PART 1 Technology Assessment, Managed Healthcare and Nuclear Medicine

The evolution of health care technology assessment (TA) can be traced to two separate but related areas of research: variations research conducted by John Wennberg and associates and appropriateness research conducted by Robert Brook and his colleagues. These lines of investigation originated in the U.S. in the 1970s out of a need to control the cost of health care, and they have had a major impact on the practice of medicine in the latter part of this century. A recognition of the inaccessibility of health care for a large segment of the population forced policy makers to seek information regarding the availability and utilization of health care services and resources. Unfortunately, information regarding the cost and effectiveness of health care interventions was largely unavailable to decision makers in that period. In this regard, physicians, payers and policy makers needed a source of better information for assisting them in their ability to make decisions concerning clinical patient care as well as guidance regarding overall reimbursement for such care. TA emerged as a process for providing needed guidance and improving patient care as a result of these research efforts.

Health care technology encompasses a very broad range of devices, agents, procedures and services. In addition, organizational and supportive systems are considered health care technologies. The principal aim of TA is to provide decision makers, viz patients and their health care providers, with information concerning the alternative interventions available to them to diagnose and treat their illness. This patient care information is of immense interest to policy makers and payers as well because it directly relates to resource expenditure through reimbursement for such services.

TA can be classified according to two main categories, primary and secondary. Primary TA involves data collection and analysis from or about patients. It may also involve the collection and analysis of cost data. Randomized clinical trials and epidemiological observational studies are common examples of primary TA. Secondary TA is a process that utilizes existing data that has been published in the peer-reviewed literature. Secondary TA also utilizes the "grey" literature (industry and government reports, professional society recommendations, etc.) as well as patient registry data provided by manufacturers and research collaboration (e.g., RTOG, ECOG, etc.). The methods used to scrutinize and understand these data include cost-effectiveness and cost-benefit analysis, meta-analysis, decision modeling and ethical and legal review methods.

Beginning in the 1970s, however, the term TA came to mean the process by which the societal impact of health care technology could be evaluated, and to those involved in this area, it came to represent "the field of research that examines the short- and long-term consequences of individual medical technologies" and "a source of information needed by policy makers in formulating regulations and legislation, by industry in developing products, by health professionals in treating and serving patients, and by consumers in making personal health decisions." The Institute of Medicine formally defined TA in 1985 as:

> "Any process of examining and reporting on medical technology used in health care, such as safety, efficacy, feasibility, and indications for use, cost, and cost-effectiveness, as well

Table 1
ORGANIZATIONAL PURPOSES FOR TECHNOLOGY ASSESSMENT

Hospitals	HMOs	Third-Party Payers
Cost-containment	Cost-containment	Cost-containment
Budget prioritization	Budget prioritization	Coverage decisions
Purchase decisions	Purchase decisions	Decision consistency measure
Identification of new technology	Coverage decisions	Determination of whether proposed technology is still experimental
Third-party payer pressure	Determination of whether proposed technology is still experimental	
Strategic planning	Federal regulation	
Institutional mission compatibility with proposed technology		

as social, economic and ethical consequences, whether intended or unintended."

It also became clear in the mid-1980s that TA could complement the emerging field of effectiveness research and many policy makers adopted TA as a central tool for demonstrating the effectiveness of health care technologies in a variety of settings.

Table 1 summarizes the purpose of TA to hospitals, health maintenance organizations (HMOs) and third-party payers. Cost-containment is generally considered the key purpose for most institutional TA efforts today. These cost-containment efforts may include outright rejection of new technologies or establishment of risk relationships with vendors (e.g., consignment, etc.). TA is conducted in these settings by a variety of mechanisms that revolve around multidisciplinary committees comprised of administrators, methodologists (biostatistics, sociologists, etc.), if available, and clinical experts.

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Hospitals and HMOs are generally concerned with technology implementation and diffusion at the local level, whereas payers are concerned with these issues at national and international levels. For instance, the BlueCross BlueShield Association, with over 70 member plans, must review and set guidelines for acceptance of new technology while recognizing that its decisions and recommendations affect millions of insured patients. Overall, it would appear that major entities such as BlueCross BlueShield or the Health Care Financing Administration (HCFA) that are responsible for making decisions about the purchase and coverage of new technologies find themselves in difficult positions. Indeed, these groups are under intense pressure to offer their clients, patients and physicians, the latest technology in a cost-effective manner. Their decisions, in turn, go to intermediate and local decision makers who are under intense pressure to keep costs down. Many decision makers, particularly at the local hospital level, are ill-equipped to evaluate study designs or patient data that are analyzed and interpreted by the TA programs. The implementation of TA recommendations at the local level is probably one of the most problematic aspects of the TA process.

Technology assessment has become such an important process in the current managed care environment, which has emerged over the past five years, that the number of TA programs has grown rapidly over that interval. A recent survey identified 115 active TA programs in 24 countries. The survey only included major programs with ongoing productivity in this area, and individual hospital programs were not evaluated. There were 58 major programs in the United States, 39 in Europe and surrounding regions and 18 in Canada. These programs evaluated a wide variety of technologies including diagnostic and therapeutic interventions.

Recent activity in TA that bears on the delivery and reimbursement of nuclear medicine (NM) services has focused on PET imaging. University HealthSystem Consortium published "Positron Emission Tomography" in 1994. The Agency for Health Care Policy and Research (AHCPR) followed with a brief TA in 1995 entitled, "Myocardial Perfusion Imaging with Rubidium-82 Positron Emission Tomography." Also in 1995, ECRI published a two-part TA on PET: "Myocardial Perfusion Imaging for the Evaluation of Ischemic Heart Disease." Additional TAs on PET were issued by the Department of Veterans Affairs and the BlueCross BlueShield Association. All of these TAs essentially recommended against adoption of PET and focused on the poor quality and dearth of clinical trials and studies involving PET imaging. On March 20, 1997, the Technology Evaluation Center (TEC) program of the BlueCross BlueShield Association considered PET for oncology applications and decided that the technology met its assessment criteria for staging lung cancer and for evaluating solitary pulmonary nodules where other imaging modalities were inconclusive or equivocal. Since this TA was commissioned by HCFA, the implications for PET imaging reimbursement were great and the successful acceptance of PET for these two applications represents the first approval of PET imaging studies for widespread utilization.

Finally, the University HealthSystem Consortium assessed ^{89}Sr systemic radionuclide therapy for painful bony metastases in 1996, and the decision regarding its efficacy and recommendation for implementation by UHC member institutions were favorable. Consequently, the above-cited examples serve to illustrate how the TA process has been applied to several NM applications with mixed results. However, as clinical NM data matures, and our understanding of the TA and reimbursement processes becomes more precise, it is anticipated that NM will grow in guideline representation in this managed care environment because of its diagnostic therapeutic utility. Just as importantly, by successfully navigating the TA process, many more NM applications will be reimbursed or reimbursed at a higher level by payers. Part II in this series will trace the assessment of PET imaging in greater detail to offer some aspects and insights into the specific nature of the TA process.

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