the pertinent studies, summarize the results of these studies, and formulate conclusions in a draft assessment. Draft assessments are then reviewed by the medical leadership of Prudential, sent to 70-80 physician consultants for review and comment, and then distributed to the five regions.

CHAPTER 3. THE PERFORMERS OF **TA**

The final review of a draft TA is done by the Technology Assessment Advisory Committee (**TAAC**), which meets quarterly and includes corporate representatives from underwriting, claim, executive management, pharmacy, marketing, contract, medical, and law. The TAAC has final authority to approve an assessment, which is issued as a Medical Technology Evaluation and Coverage Statement (M-TECS), a three-part document consisting of a claim administration summary, a clinical summary, and the longer assessment. The claim summary and full assessment are proprietary and distributed only within Prudential; the clinical summary is sometimes distributed to others, such as medical personnel of affiliated medical groups. An approved M-TECS is published and distributed to the five Prudential regions, which are responsible to implement these policies in a uniform manner.

An estimated one-third of the **TAs** are new and two-thirds are updates of existing policies. Prescription drugs are reviewed by a separate Pharmacy Benefits unit. An estimated one-third of the drugs reviewed are newly approved agents and about two-thirds involve off-label use of FDA-approved drugs.

Prudential also subscribes to the BCBSA TA service and attends Medical Advisory Panel meetings, and subscribes to **ECRI's** service, to **DATTA**, and according to one officer to “whatever is out there.”

Prudential's evaluative activities go beyond technology assessment and include related efforts in health services research and practice guidelines. In 1993, when Dr. William L. Roper joined the company, he established what is now known as the Prudential Center for Health Services Research. Staffed by over twenty individuals, the center has 25 health outcomes studies underway that are intended to support the 5 million Prudential enrollees. Studies are conducted by staff and, on contract, with the Department of Health Care Policy of Harvard Medical School. These studies deal, for example, with the improvement of immunization rates;

CHAPTER 3. THE PERFORMERS OF TA

the improvement of mammography rates; guidelines for low-back pain; and diabetes management. The first of these studies are being completed and the results are being submitted to peer-reviewed journals so they may be widely available to the public. Clinical practice guidelines are also being developed at the local health plan level with guidance from the Prudential corporate offices.

TEMINEX (of The HMO Group).

The HMO Group was established in 1984 and, as of January 1, 1995, consists of thirty member and associate member plans serving more than 7 million members. The major plans include: Kaiser-Permanente, nine of whose regions joined in 1994; Group Health Cooperative of Puget Sound; **HealthPartners** of Minnesota; Harvard Pilgrim Health Plan; and Health Insurance Plan of Greater New York. The mission of the organization is to strengthen group practice **HMOs** through collaborative activities in the areas of affordability, member satisfaction, and improved health status and to promote group practice **HMOs** to purchasers, consumers, regulators, and the public. Its programs include the exchange of data to measure, report and improve performance of its member plans, the promotion of total quality management systems, management councils for meetings of senior HMO managers (directors, medical directors, finance directors, marketing directors) to share information, and clinical symposia and technical seminars on issues pertinent to prepaid group practice.

The Technology Management Information Exchange (TEMINEX) is a service to the medical directors of The HMO Group member plans. Located in Buffalo, New York, it employs approximately 2.5 full-time professionals (an MD who provides oversight, an MD, **PhD** project manager, and an epidemiologist). On request, **TEMINEX** staff provide plans with **evidence-**based secondary assessments of health care technologies. These assessments are advisory to

CHAPTER 3. THE PERFORMERS OF TA

plans, but the plans make decisions and TEMINEX publicly disclaims liability for these decisions. Plans seek TEMINEX advice on the following: the appropriate use of a health care technology in the case of a specific patient; a prospective assessment of a technology's potential impact on a plan and advice on managing that impact; support for a plan's own technology assessment activities; and assistance in clinical guideline development.

TEMINEX assessments involve a literature review, a rating of the evidence, and the opinions of key consultants regarding probabilities of success of a procedure, the best treatment centers for doing the procedure, and the best outcomes for a patient. The evidence grading is worth noting. A September 1994 TEMINEX report on "intravenous immunoglobulin for the prevention of recurrent infections in pediatric patients" responded to the question, "Does the peer-reviewed medical literature support the use of **IVIg** in pediatric patients with recurrent infections, particularly otitis media and sinusitis, who also have evidence of **IgG** subclass deficiency and/or lack of response to common antigen?" as follows:

'Two small randomized clinical trials which used **IVIg** to treat patients with multiple episodes of otitis media or chronic chest symptoms are available. These trials did not report the **IgG** subclass status of enrolled patients, were not blinded, included very small numbers of patients, and did not report confidence intervals for the treatment effects attributed to **IVIg**. Therefore, the randomized clinical trial evidence supporting the use of **IVIg** in this clinical situation cannot be adequately ranked without the help of a formal meta-analysis.

"For the specific clinical situation presented by patients with defined **IgG** subclass deficiencies and/or inability to respond to common antigen, no evidence supporting the administration of **IVIg** is available from randomized clinical trials. Reports in the literature

CHAPTER 3. THE PERFORMERS OF TA

are confined to nonrandomized historical cohort studies (Level IV evidence) and case series (Level V evidence).”

In addition to the preparation of reports, the **TEMINEX** serves as a clearinghouse for its member plans. **TEM INEX** staff survey technology assessment staff at HMO Group member plans three times a year for work in progress. They are able to use this information to inform member plans about others who may be researching the same topic, as well as to identify topics of interest to all or most plans. Sharing of assessments occurs among the members.

United HealthCare.

United **HealthCare** was primarily a national managed care organization consisting of about twenty health plans and some small amount of indemnity insurance until July 1995. It then announced its intention to purchase **MetraHealth**, a joint venture of Metropolitan Life Insurance Co. and **Travellers** Group.³ United has a formal TA program as a central office support function for its local plans. This program is staffed by one FTE professional. It also obtains four or five annually from its **ECRI** subscription for **TAs** that meet a standard of impartiality and provide an in-depth treatment of a technology; subscribes to the HAYES service (see below) as a reference tool; subscribes to the AMA DATTA service; receives the assessments of the Clinical Efficacy Assessment Program of the ACP; obtains AHCPH technology assessments and practice guidelines; and monitors the outputs of professional societies.

Over the past three years, the United TA effort has shifted from an exclusive focus on case reviews of single patients to include more comprehensive analyses of technologies, their indications, data about patient benefit, and comparison to alternative technologies. The criteria

³ The information in this section was obtained before United **HealthCare** acquired **MetraHealth**.

CHAPTER 3. THE PERFORMERS OF TA

for TA priorities are the following: the level of controversy within the medical and scientific community about the efficacy of a technology; cost implications; potential for rapid diffusion; existence of alternative technologies; impact on patient safety and health outcomes; impact on a substantial patient population; and level of public and professional demand for a technology.

TAs involve an evidence-based staff review of the literature, with attention to safety, efficacy, and outcomes. Staff may also query other national organizations for regulatory information, available clinical guidelines, published assessments on the topic in question, and any referrals that may be appropriate. The literature review is then circulated for discussion to physicians throughout the country, whose comments are incorporated into a document that is sent to the corporate medical management team.

The TA review indicates whether a procedure is safe and efficacious, or still considered experimental or unproven. Coverage recommendations are made for each indication of a safe and effective technology. In addition, there is an accompanying analysis as to why the technology does or does not surpass conventional technology. A statement about competitor policies on a technology may also be included as part of the assessment. Federal and state government mandates for health care, as well as specific health plan contract language, are reviewed during the process as these take precedence over Medical Services recommendations.

The review is sent next to a United HealthCare TA Review Committee. This committee includes health plan medical directors and health service directors, corporate representatives from claims, legal/contracts, and indemnity products. The committee reviews the draft TA and its conclusions. These comments and the draft then go to the Medical Services Management Team for a final conclusion and preparation of the assessment for distribution to member plans with the next Medical Management Manual update. Technology assessments are advisory, being one input to United's coverage decision-making process. Although the Medical Policy Manager is

CHAPTER 3. THE PERFORMERS OF TA

responsible for the incorporation of a TA recommendation into coverage policy, the Medical Director drafts the technology assessment document. The format is such that the TA is easily converted to a coverage policy statement.

Drugs are dealt with separately from procedures and devices. Diversified Pharmaceutical Services (DPS), which was a United specialty company, manages United's local health plans' pharmacy benefits. DPS was sold in 1994 to **SmithKline**, but under a contractual arrangement with United it will continue to manage pharmacy benefits for another six years.

Clinical practice guidelines, of which about 20 are developed by United each year, may result from one of two sources. A national guideline, either from AHCPH or from a medical specialty society, may provide the basis for the development of a United practice guideline. In such cases, the sources of the information used in the guideline are verified and the document is converted to United's guideline format. It is then reviewed by United corporate medical directors, medical directors of selected health plans, and United's Chief Medical Officer. A guideline is sometimes reviewed by non-United physicians expert in the area. Internal practice guidelines are developed in a manner similar to technology assessments. Guidelines, following the specified organizational review process, are distributed in the quarterly update of the Medical Management Manual.

University Health System Consortium (UHC).⁴

The UHC, an association of 70 academic health centers (AHCs), was formed in 1994 by 23 university hospitals. Its mission is "to maintain and strengthen the competitive position of its individual members and their network partners in their respective health care markets." UHC's

⁴ In October 1995, UHC formally changed its name from University Hospital Consortium to University Health System Consortium.

CHAPTER 3. THE PERFORMERS OF TA

initial focus was to obtain group purchasing economies for its members. Today, it is organized around the following activities: (1) group purchasing of major capital acquisitions, pharmaceuticals, IV delivery products, materials and supplies; (2) information resource services; (3) “value management” [see below]; and (4) market management.

Market management focuses on assisting UHC members to conduct local health market analyses and to formulate appropriate strategic responses regarding the management of enrolled populations, to obtain national contracts for UHC members’ managed care products, to analyze **capitation** arrangements, and to design primary care networks for contracting in an increasingly **capitated** market. A central element in this area is the UHC four-stage market evolution model that evaluates the implications for an AHC of local market penetration by managed care plans.

Under “value management,” the Clinical Practice Advancement Center (CPAC) of UHC has programs related to: clinical information management; clinical process improvement and measurement, e.g., benchmarking, guidelines use, and outcomes management; clinical research; and technology assessment. CPAC was formerly called the Technology Advancement Center (TAC), which was created in 1988 to provide UHC members with an expert resource in “**technology** development, assessment, acquisition and management.” This statement reflects the complex and multi-faceted orientation that hospitals have toward medical technology.

Technology assessment at UHC began in 1989 with a committee-directed effort. In 1991, UHC concluded that more structure was needed and a full-time staff member was assigned to the TA effort. Currently, 6 **FTEs** are devoted to TA, with outside consultants used as needed. The effort today is directed to ‘evaluating and comparing the safety, effectiveness, efficiency, appropriateness, cost and clinical outcomes of new and existing technology and disseminating the critical information provided by such assessments.’ TA has been defined by the principal UHC staff officer as “the process that examines the available evidence to form a conclusion as to

CHAPTER 3. THE PERFORMERS OF TA

the merits or role of a particular technology in relation to its possible use, purchase, or reimbursement in current medical practice” (Matustewski, 1995).

Priorities for TA are established by a staff review of the literature and an annual survey of UHC members. The annual surveys have generated a steadily increasing number of distinct topics: about 100 in 1992, about 150 in 1993, and 199 in 1994. A technology is considered for assessment if it is used with a large number of patients, is controversial, expensive, risky or unproven, has reimbursement difficulties, has multiple accepted treatment uses or diagnostic methods, or displays unexplained variation in medical practice or outcomes. The UHC TA program issues approximately 10-12 **TAs** per year, with an additional 18-20 new drug monographs. These assessments list appropriate uses, promising but unproven uses, and inappropriate uses of a given technology. UHC also publishes a Technology Assessment Monitor, a guide to the published **TAs** of other organizations, and a monthly newsletter, **Technology Alert**.

In short, UHC has developed a TA effort that is embedded in an integrated program of related activities and responds to the needs of its members for information on the use of **high-impact** medical technologies. It does so by literature review, consensus panels, surveying member practices, analyzing UHC databases, benchmarking best practice, reporting back to its members through its reports, and recently by providing feedback through reports and focused educational conferences that report on member use of best practice information. UHC TA documents are available for purchase for **\$50-\$100** to any interested party. In addition, under a contractual arrangement with the Department of Veterans Affairs, all DVA member hospitals now receive UHC TA products.

CHAPTER 3. THE PERFORMERS OF TA

D. Federal government activity (in brief).

During the past decade, federal agency or federally-sponsored TA activities have remained stable or have diminished in level of **effort**.⁵ The National Institutes of Health, through the Office of Medical Applications of Research (OMAR), continues to conduct its consensus conferences at a steady level of 1 O-1 2 each year. The Office of Health Technology Assessment (OHTA), now housed in the Agency for Health Care Policy and Research (successor to the National Center for Health Services Research and Health Care Technology Assessment), performs work that is regarded as of high quality, but at such a modest level of effort that it is not a major force on the national scene.

The Health Care Financing Administration (HCFA), which seeks advice from OHTA for some of its coverage decisions, has been politically constrained from converting a 1989 proposed rule to a final rule that would strengthen the Medicare coverage decision process by, among other things, incorporating cost-effectiveness as one element supporting its decisions. In late 1995, however, HCFA contracted with **ECRI** to perform technology assessments similar to those conducted by OHTA.

The Department of Veterans Affairs (DVA), which is basically a large, publicly funded hospital system, has been politically sheltered to some extent from the budgetary pressures that have constrained other federal government agencies. It sponsored a conference on technology assessment in early 1995 and now has a full-time experienced TA professional who is developing an assessment program. The DVA also has an agreement with UHC by which a

⁵**FDA** evaluates therapeutic products (drugs, **biologics**, and medical devices) for safety and effectiveness, as required by law. Although some analysts regard FDA as a technology assessment agency, the FDA does not see itself in that light. Thus, they are not included here.

CHAPTER 3. THE PERFORMERS OF TA

single copy of UHC TA reports are sent to each **DVA** hospital.

CHAMPUS, the health insurance agency of the Department of Defense that provides for the care of military dependents, has no internal TA capability, but in the Fall of 1995 it contracted with BCBSA for TA services. **CHAMPUS** also uses **ECRI** assessments regularly.

Among the Congressional staff agencies, the technology assessment picture is mixed. The Prospective Payment Assessment Commission (**ProPAC**) has displayed much less concern for medical technology and its assessment in recent years than it did after its inception in the mid-1980s. Its sister agency, the Physician Payment Review Commission (pprc) has included chapters on technology in recent reports: in 1994, it addressed "Coverage decisions and technology assessment"; and in 1995, it followed with a discussion of "Improving Medicare coverage decisions." The Office of Technology Assessment (OTA), which led the way in pioneering technology assessment in the federal government, including TA in the health arena, was terminated by the 104th Congress at the end of fiscal year 1995. The General Accounting Office has conducted specific studies that might be designated as **TAs**, though it has no systematic TA program; moreover, it faces an overall 25 percent reduction of budget and staff in fiscal years 1996 and 1997.

In short, in the past decade, the federal government has not established and maintained a strong presence in TA. By contrast, in response to changes in the health care market, driven initially by large corporate purchasers of medical care and, secondly, by the managed care organizations that are reorganizing care delivery, private sector TA activity has grown significantly.

E. The new organizational pattern of TA.

CHAPTER 3. THE PERFORMERS OF **TA**

It is important to recognize the new relationships that have emerged between government and non-government organizations and between national, regional, and local organizations. In the 1970s and '80s, TA was strongly associated with efforts to create a national organization, first in the federal government and then in the non-profit private sector. A federal agency, the National Center for Health Care Technology, established in 1978, was focused both on research-by statute-and on Medicare coverage decision-making-by delegation of administrative authority. The latter proved to be its undoing; it was disestablished in 1982. Its organizational legacy, the Office of Health Technology Assessment, is a slimmed-down version of the original concept with a Medicare coverage advice charter. Regrettably, research support fell by the wayside.

A private sector effort, the Council on Health Care Technology of the Institute of Medicine, National Academy of Sciences, was established in 1985 and was justified as a **private-public** cooperative effort. Its Congressional charter, budgetary constraints, and organizational resources limited its performance, however, as did the clarity and strength of demand for its services. It was disestablished in two steps: the statutory authorization for public financing was withdrawn in 1989, and the IOM terminated the organization within the following year. Thus, over a period of roughly twenty years, aspirations for a strong national TA entity have not materialized.

However, the intellectual support for a centralized national capability has hardly expired. Fuchs believes that the need exists for a large organization, financed by major payers, that is dedicated exclusively to technology assessment. Its mission would include both the direct conduct of **TAs** by its own professional staff and the contract support of **TAs** by others (Interview, March 1, 1995). The PPRC, in 1994, as noted above, recommended a "single national entity [that] should decide for all health plans whether selected major new technologies and treatments are covered for particular indications" (PPRC, 1994).

CHAPTER 3. THE PERFORMERS OF TA

In the past decade, however, a strong, decentralized **TA** capability has developed in the private health care sector of the United States, consisting of a small number of national organizations and a growing number of larger health plans. In this context, the federal government is only one player in a decentralized **TA** community, and a modest one in volume of output and timeliness of product. Moreover, the federal government is in a relatively weak position to exert leadership within this **TA** community along the lines envisaged in the 1980s.

The organizational development in the private sector can be characterized in the following way. First, two organizations--Blue Cross and Blue Shield Association and ECRI--have experienced strong growth in response to increased private sector demand. BCBSA has expanded beyond a **TA** service to its member organizations and now offers a subscription service to all those able and willing to pay. It now conducts approximately 40 **TAs** a year. ECRI, building from its base of hospital-oriented, device evaluation, has also developed a subscription service, whose customers are able to request **TAs** on medical devices, pharmaceuticals, and clinical procedures of their own choosing in addition to obtaining assessments on topics done for several parties.

Second, several organizations confront or have confronted complicated organizational challenges. The American College of Physicians, long a leader in the quality of its assessments through its Clinical Efficacy Assessment Program (CEAP), has been financed over time by a combination of contracts, foundation grants, internal ACP funds, and volunteer time. Whether this resource base is adequate to sustain the CEAP in the next decade remains to be seen. The American Medical Association **DATTA** program, after a contraction due to budgetary cuts in all service areas several years ago, appears to have stabilized in level of effort, has augmented its consensus-based activity with more systematic reviews of the literature, and has developed a subscriber base. The American Hospital Association technology program, which also contracted

CHAPTER 3. THE PERFORMERS OF TA

earlier in this decade due to changes in the organization's leadership and a subsequent review of all **AHA** services, also appears to have stabilized as member-service effort, including the distribution of assessments of the University Hospital Consortium.

Third, constituency TA organizations have emerged in the past decade that serve *special clientele*. Although the primary value of the University Hospital Consortium (UHC) to its members probably lies in its aggressive effort to analyze the implications of managed care for academic health centers, UHC has developed a TA program in the context of an array of clinical practice improvement efforts that responds to the needs of its 70 university hospital/health system members. Given its technical competence and its demand-driven program, UHC may emerge in the next decade as a strong national organization addressed to the TA needs of the hospital sector, especially as hospitals evolve into integrated health delivery systems. Its contractual arrangements in the past year with both the American Hospital Association and the Department of Veterans Affairs for the distribution of UHC documents suggest this possibility.

The Technology Management Information Exchange (TEMINEX) is another constituency organization that has developed to serve the TA needs of the HMO Group, an organization of 30 group and staff model health maintenance organizations. Finally, in Minnesota, the Institute for Clinical Systems Integration (ICSI), created in response to an RFP from the Business Health Care Action Group, serves the needs of about 20 Minnesota health plans, mainly with respect to clinical guidelines but also to TA.

Some TA organizations can be defined in terms of *differentiated products*. HAYES, for example, has chosen to produce a large number of TA reports, very rapidly, and to update these on a regular basis. Its assessments do not involve the staff input of a BCBSA or an ECRI, but at present it appears that they do respond to a market need.

CHAPTER 3. THE PERFORMERS OF TA

Fourth, several national insurance and managed care organizations, such as Prudential, Aetna, and United Health Care, have developed technology assessment efforts that involve substantial internal staff resources for the conduct of TA, as well as for monitoring the **TAs** of others for an audience of their local health plans. These organizations are reviewing the scientific literature more systematically than before as a way to make or guide coverage **decision-**making for their member health plans. They are also building outward in a number of different ways to create related evaluative capabilities regarding clinical practice guidelines and health services research units.

Fifth, several individual health plans have well-developed TA capabilities. Group Health Cooperative of Puget Sound, for example, has had long-standing internal committees for the evaluation of new technologies (procedures and devices) and pharmaceuticals, and the development of prevention guidelines and therapeutic and diagnostic practice guidelines. Recently, Group Health has begun to link these related efforts, all of which share a common methodology, in an integrated system. This system is also supported by an internal **physician-**education effort focused on evidence-based medicine and by a high quality health services research unit. Overall, the organization is making substantial data system investments. Harvard Community Health Plan has a TA effort as an element of its overall quality improvement efforts. Kaiser Permanente of Southern California is developing an integrated practice guidelines and TA effort.

In general, we observe several broad patterns of organizational development in TA. One pattern might be called “distributed centralization.” In this case, the federal government is a player, but one with a much more limited role than envisioned a decade ago. It now shares this role with several other private national organizations, such as BCBSA, ECRI, and UHC. A second might be called “dedicated centralization.” In this case, TEMINEX, Aetna, Prudential, and

CHAPTER 3. THE PERFORMERS OF TA

United HealthCare serve their own national member organizations. A third pattern is a mix of decentralization and centralization, in which organizations such as the Institute for Clinical Systems Integration (ICSI), Group Health Cooperative of Puget Sound, and Harvard Community Health Plan, are producers of assessments for their own organizations at the same time as they are consumers of the TA output of the national organizations.

CHAPTER 3. THE PERFORMERS OF TA

REFERENCES

- Catalona, W.J., Smith, **D.S.**, Ratliff, T.L., Dobbs, **K.M.**, Coplen, D.E., and Yuan, J.J., 1991. "Measurement of prostate specific antigen in serum as a screening test for prostate cancer," New England Journal of Medicine, Vol. 324, pp.1 156-ff.
- Eddy, D. M., ed., Common Screening Tests, Philadelphia, PA., American College of Physicians.
- Group Health Cooperative of Puget Sound, 1995. Guidelines: Prostate Specific Antigen (PSA) as a Screening Test for Prostate Cancer, Seattle, WN., GHCP.
- Handley, MR., and Stuart, M.E., and Kirz, H.L., 1994. "An Evidence-based Approach to Evaluating and Improving Clinical Practice: Implementing Practice Guidelines," HMO Practice, Vol. 8, No. 2 (June), pp. 75-83.
- Handley, MR., and Stuart, **M.E.**, 1994. "The Use of Prostate Specific Antigen for Prostate Cancer Screening: A Managed Care Perspective," The Journal of Urology, Vol. 152 (November), pp.1 689-1 692.
- Institute of Medicine (Goodman, C., ed.), 1988. Medical Technology Assessment Directory, Washington, D.C., National Academy Press.
- Institute of Medicine (Mosteller, F., ed.), 1985. Assessing Medical Technologies, Washington, D.C., National Academy Press.
- Matuszewski, K.A., 1995. "Technology Assessment," pp. 123-148 in Oleske, D.M., ed., Epidemiology and the Delivery of Health Care Services: Methods and Applications, New York, Plenum Press, 1995.
- Physician Payment Review Commission, 1994. Annual Report to Congress. 1994, Washington, D.C.
- Physician Payment Review Commission, 1995. Annual Report to Congress. 1995, Washington, D.C.
- Sox, H.C., Jr., ed., 1987, 1990. Common Diagnostic Tests: Use and, 1st edition, 2nd edition, Philadelphia, PA., American College of Physicians.
- Stecher, T.J., Evans, R.W., Mosser, G., Reed, M.K., and Smith, J.C., 1995. "Technology Assessment at the Institute for Clinical Systems Integration and Health Partners," HMO Practice, Vol. 9, No. 1 (March), pp. 22-26.
- Stuart, M.E., Handley, M.A., Thompson, R.S., Conger, M., Timlin, D., 1992. "Clinical Practice and New Technology: Prostate Specific Antigen (PSA)," HMO Practice, Vol. 6, No. 4, pp. 5-1 1.

CHAPTER 3. THE PERFORMERS OF TA

Stuart, **M.E.**, and Handley, M.A., n.d. **An Evidence-Based Approach to Changing Clinical Practice**, Seattle, WN., Group Health Cooperative of Puget Sound.

TEMINEX Report: Study #26, September 1994. **Intravenous Immunoglobulin for the Prevention of Recurrent Infections in Pediatric Patients**, Buffalo, N.Y., The HMO Group.

Taubes G., 1996. "Looking for the Evidence in Medicine," **Science** 272 (5 April):22-24

CHAPTER 4. THE CONDUCT OF TECHNOLOGY ASSESSMENT

In this chapter, we discuss several major developments that have occurred in the past decade in the conduct of technology assessment. In our judgment, these developments flow from the diffusion of TA into the private health care system and reflect the analytic needs of that system. The discussion is organized according to the following topics: the changed evaluative context within which TA is conducted; the emergence of a sharp focus on evidence-based assessments, with important implications for consensus-based decisions; the evaluation of the financial implications of medical technologies, with special attention to cost-effectiveness analysis; the expansion of the scope of TA to include the evaluation of drugs *after* FDA approval for marketing; settled issues, such as organizational decisions supported by TA, evaluative criteria, priority-setting, and stage of technology development; and open issues, such as the relation of TA to clinical trials and to medical information systems.

A. The Evaluative Context of TA

The past decade has witnessed the quiet but forceful emergence of health services research as an important factor in U.S. health policy and the delivery of health services. As commitments to public sector TA eroded, other health services research initiatives arose that were directed to many of the same general objectives but that had different origins and followed independent pathways of development. Notable among these were effectiveness, appropriateness, and outcomes research, and clinical practice guidelines.

Technology assessment in medicine received its main impetus from the creation of the Office of Technology Assessment (OTA) as a Congressional staff agency in the early **1970s**, and the establishment of a health program within OTA. Although OTA funded external investigators

CHAPTER 4. THE CONDUCT OF TA

in support of its studies, it did so at relatively modest levels. OTA did play a substantial role, however, in the legislation that created the National Center for Health Care Technology (NCHCT) within the Public Health Service (PHS) in 1978, and NCHCT did have an initial statutory mission to support TA-related research. **NCHCT's** subsequent political difficulties resulted not from its research support but from the administrative delegation of PHS authority to advise Medicare on coverage decisions. After its demise in 1982, the residual NCHCT functions absorbed by the National Center for Health Services Research in the Office of Health Technology Assessment (OHTA) were related mainly to advising Medicare on coverage decisions. Dedicated support for TA-related research ended, although some TA research received support within the general health services research program of NCHSR. This association of TA with a quasi-regulatory advisory function, but not with research, was maintained when NCHSR was reconstituted as the Agency for Health Care Policy and Research (AHCPR) and continues to the present.

One legacy of this statutory and administrative history is that the integration of TA within health services research has proceeded more slowly than it might have under otherwise. However, four developments within health services research have laid the foundation for greater integration: effectiveness, outcomes, and appropriateness research and clinical practice guidelines.

Effectiveness: The conceptual core of “effectiveness” is what works in normal, day-to-day clinical practice, as distinct from “efficacy” or what works under carefully controlled conditions, such as a randomized clinical trial. An “effectiveness” initiative sponsored by the Health Care Financing Administration in 1988-89, for example, set the stage for the creation of a Medical Effectiveness Program within AHCPR in 1989 (Roper, 1988; IOM, 1989; IOM-Heithoff & Lohr, 1990). The concept of effectiveness provides the intellectual basis for going beyond narrower FDA determinations of efficacy in the case of drugs and

CHAPTER 4. THE CONDUCT OF TA

devices and also provides the basis for evaluating the claims about procedures. It focuses on the relation of diagnostic and therapeutic interventions to patient monitoring and patient outcomes.

- **Outcomes:** The core issue of outcomes research is the benefit to the patient of clinical intervention. The focus on medical outcomes reflects, among other things, a **several-**decade evolution within quality assurance from concern for structural measures of quality to process measures to a more **recent** concern for patient outcomes. (See Bonabedian, 1966, for the conceptual foundations of the quality assurance.) It also reflects an expansion of the outcomes that should be measured from mortality and the clinical and laboratory values of morbidity to include functional, health status, and health-related quality of life (Stewart and Ware, 1992; Patrick and Erickson, 1993).
- **Appropriateness:** The concern for appropriateness is whether the benefits of intervention exceed the risks when clinicians use effective medical procedures for given patients presenting with specific characteristics (Brook, 1986). Not all procedures, however effective for their primary indications, are appropriate for all patients or all indications. Thus, population-based effectiveness and outcomes data are related to specific patient indications in judging appropriateness.
- **Clinical practice guidelines:** Clinical practice guidelines have a long history in medicine, but received a major impetus in the 1989 legislation that established AHCP. The agency's development of guidelines has resulted, among other things, in increased rigor in identifying the scientific underpinnings of clinical practice (IOM-Field and Lohr, 1990; IOM-Field and Lohr, 1991).

CHAPTER 4. THE CONDUCT OF TA

These various efforts are **all** close cousins to TA. What is common to all is the search for the scientific bases of best practice, defined as delivered health benefits to populations of patients and to individual patients (IOM-Lohr, 1990). Whether these efforts are directed to utilization management and cost control or to quality assurance may be more in the eye of the beholder than in the effort itself (Brook, 1988; Brook, 1993).

Of these intellectual cousins, there is a certain confusion about the relationship between TA and guidelines. Some argue that “clinical practice guidelines can be viewed as a unique form of health technology assessment that is intended to affect clinical decisions directly, as well as indirectly, through insurance payment or other policies that are linked to those guidelines” (OTA, 1994). Advocates of this view see TA as the umbrella under which other activities are assembled. As a practical matter, however, many guidelines have been developed without reference to TA and, generally speaking, many guideline developers are unaware of or agnostic about the relationship with TA. At best, they see TA as one element in an array of evaluative activities. Although it is possible to develop a logical statement of the conceptual relationship between TA and guidelines, it may be impossible to generate one that commands widespread agreement. Moreover, it may be unimportant to do so as the issue gets sorted out in a practical way in operational settings.

Having said this, the following table attempts to differentiate between TA and guidelines. It suggests that **TAs** and guidelines have in common a philosophy of evidence-based assessment and the clinical questions they ask. They may or may not share an orientation to specific technologies or procedures. If they do not, it is because guidelines are often directed to the management of a clinical condition or disease entity, sometimes with respect to a defined patient population. In that respect, guidelines are likely to be assessing not a single technology

CHAPTER 4. THE CONDUCT OF TA

or procedure but a family of technologies. The focus of a TA, on the other hand, is usually on a specific technology, i.e., a drug, device, or procedure. **TAs** and guidelines also are likely to support different organizational decisions, with TA linked strongly to coverage decision-making and guidelines to clinical practice. **TAs** and guidelines share a concern for existing technologies, but **TAs** usually have new technologies to themselves. This focus of TA on new technologies means that data tend to be scarcer than is true for guidelines.

Clearly, these two activities have much in common and, depending on how they are defined, may also have distinct characteristics. In the interest of practical reason, it may be useful to think about the relationship as “estuarine.” In an estuary, such as the Chesapeake **Bay**, upstream fresh water rivers and streams flow into a bay that empties downstream into the salt-water Atlantic Ocean. The oceanic tides flow in and out of the Bay, creating a zone of interaction between fresh and saline waters that is in constant motion, is the source of nutrition to many life forms, but lacks precise boundaries. This metaphor is useful in thinking about relations between TA and guidelines. Although it may be useful scientifically to determine the saline content of the Bay at given points, many practical uses of the Bay itself are not dependent on doing so.

In the operational settings described in the previous chapter, two patterns are apparent in the relationship between TA and guidelines. First, those organizations that have few direct relationships with physicians do conduct technology assessments; typically, they do not develop clinical practice guidelines. Analytic organizations, such as BCBSA and ECRI, a membership organization like UHC, and the corporate offices of managed care organizations having many health plans display this pattern. However, those organizations that have close working relations with physicians, such as local **HMOs**, are moving increasingly both to conduct **TAs** and to develop practice guidelines.

CHAPTER 4. **THE CONDUCT OF TA**

TABLE 4.1. TECHNOLOGY ASSESSMENT AND CLINICAL PRACTICE GUIDELINES

Dimension of Comparison	Technology Assessment	Clinical Practice Guidelines,
subject of assessment	specific medical technology or procedure	a) specific technology; b) family of technologies to manage a clinical condition or disease entity; c) clinical condition or disease entity
assessment questions	clinical safety, efficacy, effectiveness and health outcomes; cost-effectiveness	clinical effectiveness, appropriateness, outcomes
stage of development of assessed technology	new and existing	existing
organizational decision supported	coverage & reimbursement, procurement of equipment, management of technology costs	clinical practice and patient management; patient information
philosophy & methods	evidence-based	evidence-based
data availability	limited	ranges from limited to extensive

CHAPTER 4. THE CONDUCT OF TA

B. Evidence-based Technology Assessment

The central questions of TA, which have been relatively stable for a long time, are primarily clinical: is a given technology or procedure safe? is it efficacious under conditions of rigorous control? is it effective under conditions of normal clinical use? what is its clinical effectiveness relative to alternative technologies? is it cost-effective relative to other technologies?

Technology assessment, in general and in medicine, has been concerned conceptually with second-order consequences of technology, namely, the social, economic, legal, and ethical effects and implications of technology for society. The operational concerns of TA in medicine focus more on the evaluation of immediate clinical issues, however, although ethical issues may receive attention in specific cases as warranted. Attention to the broader social, legal, and ethical implications of medical technology often receive special attention, frequently by bioethicists. The Program of Ethical, Legal, and Social Implications (ELSI) of the Human Genome Project is a good example of this phenomenon.

In interviews conducted for this research, it became clear that a major semantic shift had occurred between the mid-1980s and the mid-'90s in the way in which TA was described, a shift that reflected an underlying philosophic change in the orientation to TA. In interview after interview, whether face-to-face or on the telephone, regardless of geographic location or institutional affiliation, the recurring refrain was "We have an *evidence-based [TA]* assessment procedure." These words were used by representatives of the American College of Physicians, Blue Cross and Blue Shield Association, ECRI, Group Health Cooperative of Puget Sound, Institute for Clinical Systems Integration of Minnesota, Harvard Community Health Plan, Kaiser Permanente of Southern California, Blue Shield of California, Blue Cross and Blue Shield of

CHAPTER 4. THE CONDUCT OF TA

Oregon, Teminex of the HMO Group, University Hospital Consortium, and the list goes on. In fact, both TA and clinical practice guidelines are increasingly described as evidence-based.

The consistency with which **evidence-based** is used from one organization to another is remarkable in itself and, it is safe to say, reflects conscious value and policy choices by the individuals and organizations using the term. One root of this semantic/philosophic shift is the work centered at the Department of Clinical Epidemiology and Biostatistics of **McMaster** University (Evidence-Based Medicine Working Group, 1992). This group, which includes individuals from other Canadian and U.S. institutions, has generated a series of papers in the *Journal of the American Medical Association* under the heading of "Users' Guides to the Medical Literature" (Guyatt and Rennie, 1993; **Oxman**, et al., 1993; Guyatt, et al., 1993; Guyatt, et al., 1994; Jaeschke, et al., 1994a; Jaeschke, et al., 1994b; Levine, et al., 1994; Laupacis, et al., 1994; **Oxman**, et al., 1994; Richardson, et al., 1995a; and Richardson, et al., 1995b). The conceptual core of this literature is this: "Evidence-based medicine *de-emphasizes* intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and *stresses the examination of evidence from clinical research* [emphasis added]" (Evidence-Based Medicine Working Group, 1992).

In this country, David Eddy has contributed strongly to the shift in thinking with his contrast of the traditional approach to the evaluation of health practices to the "explicit approach"--which is "characterized by an explicit and systematic analysis of evidence, estimation of outcomes, calculation of costs, and assessment of preferences" (Eddy, 1992). In fact, the increasing rigor and clinical focus of much of health services research and its diffusion into clinical use contributes to this general development of evidence-based medicine. An indication of the penetration of this thinking into clinical practice is found in Stuart and Handley (**n.d.**),

CHAPTER 4. THE CONDUCT OF TA

whose manual, "An Evidence-Based Approach to Changing Clinical Practice," is used as the basis for physician education within Group Health Cooperative of Puget Sound.

Comprehensive assessments of a medical technology or procedure ideally include the relationship of the given health intervention to the scientific evidence, to health outcomes of patients, to costs, and to patient preferences. Such assessments are motivated by a desire to reduce variation in clinical practice that is unexplained by disease incidence, patient characteristics, or resources; to reduce or eliminate inappropriate use of medical procedures; and to promote the use of effective interventions. They are also intended to maximize the value of delivered services (either by maximizing outcomes for a given level of resources or minimizing resource use for a given level of health outcomes) through a process that relates the marginal cost of an intervention to its marginal benefit. In this context, evidence-based assessments may include some or all of the following elements:

- The adoption of formal, explicit, and systematic methods of evaluation of the evidence and the rejection as inadequate of methods that are informal, implicit, and unsystematic (e.g., reliance upon informal consensus of experts);
- The systematic review of the published (and sometimes unpublished) clinical literature;
- The combining of the results of multiple studies by meta-analysis;
- The extraction and presentation of evidence from the literature in evidence tables that are related to specific clinical questions;
- The grading of the quality of the literature from which the data are drawn;
- The compilation of a balance sheet that arrays the benefits and harms of a given **clinical** intervention;
- The formulation of a recommendation regarding coverage, clinical practice, or the need for additional clinical evaluation in relation to a) what is known, b) what is not known and

CHAPTER 4. THE CONDUCT OF TA

about which no conclusion can be drawn, and c) what is not known but that for which expert clinical opinion (consensus) exists.

There are several implications of the commitment to “evidence-based” technology assessments for consensus processes. In the 1985 IOM report (IOM-Mosteller), a lengthy chapter on **TA** methodologies included a section on “group judgment processes.” Concern for such processes is seldom expressed today. In contrast, as the prior discussion indicates, the literature on evidence-based methodology is substantial and growing. These developments reflect the growing importance attached to systematic review of the literature and a turning away from unsystematic expert opinion as a means for assessing the scientific bases of medicine. It is worth noting that the consensus development program of the National Institutes of Health has always conducted extensive literature searches in support of its efforts, but has not systematically compiled evidence tables or graded the quality of the literature. Also, the Diagnostic and Therapeutic Technology Assessment (**DATTA**) program of the American Medical Association has evolved in recent years from basically an opinion poll of expert physicians, without reference to the literature, to a poll in which respondents are provided the literature review at the same time they are asked for their responses.

The concern for consensus does arise in two areas, however. When an evidence-based TA has been done to determine clinical effectiveness, it often becomes an input to a coverage and reimbursement decision. In such cases, decisions about the use of a technology or procedure often require the consideration of financial, legal, and other factors and some collective or consensual decision process may be used.

In addition, cases involving terminally ill patients who wish access to procedures that are regarded by advocates as the best available and by skeptics as experimental, but for which the

CHAPTER 4. THE CONDUCT OF TA

evidence about the effectiveness of a procedure is lacking or ambiguous in meaning, health plans often invoke some expert consensus process in reaching their decision.

C. TA and Economic Analysis

There is an extensive health policy literature on cost-effectiveness. A recent book by Sloan (1995), for example, with more than twenty pages of references, discusses the evaluation of clinical effectiveness, the estimation of quality-adjusted life-years (QALYs), the measurement of costs, the analysis of incremental cost-effectiveness, the valuation of health benefits in monetary terms, discounting, statistical issues, decision trees and Markov models, and the use of cost-effectiveness analysis in actual decision-making. The technology assessment literature has included conceptual and case study applications of cost-effectiveness analysis at least since the early 1980s (OTA, 1980; Warner and Luce, 1982).

However, the historic emphasis of TA has been on clinical effectiveness, not **cost-effectiveness**. Not surprisingly, this remains true today, given that so much of medicine lacks clear demonstration of a scientific basis. By contrast, the use of cost-effectiveness analysis (CEA) in TA has been relatively limited. Two factors may account for this: first, the incentives to use such analysis in the health care marketplace have not been strong enough until recently to encourage its development as a practical decision-making tool. Second, the methodologies of practical application, as distinct from the methodologies of research, have not been well developed.

Both the incentives to use CEA and the methodologies of application are changing. Driven by cost containment and quality assurance objectives, health plans are increasingly examining the clinical effectiveness of interventions in relation to their financial implications.

CHAPTER 4. THE CONDUCT OF TA

Consideration of these implications reflects the increasingly-held belief among many health plan managers that technology has become a cost center for the organization, not a revenue center, and should be managed accordingly.

The initial steps to link TA and the cost impact of technology typically involve using **TAs** as inputs to financial decisions, for example, to estimate the impact of a technology on the premium or cost structure of the health plan or on its revenue-generating potential in a local health market. This foreshadows the formal inclusion of cost-effectiveness analysis in TA. Two patterns can be observed.

One pattern relies on establishing an “arms-length” relationship between a technology assessment and decisions about financial implications. An evidence-based review of the literature is conducted for and reviewed by an expert panel, which restricts itself to a recommendation dealing exclusively with clinical effectiveness; the TA recommendation is then sent to another body, such as a benefits committee, whose responsibilities include making financial decisions for the plan. This two-step process separates the conduct of an assessment from the decision about its use. It is favored by many and deemed essential by some. The reasoning is that only an arms-length relationship ensures that financial considerations do not distort the assessment of the scientific and clinical evidence of effectiveness. In Minnesota, for example, the Institute for Clinical Systems Integration (ICSI) develops practice guidelines and **TAs** for Health Partners, an HMO, and number of participating medical groups. **ICSI** restricts itself to assessing the science, i.e., to clinical effectiveness. **HealthPartners** then uses these assessments as inputs to policy decisions in which financial considerations are a major, if not dominant element. ECRI, to take another example, markets its **TAs** partly on the basis of their independence from the economic implications of health plan coverage and payment decisions.

CHAPTER 4. THE CONDUCT OF TA

A second pattern is that the body conducting a TA is responsible for decisions both about the clinical effectiveness and the financial implications of a technology. An example of this is the Pharmacy & Therapeutics (P&T) Committee of Group Health Cooperative of Puget Sound (GHC), which assesses the clinical effectiveness of a new drug in relation to existing drugs in the same class, and then estimates the economic effect on the plan, taking into account the price of the new drug, its probable use, substitution effects, etc. If the estimated impact is less than \$50,000 per year in additional costs to GHC, the committee has authority to act on behalf of Group Health. If the estimated impact is greater than \$50,000, the P&T recommendation goes to the Executive Council for a decision about adding the new drug to the formulary. The Committee on Medically Emerging Technologies (COMET) of Group Health has similar authority.

Neither of these patterns involve the use of formal cost-effectiveness analysis. There are signs, however, that health plans and TA performers are moving slowly toward incorporating cost-effectiveness analysis into operational decision processes. But early efforts are modest and much distance must be traveled before the technique becomes part of day-to-day **decision-making**.

BCBSA has taken the initial steps to include cost-effectiveness analysis in its **TAs** of diagnostic procedures. In mid-1995 it began by conducting a clinical assessment of positron emission tomography (PET) myocardial perfusion imaging for the detection of coronary artery disease (CAD). It focused on indications for "intermediate risk" patients (defined as a probability between 25% and 75% of having CAD). PET was compared to the alternative non-invasive diagnostic technologies of planar (PLANAR) scanning or single photon emission computed tomography (SPECT) using thallium-201 or **technitium-99m** sestamibi; exercise cardiography (ECHO); exercise electrocardiography (ETT or treadmill testing); and coronary angiography. The health outcomes that BCBSA evaluated were: the mortality and morbidity of the noninvasive

CHAPTER 4. THE CONDUCT OF TA

tests, the mortality and morbidity of coronary angiography, and the mortality and morbidity associated with CAD and any of its treatments, relative to four test results (true positive, false positive, true negative, false negative).

The clinical literature provided no direct evidence that PET imaging for the detection of CAD had an effect on health outcomes. The search for evidence, therefore, focused on comparisons of test performance and then on how each of the four possible test results might influence subsequent patient management and health outcomes. The two assessment questions were these:

- For detection of CAD in people at intermediate risk, what were the probabilities of the four outcomes for PET? What were the probabilities of each of these outcomes for the other noninvasive tests for CAD?
- If PET and alternative noninvasive tests were used to determine which patients should receive coronary angiography, how did the test performance characteristics influence the outcomes of CAD?

To be included in the assessment, published papers had to indicate that angiography and at least one of the noninvasive test(s) were performed on the same patients; that sufficient data on the noninvasive tests were available to predict the results of coronary angiography for determining the precise number of the four outcomes, and that an FDA-approved PET radiotracer was used for the PET studies. Studies had to be of high quality, the study population had to be the same as the patients of concern to the assessment, and additional inclusion and exclusion criteria were applied.

The results of the clinical TA in terms of test performance were that PET scanning was shown to be “at least as accurate” as alternative noninvasive tests for CAD in persons at intermediate risk of the disease. PET was more sensitive than all other tests; and it was at least

CHAPTER 4. THE CONDUCT OF TA

as specific as all other tests, save echocardiography, which is less sensitive. For the effect on patient management and health outcomes, PET yielded minimal gains in life expectancy of **QALYs** when compared to SPECT.

A companion cost-effectiveness analysis (CEA) was conducted for this clinical assessment of PET MPI by Dr. Alan Garber, a member of the BCBSA Medical Advisory Panel, and Dr. Neil Solomon. The analysis adopted a societal perspective, which included all social costs and benefits. It sought to determine a cost-effectiveness ratio or the “dollar cost per unit improvement in health” of a specific health intervention when compared to a well-defined alternative intervention. For comparison, the analysis dealt with PET and the five alternatives and focused on the difference in costs between the intervention and its alternatives as well as on the difference in health effects. It sought to measure health effects in terms of quality-adjusted life years (**QALYs**), which go beyond life expectancy to include quality of life improvements. The study discounted future costs and health effects at an annual rate of 2 percent. Cost data were obtained from physician fee surveys, a large insurer, a large HMO, and from the literature.

The CEA showed: PET costs per procedure were much higher than SPECT (\$1,500 versus \$470 Medicare reimbursement), the next most costly noninvasive test. PET resulted in slightly more **QALYs** than SPECT, but slightly fewer than going directly to coronary angiography and avoiding noninvasive tests. And the cost-effectiveness ratio was on the order of half a million dollars (the dollar cost of an additional QALY) when comparing PET to SPECT. When the level of CAD prevalence was varied for **55-year** old men (**25%, 50%, and 75%**), immediate angiography was slightly better than PET for all three levels, at slightly lower cost.

Garber summarized the lessons of the cost-effectiveness analysis in this way:

The computational challenge is increased by the number of alternative diagnostic technologies and the treatments considered;

CHAPTER 4. THE CONDUCT OF TA

- relevant data are sometimes difficult to obtain and therefore some assumptions are necessarily arbitrary;
- assumptions are also required regarding patient management after diagnosis;
- simplification of the analysis is possible, but how to do it is “not always obvious”;
- sensitivity analyses to compensate for uncertainty are complex when there are large number of uncertain parameters;
- criteria for determining the intermediate risk patient are critical but how to apply them is not straightforward; and
- results of diagnostic tests may be operator-dependent.

Even so, Garber concludes, CEA generates useful but unexpected results: “In any complex question (and especially in evaluations of diagnostic tests), the apparently simple rapidly becomes complex. Data limitations become a prominent problem. Also it is somewhat difficult to locate facts by literature search even when data on a particular question exist. For example, relevant data may be reported in papers that are mainly addressed to a different topic.” Thus, the feasibility of CEA, performed by skilled analysts as a complement to the assessment of clinical effectiveness, was demonstrated. The analysis also provided substantial insight beyond that of a clinical effectiveness assessment and identified some of the challenges of application.

In the case of new drug evaluation, CEA is being used increasingly by pharmaceutical companies seeking to demonstrate the cost-effectiveness of their products compared to alternative drugs. This is true both in the United States and in Canada (Detsky, 1993). **Hillman** and colleagues, in 1991, reported that they had conducted 33 economic analyses for fifteen pharmaceutical companies since 1978 (Hillman, et al., 1991). Such analyses, they indicated, were increasingly being used for marketing purposes and to obtain formulary approval.

CHAPTER 4. THE CONDUCT OF TA

In the past few years, the discussion of CEA in the evaluation of drugs has turned on the principles that ought to govern the reporting in the literature of cost-effectiveness analyses sponsored by drug firms (Hillman, et al., 1991; Task Force on Principles for Economic Analysis of Health Care Technology, 1995), focusing on the minimization and control of bias. In this context, the editors of the New England Journal of Medicine issued a policy in 1994 regarding **cost-effectiveness** analyses that stipulated highly restrictive conditions that submitted papers had to meet to be considered for publication: support from an industrial firm had to be to a non-profit entity, not to an individual or group of individuals; written assurance was required to ensure the authors' independence in all aspects of the study, analysis, and reporting of results; and the manuscript had to include all data, all assumptions on which data were based, and a description of any model used in the analysis (Kassirer and Angel, 1994). Quite clearly, the assessment of drugs by CEA has crossed an analytic threshold and a controversy about reporting results has begun that is likely to continue for several years.

There are also some indications that the wider use of CEA may be diffusing to the medical device industry. In 1995, a two-volume report was issued by Medical Alley of Minnesota', "Measuring Cost Effectiveness: A **Roadmap** to Health Care Value." The first volume dealt with 'Issues and Methods,' the second was 'A Technical Guide.' The report resulted from a task force that met "to produce a clear, concise publication that will provide any healthcare organization -- no matter what their level of sophistication in presenting the value they add to healthcare -- with a practical guide that will allow it to more effectively meet the needs of the current and future healthcare environment." (Letter from Thomas L. Meskan, President, Medical Alley, August 2, 1995) The mission of the task force was to state "a consensus position"

'Medical Alley is a Minneapolis-based association whose members include the great majority of Minnesota medical device firms, as well as some purchasers and providers of care.

CHAPTER 4. THE CONDUCT OF TA

describing cost-effectiveness analysis and to develop “a practical set of guidelines” to demonstrate or assess cost-effectiveness.

The Medical Alley task force developed a checklist of twelve items for assessing the value of a drug, device, procedure, use of knowledge and/or process applied to human health. These items are indicated in the table on the following page:

CHAPTER 4. THE CONDUCT OF TA

Table 4.2. MEDICAL ALLEY: CHECKLIST FOR ADDRESSING A TECHNOLOGY'S VALUE

Foundations of Cost Effectiveness Evaluation

1. Describe the technology and its potential benefits. Include demographic information and information on appropriate use.
2. State the perspective used to compare costs and benefits.
3. State which technology alternatives are compared.
4. State which analytic tools were used, and explain why they were **chosen**.

Measuring Costs

5. Describe the data sources used for all financial costs included in the evaluation.
6. **State** whether costs relating to productivity or lost work days (indirect costs) are included and listed separately.
7. Where appropriate, break down cost information into a per member per month rate for a given population.

Measuring Outcomes

8. Describe the dimensions of health outcomes included in the evaluation.
9. Describe the sources used to gather health outcomes data.

Issue of Time and Uncertainty

10. State the time horizon used to determine costs and outcomes.
11. Describe the discount rate(s) included in the analysis.
12. Test key assumptions using sensitivity analysis.

CHAPTER 4. THE CONDUCT OF TA

The task force took a different conceptual approach to the economists' argument for a societal perspective on costs and benefits. It encouraged the "consideration of a community perspective" as part of a CEA, identifying this as characteristic of "the insurer, the manufacturer, the clinic or hospital, the patient, or the entire population." It justified its community perspective as follows:

A broad perspective, including the needs of an entire community, should be one of the considerations when conducting a cost effectiveness evaluation. A community perspective is more focused than a societal perspective, and allows for local decisions to be made concerning healthcare interventions. The Task Force defines community as the population receiving care from a health system. Membership may consist of individuals living within a geographic service area or persons in other well-defined sub-populations (e.g., those enrolled in a public or private health plan). (Medical Alley, 1995)

This difference between a society and a community perspective reflects an underlying tension that must be negotiated if CEA is to move forward within technology assessment.

Research-based advocates of CEA are unlikely to see the Medical Alley report. Those who do may be inclined to dismiss it for its simplicity. Neither volume of the report is lengthy; few illustrative cases are provided; and the technical guide adds relatively little to the first volume. But dismissal would be unfortunate. A more useful response would be to view the document as the basis for a sustained discussion between TA analysts and the medical device industry about the problems of CEA application. For we now have reached the point where real-world application of CEA is the market test that this method must meet in the years ahead, not whether economists are persuaded of its utility.

D. The Broadened Scope of TA

The OTA definition of medical technology is “the drugs, devices, and medical and surgical procedures used in medical care, and the organizational and supportive systems within which such care is provided.” As a practical matter, though, the working limits of TA have generally been restricted to medical devices and medical and surgical procedures. However, the scope of TA has been broadened in recent years to **include** the evaluation of drugs *after* FDA approval for marketing.

The assessment of drugs has often been dealt with in the TA literature by reference to the Food and Drug Administration (FDA) and reliance on its premarket review process. The basis of FDA approval is evidence from two adequate and well-controlled clinical studies that a drug is safe and effective. FDA evaluation of a drug is usually taken as a fixed referent for payers, insurers, and managed care organizations, for the definition of safety and efficacy. Moreover, until recently, FDA approval resulted in a near-automatic decision by insurers, hospitals, health plans, and others to include a medication in a formulary or in a benefit package.

However, the evaluation of prescription drugs is changing in complex ways. First, the Food and Drug Administration (FDA) remains under constant pressure to reduce the time for review of New Drug Applications (**NDAs**). One consequence of this pressure has been to introduce accelerated approval of new drugs in the areas of oncology, human immunodeficiency virus (HIV) and AIDS, and other life-threatening illnesses. This is sometimes known as “fast track” review. A corollary of fast track review has been the use of surrogate end-points in the case of drugs for the treatment of AIDS, endpoints that are measured by laboratory values but that lack supporting clinical outcomes data. An example is the use of CD-4 counts as a measure of efficacy of drugs to treat AIDS, as distinct from clinical measures of effectiveness.

CHAPTER 4. THE CONDUCT OF TA

Second, drug firms, on their own initiative but in response to increased competitive forces in the marketplace, have increased the complexity of clinical trials in two ways. Under the rubric of **“pharmacoeconomics,”** they have begun to use cost-effectiveness analysis (CEA) in the clinical trials to evaluate their own new drugs. (The emergence of pharmaceconomics is too recent and too deeply embedded in activities of private pharmaceutical firms to be well understood outside the drug industry.) But several uses of CEA by drug firms can be hypothesized: CEA may be a tool that is used internally in product development decisions; CEA data derived from clinical trials are likely to be used in marketing new drugs relative to their competitors; and drug firms may be seeking to understand CEA before it is used against them by regulators or payers.

In addition, drug firms have increasingly used quality-of-life measures in clinical trials for new drugs. This development expands the relevant health outcome measures beyond mortality, morbidity, laboratory, and clinical measures, as well as expanding the domain of effectiveness, to include measures of how well patients function and perceive the quality of their lives. In the drug area, the use of quality-of-life measures reflects the fact that the most effective differentiation of the effects of a new drug, especially in the treatment of chronic disease, is often measured by a quality of life instrument.

Third, and most important from a TA perspective, as competitive market pressures have increased, an increasing proportion of health care decisions about drug prescribing have shifted from the individual office-based physician to health plan and hospital-based pharmacy and therapeutics (P&T) committees that decide about which drugs to list on their formulary. (The United States has been characterized as the last major industrialized country of the world to move from the individual physician to a corporate entity as the principal customer of prescription drugs.)

CHAPTER 4. THE CONDUCT OF TA

Although these P&T committees have existed in hospitals and **HMOs** for some time, they once consisted mainly of pharmacists but now have a more diverse membership that reflects drug prescribers and users within the health plan. These P&T committees constitute an “infrastructure” that is being reinvigorated to scrutinize the addition of new drugs to the formulary more closely than before. The analytical questions of interest to P&T committees are the clinical effectiveness of a new drug, especially in relation to other drugs having similar therapeutic capabilities, and the relative cost of the new drug compared to existing drugs. These committees take the safety and effectiveness requirements of the FDA as a starting point but go beyond FDA judgments to make their own determinations about clinical effectiveness.

Two institutional patterns exist for the evaluation of new drugs. In some organizations, such as the BCBSA Technology Evaluation Program, a single committee will consider all new technologies (drugs, devices, procedures). This “full service” approach also characterizes UHC, for example, and is the direction in which **ECRI** is moving. More frequently, however, as in the case of Group Health Cooperative of Puget Sound, a pharmacy and therapeutics (P&T) committee will deal with questions related to new drugs, while a “new technologies” committee will deal with medical devices and procedures. But these two patterns are not fixed and may very well change over time.

Off-label uses of FDA-approved drugs and **biologics** are the frequent subject of **TAs** in the drug area. For example, BCBSA, at its June 1995 meeting, considered the following off-label uses of FDA approved drugs: epoetin alfa for myelodysplastic syndromes (**transfusion-**dependent patients) and for chronic anemia of cancer; human antihemophilic factor maintenance therapy for severe hemophilia **A**; intravenous immune globulin for refractory systemic lupus erythematosus; epoetin alfa therapy following allogeneic bone marrow transplantation or **high-**dose chemotherapy with autologous stem-cell support; interferon therapy for off-label oncology

CHAPTER 4. THE CONDUCT OF TA

indications for lymphomas, leukemias, or plasma-cell malignancies and, separately, for solid tumors; and serum tumor markers for the diagnosis and monitoring of breast cancer.

Similarly, Blue Shield of California, at the March 22, 1995 meeting of its Medical Policy Committee on Quality and Technology, reviewed the use of prolotherapy for the treatment of chronic back pain. Prolotherapy consists of a series of intraligamentous injections in the spine using a solution of dextrose, glycerin, and phenol--all of which are FDA-approved medications. Nevertheless, the Medical Director of Blue Shield of California, using the BCBSA criteria, concluded that clinical studies conducted since Blue Shield's policy on prolotherapy had been adopted in 1992 did not permit conclusions about the effect of prolotherapy on health outcomes; that a judgment about whether the treatment improved net health outcomes could not be reached; and that the criteria that prolotherapy be as effective as established alternatives and that improvement be attainable outside investigational settings were not applicable. After discussion, the committee voted that prolotherapy "remains investigational."

In June 1995, to take another example, the Blue Shield of California committee considered the indications for the use of Intravenous Immunoglobulin (IVIG) for a variety of conditions. FDA had approved **IVIG** for the following five indications: (1) treatment of primary immunodeficient states; (2) prevention of bacterial infections in patients with hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell chronic lymphocytic leukemia (CLL); (3) prevention and/or control of bleeding in a patient with Idiopathic Thrombocytopenic Purpura (ITP); (4) prevention of infection in HIV-infected children; and (5) prevention of infection and/or graft-versus-host disease in bone marrow transplant patients. Prior Blue Shield reviews of **IVIG** indications in October 1990 and October 1992 had resulted in coverage of all but the fourth item in the above list, as well as neonates disposed to Group B streptococcal infections, Kawasaki disease, coagulopathy due to inhibitors of antihemophilic

CHAPTER 4. THE CONDUCT OF TA

factor (Factor VIII), and Guillain-Barre syndrome. Based on the Medical Director's 1995 review of the literature and resulting recommendation, the committee added chronic inflammatory demyelinating polyneuropathy (CIDP), pediatric HIV disease, and refractory dermatomyositis to the list of "eligible for coverage" indications. But the other proposed **IVIG** uses were not supported by "well-designed clinical trials published in the peer-reviewed literature," and as a result all other indications were deemed investigational.

E. Settled Issues

Several issues in technology assessment appear to have been settled in the past decade. These include the organizational decisions supported by TA, the evaluative criteria for assessing a technology, the means of setting priorities for conducting assessments, and the stage of technology that is the object of TA.

Organizational decisions. The principal decisions of insurers and health plans that are supported by TA are coverage and reimbursement decisions, especially for **TAs** focused on new technologies. A recurring question of TA is whether the data provide sufficient basis for determining that a given technology or procedure satisfies a set of criteria that make it "eligible for coverage," i.e., eligible for inclusion in the set of covered benefits? Coverage decisions may arise when a new technology or procedure is diffusing into clinical practice for which a general medical policy has yet to be established. Coverage decisions sometimes arise in reference to a specific decision that a plan must make with respect to the immediate treatment of a particular patient, i.e., a physician has a patient for whom a given procedure is being considered and inquires about the clinical effectiveness of the procedure.

CHAPTER 4. THE CONDUCT OF TA

In addition, **TAs** are increasingly being used in support of clinical practice guidelines. This practice varies, however, as a function of whether the organization has a mandate to go beyond TA advice on coverage decisions. National organizations, such as BCBSA and ECRI, have no organizational or legal basis for advising physicians through clinical practice guidelines. A local managed care organization, such as Harvard Pilgrim Health Care, Health Partners, or Group Health Cooperative, may have working relations with its affiliated physicians that encourage practice guidelines.

Evaluation criteria. Technologies and procedures that are selected for assessment need to be evaluated with respect to certain criteria. The most clearly developed and widely cited criteria for evaluating medical technologies have been developed by the Blue Cross and Blue Shield Association (BCBSA). These five criteria were cited in the prior chapter in a more elaborated form and are listed below in an abbreviated way:

- “1. The technology must have final approval from the appropriate government regulatory bodies.
- “2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
- “3. The technology must improve the net health outcome.
- “4. The technology must be as beneficial as any established alternative.
- “5. The improvement must be attainable outside the investigational settings.”

Organizations that conduct **TAs** typically use some variant on these criteria. They may also vary in the extent to which the criteria are explicit and formally incorporated into organizational decision processes. A noteworthy characteristic of these criteria, and of most of those used in TA, is their emphasis on clinical effectiveness, especially relative to established alternatives.

Priority-setting. One methodological issue that has received a good deal of attention is that of setting priorities for determining which technologies to assess. This issue arises because

CHAPTER 4. THE CONDUCT OF TA

the number of candidates for assessment is always very substantial, resources are always limited, and some selection must be made of assessment topics.

Priority-setting for TA was outlined in a 1992 **IOM** report (**IOM-Donaldson**, 1992) that was prepared for the AHCPH. This report proposed the following seven-step process for AHCPH to follow: (1) select priority-setting criteria and assign a weight to each; (2) solicit nominations of candidates for technology assessment; (3) reduce a large list of nominees to those on which to obtain the data needed for priority-ranking; (4) obtain the needed data set; (5) for each topic, assign a score for each relevant attribute; (6) calculate priority scores for each topic and rank topics in order of priority; and (7) have an AHCPH panel review the priority list and select assessment topics. The proposed selection criteria focused on clinical conditions: prevalence; cost; clinical practice variations; burden of illness; likelihood that results of the assessment would affect patient outcomes and costs; and ethical, legal, and social issues. A similar report published in 1995 addressed priority-setting for clinical practice guidelines (**IOM-Field**, 1995). These reports define the idealized processes of priority-setting.

Organizations that conduct **TAs** often use these priority-setting models as a point of departure for designing their operational systems. Typically they adapt their actual processes to the practical realities they confront. BCBSA, for example, publishes a monthly list for its members and subscribers of assessments in progress, planned **TAs**, and topics under consideration. It determines its TA priorities by a combination of staff and member-subscriber suggestions: the staff monitor **25-30** journals, the trade press, and attend scientific meetings. In addition, it surveys its members-clients directly for their suggestions. Finally, the last agenda item of every Medical Advisory Panel meeting is a review of the priority list, which is updated continuously.

CHAPTER 4. THE CONDUCT OF TA

ECRI priorities for technology assessment derive from interaction between its professional staff and client-subscriber demands, which occurs formally and informally on a sustained basis. In this interaction, it draws on its extensive knowledge base, having received many calls daily on devices and device-using procedures for the past 20 years. In addition, many technologies that receive an initial **ECRI** assessment become topics for continuing surveillance and potentially for reassessment. Reassessment priorities are set when a change in the clinical context of a technology is reported in the literature.

One virtue of the distributed decentralization pattern of TA organization discussed in Chapter 3 is that different entities have different priorities. Thus, the number and range of **TAs** actually conducted is greater than could be expected from a single TA organization. There is, of course, some clustering around the “hot button” topics of the day. But there is also a distribution of TA topics that reflects the particular needs of the different TA organizations and their clients.

Stage of technological development The literature often specifies the domain of TA as new and emerging, existing, and obsolete-but-still-used technologies. Those engaged in the conduct of TA on a regular basis, however, are mainly concerned with new technologies, which may mean the initial application of a technology or new uses of an existing technology, e.g., an off-label use of a Food and Drug Administration-approved pharmaceutical. Performers of TA often give rough estimates of two-thirds of their efforts being devoted to new technologies and one-third to existing technologies. Obsolete technologies do not occupy much attention, as a practical matter. However, the “balance” between the assessment of new and existing technologies is empirical, deriving more from practical needs than from policy and likely to fluctuate over time.

F. Open Issues

CHAPTER 4. THE CONDUCT OF TA

in the course of this study, the respondents to the interviews raised several issues related to technology assessment, which had not been anticipated in the early stages of the research. Two--clinical trials and data systems--are mentioned here briefly, both of which are important and deserve greater attention.

Clinical trials. The relationship of technology assessment to clinical trials is more complicated than it seems at first glance. The relationship comes into play most directly for **TAs** focused on the evaluation of new medical technologies (drugs, devices, and medical and surgical procedures) for purposes of making a coverage decision. Although the study did not set out to examine this matter, the following issues were identified by several respondents in the course of interviews.

In the main, responsible insurers, managed care plans, and integrated delivery systems wish to make coverage decisions on the basis of scientific data about a technology's effectiveness. Conversely, these organizations do not wish to finance ineffective treatment, both for cost and clinical reasons. In order to make informed coverage decisions about new clinical technologies and procedures, however, they need good quality clinical data. Thus, such organizations depend on the clinical trials literature for information about clinical effectiveness, especially for procedures that do not involve FDA-regulated trials done in support of drug or medical device evaluation.

A major problem arises for TA organizations, however, because the quality of the clinical trials literature is not uniformly high. Indeed, when evidence-based literature reviews are conducted to identify critical studies and to compile evidence tables, and when complementary efforts attempt to grade the key studies on the basis of methodological quality, analysts often give such studies relatively low grades--"no better than a **C**" according to several respondents. **The** most frequent reasons for the low grades are these: there is a paucity of data on controls or

CHAPTER 4. THE CONDUCT OF TA

there are no controls; there is a lack of clarity in the definitions of patient groups and outcomes of interest (sample selection criteria are not specified, or there are few controls for bias, or sample size is too small); there is often a failure to **define objective measures of outcome and to obtain outcome data** for baseline and post-intervention; the period of follow up post-intervention is too short relative to the natural history of the disease; or follow up reporting is incomplete.

One unintended consequence of the robust analytical TA and guidelines capability that now exists in the private health care sector, therefore, has been the development of a cadre of critics of the clinical trials literature among the ranks of TA assessors and guidelines developers. At the present time, however, there is no feedback loop for information about the critical appraisals of the clinical trials literature to flow back to the sponsors or performers of such trials. This issue is more serious for procedures than for pharmaceutical firms' trials of new drugs because FDA regulatory requirements impose substantial rigor on drug trials. FDA controls include a detailed section of the *Code of Federal Regulations* (21 CFR, Subchapter D, Drugs for Human Use), a *Guideline for the Format and Content of the Clinical and Statistical Sections of New Drug Applications (NDAs)*, the review of **NDAs** by FDA professional staff, and the final review of an application, which contains the results of trial data, by an external expert advisory committee. In the case of procedures, which do not require FDA approval, however, sponsors and performers of clinical trials have practically no connection to those who eventually will evaluate and use the results of their work.

One source of the above problem, according to some managed care officials, is that the management of government-sponsored clinical trials is often weak. The critique is that there are too many trials, of too weak design (often too few controls), with too slow a patient accrual rate, and that trials are often conducted without reference to outcomes of interest to payers or

CHAPTER 4. THE CONDUCT OF TA

patients. Issues of common design across a number of related trials have not been addressed with an eye to the accumulation of results through **meta-analyses** (Chalmers, 1994).

The basic rationale for clinical trials is that the accumulation of scientific results in laboratory and animal studies are sufficiently promising to warrant clinical trials involving human subjects. However, the critics argue, trials are not always intended to establish clinical effectiveness. Consequently, results are often not germane to the needs of those responsible for medical decisions about effective and appropriate interventions in the settings in which physicians normally encounter patients and for which insurers and managed care organizations must pay. One source of this difficulty, in the view of some respondents, is that trials are often driven by the norms and values of academic medicine, which include the quest for tenure, the creation of an academic niche in the medical marketplace, and the search for revenue for the institution.

Several other problems have been identified. One is that basic data about **government-sponsored** clinical trials are not easily available. Many parties report frustration, for example, at being unable to obtain an inventory of government-sponsored clinical trials. A related issue is that the reporting of clinical trial results in the scientific journals has not yet been standardized. Movement in that direction has been reported by Rennie (**JAMA**, April 5, 1995). Third, no mechanism exists for responsible managed care and provider organizations to routinely indicate to the federal government their priorities for clinical trials or to indicate the patient-related outcomes that should be considered.

Finally, from the perspective of NIH and the medical research community, the issue of payment for clinical trials has become much more complicated in the past decade than it was previously. Insurers were once looked upon as a source of payment for such trials but have basically withdrawn from subsidizing research on “experimental” procedures. Some insurers who

CHAPTER 4. THE CONDUCT OF TA

have been reluctant to pay for clinical trial research, however, have now begun to think that paying for investigational care for beneficiaries enrolled in a clinical trial is a reasonable approach to the matter. However, the issue of payment for clinical trials remains an unresolved question about which a sustained discussion involving all parties is clearly needed.

A range of possible responses to the above issues might be considered. One is to create a feedback loop between the performers and users of **TAs** and the sponsors and performers of clinical trials so that information about the quality of clinical trials as judged by assessors is routinely compiled and circulated. Another is to increase the basic data about clinical trials that are widely available to the public, including purchasers of care and managed care organizations. A third is to create a mechanism by which responsible insurers, managed care organizations, and providers communicate their priorities for clinical trials, including outcomes questions, to managers of government-sponsored clinical trials on a regular, perhaps annual, basis. Finally, a sustained discussion among the appropriate parties needs to be established regarding payment for clinical trials.

TA and d-stems. The definition of medical technology has always encompassed “the organizational and supportive” technologies of health care, which might also be called “efficiency” technologies. Although these “efficiency” technologies intersect with therapeutic and diagnostic technologies, they have often been ignored in the TA literature. However, technologies such as computer-based information systems, electronic patient records, and physician and nurse work stations are taking on added operational importance in the present environment, particularly as the achievement of cost-reducing efficiencies is seen as a way to free up resources that might be allocated to other purposes, including new therapeutic interventions. To the extent that efficiencies can be gained through investments in information

CHAPTER 4. THE CONDUCT OF TA

systems, they will influence the ability of providers and health plans to maintain delivered quality at lower costs.

Several years ago, it was thought that large administrative databases would provide useful information about the effectiveness of clinical interventions. That hope has waned, if not evaporated, as the limits of current databases have become apparent. In addition, the investments required to bring such databases to an acceptable level of usefulness have at times appeared prohibitive.

Nevertheless, the “efficiency” technologies are, today, the focus of very substantial investment. The investments currently being made in data systems by major health plans may create a capacity in the future to acquire both financial and clinical data in a way that can support a large array of plan decisions. For decisions about new technologies, the available data about effectiveness are often absent, not easily accessible, or of poor quality. Nevertheless, a payment decision is often required. However, the absence of data, which is a constraint on researchers, is not always a practical reason why a decision-maker can avoid a determination on coverage of a new procedure. In some instances among the managed care plans interviewed for this study, a decision to cover a procedure made in the absence of good data about effectiveness was accompanied by putting in place a technology-specific surveillance or tracking mechanism to capture data about the outcomes of care and thus to learn on a real-time basis from clinical experience. One major issue related to but distinct from TA, therefore, is the need for sustained attention to the design of information systems that permit the linking of financial and clinical information and allow prospective studies to compensate for the absence of literature-derived data.

G. Conclusions

CHAPTER 4. THE CONDUCT OF TA

What do we learn from this chapter? First, it is clear that TA is one of a family of evaluative activities that are diffusing steadily within health care organizations. Health services research has provided the foundation for most of these efforts--effectiveness, appropriateness, and outcomes research; quality assessment and assurance and continuous quality improvement; technology assessment; and clinical practice guidelines. At the federal government level, the originating sponsor of many of these endeavors, conceptual distinctions among them have often been reified, then enshrined in specific programs or organizations, which have acquired their respective supporting constituencies. In the process, commonalities among these distinct efforts have often been lost from sight.

In the private sector of health care, including managed care, technology assessment is sometimes independent of clinical practice guidelines, sometimes closely related to them, and both of these activities have various relations to applied health services research. As these evaluative efforts diffuse in the next decade, a priority that public and private decision makers should pursue is to strengthen the common foundations of TA, guidelines, and health services research, i.e., a concern for clinical effectiveness in day-to-day clinical settings.

Second, one of the most significant findings to emerge from this research has been the strength of the orientation to evidence-based assessments that characterized practically all respondents. Rigorous evaluation of clinical effectiveness, based on a systematic review of scientific and clinical evidence, has become the norm among the TA organizations interviewed for this study. For TA, and for other efforts to evaluate medical effectiveness, a priority of public and private decision makers should be to broaden, deepen, and generally strengthen this commitment to evidence-based assessment of the scientific foundations of clinical interventions. One benefit of such a commitment will be to bring the appropriate role of expert consensus into clearer focus.

CHAPTER 4. THE CONDUCT OF TA

In this context, it is worth noting that the philosophy, underlying assumptions, and methods of TA have been set forth clearly in the literature (IOM-Mosteller, 1985; Sox, 1990; Eddy, 1991; Eddy, 1992; IOM-Donaldson, 1993; and IOM-Field, 1995). In 1985, the IOM-Mosteller volume, Assessing Medical Technologies, devoted a lengthy chapter to the following TA methodologies: randomized controlled trials; evaluations of diagnostic techniques; a series of consecutive cases; the case study; registries and data bases; sample surveys; epidemiologic methods: surveillance methods; quantitative synthesis methods, primarily meta-analysis; group judgment methods; cost-effectiveness and cost-benefit analyses (accompanied by an illustrative appendix); mathematical modeling; and social and ethical issues in technology assessment.

The IOM-Mosteller report recommended that a greater commitment be made to generating primary data on the safety and efficacy of new medical and surgical procedures, to determining the cost-effectiveness and public policy implications of those procedures, and to postmarketing surveillance of drugs and medical devices, and to doing the same for medical technology already in use. It also recommended increased research to improve the various methods of TA, including strengthening the weaker methods and increasing the use of the stronger methods. Finally, it recommended increased resources for training researchers in medical technology assessment, both for advancing the methodology and for applying those methods to the many unevaluated technologies. Although the methods of TA are obviously “good enough” for operational use at this time, it would be worthwhile to review the progress made in the decade since the IOM-Mosteller report in order to determine whether additional research on assessment methodology is warranted, especially for use in applied settings.

Third, continuing attention should be given to the use of cost-effectiveness analysis in the assessment of medical technologies. The emphasis should be on the conceptual, methodological, and data challenges of application in operational settings. The question of

CHAPTER 4. THE CONDUCT OF TA

“societal” versus “community” perspective, for example, deserves thorough discussion, as does the issues of the incentives that govern the use of CEA. The primary audience for this discussion, it should be clearly understood, is not one of health economists or policy analysts, but current and prospective users of CEA.

Fourth, it should be clearly recognized that the scope of TA has become increasingly “full-service,” including drugs, medical devices, and clinical procedures. Prior reliance on FDA evaluations of the safety and efficacy of new drugs is now augmented in many cases by the reviews by pharmacy and therapeutics (P&T) committees that take FDA evaluation as a starting point for formulary decisions, not as an automatic basis for adding a drug to a formulary.

Finally, the weaknesses of the clinical trials literature that are revealed by evidence-based assessments should become the basis for creating systematic feedback to the sponsors and performers of such trials. The clinical trials priorities of payers, insurers, and managed care organizations should be systematically ascertained and communicated to the appropriate federal government and private sector sponsors of such trials. Both objectives could potentially be accomplished through an annual meeting, sponsored by AHCPR or NIH, that focused on determining the top three to five clinical trials that payers/insurers believed were needed, and on methodological and management issues related to clinical trials. Such a conference could also be the vehicle for examining the difficult issue of who should pay for clinical trials and under what circumstances.

REFERENCES

Berwick, DM, 1989. “Continuous quality improvement as an ideal in health care,” *New England Journal of Medicine* **320:53-56**.

CHAPTER 4. THE CONDUCT OF TA

Brook, RH, **Chassin, MR**, Fink, A, et al., 1986. "A method for the detailed assessment of the appropriateness of medical technologies," *International Journal of Technology Assessment in Health Care* **2(1):53-63**.

Brook, RH, **1988**. "Quality assessment and technology assessment: critical linkages," in Institute of Medicine (Lohr, KN, and Rettig, RA, eds.), 1988. *Quality of Care and Technology Assessment*, Washington, D.C., National Academy Press.

Brook, RH, 1993. "Using scientific information to improve the quality of health care," *Annals of the New York Academy of Medicine* **vol:74-85**.

Chalmers, TC, 1994. "Implications of **meta-analysis**: need for a new generation of randomized control trials," pp. 1-4 in McCormick, KA, Moore, SR, and Siegel, RA, eds., 1994. *Clinical Practice Guidelines Development: Methodology Perspectives*, Agency for Health Care Policy and Research, Department of Health and Human Services.

Detsky, A, 1993. "Guidelines for economic analysis of pharmaceutical products: a draft document for Ontario and Canada," *PharmacoEconomics* **3354-361**.
Eddy, DM, ed., *Common Screening Tests*, Philadelphia, American College of Physicians, 1991.

Donabedian, A, 1966. "Evaluating the quality of medical care." *Milbank Memorial Quarterly* **44: 166-203**.

Eddy, DM, **1992**. *A Manual for Assessing Health Practices & Designing Practice Policies: The Explicit Approach*, Philadelphia, PA., The American College of Physicians.

Evidence-Based Medicine Working Group, 1992. "Evidence-based medicine: A new approach to the teaching of medicine," *JAMA* **268:2420-2425**.

Guyatt, GH, Rennie, D, 1993. "Users' guides to the medical literature," *JAMA* **270:2096-2097**.

Guyatt, GH, Sackett, DL, Cook, DJ, for the Evidence-Based Medicine Working Group, 1993. 'Users' Guides to the Medical Literature: II. How to use an article about therapy or Prevention. A. Are the results of the study valid," *JAMA* **270:2598-2601**.

Guyatt, GH, Sackett, DL, Cook, DJ, for the Evidence-Based Medicine Working Group, 1994. 'Users' Guides to the Medical Literature: II. How to use an article about therapy or prevention. B. What were the results and will they help me in caring for my patients?" *JAMA* **271:59-63**.

Hilman, AL, Eisenberg, JM, Pauly, MV, Bloom, BS, **Glick, H**, Kinosian, B, and **Schwarz, JS**, 1991. "Avoiding bias in the conduct and reporting of cost-effectiveness research sponsored by pharmaceutical companies," *New England Journal of Medicine* **324:1362-1365**.

Jaeschke, **R**, Guyatt, GH, Sackett, DL, for the Evidence-Based Medicine Working Group, **1994a**. 'Users' Guides to the Medical Literature: III. How to use an article about a diagnostic test. A. Are the results of the study valid," *JAMA* **271:389-391**.

CHAPTER 4. THE CONDUCT OF TA

Jaeschke, R, Guyatt, GH, **Sackett**, DL, for the Evidence-Based Medicine Working Group, 1994b. "Users' Guides to the Medical Literature: III. How to use an article about a diagnostic test. B. What are the results and will they help me in caring for my patients?" **JAMA 271:703-707.**

Laupacis, A, Wells, G, Richardson, WS, **Tugwell**, P, for the Evidence-Based Medicine Working Group., 1994. "Users' Guides to the Medical Literature: V. How to use an article about prognosis," **JAMA 272:234-237.**

Levine, M, Walter, S, Lee, H, Haines, T, Holbrook, A, Moyer, V, for the Evidence-Based Medicine Working Group, 1994. "Users' Guides to the Medical Literature: IV. How to use an article about harm," **JAMA 271:1615-1619.**

Institute of Medicine, 1969. *Effectiveness Initiative: **Setting** Priorities for Clinical Conditions*, Washington, D.C., National Academy Press.

Institute of Medicine (Donaldson, M, ed.), 1992. *Setting Priorities for Health Technology Assessment: A Mode/ Process*, Washington, D.C., National Academy Press.

institute of Medicine (Field, MJ, ed.), 1995. *Setting Priorities for Clinical Practice Guidelines*, Washington, D.C., National Academy Press.

Institute of Medicine (Field, MJ, and Lohr, KN, eds.), 1990. *Clinical Practice Guidelines: Directions for a New Program*, Washington, D.C., National Academy Press.

Institute of Medicine (Field, MJ, and Lohr, KN, eds.), 1991. *Clinical Practice Guidelines: from Development to Use*, Washington, D.C., National Academy Press.

Institute of Medicine (Goodman, C, ed.), 1988. *Medical Technology Assessment **Directory***, Washington, D.C., National Academy Press.

Institute of Medicine (Heithoff, K.A., and Lohr, K.N., eds.), 1990. *Effectiveness and Outcomes in Health Care*, Washington, D.C., National Academy Press.

Institute of Medicine (Mosteller, F, ed.), 1985. *Assessing Medical Technologies*, Washington, D.C. , National Academy Press.

Kassirer, JP, and Angie, M, 1994. "The journal's policy on cost-effectiveness analysis," *New England Journal of Medicine* **331:669-670.**

Medical Alley, 1995. "Measuring Cost Effectiveness: A **Roadmap** to Health Care Value: Vol 1 ., Issues and Methods; Vol. 2, A Technical Guide," Minneapolis, Minnesota.

McPherson, K, Wennberg, JE, Hovind, OB, et al., 1982. "Small-area variation in the use of common surgical procedures: an international comparison of New England, England, and Norway," *New England Journal of Medicine* **307:131 O-131 4.**

Office of Technology Assessment, U.S. Congress, **The Implications of Cost-Effectiveness Analysis** Medical Technology, Washington, D.C. August 1980.

CHAPTER 4. THE CONDUCT OF TA

Office of Technology Assessment, U.S. Congress, 1980. The Implications of Cost-Effectiveness Analysis of Medical Technology, Washington, DC., Government Printing Office.

Office of Technology Assessment, U.S. Congress, 1994. Identifying Health Technologies That Work: Searching or Evidence, Washington, D.C., Government Printing Office

Oxman, AD, Sackett, DL, Guyatt, GH, for the Evidence-Based Medicine Working Group, 1993; "Users' Guides to the Medical Literature: I. How to get started," **JAMA 270:2093-2095**.

Oxman, AD, Cook, DJ, Guyatt, GH, for the Evidence-Based Medicine Working Group, 1994; "Users' Guides to the Medical Literature: VI. How to use an overview," **JAMA 272:1367-1371**.

Patrick, DL, and Erickson, P, 1993. *Health Status and Health Policy: Allocating Resources to Health Care*, New York, Oxford University Press.

Rennie, D, 1995. *Journal of the American Medical Association* [full citation needed]

Richardson, WS, Detysky, AS, for the Evidence-Based Medicine Working Group, 1995a "Users' Guides to the Medical Literature: VII. How to use a clinical decision analysis. A. Are the results of the study valid," **JAMA 273:1292-1295**.

Richardson, WS, Detsky, AS, for the Evidence-Based Medicine Working Group, 1995b "Users' Guides to the Medical Literature: VII. How to use a clinical decision analysis. B. What are the results and will they help me in caring for my patients?" **JAMA 273:161 O-I 613**.

Roper, WL, Winkenwerder, W, Hackbarth, GM, et al., 1988. "Effectiveness in health care: an initiative to evaluate and improve medical practice," *New England Journal of Medicine* **319:1197-1202**.

Sloan, F., ed., 1995. *Valuing Health Care: Costs, Benefits, and Effectiveness of Pharmaceuticals and Other Medical Technologies*, New York, Cambridge University Press.

Sox, HC, ed., *Common Diagnostic Tests: Use and Interpretation*, 2nd edition, Philadelphia, American College of Physicians, 1990.

Stewart, AL, and Ware, JE, Jr, eds., 1992. *Measuring Functioning and Well-Being*, Durham, N.C., Duke University Press.

Stuart, ME, and Handley, n.d. *An Evidence-Based Approach to Changing Clinical Practice*, Seattle, WA., Group Health Cooperative of Puget Sound.

Task Force on Principles for Economic Analysis of Health Care Technology, 1995. "Economic analysis of health care technology: a report on principles," *Annals of Internal Medicine* **122:61-70**.

Warner, KE, and Luce, BR, 1982. *Cost-Benefit and Cost-Effectiveness Analysis in Health Care: Principles, Practice, and Potential*, Ann Arbor, MI, Health Administration Press.

CHAPTER 5. USING THE RESULTS OF TECHNOLOGY ASSESSMENT

Although technology assessment appears well-established in the organizations interviewed for this study, thus supporting the view that a strong private sector demand exists for TA, it is not known how widely TA has diffused in the managed care, hospital, or other sectors of the health care system. Nor is anything known about how TA is likely to diffuse in the next five years in any of the major sectors. Finally, it is unclear whether organizations that have made a commitment to TA today will be among the economic winners or losers in tomorrow's competitive health care marketplace.

What is known is that the inclusion of a TA capability as a requirement for accreditation of health maintenance organizations (HMOs) by the National Committee on Quality Assurance (NCQA) in early 1995 guarantees the further diffusion of TA in the managed care sector. And, given that the hospital sector will face greater incentives to manage medical technology in a cost-effective way in the period ahead, the incentive to conduct hospital-based TAs can be expected to increase as well.

In the physician sector, increased TA can be expected by some medical specialties, such as radiology (Fryback, 1995), that have a well-established tradition of evaluating the economic implications of technologies. But in general it is not obvious how changing patterns of physician practice and organization will affect physician incentives to use TA. Specialty societies may place greater emphasis on clinical practice guidelines than on TA, as the former are more immediately and centrally related to medical practice.

It should be recognized that the emergence of a robust TA capability, in concert with the widespread development of clinical practice guidelines and the creation of applied health services research units, represents a new model for translating the results of medical research into scientifically-based clinical practice. Overstated for purposes of argument, the older model often assumed implicitly that medical research reported in the peer-reviewed literature was read

CHAPTER 5. USING THE RESULTS OF TA

and synthesized by the physician in his office, or was effectively summarized in continuing medical education (CME) courses, and that individual physicians modified their practice accordingly. The older model, in short, held that good information led to behavioral change. However, researchers—including those who assess medical technologies—often overestimate the effect that good scientific research, clinical trials results, practice guidelines, and **TAs** have on physician behavior change and on the costs and quality of care. The behavioral literature suggests that it is difficult to change practices by relying on information alone.

The new model is predicated on the assumption that a systematic and comprehensive evaluation of the science underlying medical practice is a multi-step process that requires a deliberately organized effort that is well beyond the capabilities of the busy physician in his office or most CME programs. The results reported in this study suggest strongly that this assumption has a sound foundation in practice in the private sector of medicine. In addition, however, TA organizations need to see themselves as institutions engaged in the translation of medical science into validated clinical knowledge in concert with other evaluative efforts, such as clinical practice guidelines and health services research. This recognition appears to be taking hold as reported in the prior chapters. When TA information is reinforced by feedback and educational mechanisms, in settings where the economic incentives to use information are favorable, behavioral change is possible. The development of systems that deal with all aspects of generating and using the results of **TAs** is beginning. This chapter documents some of these efforts.

Coverage decision making. The emergence of TA subscription services strongly suggests the utility of assessments. But such services, such as BCBSA and ECRI, for example, are primarily dependent on the willingness of new and continuing subscribers to pay for their

CHAPTER 5. USING THE RESULTS OF TA

services. They do little monitoring of actual use. Although the data are limited, it appears that there are two uses made of TA subscription services. First, a TA from BCBSA or **ECRI** is used as a point of reference for an organization conducting its own TA. Second, a TA is used as an input to organizational decision about coverage.

An example of the use of subscription services is provided by CIGNA, one of the nation's largest managed care organizations, with 3.3 million **members** in approximately 45 health plans. It has a centralized TA function in the Hartford home office, managed by one full-time professional who reports to the National Medical Director. CIGNA does not conduct **TAs** itself, however, but subscribes to the BCBSA technology evaluation service and attends meetings of the Blue Cross Medical Advisory Panel. When CIGNA receives an assessment from BCBSA, it reviews the TA with its own Technology Assessment and Case Review Council of seven to eight members, who are drawn from the medical directors of the plans. This council considers the political, insurance, benefit, legal, and ethical issues associated with an assessment and converts the BCBSA assessment to a CIGNA policy. In addition, CIGNA contracts with four medical schools--Columbia University, Emory University, University of California at San Diego, and the University of Chicago--for review of cases involving individual patients.

Flexibility for terminal illness. Coverage decision-making has typically been binary: either a procedure or technology is approved or it is **not**. If not approved, a request by a physician or patient for payment for a procedure is denied. This has created problems in cases where the effectiveness of a procedure has not been established, but the patient has a terminal illness and the procedure is believed by experts to be the "best available" treatment. In particular, the use of high dose chemotherapy with autologous bone marrow transplantation for

CHAPTER 5. USING THE RESULTS OF TA

the treatment of breast cancer has been the focus of substantial controversy, including costly litigation.

Aetna responded to the complexities of high visibility terminal illness cases involving high technology, high risk, and high cost medical procedures, by stimulating the creation of the Medical Care Ombudsman Program (MCOP). The effort began with the assumption that a procedure that has reached the level of a Phase III¹ National Cancer Institute clinical trial meets a prima facie test of “substantial promise” of effectiveness. This is a decidedly weaker formulation than that effectiveness has been established.

When cases arise in which patient and physician wish to have such a procedure and request authorization and payment for it, but the health plan medical director questions its appropriateness on the grounds that it has not been shown to be effective, Aetna does not automatically deny coverage. It now refers such cases to the MCOP of the Medical Care Management Corporation in Bethesda, Maryland. The MCOP has established and maintains a roster of nationally prominent, board certified experts, most of whom are oncologists, who are available to review specific cases as they occur. Typically a review involves three experts, each of whom independently examines the patient’s medical record and makes a recommendation as to whether the specific procedure is or is not appropriate for the individual patient. If one expert recommends that treatment is appropriate for the patient, Aetna covers the procedure for that patient. If all three experts recommend against treatment, they agree in advance to go to court, if necessary, and defend their judgment.

¹ In Phase I trials, testing for safety and pharmacological profiling in humans is done; Phase II trials involve initial testing of effectiveness in humans; Phase III trials involve extensive clinical trials of effectiveness in humans.

CHAPTER 5. USING THE RESULTS OF TA

The merits of this approach are that the patient and the treating physician receive the benefit of a patient-specific expert review of appropriateness, the coverage determination is based on the judgments of nationally recognized experts, and the insurer has a basis for a decision that minimizes its legal liability. MCOP now has over 100 corporate clients, has processed more than 2,500 cases. The cases referred to MCOP involve new procedures about which substantial scientific uncertainty exists and for which evidence-based **TAs** have yet to provide a clear indication of effectiveness. The institutional response constitutes the introduction of flexibility in a heretofore rigid coverage decision process.

Member service feedback. There are many uses of **TAs** that go beyond the use of subscription services. An example is provided by University Health System Consortium (UHC), which has been engaged in the systematic production of **TAs** since 1992. More recently it has developed various mechanisms for increasing the use of TA among its members.

One effort has been a “benchmarking” project conducted with Sun Health Systems that surveyed 400 hospitals (9 in the Sun system, all of the member hospital of UHC, and some **non-UHC**, non-Sun hospitals) to obtain baseline data about the nature and extent of TA activity. There were 93 respondents, not identified by organizational affiliation; about three-quarters were single hospitals and the rest were equally divided between multi-hospital systems and integrated delivery systems.

Only 5 percent of the hospitals had one individual solely responsible for technology assessment. Nearly one-half the respondents reported that responsibility for the evaluation of capital equipment (45%) and clinical services (55%) **was** lodged in one individual, as distinct from a group or formal committee. Evaluation of pharmaceuticals was the responsibility of a formal committee, however, in over 90% of the cases. The use of standard formats for supporting data

CHAPTER 5. USING THE RESULTS OF TA

Table 5. 1. UHC Hospital TA Benchmarking Study

	General Information	Capital Equipment Evaluation	Evaluation of Drugs	Clinical Services Evaluation	Information Systems Evaluation
Respondents	N = 93				
One person with TA sole responsibility	5%				
Monitor new technology effectiveness	44%				
Evaluation by individual or committee		45% 55%	>90%	55% 47%	51%
Use standard format or supporting data		29%	>40%	15%	9%

ranged from a low of 9% in the case of information systems to 40% for drugs.

A second UHC effort attempted to help member organizations to plan and implement a strategy “to limit and/or reduce expenditures” for radiopaque contrast media. A report issued in January 1995 summarized a 1993 assessment on “Low osmolality contrast media” (LOCM), which in turn had updated a 1991 assessment. The 1993 TA recommended the development of formal guidelines for use of LOCM, the use of the American College of Radiology and American College of Cardiology guidelines on this topic as a starting point, the establishment of a compliance oversight mechanism, and ‘continuous reevaluation and revision” of guidelines. In addition, the 1995 report documented recent LOCM successes at two institutions--University

CHAPTER 5. USING THE RESULTS OF TA

Medical Center, Tucson, and University of Pittsburgh Medical Center, and added descriptive abstracts of the experience of the University of North Carolina Hospitals and the Robert Wood Johnson University Hospital in New Jersey. These reports indicated the annual savings to each hospital (or system) from implementing LOCM protocols and guidelines.

A third UHC implementation effort was the assessment of **53** off-label uses of intravenously administered immunoglobulin (**IVIG**) preparations, which made accompanying recommendations. The assessment panel included board certified physicians in critical care, hematology, immunology, neurology, oncology, pediatrics, rheumatology, and two hospital pharmacists. It published its findings in the Journal of the American Medical Association, thus reaching a very large audience.

Finally, UHC hosted an educational conference in early October 1995 on stereotactic radiosurgery. Two devices are on the market, one costing \$1.5 million and the other \$3 million. Little clinical literature exists evaluating their relative effectiveness and cost-effectiveness. UHC identified 16 member hospitals that were prepared to buy the more expensive device without awareness of the availability of the other machine. The conference brought together clinicians, administrators, **CEOs**, and Chief Financial Officers. The conference succeeded in highlighting the unsupported claims of the expensive device and has led to a clinical trial by the manufacturer of that system.

Management of technology use. Another use of TA is to provide options for insurers, managed care organizations, and health plans that are more sensitive to innovation, medical practice, and plan management of technology than simple approval or denial of a technology or procedure for coverage. Several uses of TA by Blue Cross and Blue Shield of Oregon illustrate the use of TA for the rational management and introduction of medical technology.

CHAPTER 5. USING THE RESULTS OF TA

In the early **1990s**, the national BCBSA decided to participate with the National Cancer Institute in clinical trials of high dose chemotherapy with the support of autologous bone marrow transplantation (**ABMT**) for the treatment of breast cancer. Through BCBSA, a set of the Blue's plans agreed to finance the patient care portion of its' plans beneficiaries treatment for breast cancer if patients were willing to enroll in a **randomized clinical trial that included ABMT**.

Although the overall experience with this initiative has been disappointing, as many women have refused to be randomized and as patient accrual has been very slow, it has been very satisfactory for Blue Cross Blue Shield of Oregon. The Medicare Director of Oregon BCBS found the ABMT clinical trial option freed him from the tyranny of a Yes/No (approve/deny) coverage decision and allowed him to indicate to a physician that it was not known whether the treatment was effective but the option was available if the patient would enroll in a clinical trial. In three years of experience with approximately 50 subscribers, BCBS Oregon has met all the subscribers concerns, with one exception. This has meant that some women were turned down for the procedure, most were enrolled in a **randomized controlled trial (RCT)**, and a few (e.g., three men) who were not eligible for an RCT had the service paid for in a non-RCT study.

An extension of this development is that Oregon BCBS is beginning to take the initiative in identifying medical centers to conduct clinical trials of new procedures and thus provide better information about clinical effectiveness than would be obtained if enthusiasts for a procedure were given **carte blanche**. One area in which this is occurring involves magnetic resonance angiography (MRA) for the diagnosis of cerebral vascular disease. MRA is basically a software add-on to an already-installed magnetic resonance imaging (MRI) machine. Compared to the multi-million dollar cost of the MRI machine, which has been already been absorbed, the add-on costs of several hundred thousand dollars for MRA are relatively modest. MRA is a non-invasive diagnostic procedure for at-risk patients that has the prospect of replacing conventional

CHAPTER 5. USING THE RESULTS OF TA

angiography, an invasive diagnostic procedure with a number of risks. The advent of MRA, however, also opens the possibility of using the technique to screen asymptomatic patients, usually diagnosed by ultrasound. Screening complicates the potential cost impact substantially, raising again the old issue of duplicate and overlapping tests (ultrasound and MRA).

BCBS of Oregon is paying for the procedure in Bend, Oregon, where high quality images are being obtained with a third-generation MRA program; first-generation images are not being reimbursed. The literature at this time is not helpful, according to the Dr. John Santa, the BCBSO Medical Director: "It [the literature] says that MRA is coming, it's not quite here, yet it will be here soon." Consequently, BCBS of Oregon surveyed neurologists, neurosurgeons, and vascular surgeons and asked two questions: (1) "If MRA is done, are you using the images to make treatment decisions?"; and (2) "Has MRA replaced conventional angiography?" The answers were: First, in the centers approved by BCBS Oregon for this diagnostic procedure, MRA images are being used to make treatment decisions. Second, MRA has clearly replaced conventional angiography in these centers. However, technical competition among imaging modalities is changing the situation still further. Sufficiently good images of the carotid artery are now being obtained with ultrasound (US), a competing modality, so that some surgeons are proceeding to operate on the basis of the US image alone-- without using either conventional angiography or MRA.

Radiologists were also surveyed for data showing that MRA had replaced conventional angiography. They confirm that MRA has replaced angiography in approved demonstration sites. Santa reports one radiologist saying: "This is an interesting exercise. It lets me tell my colleagues that we can't get by just by showing them the images. We have to have data that show the effect."

CHAPTER 5. USING THE RESULTS OF TA

A more general interest was expressed by Dr. Santa in technology “roll out” strategies. Such strategies involve designating regional centers for exclusive reimbursement in the initial stage of a new technology. These centers would be required to develop protocols for use. They would then be asked to teach others how to provide treatment using the protocols. Adherence to protocols would become a criterion for reimbursement as the technology diffused beyond the initially designated centers. Ore'on BCBS has done something similar to this for sleep disorder studies, is doing it for MRA and brachytherapy for prostate cancer, and is considering such a strategy for pallidotomy, minimally invasive surgery, and lung reduction surgery. The intent is to avoid episodes like the oncologists' advocacy of ABMT and the general surgeons advocacy of laparoscope cholecystectomy, both of which diffused widely before adequate evaluation.

Dedicated use systems. There are health plans that conduct assessments of medical technology in direct support of their operational decisions. They provide a clear indication of use of TA. Group Health Cooperative of Puget Sound, for example, conducts **TAs** and reviews pharmaceuticals for their clinical effectiveness and cost implications. GHC develops guidelines for the purpose of guiding physician behavior and improving patient outcomes. The organization supports these efforts with a physician education program about evidence-based clinical practice. Organizations like GHCPs typically have a far richer view of the complexities, limits, and needs for the practical steps that are necessary to translate TA into behavioral change by clinicians. Among other things, they are often investing heavily in data systems to capture clinical and financial information, integrate such data, and provide it to both management and physicians.

CHAPTER 5. USING THE RESULTS OF TA

The emergent infrastructure. As the science of application advances, institutional channels of communications and hierarchies of decision-making are being established that link the generators, synthesizers, and users of clinical science--medical research, technology assessment, and practice guidelines--in new and tighter relationships. One important development in this respect is the emergence of a decentralized TA performer capability, as indicated in Chapter 3. It is important to recognize that this robust **performer capability** is also creating a more highly decentralized infrastructure of *user capability or receptor sites* that can only facilitate communication from TA performers to TA users. **Increased** demand for TA, a decentralized TA performer capability, increasing numbers of organizational entities and individual physicians disposed to evidence-based **clinical** practice--these are the factors that suggest use of TA is likely to increase in the future.

Several respondents in this study commented that "the science of application had lagged the science of discovery." By this they meant that the investment in research, including TA, had not been accompanied by an appropriate investment in seeing how such research was used. They argued that an applied clinical or health services research capability was needed. In the face of increased demand for TA and other evaluative activities, it may be appropriate for the federal government to support work on the development and diffusion of strategies to move both TA methodologies and results into operational use.

The elements of a sophisticated model of TA implementation should, at minimum, be at least as sophisticated as the strategies that drug companies have used in the past for influencing the prescribing behavior of individual, office-based physicians. They should include: recognition of the importance of the demand for TA as a critical factor in its eventual use; the existence of a TA capability able to translate existing scientific information into usable form; the establishment and maintenance of communication channels from TA producers to prospective users and the

CHAPTER 5. USING THE RESULTS OF TA

transmission of assessments along those channels; incentives to use TA at the receptor *sites* by receipt of information, comparison to current practice, and modification of behavior as appropriate; the accountable reporting of experience to interested parties; and feedback loops among all elements in the system.

CHAPTER 5. USING THE RESULTS OF TA

REFERENCES

Fryback, D.G., ed., 1995. Introduction to Technology Assessment for Radiologists: A Vision Beyond Tomorrow, Vols. 1 and 2, Milwaukee, Wisconsin, GE Medical Systems-Association of University Radiologists Radiology Research Academic Fellowship (GERRAF) Program.

CHAPTER 6. IMPLICATIONS FOR PUBLIC-PRIVATE RELATIONSHIPS

The prior chapters discuss technology assessment in the private health care sector, with a focus on TA in managed care organizations. Thus, the emphasis of this report differs from the historical concern in much of the literature with federal government TA activity. It is appropriate under the circumstances, however, to step back and ask what major conclusions flow from this analysis and what implications these conclusions have for the relationships between public and private health care technology assessment. The chapter considers, first, the demand for TA and then, respectively, the organization of technology assessment, its conduct and use, and the role of the federal government.

A. The Demand for TA

The demand for TA in the private sector of the U.S. health care system appears to be strong and to have increased substantially in recent years, as suggested by this report. On the other hand, there are no precise baseline data from which to measure this demand and no quantitative estimates of its magnitude. Occasionally, this demand has focused explicitly on technology assessment. More often, however, the demand for TA is embedded in the search for ways to contain costs and for a concomitant demand for quality measurement and quality improvement. This increase in demand has been driven in the first instance by the purchasers of health care, especially large corporations. In addition to their concern for keeping health care costs within reasonable bounds, some of these corporate purchasers have been forceful advocates for information about the quality of care provided by the health care plans with which they contract.

CHAPTER 6. PUBLIC-PRIVATE IMPLICATIONS

Managed care health organizations, which provide an increasing proportion of health care in this country, are the second major source of increased private sector demand for TA and evaluative services. They are responding both to purchasers, who have expressed themselves through organizations such as the National Committee on Quality Assurance, and to what they see as their own strategic needs and opportunities in the marketplace. The working assumption of both the purchasers and managed care organizations is that the ability to demonstrate the value of delivered health care services, that is, the relation of the quality of services to their costs, will be a requisite of survival in the competitive health care market.

One major implication of this increased demand for TA is that the federal government should act in a way comparable to the private sector in its capacity as a major *purchaser* of health care services. The argument for a stronger federal government purchaser of health care services is sound at both conceptual and practical levels, given the significance of Medicare and Medicaid expenditures in federal and state government spending. The current efforts in Congress and the Administration to increase the reliance on managed care in both the Medicare and Medicaid programs, driven in large measure by cost containment pressures, should be accompanied by a strengthened capability for assessing the value of services paid for by those programs, both for individual beneficiaries and for populations of patients.

The political challenges of this task should be clearly understood. The ability of the federal government to act as a prudent buyer of health care services often has been limited, however, by the fact that beneficiaries, providers, and suppliers have frequently opposed such a role. The response to these groups ought to be that the government should be no less effective a purchaser of health care than purchasers in the private sector. In this context, the rationale for TA must be the quest for value that the government is obliged to pursue.

CHAPTER 6. PUBLICPRIVATE **IMPLICATIONS**

It is not necessary, however, that the federal government create a large, centralized TA organization as the only way to increase its capability as a purchaser. It may choose to acquire some of its assessments by contracting with the private sector, as **CHAMPUS** has done with Blue Cross Blue Shield Association and HCFA has done with ECRI. On the other hand, it would be prudent for the government to retain a competent TA entity to ensure the retention of a substantive TA contract management capability, to stay abreast of methodological developments in the field, to assist in the formulation of assessment-related research efforts, and to avoid complete dependence on the private sector.

B. The Organization of Technology Assessment

In the 1970s and '80s, TA was strongly associated with efforts to create a national assessment organization. The federal National Center for Health Care Technology (1978-82) focused both on research and on Medicare coverage decision-making, which proved to be its undoing. Its organizational legacy is the Office of Health Technology Assessment, now a unit in the Agency for Health Care Policy and Research. The National Center was followed by a legislatively authorized, non-profit Council on Health Care Technology (1985-89) within the institute of Medicine. This private-public effort was limited in financial and organizational resources and in the clarity and strength of demand for its services. Although the Physician Payment Review Commission, in 1994, recommended the creation of "A national entity [that] should decide for all health plans whether selected major new technologies and treatments are covered for particular indications," this proposal generated no response. Thus, over a period of nearly twenty years, aspirations for a strong national TA entity have not materialized.

CHAPTER 6. PUBLICPRIVATE IMPLICATIONS

In the past several years, however, a **distributed TA institutional** capability has emerged in the private U.S. health care sector, centralized in some aspects and decentralized in others. This distributed TA institutional “system” encompasses a robust analytical capability that did not exist a decade ago. The organizations in this system include a small number of national organizations, some providing subscription services (such as BCBSA and **ECRI** and, to a lesser extent, AMA and HAYES) and others providing member services to a given constituency (such as UHC, TEMINEX, and **AHA**). Also included are many of the national managed care organizations (e.g., Aetna, Prudential, and United **HealthCare**) and some regionally defined insurers and health plans (e.g., Blue Shield of California, ICSI, Group Health Cooperative of Puget Sound, Harvard-Pilgrim Health System, and Kaiser-Permanente of Southern California).

In this context, the federal government is only one player in the TA community, and not the dominant one. Moreover, it is in a relatively weak position to exert leadership within TA along the lines envisaged in the 1980s. The modest volume of output of OHTA, for example, provides little leverage on the actions of others. None of the respondents interviewed in this study advocated a strong TA leadership role for the government.

What are the implications of these organizational developments? One implication is that the public-private *division-of-labor* in technology assessment needs to be reconsidered. On the **private** side, one benefit of this distributed TA system is that both the number and range of **TAs** that are performed are greater than in a centralized system. Greater opportunities exist for the expression of demand by users of **TAs** and thus for the differentiation of producer responses to that demand. In addition, the market will tend to arbitrate among TA performers in terms of the number required to meet private sector needs, as well among competing services in terms of a costquality or price-quality trade-off. On the other hand, the market will not necessarily set

CHAPTER 6. PUBLIC-PRIVATE IMPLICATIONS

standards for the conduct of TA, nor will it support TA-related research no matter how justifiable is the social utility of such research.

Centralization of TA has often been justified in terms of the need to eliminate duplication, but too little attention has been given to the value of overlapping or multiple studies. Presently, many TA users obtain the services of more than one TA producer, but few users obtain all available services. This user behavior allows a balance to be struck between useful redundancy and unnecessary duplication. Seldom is a single study, clinical trial, or assessment definitive in terms of clinical effectiveness and, consequently, redundancy among competing TA services allows for a validation process to occur by which the assessments of one TA organization are compared to those of another.

In addition, the decentralization of TA to multiple performers and users may facilitate physician buy-in to the results of TA. The remoteness from clinical practice of any centralized TA body, whether governmental or non-governmental, may and probably does inhibit communication to practicing physicians. By contrast, a TA performed by an organization with which a physician is affiliated, such as a managed care organization, is more likely to capture the doctor's attention and have greater face validity with him or her than the TA product of a centralized body.

Given the emergence of a robust private sector TA capability and the loss of a TA leadership role for the federal government, it is now essential to clarify the role of the federal government. One role suggested in the prior chapter, and reiterated above, was that the government should reinforce the demand for TA through its role as purchaser of health care services. Another role is that of supporting TA-related research, including the methodological issues suggested in Chapter 4 of generating more primary data, strengthening weak methods, increasing the use of strong methods, and training TA researchers. Because the value of research results cannot be captured easily by the producer of research, the private sector has an

CHAPTER 6. PUBLIC-PRIVATE IMPLICATIONS

incentive to under invest in the socially optimal level of research, including TA-related research. Only the government can respond to the need for research. Ironically, the National Center for Health Care Technology (1978-82) was established legislatively to support research but met its end largely because an administrative delegation of authority required it to support Medicare coverage decision-making. A consequence of its demise was that little TA-related research has been supported by the federal government in the past two decades. It may now be appropriate to review the need for such research.

Indeed, methodological research offers a legitimate and acceptable way for the federal government to assist in setting and maintaining standards for the performance of technology assessment. Less driven by market forces, the government is in a much better position than private sector organizations to strengthen the rigor of current methodologies and to address methodological challenges that arise as the field continues to develop.

Another implication of the organizational developments within TA is the need to rethink the issue of coordination. It is often presumed that a centralized body is better able to coordinate the efforts of the multiple performers than are multiple organizations in a distributed system. This argument often overlooks the values of useful redundancy discussed above. It also ignores the administrative requirements of coordination. Administrative resources are always scarce, and consequently centralized coordination is prone to shortages of time, money, and personal. It is thus vulnerable to bottlenecks or queuing at all stages of the TA process--priority setting, conduct of assessments, and reporting of results. In addition, centralized coordination also facilitates the coordination of political opposition without generating much political support.

By contrast, a distributed TA system consisting of a number of assessment organizations manages to coordinate both TA producers and users. On the user side, as mentioned above, many obtain several of the available TA services and, via the low priced newsletter products, are

CHAPTER 6. PUBLIC-PRIVATE IMPLICATIONS

easily able to track the output of all relevant **TA** producers. On the producer side, as the director of one TA program wrote: “I would propose that all quality TA organizations review/consume the work of other TA organizations, i.e., I have collaborative document sharing with ECRI, AMA, **AHA**, etc. ... I expect my TA authors to always review the TA work of others (e.g., OHTA, AHCPR, **ECRI**, USP-DI, international, etc.) to continually build on the strengths of existing work.”

C. The Conduct of TA

Several noteworthy features of TA that were encountered in this research deserve recapitulation here, albeit briefly.

1. Evidence-based TA. The primary impression of TA in the private sector in 1995 is the prevalence, even dominance, among those organizations interviewed during this research of an underlying commitment to evidence-based assessments. This emphasis on systematically and rigorously assessing clinical effectiveness is clearly new. At one level, it reflects the seriousness with which the evaluation of effective medical care is now taken, a result of the diffusion of health services research into the organization, delivery, and practice of medicine. At another level, it also reflects a turning away from informal, primarily consensus-based processes *as a way to establish the science underlying clinical practice*. To be sure, an expressed commitment to evidence-based medicine may simply draw a patina of legitimacy over essentially unchanged, informal, and consensus-based practices. By and large, however, the commitment to evidence-based assessments is accompanied by a set of methodologies that demonstrate the reality of the commitment.

CHAPTER 6. PUBLIC-PRIVATE IMPLICATIONS

The concern for evidence-based assessments, still in its youth, both broadens and deepens the evaluation of medical technologies:

- It goes beyond the FDA's evaluation of *pharmaceuticals* for safety and efficacy to include P&T committees' assessments of relative clinical effectiveness and cost-effectiveness.
- It is broader than the evaluation of therapeutic *products* (drugs and devices) for safety and efficacy and includes clinical *procedures*.
- It reaches beyond narrow assessments of the clinical effectiveness of both products and procedures to ask about *relative clinical effectiveness*, potentially subjecting "me too" products and marginally beneficial procedures to a new level of scrutiny.
- It underlines the dependence of the assessment process on *clinical trials* and highlights the *management weaknesses* of many trials in terms of design, controls, rates of patient accrual, quality of data management, and quality of reporting results in the literature.
- It suggests the prospective need for increased *Phase IV surveillance* of new therapeutic products in the event that pending FDA "reform" legislation reduces existing evidentiary requirements for pre-market approval.
- It connects to the concern for *value*, i.e., the relation of resources and outcomes, and thus links prospectively to cost-effectiveness analysis.

The implication of this commitment to evidence-based assessments, which characterizes **AHCPR's** efforts both in TA and clinical practice guidelines, is that all parties--public and private--should search for ways to strengthen this commitment wherever possible. How might that be done? A more aggressive use of TA by the federal government in its capacity as purchaser of services has been suggested above, as has a sustained TA-related research effort, especially one focused on methodological issues. Other approaches that ought to be considered include

CHAPTER 6. PUBLIC-PRIVATE IMPLICATIONS

searching for ways to make cost-effectiveness analysis more useful as a tool in operational settings and for improving the quality of clinical trials.

Although the use of cost-effectiveness *analysis* in technology assessment has been discussed for more than a decade, its actual use has been quite limited. However, as the demand for more rigorous evaluation of clinical effectiveness has increased, the demand for CEA has also increased. One factor limiting the use of CEA has been that its proponents have been mainly academics and there has not been a widespread user community among those in non-academic settings, which may imply a need for training efforts. **More significant, the problems of applying CEA in operational settings, especially those stemming from the limitations of data, deserve systematic attention, perhaps through conferences that bring academics and users together on a regular basis.** Finally, the philosophic issue of whether a societal, community, or even narrower perspective should inform CEA in the context of the competitive marketplace requires more than passing acknowledgment. If market incentives drive TA users to adopt a narrow perspective on costs, i.e., limiting their analytical concerns to the likely effect of a given technology on health plan premiums or hospital revenues and competitive position in the local health market, capacity to attract physicians, etc., the utility of CEA in a distributed TA system will be limited. Conscious-raising has occurred regarding CEA, tentative steps toward application are being taken, but substantially greater public and private sector cooperation can help to clarify both the methodologic and philosophic issues of application in operational settings.

Clinical *trials* are essential to technology assessments. Evidence-based **TAs** always involve a literature review, usually the compilation of evidence tables, sometimes meta-analyses, and often a grading of the studies being examined. In such reviews, the clinical trials literature quite frequently receives very low marks on quality-design, controls, rates of accrual, and

CHAPTER 6. PUBLIC-PRIVATE IMPLICATIONS

reporting of results. As a result, the distributed TA performers who use this literature are increasingly made aware of its shortcomings.

However, the knowledge that these sophisticated users of the clinical trials literature have acquired has not yet been transmitted back to the sponsors and performers of trials. Effective feedback loops between the users and the generators of the literature apparently do not exist. Nor do mechanisms exist for purchasers or payers of health care to indicate their priorities for clinical trials, which are determined largely by researchers in academic medicine.

An *institutional disconnect* exists between those payers who wish to know what procedures are clinically effective and the academics who generate the literature. One implication of this disconnect for public-private cooperation is that a series of conferences, workshops, or symposia, might be organized to examine the issues associated with the relation of clinical trials and the effectiveness of new procedures flowing into **clinical** practice. Such an initiative would involve NIH, FDA, AHCPR, and HCFA, as well as pharmaceutical and medical device firms, academic researchers, and purchasers and payers of care.

More generally, both public and private sector organizations should commit themselves to increasing the proportion of new technologies and procedures subjected to rigorous TA analysis until the *expectation* of such evaluation is shared by all parties, including those bringing new products and procedures to the market, and until those expectations are *embedded in operational policies and procedures*. This commitment is necessary in order to ensure that the beachhead of evidence-based assessments is secured and safely beyond political challenge.

2. TA and Clinical Practice Guidelines. One apparent consequence of federal government efforts in technology assessment has been to reify distinctions between TA and related evaluative efforts, such as clinical practice guidelines. As a result, differences are

CHAPTER 6. PUBLIC-PRIVATE IMPLICATIONS

emphasized and commonalities receive little attention. Although TA advocates often view practice guidelines as a special form of TA, guidelines developers may or may not be aware of TA as they go about their business. Moreover, the relationship between TA and clinical practice guidelines is being clarified in the operational setting in ways that tend to ignore the more doctrinal arguments at the conceptual level.

The two activities share an orientation to evidence-based assessments and have basically a common methodology. They may differ, however, with respect to the availability of data. A major factor limiting **TAs** is the inadequacy of data at the time that a new technology is introduced and when advocates for its use command the relevant “expertise” and press for a favorable coverage decision. In the case of new drugs, this data limitation is largely overcome by FDA requirements of adequate and well-controlled clinical studies that demonstrate safety and effectiveness. For surgical and medical procedures, however, no such regulatory requirements drive the systematic acquisition of data before their introduction. So procedures may become well-established before they are studied and thus harder to remove from practice. **Evidence-**based assessments raise the requirements for clinical effectiveness data to be obtained before coverage decisions are made. The development of guidelines is less likely to be hampered by data limitations in the same way, as the subjects for guidelines are typically procedures, clinical conditions, or disease states for which a good deal of clinical experience exists. But the relative data needs of TA and guidelines deserve attention in an integrated way as does the search for creative means of data acquisition to serve the ends of each.

TAs and guidelines may also differ with respect to a focus on specific technologies or procedures, which both may have, or on the management of a clinical condition or disease state, which often characterizes guidelines. In addition, **TAs** support coverage decisions in the main; guidelines are oriented to modifying physician behavior

CHAPTER 6. **PUBLIC-PRIVATE** IMPLICATIONS

The relationship was described earlier in this report as “estuarine,” with TA corresponding to upstream fresh water, guidelines to oceanic salt water, and the estuarine relationship referring to the zone in which fresh and salt water meet and mix. The implication for public-private cooperation is that the further development of each activity should be coordinated, if not integrated, in the interest of promoting a deeper understanding of differences and commonalities, furthering evidence-based assessment of medical interventions, and advancing the concern for the value of delivered health services.

D. The Use of TA

Technology assessment, by the mid-1990s, has developed to the point where the primary challenge of the next decade is to encourage its widespread diffusion and to develop the strategies and tools of practical application that characterize operational use. Such diffusion should be directed to increasing the value of delivered health services by bringing costs under control and into relation with quality.

Encouraging wider use of TA cannot be predicated on the assumption that a good assessment reported in the literature is sufficient to ensure its adoption. A more sophisticated model of information flow and behavior change needs to include attention to the message and its quality, to the source of the message, to the channels of reaching prospective users, to the receptivity of users to the message, and to modification of both TA message content and processes as a result of feedback from users.

Meeting this challenge of wider application is made easier by the growth of a **physician-**based analytical capability committed to evidence-based assessment of new technologies and

CHAPTER 6. PUBLIC-PRIVATE IMPLICATIONS

procedures as well as of clinical practice guidelines. It is important to recognize that a corollary of the emergence of a robust, distributed TA *performer capability* is the parallel creation of a larger number of physicians and other clinicians who are grappling with the implications of **TAs** and practice guidelines. Thus, a highly decentralized set of *receptor* sites for TA results is coming into existence within the physician community. Communication from TA performers is thus made easier when there are TA users to receive the message.

How should we think about encouraging the uses of TA? First, TA should be used consistently as an input to coverage decisions, even though factors other than evidence-based assessments inevitably enter into such decisions. Second, TA should be used as a way to benchmark best practice and to provide feedback to users through educational conferences and other means. Third, TA should be used as a feedback to the design and sponsorship of clinical trials and to priority-setting for such trials.

Fourth, TA should also be used to introduce greater flexibility of response to the emergence of new technologies and procedures. Examples of flexible response include using enrollment in clinical trials as a way for dealing with promising but unproved, high-visibility procedures for treating terminally ill patients; using independent third-party evaluation of appropriateness of patient for experimental procedures, especially when procedures treat terminally ill patients; and use of TA to promote rational ‘roll out’ of new technologies in patterns of protocol-based, data-driven, controlled diffusion.

Finally, TA should be used to reinforce the development and use of evidence-based practice guidelines and to train the next generation of physicians in the meaning and implications of evidence-based medicine.

E. The Role of the Federal Government

CHAPTER 6. PUBLIC-PRIVATE IMPLICATIONS

Is there a TA role for the federal government given a vigorous private sector TA capability? One thing is clear: a federal government “leadership role” of the kind envisioned in the 1970s and ‘80s has very little support. In light of the demise of health care reform legislation in 1994, and the composition of the current Congress, it is very unlikely that such a role is feasible. The collapse of the potential for a strong federal government leadership role, then, raises the question of public-private *cooperation*. Although cooperation moves in the direction of a limited federal government role, it should be understood that a minimalist role does not imply a nihilistic view of governmental responsibilities. Cooperation describes a wide range of possible relationships: coordination, collaboration, contracting, technical assistance, and the production of collective or public goods.

Coordination raises the questions of whether the current informal coordination among public and private TA performers is adequate? The relative efficiency of centralized or decentralized coordination is more a matter of philosophy than science. It is clear, however, that a certain amount of coordination currently takes place on an informal basis, with every TA organization basically keeping book on every other TA organization. Information flows easily in this distributed TA system, if not freely. This decentralized and informal coordination of information and decision-making among TA performers may be as effective or efficient as that of centralized coordination. It is not demonstrably worse.

Collaboration is another form of cooperation that involves some mutual contribution of resources to a common effort. Although attractive in principle, collaboration is difficult to organize in practice: public bodies may have private advisory committees but may not delegate decision-making to such bodies, save by statute; private entities may have public liaison representatives, but public officials may not serve in official capacities in such organizations; and the commingling of public and private resources is not readily sanctioned.

CHAPTER 6. PUBLIC-PRIVATE IMPLICATIONS

“Soft” collaboration between the government and the private sector regarding TA may occur, however, through informal coordination and contracting. This may be the most effective way to help the government fulfill its obligations as a value-oriented purchaser of health care, based on the premise that the government should be as effective a purchaser as the private sector. Although enrolling more Medicare beneficiaries in managed care will limit **HCFA’s** role in defining the benefit package, a continued fiduciary role exists to ensure that effective health care is purchased for these beneficiaries, especially as smaller health plans assume greater responsibility for providing health care services. Examples of “soft” collaboration include agreement on the criteria for reporting the results of **TAs**, clinical trials, and effectiveness research, and other efforts to strengthen the methodological foundation of these activities.

Contracting may be seen as a form of public-private cooperation, which is the approach now being taken by **CHAMPUS** in contracting with BCBSA for TA services and by HCFA in contracting with ECRI. Effective contract management, however, argues for the retention of a technical capability within the government in order to avoid undue reliance on the private sector.

Tech&a/assistance is yet another form, but one that implies an asymmetry of expertise: if such an asymmetry exists today, it favors the private sector and argues for government contracting from the private sector.

Finally, the *production of public goods* argues for cooperation where the benefits of an activity are available to all and cannot be captured by the party generating the benefits. In such situations, the private sector faces economic incentives that will cause it to under invest in the socially optimal level of that activity. Research, especially on analytical methodologies, is such a public good that defines a role for the federal government. Such research ought to include the further development of TA methodologies, especially the methodologies of application, both for analytic and standard-setting purposes. Research defined by this role encompasses the conduct

CHAPTER 6. PUBLIC-PRIVATE IMPLICATIONS

of clinical trials, priority-setting for such trials, cost-effectiveness analysis, increased evaluation of new drugs by managed care organizations, and the implications of special topics such as the revolution in genetics and molecular biology and appropriate TA responses to treatments for terminal illness.