Medical technology presents both opportunities and problems: the former lie in its potential to assist in preventing, treating, or diagnosing health conditions or in rehabilitating and improving the function of those with health problems; the latter occur in the areas of cost, efficacy, and safety. Technology has contributed much to advancing health in this century. WHO and PAHO are deeply committed to promoting the development and use of appropriate medical technology. The array of potential drawbacks associated with this technology include: increasing costs, problems of efficacy and safety, issues concerning technology transfer from more to less developed countries, and political and social concerns such as the distribution of resources within a country.

These problems and opportunities have generated a variety of policies ranging from promoting certain types of research, to regulating the import of certain devices and controlling the adoption of new technology through budgetary means. Policy mechanisms are mentioned here merely to indicate that the main purpose of technology assessment is to assist policy makers in decisions that are implemented through public institutions.

The growing prominence of medical technology as a policy issue for all countries has stimulated a similar concern in the area of technology assessment whose central aim in the health sector is to question whether a particular action or policy is worth pursuing. This practical focus is essential—if the results of an assessment are not used, there is little point in doing it.

Definitions

Technology has been defined as the "systematic application of scientific or other organized knowledge to practical tasks" (1). Medical technology, then, may be understood 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" (2). This article focuses on drugs, devices, and procedures.

Technology assessment is a comprehensive form of policy research that examines the short- and long-term consequences (e.g., societal, economic, ethical, legal) of the application or use of technology. Its goal is to provide decision-makers with information on policy alternatives such as the allocation of research and development funds, formulation of regulations, or development of new legislation (3). Medical technology assessment tends to focus on efficacy and safety by asking "Does it work?" "Is it safe?" and "How large an impact on the health status (e.g., mortality) can we expect from widespread application?" There are many aspects open to evaluation besides the efficacy and safety of medical technology.

Technology assessment provides a basis for a functional definition of appropriate health technology—one especially suited or compatible with needs, whose efficacy and safety (for the populations and health conditions affected), costs (in the context of local financing and priorities), and cultural compatibility meet the requirements of the local area or group (4). Assessment reveals whether or not the technology satisfies these needs.

Broad social, ethical, and cultural concerns are not evaluated by epidemiological methods, so they will not be addressed here; costs, however, can be assessed in this type of study and will be discussed briefly subsequently. This article focuses primarily on assessing the efficacy and safety of medical technology.

Determining Needs

The appropriateness or utility of a technology is grounded in knowing the status of the society's needs. The major tool for determining these is the evaluation of present health conditions through routine data collection and epidemiological surveys. Often, important information for determining these necessities is not available, especially in less developed countries. The best obtainable data should be used in planning health care services which ought to include selection and deployment of appropriate technological interventions.

The Distribution of Technology

Knowledge of what technology is already implemented is an element of rational planning that helps pinpoint unmet needs.
Like diseases, technologies may be identified through a variety of epidemiological techniques. Existing registries and data sources are obviously the easiest way to determine the distribution of technology; for example, the U.S. Food and Drug Administration requires the reporting, for regulatory purposes, of any new computed tomography (CT) scanner installed in the United States. Health planning agencies often have data on existing medical technology; unfortunately, technologies regularly reported in this way are the exception.

Medical technology is also frequently the subject of routine, recurrent surveys: the Hospital Discharge Survey of the U.S. National Center for Health Statistics asks about certain technologies, especially surgical procedures; the American Hospital Association conducts an annual survey of hospitals in the United States and includes a number of questions on specific technologies and technological applications.

Few technologies can be identified this easily; often, a special survey is required to determine their distribution. For example, the U.S. Office of Technology Assessment carried out a survey to determine the location of CT scanners in the United States (5). In this instance there were a number of data sources, but none of high quality. Health planning agencies were asked to verify data and contradictions or gaps were confirmed by directly contacting the institutions and offices involved. Likewise, a special survey was made in Mexico to determine the presence of certain technologies in public hospitals (6). J.F. Wennberg and his colleagues (7) studied small area variations in discretionary surgery using such data. They found that rates varied dramatically between different contiguous areas in New England. They also encountered remarkable differences among countries: the rate of hernia repair in New England is 276 per 100,000 (age- and sex-adjusted), compared to a rate of 186 in Norway and 89 in England. Rates in England and Norway also vary considerably among different areas. Results such as these indicate that technology is not being used rationally.

The main purpose of this kind of research is a quest for causes or determinants, as in epidemiology. Why does a technology have a certain distribution? How could it be affected? Public policies can also be examined in light of their results. Research in the United States indicates that health planning agencies produced little impact on the distribution of CT scanners, but that public agencies which controlled rates of reimbursement to hospitals had a significant effect (8).

Little is known about the distribution of medical technology in Latin America. While it is often said that expensive technology is found primarily in private hospitals, no systematic information is available on the subject; much fruitful research could be done in this area. The effective use of machines is another problem which needs investigating: 96% of all medical equipment imported in one country between 1973 and 1976 was not functioning in 1981 in part due to a lack of maintenance, but also because much of the equipment had not even been removed from its crates.

Examination of Efficacy

Overall, little is known about the efficacy of specific technologies. Few have been studied by rigorous methods (2) and this greatly hampers a rational approach to their deployment. In the United States, while there is an apparent overuse of many technologies, information on the efficacy and safety of medical technologies is increasingly used in making policy decisions (e.g., whether specific procedures should be provided by the Medicare program).

Specific methods are available for evaluating the effect technologies have on health. There are methodologic principles that guide the interpretation of any particular investigation. Each method has its strengths, weaknesses, and limitations for detecting favorable or unfavorable outcomes associated with a technology. Some of these methods are purely epidemiological; others, such as the randomized clinical trial (RCT) use epidemiological principles and depend on statistical methods for their design and interpretation.

Perhaps the most important use of epidemiological principles in approaching efficacy, however, is in the interpretation of available data. Often, planners fail to carefully scrutinize available study data which frequently contains important clues to efficacy. The data should be sufficient to give an idea of expected effects of applying a technology, especially in comparison with its alternatives. This can be critical in designing an experimental study.

RCT's are considered the most definitive method for evaluating the efficacy or health benefits of a technology (9). An essential element of an RCT is randomization: patients are randomly assigned to one of at least two groups—one or more study groups in which subjects are exposed to the experimental treatments, and a comparison group in which the subjects are exposed to the control situation. The control con-
dition can be either no treatment (usually a placebo treatment), the standard treatment (for comparison with a new treatment), or a variation (e.g., a different dosage) of the experimental treatment. The basic question is: are the effects observed in the experimental group also observed in the comparison group? If the answer is essentially "no", the effects observed in the experimental group can be attributed (within the limits of probability) to the treatment technology.

Efficacy assessment in the area of diagnostic technologies is more complicated. A treatment technology should result in a clear health objective, such as preventing mortality or morbidity. The main product of a diagnostic technology is a diagnosis and epidemiological concepts of sensitivity, specificity, reliability, and validity are often used in an attempt to determine the efficacy of diagnostic methods. Screening procedures are even more awkward to evaluate using standard questions related to yield and whether there is an efficacious treatment available for those conditions.

Because of primarily logistical and financial difficulties encountered in conducting RCT's, other epidemiological methods are being increasingly applied to medical technology. Observational studies may be valuable in generating or testing hypotheses about the effects a technology has on health once it is widely diffused. These studies also may be considered in situations where experimental ones are inappropriate or impossible to conduct. The common element in all observational studies is that the investigator does not control the application of the technology under study. The division of a population group into "cases" and "controls" or "exposed" and "unexposed" occurs through mechanisms unrelated to carrying out a study, such as the treatment preference of a physician. This leads to almost inevitable questions about the validity of the results of such studies. Observational studies may, nonetheless, allow evaluators to rule out competing explanations for the observed effects.

Another important factor in considering the results of efficacy studies is that an experimental study examines effects in a controlled setting. For the most part, this means that the staff are well-trained, the technology is used as optimally as possible, the patient is closely observed, and so forth. However, when applied in the community, a technology of previously demonstrated efficacy may not have beneficial effects: the patient may not take the drug; the surgeon may not be skillful; and the disease in the community setting may be less severe than the form found in the teaching hospitals. These real-life factors modify the health benefits the population receives. "Effectiveness" refers to benefits obtained in the community setting, and is studied by the epidemiological methods described above. Unfortunately, there have been few studies of effectiveness, and little is known about how the efficacy and effectiveness of specific technologies compare.

Finally, the policy maker is not necessarily interested merely in the question of whether a technology is efficacious. He or she usually will wish to know its efficacy in comparison with something else. What are the alternatives? How effective are they? Few technological studies are comparative and in general, this question cannot be effectively addressed by available data.

**Examination of Safety**

While the experimental study is the most important tool used to examine efficacy, epidemiology serves most effectively to determine technological safety. Most adverse consequences of medical technology occur at low rates and prospective experimental studies are necessarily limited in size. Therefore, an experimental study usually will not result in enough adverse consequences to determine with confidence that these were due to the technology in question.

There is a great deal of experience in studying drug safety. In addition to the very important animal studies, post-marketing surveillance using a prospective cohort design has proved useful. Typically, a user population of a particular drug is entered into a registry and followed over time through various health events, the rates of which are compared with those in a non-user population. Unusual medical occurrences may thus be associated with the use of the drug. Drug reactions may also be determined by methods such as reporting and special surveys; case-control studies are particularly useful for discovering rare complications.

Little systematic information is collected on the safety of technologies other than drugs. The mortality rate for surgical procedures is generally known from case reports. Some safety factors may be noted, depending on the technology and the setting in which it is used: if the technology is used primarily in the hospital, for example, common effects are likely to be observed while less severe ones often go undetected;
and such “trivial” effects as pain may not even be considered a problem by physicians providing the treatment.

**Examination of Costs**

Examined independently, costs have little meaning, even in poor countries; rational choice requires that they be seen in relation to benefits. Without knowing costs, benefits likewise resist interpretation. Ideally, the policy maker should consider both when making choices; the goal of technology assessment is to improve and inform that choice.

Cost-effectiveness analysis is probably the best available method for establishing costs in relation to benefits in the health field. However, this analysis cannot be usefully made of a single procedure—it must examine alternatives; this means that it is quite often difficult to put epidemiological data in a form that is useful for cost studies.

One option that has not been widely implemented is to include cost or economic aspects in a clinical or epidemiological evaluation (10). This could be done relatively easily in a prospective study requiring the participation of economists in a cooperative venture. Epidemiologists need technical assistance in making economic studies as do clinicians in performing epidemiological studies.

**Summary and Conclusions**

In an area of limited resources, choices become more and more problematic, particularly in less developed countries where health expenditures are being reduced. Now is the time to expand the use of technology assessment as an aid to making choices. An important implication of this situation is the need to include this kind of assessment in training and educating health professionals such as epidemiologists.

It should be remembered that these choices are not technical, but political and social in nature. They are appropriately made by politicians and policy makers on the basis of many factors, including some that cannot be easily assessed. Scientific studies, however, can aid policy making. The foregoing indicates how epidemiology can contribute to the development of knowledge on the effects of technology. The challenge is to appropriately integrate assessment results into the decision-making process.

**REFERENCES**

(6) Institute for Health Policy, Project Hope Center for Health Information. Appropriate health care technology transfer to developing countries: A project HOPE Conference Report. Millwood, Virginia: The People-to-People Health Foundation, Inc.; 1982.
(8) Bice, T. Personal communication.