ASK THE EXPERT

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This new department provides a forum for *JNMT* readers to ask technical questions and receive answers from an expert in nuclear medicine technology. Send your questions and comments for future *Ask the Expert* columns to: Frank J. Papatheofanis, MD, PhD, UCSD Medical Center Hillcrest, 200 West Arbor Dr., San Diego, CA 92103-8758 or fax 619-543-1975.

Question: **Please explain what technology assessment is, who does it, how it is performed and what impact it has on nuclear medicine.**

What is technology assessment?

Over the past decade this nation's capacity to provide health care has been limited by serious fiscal constraints. Many are concerned about the high cost of health care and its availability. The responsible allocation of health care resources has come under intense scrutiny from the federal government, insurance companies, and manufacturers and deliverers of medical products and services.

Coverage and payment issues are tied to health care access because most services are not provided to underinsured or uninsured individuals and reduced utilization patterns emerge for more expensive technologies (*1*). Many medical professional groups and societies have proposed clinical practice guidelines in a systematic effort to curb excessive spending. The desire to optimize patient care by employing such strategies is also fueled by a desire to offer cost-effective services to as many patients as possible.

The discipline of medical technology assessment emerged in the mid-1970s from the considerations of the cost and cost-effectiveness of high-quality health care. Several notable health economists, including Victor Fuchs, voiced serious concerns regarding the allocation of resources for health care. Fuchs argued that the flat part of the cost-benefit curve represented a threshold beyond which increased expenditures offered no proportional rise in the availability or quality of medical technology. His analysis explained that increasing the financial resources allocated to health care did not result in an appreciable improvement in quality, technology-driven health care for more individuals because of the fall in the cost-effectiveness of the proposed technology. Such arguments questioned the significance and utility of expensive technologies, particularly in diagnostic imaging.

As a result, many groups undertook technology assessment in an attempt to analyze the efficacy of new and existing technologies. Such assessments became crucial to the rapid acceptance and dissemination of any new technology. Computed tomography (CT) and magnetic resonance (MR) imaging are examples of early technologies that underwent intensive technology assessment immediately after their introduction to the marketplace. The ultimate success of MR is partly due to the early formal assessment of this technology and the identification of the unique and most useful features of the technology for clinical problem solving (*2,3*).

Technology assessment is defined by the Institute of Medicine 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, cost-effectiveness, as well as social, economic, and ethical consequences, whether intended or unintended" (*4*). This definition may be restricted or broadened to fit the particular analysis, technology or health care service.

How is technology assessment performed?

The techniques of technology assessment are grounded in quantitative and semi-quantitative methods with roots in economic and social analyses. Statistical methods, in particular, are used to strengthen arguments and to provide a valid analysis of published data on the technology of interest. Meta-analysis and other tools for the evaluation of large numbers of patient or product data are employed in such analyses.

Technology assessment begins with the formulation of key questions about a technology: What are the patient indications for the technology? Is the technology safe? Has the technology received regulatory approval? etc. The nature and specificity of these criteria largely defines how strict the assessment must be in order to yield valid information to accept or reject the technology in question. These criteria also permit specific comparisons between new and existing technologies.

The strictness of the analysis is also defined by the quality of evaluable data available for analysis. These data are generally obtained from published reports, manufacturer's registry data, other registry data and other "grey literature." Many assessments founder because of the lack of evaluable data. Randomized, prospective clinical trials yield the most unbiased and complete results on a technology, provided a sound study design was used. Clinical series, case reports and other publications yield less complete data, and there is always a question of biases, such as patient- or treatment-selection bias. As a result, an assessment based on clinical series or case reports does not carry the power of one that incorporates data obtained from randomized clinical trials.

Any formal assessment of technology should offer a conclusion and recommendation regarding the usefulness of the technology for the intended use (*5*). Such a conclusion and recommendation relies on the fit between the assessment criteria and the evaluable evidence. If the published literature and other sources of information establish that a technology satisfies the criteria established at the outset, then a positive recommendation regarding the technology is justified. Otherwise, if the technology fails to meet previously-identified assessment criteria, then a negative recommendation should follow. Once established, the assessment criteria should not be modified or adjusted to accommodate any technology. Assessment criteria play a central role and the definition of suitable criteria for the evaluation of diagnostic imaging technologies remains an area of active investigation. That is because criteria used for the evaluation of a cardiac study, for example, might not be appropriate for a nuclear medicine study. Useful criteria for the evaluation of imaging technologies must be established in order to validate these technologies and effectively position

them in clinical guidelines and practice patterns.

Who performs technology assessment?

Many interested parties have developed expertise in technology assessment (*6*). The federal government's role in technology assessment dates back to the 1970s. The federal agencies legislated to perform technology assessment include the National Center for Health Care Technology (NCHCT), the Center for Health Care Technology (CHCT), the Office of Health Technology Assessment (OHTA) and the Agency for Health Care Policy and Research (AHCPR). These organizations have had various degrees of effectiveness in serving the federal government as resources for technology assessment. The Blue Cross and Blue Shield Association (BCBSA) has the longest-standing private-sector technology assessment program. The University Hospital Consortium (UHC) also has developed an effective technology assessment program that serves over 70 academic medical centers in the U.S.

Implications for nuclear medicine

The impact of cost-effectiveness (*7*) and cost-containment measures (*8*) on nuclear medicine have caused concern among those in the field. By incorporating technology assessment measures in clinical trial and primary study designs, the usefulness of nuclear medicine studies to clinical medicine may be validated. Positron emission tomography (PET) and other costly nuclear medicine imaging studies may gain wider acceptance if the assessment and evaluation techniques used for the validation and dissemination of CT and MR are carefully considered. Technology assessment represents a powerful tool for introducing new diagnostic imaging modalities in a convincing and rigorous manner.

REFERENCES

1. McNeil BJ. Socioeconomic forces affecting medicine: times of increased retrenchment and accountability. *Semin Nucl Med* 1993;23:3–8.
2. Schersten T, Sisk J. An international view of magnetic resonance-imaging and spectroscopy. *Int J Technol Assess Health Care* 1985;1:479–480.
3. Bradley WG. Comparing costs and efficacy of MRI. *Am J Radiology* 1986;146:1307–1310.
4. Institute of Medicine. *Assessing medical technologies*. Washington, D.C.: National Academy Press; 1985.
5. Berkowitz DA. Overview of the technology assessment process. *Decisions in imaging economics* 1993; 6:7–12.
6. Papatheofanis, FJ. Technology assessment in radiology. *Decisions in imaging economics* 1995;8(6): 63–66.
7. Patton DD. Cost-effectiveness in nuclear medicine. *Semin Nucl Med* 1993;23:9–30.
8. Henkin RE. The potential impact of the resource-based relative value scale on the practice of nuclear medicine. *Semin Nucl Med* 1993;23:51–58.