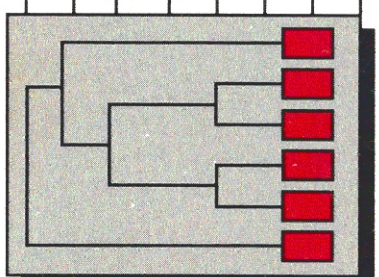
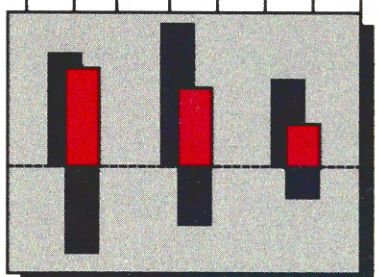
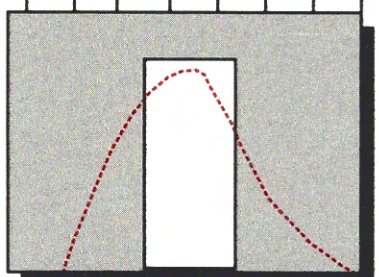
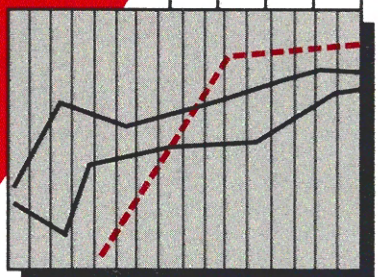
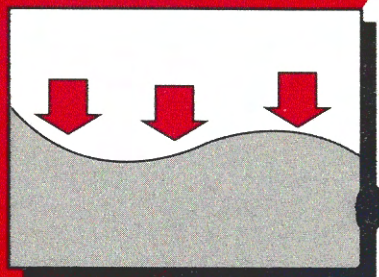


Pan American Health Organization

HEALTH TECHNOLOGY ASSESSMENT METHODOLOGIES FOR DEVELOPING COUNTRIES

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Health technology assessment methodologies for developing countries

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Preface

If at least a part of the considerable effort being focused by industrialized countries on producing state-of-the-art technology were being used to find solutions to the pressing social and health needs of the people on this planet, there would be more reason for optimism about the role of technology in Third World societies. As it stands, technology transfer can bring its own associated problems: it frequently introduces new risks, spurs a rise in health care costs, and, through synergistic effects, promotes high levels of specialization. The most fundamental problem, however, becomes evident when the social distribution of technology's benefits is analyzed.

The indiscriminate incorporation of technology is contributing to a polarization of health services within societies. While the elite in developing countries have access to private hospitals with services equivalent to those in developed countries, the rest of the population must depend on public hospitals and services frequently lacking the most critical supplies and unable to modernize their technological infrastructure. In addition, shortages of parts and deficiencies in maintenance have paralyzed many installations, affecting as much as 96% of the medical equipment in extreme cases. As a result of the distortion in investments at the tertiary level and the imbalance in the health sector's institutional makeup and organization, in most developing countries, including those of Latin America and the Caribbean, priority is given to intensive coverage of small portions of the population with the highest levels of income and fewest health risks.

Owing to a variety of social, economic, and political factors, large segments of the population are completely or partially excluded from the benefits stemming from basic health technology, such as improved hygiene, sanitation, and nutrition, and their access to preventive, diagnostic, and therapeutic technologies is seriously restricted. At a time when growing populations, the urbanization process, and the effects of the economic crisis are aggravating this situation, governments are becoming aware that the incorporation of technology is not only a technical issue but also a priority topic for public health policy.

Health Technology Assessment Methodologies for Developing Countries is a publication designed to promote evaluative research in this area and the training of researchers in faculties of medicine, public health schools, health management training programs, and related courses of study. This capacity needs to be expanded and strengthened through collaborative efforts involving national research and training institutions as well as international organizations.

Traditionally, technology assessment has been more oriented toward evaluating the safety, effectiveness, and cost of single technologies. The transition to evaluation practices centering on the needs of the population of the Third World brings to the forefront issues such as equitable distribution, the quality of care, probability of access, and other ethical, social, economic, and political concerns. This publication is a challenge to the technology assessment community to expand the framework of their discipline to encompass the broader impacts of technology on the health of large population groups exposed to the greatest risk.

Activities associated with technology, including research and development, production, international trade, capital investment, and technology allocation policies, must be included in the broader framework of technology development. In addition, health technology needs to be recognized in national policy as a key component of development.

PAHO is committed to supporting technology assessment research in the broad framework of technology development and as an integral component of health policy analysis. This new publication is directed toward sustaining that commitment.

Carlyle Guerra de Macedo
Director

Introduction

This publication reviews the main concepts and methodologies involved in health technology assessment and discusses its potential contribution to improving health care delivery in developing countries. In the last two decades, the need to assess new and costly medical technologies has become more prominent in developed countries in light of increased health care costs and concerns about the safety and utilization criteria of a growing number of technological procedures. However, the problems developing countries face in utilizing and assessing health technologies are not typical of those in developed nations, and hence an approach is required that takes account of their uniqueness.

Technology has been defined differently by different authors. To Galbraith (1) technology “means the systematic application of scientific or other organized knowledge to practical tasks.” Within the context of medical care delivery, technology has been defined by the United States Office of Technology Assessment (OTA) 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). In the broader context of health care, the OTA definition must be expanded to encompass knowledge that can be used by health care providers and by communities to solve or ameliorate health problems and improve health status.

Before health technologies can be assessed, the role they are to play in influencing the health level of the population and individuals must be understood. “Health” represents a complex state involving not only physical wellness but also social and psychological well-being. In view of these multiple determinants, it is often impossible to measure health with a single indicator that can be used in international comparisons. However, a number of simple, cause-specific indicators do show that many biological health problems that have been reduced to a minimum in developed countries still plague most Third World countries. Such indicators are infant mortality rate, prevalence of infectious and parasitic diseases, and, more universally, life expectancy. This observation indicates that although in most developed countries the role of health technologies can be analyzed in terms of their impact on “quality of life,” in less developed countries priorities can still be established on the basis of mortality statistics, which are the best health problem indicators available for most of these countries.

In understanding the relationship of medical technology to cause-specific mortalities and life expectancy, it is critical to first become aware of the differences between developed and developing countries regarding the history and spread of health technologies.

The development of modern medical technologies can be traced back to discoveries in the physical and biological sciences during the 17th century (3). But it is only since World War II in the industrial nations of the Northern Hemisphere that there has been an almost explosive process of innovation and diffusion of modern medical technologies and an increase in the number of medical procedures that lead to a cure or other sensational results (3). Before this latter phase occurred, however, socioeconomic changes and the sanitation movement of the 19th century brought the nonmedical technologies (nutrition, hygiene, health education, coordinative services) to a large majority of the population in these countries, independent of individual need, marking the beginning of the largest "preventive" campaign in history. The results of the large-scale diffusion of the nonmedical technologies were evidenced in the first decade of the 20th century by the fall in incidence and mortality rates of diseases such as tuberculosis (4), typhoid fever (5), and pneumonia (5), even before modern treatment methods had been developed. The advent of modern medical technology dealt the final blow to infectious and parasitic diseases and complications of birth in developed nations, leaving degenerative and chronic diseases as the main health problems in these countries.

History has been quite different in developing countries. Owing to socioeconomic problems and the time lag of development relative to population size, these countries have been unable to disperse the nonmedical technologies on a mass scale. In recent years, this feat has been achieved by a small number of countries such as Costa Rica, Sri Lanka, and Cuba (6), with results that confirm the experience of more developed countries. Modern technologies have reached the Southern Hemisphere. Some population groups in these countries enjoy standards of living similar to those in rich nations. This circumstance has created a demand for the same modern, and often costly, technologies that are being marketed in the north. The political and economic power of elite groups in developing countries and international pressure for the sale of modern equipment—often referred to as "technology transfer" and tied to intergovernmental loans and donations from philanthropic organizations—have led to facilities in most large urban centers of the Southern Hemisphere that duplicate those found in a modern hospital of a developed country (7). The result of this anomalous process is an imbalance in the allocation of scarce technological resources among populations with heterogeneous health problems and needs, which is aggravated by inappropriately distributed health manpower and lack of infrastructure.

It would be naive to propose that developing countries should proceed through the same stages as the developed countries did in the quest to improve health standards for their populations. Nevertheless, although the cultural and economic realities of these two worlds differ, many modern technologies should be explored in developing countries, since they are more cost-effective than alternatives available a half century ago. Vaccines are one example. The answer seems to lie in the wise selection and well-planned extension of technological options that are appropriate to local conditions and can produce optimal health improvements

within the limitations set by available human and financial resources. This is easy to say, but a formidable task to accomplish; it requires appraisals from the economic, epidemiological, and clinical points of view. In addition, the word “appropriate” means not only that the necessary infrastructure should be available, but that the technology should not be harmful to the environment or social relationships, or at odds with ethical values or the legal system.

The tools needed to tackle the huge problem described above fall within the domain of the discipline of technology assessment, which first evolved in developed countries for social applications but was quickly adapted for use in the health field. In the United States, the National Academy of Sciences’ Council on Health Care Technology of the Institute of Medicine recently published the first medical technology assessment directory¹ in an effort to organize current information from a broad spectrum of assessment programs throughout the world. It constitutes a valuable guide to the field of medical technology assessment and includes more than 3,000 citations.

It is considered that health technology assessment (HTA) can be even more useful to developing countries than to countries with abundant resources (8, 9). The present publication was written with a view toward the important potential of HTA for leading to a more rational utilization of health technologies in developing countries. It analyzes the main concepts and methodologies of HTA (Chapters I, II, and IV) and discusses different strategies that can promote their optimal use (Chapters III and V).

¹Council on Health Care Technology, Institute of Medicine. *Medical Technology Assessment Directory*. Washington, D.C., National Academy Press, 1988.

Chapter I

An overview of technology assessment

The observation that technology has great potential to influence our daily life, drastically or in subtle ways, has been made through the ages by philosophers and laymen (10). However, it was in the 1960s, with the evolution of systems analysis and forecasting techniques, that concern with the unforeseen and long-term impacts of technologies—ever increasing in scale and pervasiveness—was merged with analytical techniques to form the new discipline of technology assessment. Typical objects of study at that time were supersonic flight, mobile communications, offshore oil operations, solar energy, and remote sensing (11).

Technology assessment has been defined in several ways. According to Coates (12), technology assessment “is a class of policy studies directed to examining the broadest social implications of the introduction of a new technology or the expansion or extension of an existing technology.” Alternately, technology assessment is defined as the process of identifying the “higher-order” impacts (second, third, and so on) that go beyond a technology’s intended utility (13). More simply, some have described technology assessment as a common-sense “look before you leap” approach used to identify all the social consequences of new technologies, especially those that have the potential to affect large numbers of people. Finally, Lee and Bereano (14) extended the concept and objectives of technology assessment by stating that besides identifying higher-order impacts it should also examine whether the impacts have been planned or not, and then describe the beneficial or adverse nature of the consequences. They emphasize the uncertainty and complexity of the problems faced.

The potential benefits of technology assessment to society, apart from protecting it against technological disasters, can be envisaged broadly as fostering democracy and, more specifically, serving as a social policy tool. Although technology assessment could be used to advance the particular interests of corporations and other groups (15), it can work as a mechanism for public participation and information if due caution is exercised in forming the assessment team, deciding the study contents, and disseminating conclusions (15, 16). The creation of an Office of Technology Assessment by the U.S. Congress in 1972 can be appreciated from this perspective.

Contributing to the formulation of public policies is an intrinsic objective of technology assessment. Since technological choices can shape the economic, social, and cultural evolution of a society, policies can only be formulated with confidence if the impacts of different technological alternatives are comprehensively

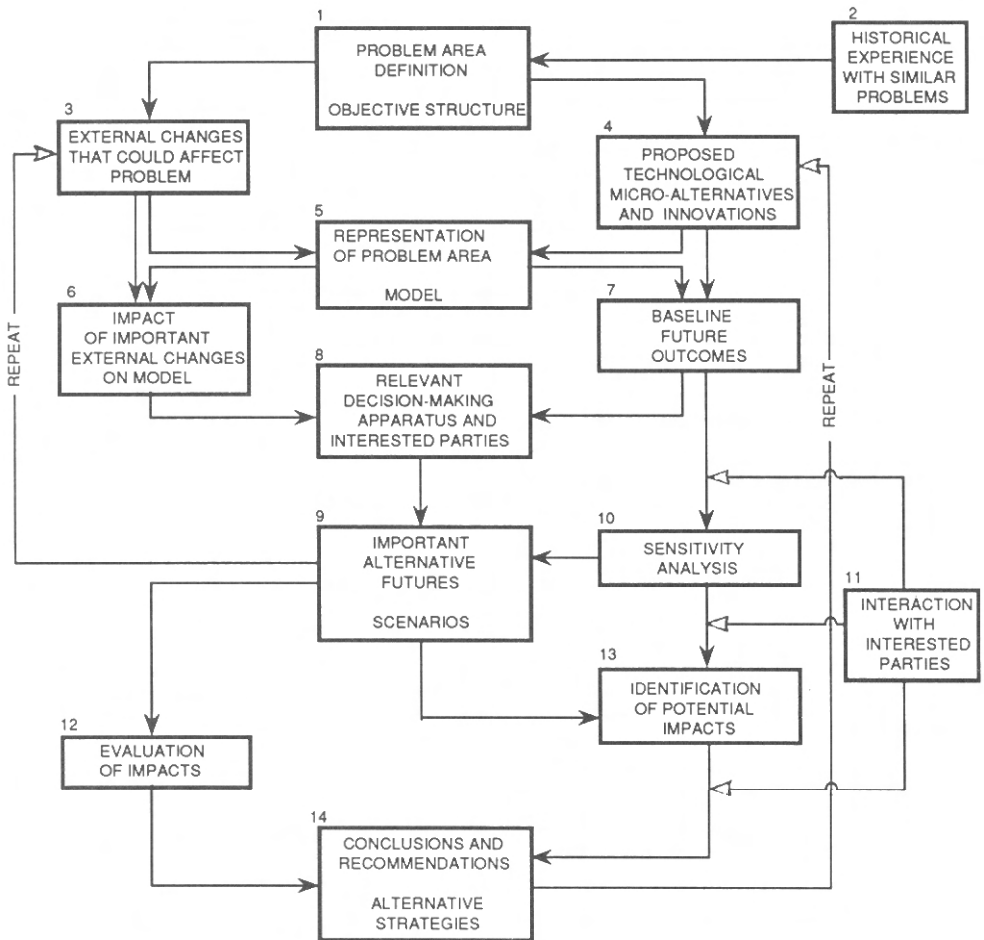
analyzed. It is generally agreed that all assessments should include some degree of policy analysis, which means a discussion of alternatives and their ramifications (11, 14). However, there is considerable debate among experts regarding the degree to which assessors should advocate one particular policy among the alternatives (11). Some argue that policy advocacy gives greater respectability to a study (17), while others believe it increases the biases inherent in technology assessment when dealing with value-laden issues (11, 16).

No aspect of technology assessment has received more attention than the methodology required to reach its objectives. The possibility of finding a single "cook-book recipe" has been discarded by most. The general view is that each assessment requires a combination of techniques that are appropriate for the technology studied, the level of information available, and the dimension of the problem involved. Coates (12) proposed a framework of 10 well-defined steps to guide technology assessment:

1. State the problem to be considered (a broader restatement or recasting of the problem is usually needed after analysis is under way).
2. Define the system (technology) and specific alternatives (micro-alternatives) that could accomplish the same objective.
3. Identify potential impacts. This is a creative enterprise requiring imagination and speculation.
4. Evaluate potential impacts. This effort is a mixture of firm-handed analysis and informal judgment necessarily conducted on semifirm footing.
5. Define the relevant decision-making apparatus—a step that is often neglected.
6. Lay out options for the decision maker. Since traditional categories may now be inadequate, new inventions and imaginative development of options are usually appropriate and often needed.
7. Identify interested parties (potential "winners" and "losers"), including both overt and latent interests.
8. Define macro-alternatives—not the alternative technologies considered in Step 2, but broader system alternatives. This step provides a standard against which conclusions drawn in Steps 1 through 7 can be challenged.
9. Identify exogenous variables—events that may disturb the system.
10. Draw conclusions, and possibly make recommendations.

Arnstein *et al.* (18) modified Coates' stepwise procedure into a more dynamic model reflecting the interactive nature of technology assessment studies and allowing for other parallel activities (Figure 1).

Figure 1. Methodological framework proposed by Arnstein *et al.* (18) for policy-oriented technology assessments.

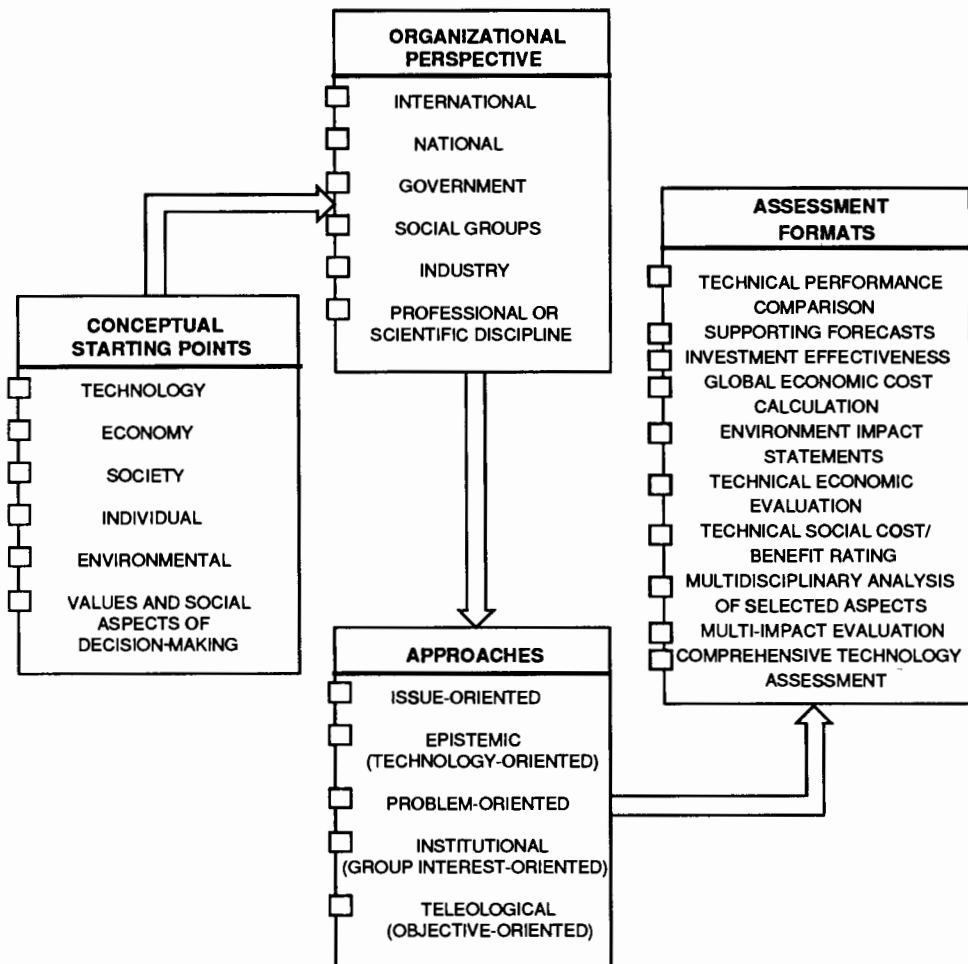


A single technology assessment exercise may utilize several different techniques: systems analysis, Delphi, input-output matrices, interpretative structural modeling, simulation, cost-benefit analysis, relevance trees, group brainstorming, and a number of different modeling approaches (14, 18, 19, 20). Some of these techniques are described in more detail in Chapter IV. Although the development of systems analysis has been instrumental to the conceptualization and epistemology of technology assessment, it has not been able to fulfill its early promise in regard to the main object of interest, that is, the social impact of technology. The limitations of systems analysis in this field result from a paucity of existing knowledge about the laws and forces that guide the interaction of multiple societal sectors,

and the difficulty of quantifying and validating social indicators. More generally, Lee and Bereano (14) stress that "there is no universally accepted theory or paradigm concerning societal change, unlike the situation with respect to the physical sciences." Therefore, technology assessment should not be seen as pure science, but as an art that incorporates a number of well-established tools in a process involving intuition, sensitivity, creativity, and wisdom.

A search for the impacts and implications of technologies such as mobile communications or the artificial heart may lead to a task of unmanageable complexity and dimension due to the endless array of higher-order impacts that can be iden-

Figure 2. Typology of technology assessment studies, as proposed by Lee and Bereano (14).



tified. For this reason, most assessments must be bound by some well-defined limits in order to render the study feasible within the time and resources available. Unfortunately, there are no widely accepted rules to guide the process of setting bounds. Lee and Bereano (14) suggest a number of different aspects that should be taken into account: time allotment, geographic scope, institutional considerations, problem orientation, impact sectors, range of policy options to be considered, and input provided and output expected from the technology assessment team. Problem orientation refers to the approach adopted for the study, whether it is technology-oriented or problem-oriented. Lee and Bereano's complete classification of technology assessment studies is presented in Figure 2, where other classes of approaches are also included: group-interest-oriented (institutional), objective-oriented (teleological), and issue-oriented.

The preceding brief overview of the main concepts and elements involved in general technology assessment is important for approaching the problem of assessing health technologies, which is the real object of interest here. To what extent is the framework proposed by Coates (12) or Arnstein *et al.* (18) (Figure 1) adequate to evaluate health or medical technologies? Moreover, how should developing countries approach technology assessment, considering their problems, priorities, and resources? As the following chapters will demonstrate, these two questions are highly pertinent and should be taken into account by all persons involved in the planning and management of health technology in developing countries.

Chapter II

Applying technology assessment to health care

A. ORIGIN OF HEALTH TECHNOLOGY ASSESSMENT

Strictly speaking, health technology assessment (HTA) is not an offspring of general technology assessment, since most activities that are usually carried out under HTA were already in use by the mid-sixties when the concept of technology assessment (TA) came of age. However, technology assessment represented a new conceptual and epistemological framework that was soon transferred to health care, bringing with it many advantages. Notably, it emphasized the message that health technologies should be thoroughly evaluated, not only for their immediate health benefits and costs but also for their short- and long-term social consequences. Moreover, many techniques developed for technology assessment showed great promise for application to assessment in health care. As a new discipline, HTA enlisted multidisciplinary expertise, which is a key element for both analytical accuracy and comprehensiveness of assessments.

One of the first assessments of a health technology was a study of the impacts of the artificial heart, conducted by the National Institutes of Health (NIH) in 1969 (20). In 1975 the U.S. Office of Technology Assessment established a Health Program, which has had a considerable effect in promoting HTA (21). Currently, most developed countries have a large number of governmental, private, and academic institutions involved in HTA; there is also an international association devoted to the subject, the International Society of Technology Assessment in Health Care (ISTAHC).

Although the objective of this publication is to discuss application of HTA in developing countries, the starting point will be the main conceptual basis of HTA and experiences with this discipline, drawing mostly from studies performed in developed countries. A separate chapter will concentrate on the specific problems and priorities found in developing countries. The accumulated experiences with HTA in developed countries are relevant as examples of methodology and, more importantly, as forewarnings of the problems that developing countries are likely to face as their societies incorporate a growing number of modern and complex technologies.

B. THE LIFE-CYCLE OF HEALTH TECHNOLOGIES

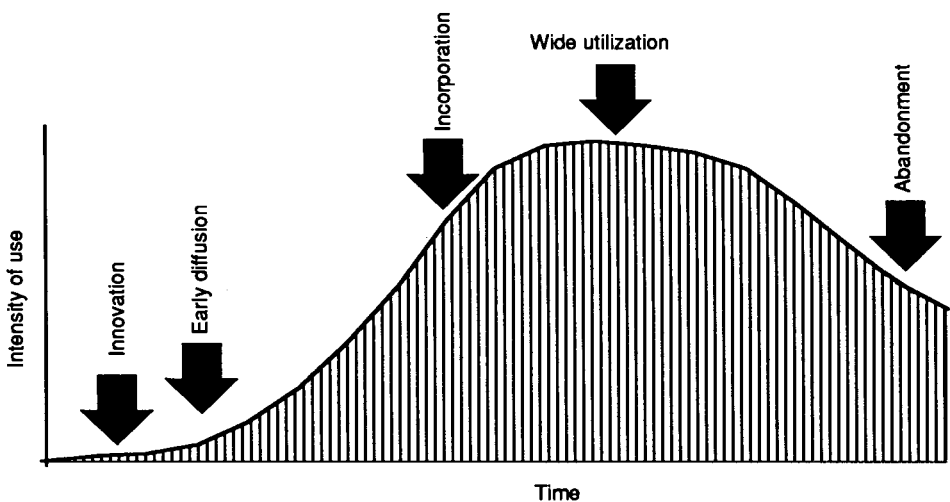
1. Life-cycle model

Very few health technologies have proven to be the definitive answer to a health problem; most commonly there is a continuous process of technological innovation that closely follows breakthroughs in the biomedical and physical sciences. Every time a new technology surfaces, it sets in motion a complex chain-reaction of impacts as it spreads and is put into use. A technology will eventually be abandoned for a number of different reasons, thus completing its “life-cycle” in health care delivery. A study of the complete cycle, depicted in Figure 3, is necessary to identify the main determinants and influences that drive this dynamic process, in order to provide the facts needed to understand it and to formulate the most appropriate and effective control policies.

2. Innovation

The process of technological innovation starts with the invention of a new product, process, or practice, and it is completed at the time of the first practical utilization. In between these two reference points there is usually some form of economic evaluation (e.g., production costs), and tests using volunteers are conducted to assess the health benefits and risks of the new technology. However, the evaluations performed at this stage usually reach diverse conclusions and have a low level of reliability. In fact, as discussed in Section C of this chap-

Figure 3. Life-cycle of health technologies. Adapted from Banta *et al.* (21).



ter, the evaluation of a new health technology during or just following its development is one of the concerns of HTA.

Very few empirical studies have been devoted to technological innovation in health care, as opposed to other industries where such studies are done for the purpose of stimulating innovation (22). However, health care has never been short on incentives for the invention of new products and processes. As an illustration of this, it should be noted that in 1984 50,000 different devices were registered with the U.S. Food and Drug Administration (FDA), and that every year another 5,000 were being added to the list (23).

The strongest determinant of innovation in health care is the persistence of disease and disability. Since in developed countries chronic illnesses account for most health problems, innovations have soared in that area (24). Clearly, economic considerations are always a factor, which explains why the health problems of developing countries have not attracted as much attention from innovators. Moreover, a gigantic medical-industrial complex has evolved in the Northern Hemisphere, and its very survival requires the continuous outpouring of new products and practices. The area of intended impact of many new technologies is not the patient's health, but medical practice itself. Examples of this kind of innovation are refinements introduced into medical instruments, such as attractive numerical displays, and the automation of functions and routines hitherto performed by physicians and other health personnel.

Biomedical research has been another important factor in the generation of medical innovations. Since 1950 NIH has committed more than US\$50 billion to biomedical research, the results of which have in large part been translated into practical applications. Scientific and technological developments in other fields of knowledge can also have applications for health care or be the decisive element that makes a new product or solution possible. This point is well illustrated by the classic diagram presented by Banta *et al.* (21), showing the interplay of basic technologies which led to the production of the first cardiac pacemaker.

If many factors serve to stimulate innovation in health care, other influences can deter it. Such a deterrent is regulation, which increases the costs of research and development and the financial risk associated with new projects. The dramatic reduction in the number of new drugs launched in the U.S. market has been the direct result of the more stringent regulatory process imposed by the FDA. Between 1950 and 1965, 5,558 new pharmaceutical products appeared on the market, but since 1966 the rate has fallen drastically, to less than 50 products introduced annually (25).

Roberts (22) points out that the process of innovation varies considerably according to the kind of technology and the area of health care. This view is supported by Barnes (26), who stresses the role that the surgeon's prestige and leadership, the absence of ethical constraints, and established doctrine had in the appearance of surgical innovations which were later discarded.

As soon as a new technology is marketed, it reaches the end of the innovation phase. At this point other forces come into play and govern the process of diffusion that will determine the degree to which the new procedure or device is accepted.

3. Diffusion

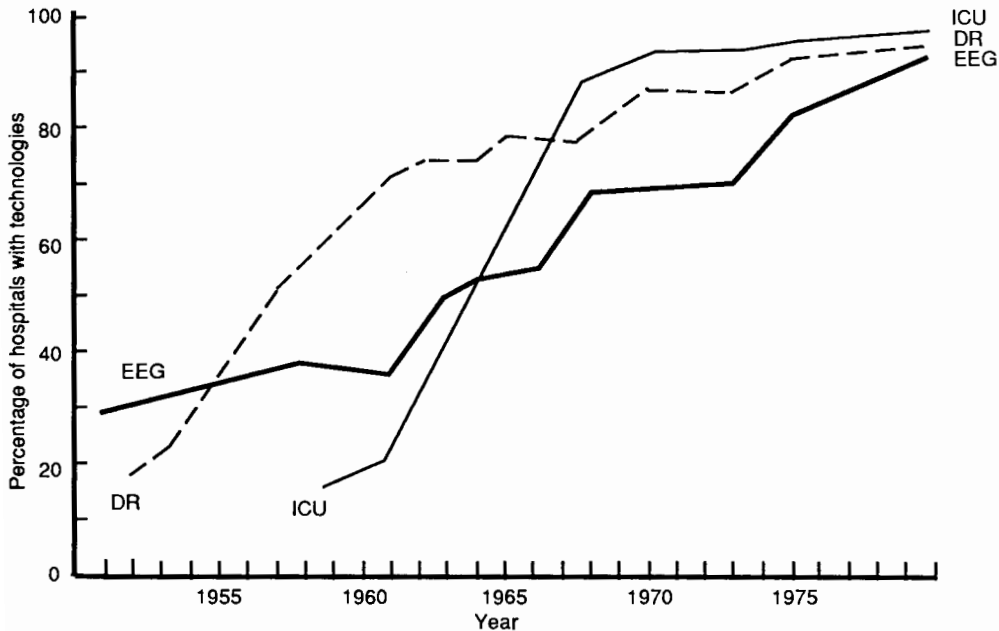
When a new technology is announced, usually publicized first by the mass media and then in scientific meetings and journals, it sets in motion strong human motivations and expectations. Patients afflicted by conditions that might be alleviated by the technology will build up new hopes and will press their doctors for access to the novelty. Physicians will be encouraged to adopt it, because of intellectual curiosity, the prospect of additional income or professional prestige, peer pressure, the eventual threat of malpractice suits, or the belief that it will lead to tangible health gains or the comfort of their patients. Hospital administrators will buy it to attract the best medical staff and to keep a competitive edge in relation to neighboring hospitals. Other health professionals may be forced to contemplate either a job loss or the need to go into a retraining program. As in the innovation phase, legislation and regulation can slow down the diffusion process, for example, by placing limits on the number of expensive pieces of equipment available to the population in each area.

A classic study by Russell (27) attempted to quantify the diffusion of hospital technologies in metropolitan areas in the United States. Figure 4 reproduces her findings for three high-cost technologies in hospitals with 200 to 299 beds. Most commonly, these curves have a sigmoid shape (21), but the growth rate can vary widely from one technology to another. Some exceptions are noteworthy: cobalt therapy remained at a constant level of 20% distribution among the same group of hospitals, and some technologies fall into disuse as quickly as they are diffused (21, 28).

Russell also confirmed that competition, hospital type and size, demography, form of payment, prestige, and the presence of teaching in the hospital are determinants of technological diffusion. Surprisingly, however, she did not detect any association between the rate of technological diffusion and the morbidity pattern of local populations.

In one of the few such studies done in a developing country, Rodríguez-Domínguez *et al.* (29) investigated the diffusion of 17 new technologies in Mexico. Their results show differences in the speeds of diffusion and a concentration of technologies in areas with greater socioeconomic development. Although the speeds of diffusion vary, it has been observed that medical devices and equipment usually encounter pressures favorable to adoption, while preventive and coordinative technologies, such as screening and information systems, suffer pressures *against* adoption (30). This finding raises the question of whether the perception of personal or corporate profit versus "community profit" is guiding the process.

Figure 4. Diffusion of intensive care units (ICU), electroencephalographs (EEG), and diagnostic radioisotopes (DR) in U.S. metropolitan hospitals with 200-299 beds. Modified from Russell (27).



4. Incorporation

When an emerging technology starts to be recognized by health care deliverers as an established technology, a change in the technology's status occurs. Often this change is brought about when the government or health insurers decide to reimburse patients or to subsidize the new technology as a result of a consensus about its benefits to health or the quality of care.

For low-cost procedures, the incorporation stage may go unnoticed. However, for large-scale technologies such as water fluoridation or heart transplants, this stage is critical because it paves the way for increased utilization and an attitude of greater confidence in the benefits of the technology. For this reason, the incorporation stage and the decision-making process underlying it deserve more investigation and attention from HTA.

5. Utilization

The routine utilization of health technologies has received very little attention from investigators, and accurate data for most procedures are not available, especially for developing countries. This lack of knowledge is unfortunate, because

utilization is the most important of all phases since it is then that health benefits are accrued, critical resources wasted, and safety hazards detected.

One topic that has received some attention in the literature is the overutilization of procedures like surgery and diagnostic tests (30, 31, 32). Increasing professional specialization and regional differences in the supply of services have been identified as the main determinants of overutilization.

Health and medical services can be viewed as merit goods that are so crucial for society that the government should finance them. Many Third World countries and also some developed countries, such as Sweden and the Netherlands, provide complete or partial health services under the concept of public goods. In some other countries, like France and Japan, medical services are regarded as consumer goods. In the Third World, these two approaches coexist, and they influence the patterns of utilization of services and the rationality of technological diffusion.

In the private, for-profit sector, health technologies are incorporated into and used as consumer goods, and institutions use market analysis and strategic planning to promote the highly profitable services and technologies. In many cases, the supplier creates the demand for these services. Coverage is low, due to the income structure of the population. Under this model, the technologies are imbued with an image of prestige and quality that is further enhanced by the mass communication media. It is not infrequent that the sector producing these consumer goods is partially financed through public funds. Such is the case in the United States, where medical services are viewed as consumer goods and mainly financed as public goods.

Prepayment, social security systems, multiple public financial sources along with a variety of public and private delivery systems, and other national and international forces are influencing the complex patterns of accessibility to health services and of utilization of various technologies. It has been said that, "In general, advanced technology is concentrated in large cities, at private hospitals that serve a small, elite segment of the population. The vast majority in urban and in rural areas have no access to the benefits of advanced technology" (33).

Technology tends to be concentrated in the private sector in countries where this sector is most developed. In Latin America, such is the case in Argentina (34, 35) and Uruguay (36). In countries such as Cuba, Costa Rica, and Chile, where the private sector is less developed, the distribution of medical technology tends to be more equitable.

A study in Uruguay (36) reveals that 52% of the nation's medical technology is concentrated in the strictly private sector that serves less than 25% of the population. Uruguay's three computed tomography (CT) scanners, for example, are strictly private, and 85% of its chronic hemodialysis equipment is private. Moreover, 97% of Uruguay's technology is concentrated in Montevideo, where only 45% of its population lives.

Argentina (37) also shows unequal distribution of high-cost technology. In the

metropolitan area that includes Buenos Aires and its environs, there is one CT scanner available for every 440,000 inhabitants. In the country at large, there is one per 1,615,000 inhabitants. The same disparity occurs regarding gamma therapy and gamma cameras. Near Buenos Aires there is one such camera per 264,000 inhabitants; outside Buenos Aires there is one camera per 1,250,000 inhabitants. Poor distribution is also seen in X-ray equipment. The public-versus-private, urban-versus-rural distribution of high-technology medical equipment is shown in Table 1.

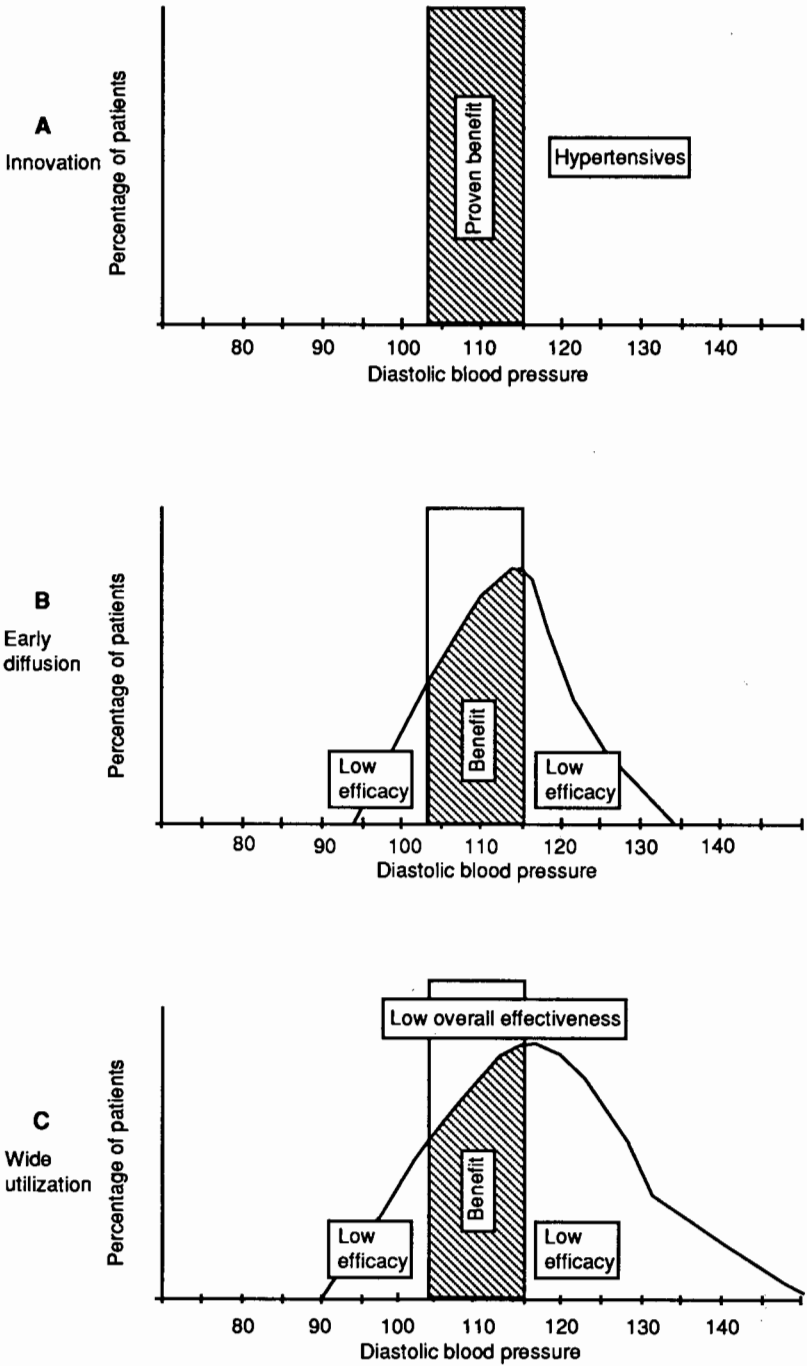
In Brazil, too, the private sector appears to possess a disproportionate amount of the available medical technology. For example, Banta (38) reports that in the late 1970s, 52 CT scanners were imported into Brazil, all of which were purchased by private institutions.

One of the main issues surrounding the utilization of health technologies is the selection of patients who will receive them based on clinical or epidemiological indications (39). Coronary bypass surgery and cesarean section delivery are good examples of technologies that have been proven to be beneficial to well-defined groups of patients, but that are many times applied indiscriminately, thereby subjecting other groups to the risks without the benefits. A hypothetical example gives a graphic illustration of this problem. Let us suppose that a new antihypertensive drug is proven to be efficacious for controlling blood pressure (BP) in individuals with diastolic BP around 110 mmHg, but not for other hypertensive patients. Based on evaluations done at the end of the innovation process, this group can be graphed as a narrow rectangle (Figure 5, top). Problems start during diffusion (Figure 5, middle), when lack of information on the part of professionals and overpromotion by salespersons lead to prescriptions being given to patients with diastolic BP outside the recommended range. Finally, when the drug is in routine use, it will be marketed under many different trade names, and inappropriate utilization may reach the extent represented in Figure 5 (bottom). By then, the overall benefit and effectiveness of the new drug will be drastically reduced,

Table 1. Geographic and ownership distribution of high-technology equipment in Argentina.

Equipment	Total	Private		Official		Capital and Buenos Aires Province		Other provinces	
		No.	%	No.	%	No.	%	No.	%
Computerized tomographs	45	42	93.33	3	6.67	31	68.90	14	31.1
Gamma camera	88	74	84.00	14	15.99	61	69.32	27	30.68
Linear catalyzers	10	7	70.00	3	30.00	8	80.00	2	20.00
Cobalt bombs	80	61	76.20	19	23.80	54	67.50	26	32.5

Figure 5. Gradual shift in the utilization of a hypothetical antihypertensive drug.



if all the people receiving it are taken into account. This point will be pursued further in Section C of this chapter.

6. Abandonment

The rate of technological innovation since World War II has not been matched by a similar rate of abandonment of older technologies, the result being continuous growth in the available stock of health care technologies. Typically, new diagnostic technologies are justified by their higher accuracy or safety, but there are usually no significant impacts in the level of utilization of the procedures they would presumably replace. A good example is obstetric ultrasound. Although it was estimated that in 1980 29.3% of pregnant women in the United States had at least one prenatal ultrasound scanning, the utilization of X-rays remained high, with 13.1% of pregnant women receiving at least one dose (40).

The resistance to phasing out obsolete technologies can be understood as a natural defense of prior investments of time, effort, and finances by professionals and institutions when they incorporated and mastered the technologies. In many instances, the same agents who welcome an innovation also resist abandoning older technologies (41). Surprisingly, the abandonment of technologies that have been proven to be ineffective or even dangerous will be resisted for many years as a result of entrenched practice (40). Barnes (26) observes that it took up to 25 years for a number of ineffective surgeries to be discarded from medical practice. Gastric freezing for the treatment of duodenal ulcers is a more recent example of a procedure that experienced rapid diffusion followed by disillusionment on the part of medical professionals and abandonment after 25,000 treatments had been performed during six years (28).

Technologies have also been discarded for safety reasons, the classic example being the removal of dangerous drugs from the market (42, 43, 44). Social and policy pressures may play an increasing role in the future by forcing limitations on abortion or life-extending intensive care for terminal patients. In developing countries, technologies are often discarded simply because of operational inadequacy imposed by lack of infrastructure and maintenance (45).

As opposed to the many technologies that resist substitution, a considerable number of others are being forced out of the market by what can be called "artificial obsolescence." This strategy is used by many industries to enhance their sales record. In most cases, artificial obsolescence involves incremental innovations rather than radical inventions. The strategy consists of the substitution of critical parts and/or the addition of new features that have little real value for patients or doctors. The "new" models of diagnostic equipment, such as computerized electrocardiographs, and "new" drugs that use the same active substances as old ones illustrate this marketing approach. Owing to the frailty of their resources and infrastructure, the developing countries suffer most from this forced obsolescence, and HTA can be of value in generating appropriate policies to deal with this matter.

Although limited in depth and breadth, this overview of the mechanisms involved in the life-cycle of a health technology demonstrates that a myriad of determinants and variables must be considered by the HTA process in order to achieve a more rational utilization of technological resources. Toward the same end, the next section presents an introduction to the methodology of HTA.

C. MAIN CONCERNS OF HEALTH TECHNOLOGY ASSESSMENT

1. Evaluative dimensions

Using the paradigm presented by Coates (12) and Arnstein *et al.* (18) for general technology assessment, HTA should be primarily concerned with the social implications and higher-order impacts of health technologies. Such studies are needed because society has become increasingly concerned with the legal, ethical, economic, and environmental impacts of health technologies, in addition to higher-order effects on quality of life, psychological well-being, and individual self-care.

Besides social impact, however, three other elements must necessarily be included as part of any assessment of health technologies: effectiveness, safety, and cost. In fact, the evaluation of these elements should precede social considerations because negative attributes in these areas justify shelving a technological innovation before it is marketed. HTA must go beyond classical technology assessment and evaluate technical aspects such as effectiveness, safety, and cost because of the social structure and mystique surrounding health care delivery.

Consumer or industrial technologies can only survive in the market if they are competitive in terms of price and performance. In health care, however, consumers cannot exert their discretionary power; it is the physician or public health authority who determines what they pay for. Moreover, in many health care services the largest share of the cost is not borne by the individual patient but by third-party payers, such as health insurance companies and public subsidy programs. Consequently, health technologies are doubly protected from the rules imposed by a market economy and can survive even when they present an extremely low cost-effectiveness (46). Since premarketing evaluations of effectiveness can be severely limited in research design and data analysis (42), and a number of distortions can enter the picture after the technology is incorporated (see Section B.5, page 13), the knowledge that exists about the real benefits and costs of medical technologies is limited and fuzzy. A typical example of the prevailing ignorance about the effectiveness of medical technologies is the study conducted by the National Academy of Sciences (NAS) in 1969. It showed that of a total of 3,500 drugs introduced in the market between 1938 and 1962, almost 1,000 had been demonstrated to be ineffective, while another 200 were still awaiting evaluation (43).

2. Effectiveness

The distinctions between efficiency, efficacy, and effectiveness have always created some confusion when these concepts are applied to health technologies, because of the wide range of definitions adopted by different authors (21, 43, 45, 47-49). More recently, the following distinction between efficacy and effectiveness, as defined by the U.S. Office of Technology Assessment (OTA) (21), has been gaining acceptance:

Efficacy: The probability of benefit to individuals in a defined population from a medical technology applied for a given problem under *ideal* conditions of use.

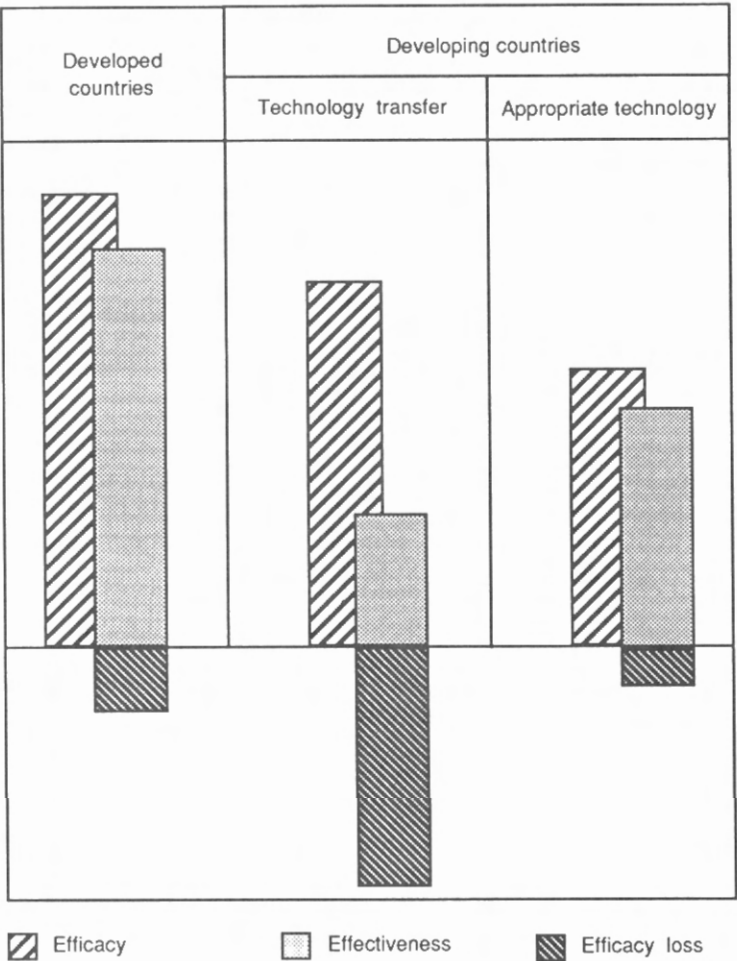
Effectiveness: The probability of benefit to individuals in a defined population from a medical technology applied for a given problem under *average* conditions of use.

The above definitions stress the importance of specifying explicitly the medical or health problem involved, the population affected, and the conditions of use of the technology. The specifications take into account the critical role of the health personnel in charge of the technology, the physical installations, and other elements related to infrastructure, such as maintenance and communication.

The concept of effectiveness, as distinct from efficacy, explains the difficulty of making accurate statements about the real health benefit of a technology, even when it has been in use for many years. First of all, during the innovation stage the technology is evaluated under ideal conditions of use, therefore yielding an estimate of its *efficacy* rather than effectiveness. The health personnel are usually of the highest caliber, support facilities are extensive, and the manufacturer/innovator is always willing to give advice and provide incentives. At this stage, the health problem toward which the new technology is directed is well defined, and patients are often selected from populations who are privileged with regard to nutrition, education, and socioeconomic conditions. Years later, in another setting, the technology is put into routine use among a different population by medical personnel who lack adequate training and motivation. Infrastructure conditions are frequently inferior to those in the original setting, and the indications for using the technology have been extended beyond original specifications (see Figure 5, p. 16). Obviously, if a piece of equipment is only operational three months per year because of maintenance or supply problems, its effectiveness, expressed as probability of benefit to a population, will be only 25% of what could be expected in a different setting.

When efficacy is measured objectively, it will usually be superior to effectiveness. In developed countries, the difference between the two under *average* conditions of use might be slight; however, in developing countries, it is usually extremely significant and a matter of great concern. Figure 6 illustrates this point and shows how the issue of appropriate technology can be addressed from the standpoint of

Figure 6. Effect of local conditions and populations on the effectiveness of a health technology.



efficacy versus effectiveness. Indeed, it is valid to wonder if the usual reaction of leading medical specialists against some endogenous solutions is not an exaggerated concern for efficacy when what really matters is the effectiveness in a given population.

In light of the distortions that can be produced during their life-cycle, as discussed in Section B, it is not surprising that most health technologies are used without a sound knowledge of their benefits. The needs and demands of the individual patient, the mission of the physician, and private enterprise's vested interests in health care all help to explain the imperfections of the market in

which health technologies flourish. Above all, the “technological imperative” and the prevalent belief in the omnipotence of physicians can force utilization even in circumstances where null effectiveness is a guarantee (50). Thus, the problems surrounding the evaluation of effectiveness are not going to be solved merely by improving research methodology and design, but require an in-depth analysis of the role of technology in health care, as well as education of health personnel and the courage to face difficult ethical issues surrounding life and death (24).

3. Safety

Most health technologies act directly upon the human body and mind. In either case, the risk of accidents leading to biological or psychological damage always exists and must be weighed, together with the original health problem involved (51). As with efficacy, the risk of a medical procedure depends on a number of factors, as mentioned in the definition adopted by OTA (21):

Risk: A measure of the probability of an adverse or untoward outcome and the severity of the resultant harm to health of individuals in a defined population and associated with the use of a medical technology applied for a given medical problem under specified conditions of use.

In addition to the variables included in the above definition of risk, it has been observed that patients’ attitudes toward risk are different from their doctors’ (52). When the risks are known, they can be taken into account and properly weighed by all interested parties (53).

Another part of the above definition states that **safety** is a “judgment of the acceptability of risk in a specified situation” (21). One obvious problem with judging the safety of a technology is that sometimes relatively high associated risks may not be detected during the innovation phase. Unfortunately, the literature is rich in such episodes. The tragedies of thalidomide, diethylstilbestrol, and the irradiation of the thymus of infants are a few reminders of the dangers inherent in any medical procedure (42). These accidents could have been avoided if more careful and thorough evaluations had preceded large-scale clinical utilization. Nowadays, most developed countries have strict regulations and surveillance systems to avoid similar mishaps (23, 25). The stringent regulations and surveillance systems sooner or later can certainly detect a technology that carries unacceptable risk, so that it can be removed from the market before it is widely disseminated.

Unfortunately, inherent unsafety is not the main cause of accidents and mishaps involving health technologies. Another important factor is **iatrogenesis**, which is the term for the production of health damage by doctors or other health personnel (51). A large number of casualties are the result of human mistakes. A technology that is otherwise safe or involves minimal risk can become lethal in the hands of individuals who lack adequate training, motivation, or infrastructure (54). Care

must be taken to identify the real cause of such accidents and to separate situations where risk is difficult to control, such as the excision of a brain tumor, from misdiagnosis or frequent therapeutic mistakes. These problems point to the great potential of HTA to bring together the many critical elements involved in the correct utilization of health technologies. Great improvement in the safety of health technologies can be gained by promptly identifying those areas where the human-machine interface is likely to be faulty, and instituting appropriate educational and regulatory measures.

4. Costs

The issue of the cost of health care is a good illustration of the different conceptual approaches required for HTA in developed and developing countries. In most developed countries health care costs have been rising faster than inflation or the GNP (55). This increase in costs is the result of many different factors (56), but technology plays a definite role—either through the introduction of new, more expensive, and more complex procedures, or by a change in the utilization pattern of standard technologies (32, 39). One medical technology, intensive care units, has by itself been responsible for increasing hospital costs by an average of 10%. Analysts generally cite a figure of 50% as technology's contribution to the overall increase in health care costs (39). Understandably, the rise in costs has brought increased awareness that health technology needs more evaluation and has pushed HTA into the forefront of discussion. Now, for the first time, austerity measures have caused some countries to face the unsettling prospect of health care rationing, with all its attendant difficult ethical decisions (24). However, this is precisely the situation developing countries have always experienced. Although traveling different paths, rich and poor countries now meet at the crossroads where health resources need to be closely scrutinized and rationally allocated. As will be discussed later, however, different conditions call for different strategies.

Evans (24) notes that health care costs cannot be considered in isolation from the expenses of other societal sectors, such as defense and the penal system, that consume a large share of the national budget but accrue questionable benefits.

There is no indication that total health care costs in developing countries, as a percentage of GNP, are rising as fast as they are in more developed ones. In fact, as of 1984 in Brazil, financial resources for health care had been falling since 1979 (57, 58). On the other hand, modern technologies continue to be imported and diffused (29, 57), implying that resources for primary care and classic technologies are shrinking at the same rate or even faster than the growth rate occurring in the tertiary sector. This observation indicates that decisions regarding use of a single technology have multiple implications for different levels of the health care system when financial resources are limited and fixed. For this reason, cost considerations are central to assessments of a health technology in developing countries, and they must take account of the benefits expected from other health technologies.

5. Social impacts

The effects of health technologies are not limited to curing or comforting; they go much further, touching many aspects of human life and relationships. For simplicity, all those impacts not related to effectiveness, safety, and cost are referred to as social impacts, which include secondary economic consequences for individuals and communities.

The pervasive impact of health technologies should not be surprising; they are like any other technology in this regard (15). Technology and the social value system are so inextricably linked that one reflects the other. Nevertheless, the fact that *health* technologies can directly affect people's social functioning gives this class of technologies an impact that is not equaled by any other technological sector in society. Family planning, organ transplantation, and renal dialysis are examples of medical or health technologies that can produce economic, demographic, ethical, psychological, and legal consequences.

Changes in the doctor-patient relationship, increases in specialization, and the institutionalization of care can be traced back to the early days of the stethoscope and the microscope (3). However, the new, "sensational" possibilities—for example, in vitro fertilization, prenatal diagnosis (and intervention), and life-extending technologies such as the artificial heart—have brought increased awareness of and concern for the far-reaching effects of health technology. In addition, simpler technologies are used more intensively than before, sometimes for screening and preventive purposes but also for purely bureaucratic reasons. According to Illich (50), this overutilization is counterproductive, since instead of health it generates higher rates of clinical iatrogenesis, as well as cultural and social damage.

Although consideration of social impact is basic to general technology assessment and can be easily identified as a priority for HTA, very few assessments in the health care field have had the comprehensiveness and depth of the models suggested by Coates (12) and Arnstein *et al.* (18). This limitation may be attributable to a lack of multidisciplinary expertise, inadequate methodology, limited resources, and an emphasis on aspects that are easier to quantify. Thus, in the field of health care it is important to distinguish between "evaluations" and "assessments." The former correspond to studies where only effectiveness and safety are considered, while the latter take into account all four basic elements discussed above. A paradigm for this class of health care studies is the recent assessment of heart transplantation supported by the U.S. Department of Health and Human Services (59).

For developing countries, assessment of the social impact of medical technologies is mandatory. It cannot be neglected without running the risk of incorporating technologies that, in addition to being of questionable effectiveness and representing inappropriate use of resources, will also have deleterious consequences for local culture, traditions, and the value system.

Chapter III

Problems and priorities for health technology assessment in developing countries

A. OVERVIEW

In light of the points presented above, it is clear that HTA needs to be part of the planning and policy-making processes of any health care system concerned with equity, efficiency, and quality. It is also clear that the conceptual and methodological evolution of HTA has been shaped by problems of immediate concern in developed nations. HTA would obviously be highly valuable in developing countries, but if it is applied without due consideration for the peculiarities and particular problems affecting those countries, its application would be doomed to failure and the historical mistakes of classic “technology transfers” would be repeated.

Although HTA is still a new field of endeavor in the developing world, some experiences with its application there have been documented. For example, a sizable amount of literature already exists for the Region of the Americas (8, 9, 29, 57, 60–64), where a small number of institutions are actively involved in research.¹

This chapter will seek to identify the problems peculiar to the countries and health systems of the developing world and to discuss the adaptations and developments that they would necessitate in the process and methodology of HTA. This analysis will conclude with a summary of the main priorities for HTA in developing countries.

B. RESOURCE LIMITATIONS

Throughout the developing world, financial and capital resources and other elements that are essential to assemble a well-structured and efficient health care system are in short supply. Inadequacies in the supply of human resources in-

¹Some institutions working on HTA: Centro Latinoamericano de Perinatología y Desarrollo Humano (Montevideo, Uruguay), Centro de Investigación en Salud Pública (Mexico), Escuela de Salud Pública (Mexico), Universidade Federal de Rio de Janeiro (Brazil), Universidade de Brasília (Brazil), Universidade de Campinas (Brazil).

clude not only maldistribution of doctors and a shortage of nurses and auxiliary personnel, but also insufficient numbers of people who are capable of producing technological innovation, assuming an administrative role, or maintaining equipment. Although the number of hospital beds in some urban areas may be adequate, other areas suffer from a lack of health facilities, especially at the primary care level where the cost of care is low and access to a facility could produce considerable gains in health.

In some countries, other sectors that contribute to public well-being are also ill-equipped, resulting in an increased burden for health care services. Significant proportions of the population do not have adequate housing or food and lack piped water, sewage disposal, and electricity. Health gains that could be obtained by improvements in these areas are missed, and the burden of illness related to these deficits is transferred to the curative sector. Essential infrastructure services such as transportation, communications, banking, and public administration are inefficient and bureaucratic, also serving to frustrate the efforts of health administrators.

The economic crisis in which many developing countries find themselves makes it doubtful that any dramatic improvements in the above situation will occur soon. If changes are to be realized in the area of health care, imagination and the wise use of whatever resources are available will be required. In this regard, HTA can be an extremely useful tool if it is appropriately adapted to each case.

The problem that HTA must address is not merely whether to say yes or no to a new and complex technology in a climate of growing concerns about costs, when the total financial resources for health care may actually be shrinking. The problem is clearly one of *selecting* the best technologies from a number of options on the basis of effectiveness and cost, while giving due consideration to their safety, social costs, and any key constraints imposed by the environment. Frequently, even when financial resources do exist, the use of some technologies is impeded because supplies and parts cannot be imported or human expertise is not available. For countries with per capita health expenditures as low as \$10 per year, it is obvious that selection of the simplest and least expensive technologies is most appropriate, and that costly options must be rejected. In developing countries, the process of assessing and choosing between health technologies, including older and classic ones, will require the development of the necessary methodologies within each country.

C. MORBIDITY PATTERNS

A significant fraction of the population in developing countries is affected by health problems that have been eliminated or reduced to a minimum in most developed countries (6). Infectious and parasitic diseases are the main representatives of this class of illnesses, which also includes malnutrition and perinatal problems. Thus, in these countries HTA needs to evaluate technologies that pertain to conditions such as malaria, schistosomiasis, and malnutrition, which are not

usually the object of assessments in the developed world. In addition, assessments will need to be more problem-oriented, instead of being the more frequently performed technology-oriented studies (14, 21, 39, 43, 55).

The situation becomes even more complex in some countries because of the epidemiologic transition that accompanies growth of the population in older age groups. The increase in incidence of chronic and degenerative diseases prompts health services to incorporate the same "halfway technologies" (65) that are promoted in the developed countries—that is, technologies to treat or postpone death from diseases that cannot presently be prevented or cured. Cardiovascular disease, cancer, and diabetes have become major causes of death in some areas, and this situation becomes an excuse for the continued growth in tertiary care services, in spite of the fact that a greater number of potential years of life continues to be lost to infectious diseases (66).

Where resources are limited, HTA can be used to construct models of regional resource allocation that represent the dynamic adaptations required of health services faced with rapid demographic and epidemiologic changes. Some methodologies useful for this purpose are presented in Chapter IV. Initially, such an exercise may indicate the need for a redistribution of resources (67), given the inequable allocation of technologies (68) that developed as a result of the political power of population groups with higher standards of living. These groups enjoy longer life expectancy and therefore demand the high-cost procedures associated with the treatment of cardiovascular and neoplastic diseases (40).

D. CULTURAL DIVERSITY

The pathway of economic and social development has led to great socioeconomic diversity among countries in the developing world, even within the same region. For example, in Latin America there are many different ethnic and indigenous groups, as well as rich local cultures that produce markedly different life-styles. Since culture influences the value system and it in turn affects and is affected by technology (21), two types of interaction problems can be distinguished. The first is the way culture might inhibit technological effectiveness; the second is the risk that certain kinds of technological innovation might be harmful to some cultures.

"Technology transfer," whereby *products* (hardware or services), as opposed to knowledge, are imported from developed countries into the Third World, represents vividly the permeation of the values of the former into the culture of the latter. Therefore, the importation of foreign (exogenous) innovation can create a clash of values of varying levels of intensity and pervasiveness.

Culture affects the perception of health and disease and the reliance of a population group on traditional medicine. A health technology that is well accepted by one population group may be rejected by another. Nonacceptance of medical technologies such as devices and diagnostic procedures is not as apparent since the patient plays a passive role. However, with the "nonmedical" technologies such as education and coordinative systems, which require some active participa-

tion, culture is a factor determining success or failure. Given the high effectiveness of many nonmedical health technologies, it is important that developing countries develop HTA methodologies capable of detecting and evaluating *a priori* sociocultural conditions that can govern acceptance or rejection of technological innovations. This stage is essential, since it can allow the fate of a technology to be judged without complicated in-depth analysis.

The second important concern relating to the interdependence between technology and culture is prompted by a situation where acceptance and compliance are not a problem, but where the values incorporated and reflected by the technology may affect the local values, leading to cultural imbalance and damage. Dealing with this problem is very difficult because it requires consensus within an ethical framework; but, depending on individual perspective, technologies such as contraceptives, abortion, blood transfusion, screening, plastic surgery, or hospices present risks of social damage. An additional difficulty is the establishment of what Lee and Bereano (14) refer to as a "paradigm of social choice" for minority groups. The problem here is to decide if the cultural environment of these groups should remain intact or if they should be integrated into the predominant society.

Finally, cultural diversity is not only found in isolated rural communities but, with increasing frequency, throughout the population strata of large urban centers. The absence of well-established guidelines and a universal social policy for dealing with cultural minorities should not prevent HTA from carefully evaluating the potential negative social impacts resulting from the use of technological innovations in health care.

"Appropriate technology" is usually regarded as a solution to the health problems of developing countries that offers lower cost and better operating reliability. This concept can be enlarged to take into account cultural diversity by defining a technology as appropriate when it does not contradict the values of the community that is going to use it. In principle, this perfect compatibility is only achievable if the technology is a natural product of the community, that is, an *endogenous solution* to the local problem (69, 70).

For many "hardware" technologies requiring some level of technical expertise, it may be unrealistic to expect the production of reasonably effective endogenous solutions. However, as stated previously, acceptance problems are primarily encountered with "software" technologies for use in such fields as organization, administration, and education. In these areas, there is no reason why local consumers should not be involved in the process of planning and decision making to ensure that the technology reflects local values, attitudes, and beliefs. This kind of participation has direct political implications.

E. POLITICAL SYSTEM

HTA evolved in democratic societies where political forces continuously debate and are held in equilibrium in an environment of open discussion of ideas and

public policies; this situation requires the neutrality of a formal approach to the problem of technology management. Democracies in the developing world have historically been more fragile, and, even in countries where freedom of expression exists, it is not common to find a tradition of grassroots movements and public participation in the formulation of policies and decisions regarding health care organization and delivery. Under these conditions, before HTA is performed its potential impact should be evaluated in light of the nature of the prevailing political system. The basic question is whether the assessment will exert any practical influence upon the application of technological solutions to pertinent health problems. Some assessments are done for local purposes, for example, when a university hospital is planning to buy equipment but is not sure of the overall benefit. In most cases, however, HTA in developing countries will be directed at major issues and its results may recommend policy changes or regulatory action by governments. If HTA has no possibility of influencing such decisions, it is a useless exercise.

In any society, democratic or totalitarian, decision making and the formulation of public policy are influenced by politics and power. However, in many circumstances political interest and the indiscriminate use of power can be held in check by technical evidence supporting a preferred line of action. To illustrate this point, a public health care system of a developed country would be in a very difficult position if it refused to reimburse for a procedure that was thoroughly tested and proven to be more cost-effective than alternatives. It would therefore seem justifiable to do assessments in some developing countries for the purpose of challenging health policies and health resource allocations that perpetuate the existing distortions and inefficiencies in the health systems (6, 67). Nevertheless, in countries where power is centralized, obtaining information and data essential for accurate assessments can be difficult. Other problems associated with the lack of data are discussed in this chapter (Section G).

F. STRUCTURE OF HEALTH CARE SYSTEMS

Most health technologies are delivered through a health care system that includes private and public institutions. The structure of a health system needs to be considered in any HTA because it directly influences the way health technologies are incorporated and utilized. Furthermore, policies and strategies for control and regulation of technological innovation should be formulated in accordance with the particular system structure in each case.

An example of the influence the health system structure can have on HTA is the situation in Latin America. In that region, most health care systems are operated by the government and social security institutions, either directly or through agreements and the purchase of services from the private sector (67). This aspect of the organization of health systems pushes HTA toward studies that are broad in scope and have far-reaching implications in the country or region. Features of health care system structure that have a direct bearing on technology utilization

are access and coverage, costs, forms of payment, human resources, and organization of services.

One aspect of health care delivery that concerns health administrators is the *quality* of services. Donabedian defines quality as "the improvement in health levels that can be attributed to health care" (71). The same author proposed that quality is determined by a set of three basic variables: structure, process, and outcome. Frenk and Peña (72) reviewed the subject of quality of care in the context of Latin American health problems and highlighted its relationship to technology. In terms of the Donabedian model (71) it is clear that health technology is an essential element of both *structure* and *process*, and can be critical in determining *outcome*. In developing countries, any discussion of quality of care must take into account the present health levels of the population.

In developed countries the care of many diseases and health conditions has reached the "near-saturation" stage, in which the levels of such health problems as perinatal mortality, incidence of infectious diseases, early mortality in diabetes, and infant mortality are very low. In most developing countries, the outcomes of the majority of health problems are significantly inferior to those in developed countries, when corrected for age. For this reason, technology incorporation and utilization to improve quality of care must concentrate on affecting outcome until the "near-saturation" stage is achieved, that is, approximately the same health levels as those in developed countries. The importance of outcome must be emphasized because the health systems in places such as Latin America (67) suffer from disproportionate provision of tertiary care and an oversupply of capital technology in relation to the real demand (68). The concern for quality of care has often justified the purchase of complex and costly medical equipment on the assumption that it is essential for improving quality, either as part of the structure or the process of health care delivery. This observation is particularly true regarding diagnostic equipment, whose impact on *outcome* is never properly evaluated.

The issue of quality of care must be approached from a regional perspective (72), and adequate methodologies for this purpose need to be added to the armamentarium of HTA.

G. INFORMATION AND DATA AVAILABILITY

In general, the developing world suffers severe limitations in the collection, analysis, and dissemination of information that is essential for HTA activities. The importance of this limitation warrants separate discussion from that of the general resources limitations outlined in Section B above.

HTA is basically an information science. Even the first step—identifying the problem to assess—requires baseline information and data, and much broader information is needed if the potential of HTA is going to be fully realized.

Data and information are severely lacking in the areas of surveillance and regulation of health technologies. Most developed countries have systems to gather

such data in regard to vaccines, drugs, devices, and a number of medical procedures (23, 25, 42). Surveillance systems are crucial for controlling the risks inherent in health technologies and also have an impact on manufacturing practices and standardization. In Latin America, for example, the newspapers frequently report the occurrence of serious accidents or hazards involving medical procedures, but the reports seldom cause health authorities to take regulatory action, and hence the problem can recur. In many cases, the “brain” exists (in the form of some constituted central authority), but it lacks “receptors and nerves” (an information system) to sense the real situation, and “muscle” to take appropriate, timely measures.

The observations about the difficult integration of “software” technologies (such as those dealing with coordination and administration) in developing countries (Section D) are germane to the problem of information management. Initiatives to collect data at the hospital, health care system, and governmental levels have been poorly implemented; data analysis is often neglected, and data retrieval for potential users is rare. Consequently, these initiatives often lead to frustration and produce resistance against future data collection efforts.

In a scenario where the amount and quality of data are limited, and health and administrative personnel are prejudiced against initiatives to change this situation, HTA requires special methodologies (Chapter IV) and a realistic assessment of the depth and accuracy possible in the studies that can be performed. At present, when faced with difficulties in data availability, the best policy is for HTA to proceed gradually—making use of the existing information, performing appropriate studies, and then using the results as an argument for the need for better and more specific data. The other alternative, which is to wait until the perfect data are obtained, is not acceptable, because it would delay HTA initiatives; instead, as stated in Section B, resource limitations necessitate new methodologies that will enable HTA to proceed. Information is an important resource and as such it needs to be used in the best way possible within the existing limitations.

H. TECHNOLOGICAL CAPACITY

Countries like Brazil, Argentina, and Mexico, which represent sizable markets and are at an intermediate stage of development, have produced some of their own health technologies. These countries can also produce innovations in other industrial sectors, such as capital goods, that require a level of technological sophistication similar to that required by health technologies. In these countries, HTA can address the formulation of development policies for local technological innovation and production in the area of health care. Such studies would also consider the problems created by international programs of technology transfer and equipment donation.

In evaluating the feasibility of local technological development, HTA must consider the availability of expertise and knowledge, as it must when faced with other

questions. In particular, a detailed examination is needed of all the know-how involved in the industrial production of the technology (product or process), as well as identification of the bottlenecks that would exist in its local development. This analysis should take account of not only installed capacity, raw materials, and production processes, but also the critical role of human resources at all levels of research, development, design, production, commercialization, and operation.

I. SOCIAL TECHNOLOGIES

This category includes the previously mentioned "software" technologies, such as information management, administration, and organization, and the important subgroup of technologies with universal social impact, such as regulation, legislation, or the health surveillance systems mentioned in Section C. Social technologies are critical to the achievement of improved levels of health because they affect not only the delivery of health care but also many other important determinants of health, such as socioeconomic conditions, jobs, transportation, personal safety, communications, and so on.

Although social technologies differ from "hardware" technologies in being more complex, pervasive, and politically sensitive, they can be evaluated by classical HTA within the same framework of innovation, diffusion, and utilization. Such studies are likely to show that social technologies are inappropriate to local conditions, are not very effective, and that in many cases the benefits do not justify the costs. Unfortunately, failures of social technologies are not as conspicuous as, for example, the "cemeteries" of broken equipment found in developing countries. Perhaps "maintenance centers" for these technologies are a possibility.

To cope with the added dimension represented by social technologies, HTA needs to use innovative methodologies that hitherto have not been tested or even proposed. If the objective of HTA is to contribute to the improvement of health, it must be applied to all kinds of technology that influence health. Social technologies deserve attention because of the high degree of leverage they have to produce change.

J. CONCLUDING REMARKS

The above discussion makes it clear that HTA activities in developing countries face requirements and challenges that are totally distinct from those in developed countries. The points raised in the previous sections are summarized below as priority activities to enable effective utilization of HTA in the developing world:

- 1) Promote the development of local multidisciplinary expertise in such areas as health and behavioral sciences, economy, sociology, anthropology, law, biomedical engineering, statistics, and others.
- 2) Promote more cooperation and exchange of experiences among developing countries, as well as cooperation with experienced entities in developed countries.

- 3) Stimulate more efficient and realistic systems to collect, analyze, and disseminate health information, and search for innovative methodologies to deal with the shortage of data.
- 4) Develop a greater sensitivity to the role culture plays in determining the effectiveness of health technologies. Also develop appropriate methodologies for evaluating the social impact of health technologies.
- 5) Emphasize community involvement in the evaluation process and definition of the criteria of appropriateness.
- 6) Give priority to studies that are broad in scope and have a potential impact on the health conditions of large population groups.
- 7) Focus on multiple technology alternatives and problem areas rather than single technologies.
- 8) Develop appropriate methodologies to assess “software” technologies and, more particularly, social technologies.
- 9) Develop strategies to guarantee the continuity of evaluation programs and to reduce their sensitivity to structural changes.

The above priorities can be complemented by two basic laws:

First law All new health technologies should be the object of assessment.

Second law A health technology should be seen as *new* until it is completely disseminated, that is, it provides coverage for all those who might need it.

Taken together, these two laws represent a “closed-loop” system of inquiry, in which the appropriateness and allocation of a health technology are continuously questioned and alternatives are considered. The second law implies that classic technologies, such as X-rays or simple surgery, should be considered “new” in areas where people still have limited access to them. Some inherent questions follow: Are these technologies appropriate for a region? How are they being allocated? Is there a limitation of human and other resources? What are the technological alternatives? These and other pertinent questions should be asked repeatedly until the technology becomes accessible and until satisfactory answers regarding cost-effectiveness and safety are produced by the assessment.

Chapter IV

Methodologies for health technology assessment

A. METHODOLOGICAL OPTIONS

This review of the methodologies that can be of use in health technology assessment is necessarily limited and incomplete. As mentioned in Chapter II, most methodologies employed in HTA have been borrowed from other areas of research such as epidemiology, clinical medicine, economy, statistics, and systems analysis. Detailed descriptions of these methods and their applications are given in standard textbooks and it is not relevant to repeat the same information here. In addition, out of the large number of techniques and their variants that are found in the literature (11, 18, 21, 30, 43, 48, 56, 60, 73), it is possible to discuss only a few in the space available.

These limitations aside, the objective is to discuss methodologies for HTA in the context of developing countries, with emphasis on integrative tools that can allow more than one aspect of technology utilization to be considered. HTA should encompass the four basic questions of effectiveness, safety, cost, and social impact. Clearly, each one of these four areas is in itself multidimensional, presenting a major difficulty for objective evaluation. Some of the methods described can be useful for integrating all four areas; other techniques are presented that are specific for a single aspect, such as effectiveness or cost. General statistical methods are not included here. Another relevant group of methods includes those that can be applied to some or all of these dimensions, as needed, such as cost-effectiveness analysis, decision theory, and modeling.

This review is intended for any professional who has a sound knowledge of basic evaluative techniques, but who would like to be able to apply that knowledge in the area of HTA, with particular reference to developing countries. Since some of these methods may be unfamiliar to some readers, a brief description of their principles is given; however, this overview should not be a substitute for thorough study of more complete instruction material.

B. EXPERT OPINION

1. Overview

The absence of formal assessments does not stop the necessary decision-making and policy formulation process that regulates the incorporation and utilization of

health technologies. Frequently, this process is based on the knowledge, opinions, and attitudes of an individual, or on a sequence of decisions made by persons at different levels in a hierarchy. A typical example is a situation in which a physician wants to purchase a new piece of equipment for his hospital practice, but the resources must be provided by the district health authority. Unless previous comprehensive studies are available, this decision-making process will be flawed because individuals seldom have all the pertinent information. Due to the multiplicity of questions and variables involved, assessment of health technology utilization and impact is not a field that lends itself to the development of super-specialists.

This serious limitation in the process of decision making, resource allocation, and policy formulation has been recognized. In many cases, depending on the balance between political power and private interests, review by an individual has been replaced by review in group meetings. Such meetings can involve a cross section of professionals, organizations, and objectives. In general, they are presided over by a chairman/mediator and include multiple, spontaneous contributions from participants. Even when free participation is allowed, however, there are many possibilities for bias and the so-called "bandwagon effect" due to such factors as the status, leadership ability, charisma, or salesmanship of a participant. In addition, standards governing the selection of participants can be bureaucratic, leading to a meeting of people from the same office or representing a narrow area of expertise. Even so, the group meeting is one approach used to increase the knowledge base and attenuate bias in the decision-making process.

The many limitations described above for conventional meetings, whatever their degree of formality, have led to the development of new communication forums aimed at increasing objectivity and structuring the way knowledge is contributed. *The three procedures described below—the Delphi method, analytic hierarchy process, and consensus conference—do not overlap in relation to requirements and objectives, but do achieve the same result, namely, that knowledge and information are obtained from groups of individuals with backgrounds and expertise related to the subject under investigation. For this purpose, the word "expert" should be used in a wider context and not restricted to the meaning of "leading professional specialist."* Studies of health technologies in rural settings will necessarily require the opinion of the local doctor, primary health care worker, pharmacist, or priest. Other studies will require representatives of consumer interests.

As mentioned previously, data collection, health information, and other resources to perform extensive studies are limited in developing countries. The judgment of experts, based on their knowledge and accumulated experiences, is therefore an important and rich resource that should be harnessed for the benefit of the community and the improvement of the present decision-making process.

In countries with scant experience with a new technology and few data, expert opinion may serve as a substitute for the whole HTA process and may result in a recommendation to incorporate or reject the technology. However, as hard data about some aspects of the problem become available, experts can concentrate on

specific areas of uncertainty, such as costs or social impact, thus leading to sounder assessments (74).

Expert opinion can never be seen as a substitute for well-designed experiments, data collection, and interpretation. However, the dimension and complexity of some problems make other approaches infeasible. One representative example of this type of problem is the formulation of overall health policies for a country, which will require the integration and participation of multiple public and private sectors.

Utilization of expert opinion is more an art than a science and requires carefully selected participants and communication methods, a skilled mediator, and thoughtful statement of conclusions.

2. The Delphi method

The Delphi method was developed for use in defense research and was later applied to many other facets of society, including health care (75–78).

In a conventional Delphi procedure, a questionnaire is presented or sent to pre-selected participants. Their answers are pooled and then turned back to the group, with the anonymity of the respondents preserved. A new questionnaire is then presented and the process is repeated until a point of consensus is established or saturation is achieved (that is, the increase in consensus becomes marginal in subsequent rounds). This basic formula can vary in either the number and form of interactions or the criteria adopted for analysis and interpretation of the responses. Variations of the latter type are self-rating by the experts and the use of subgroups to improve estimations (75).

A second, futuristic form of Delphi involves the use of computer teleconferencing (Figure 7, right-hand column), which allows the real-time interaction of a large number of experts without requiring travel.

One common criticism of the Delphi method is that it is subjective and therefore unscientific. In this regard, Mitroff and Turoff (79) reviewed the methodological foundations of the technique and concluded that it can be identified with a number of inquiry systems, but is more often Lockean in nature. In this sense, Delphi reviews are not methodologically distinct from most empirical studies performed in the health sciences.

An interesting application of the Delphi technique to health planning was the assessment of community health needs performed by Schoeman and Mahajan (76). In an area of central Texas (USA), in which the population is half-urban and half-rural, perceived needs were identified by a preliminary questionnaire sent to 103 panelists (Table 2).

After three rounds of evaluation questionnaires, the health needs for the whole area were ranked as indicated in the right-hand column in Table 2. The rankings were based on the median score of the responses after the third round, normal-

Figure 7. Characteristics of different communication techniques for organization of knowledge through expert opinion. Modified from Linstone and Turoff (75).

	GROUP COMMUNICATION TECHNIQUES				
CHARACTERISTICS	CONFERENCE TELEPHONE CALL	COMMITTEE MEETING	FORMAL CONFERENCE/ SEMINAR	CONVENTIONAL DELPHI	REAL TIME DELPHI
EFFECTIVE GROUP SIZE	SMALL	SMALL TO MEDIUM	SMALL TO LARGE	SMALL TO LARGE	SMALL TO LARGE
OCCURRENCE OF INDIVIDUAL INTERACTION	COINCIDENT WITH GROUP	COINCIDENT WITH GROUP	COINCIDENT WITH GROUP	RANDOM	RANDOM
LENGTH OF INTERACTION	SHORT	MEDIUM TO LONG	LONG	SHORT TO MEDIUM	SHORT
NUMBER OF INTERACTIONS	MULTIPLE, AS REQUIRED BY GROUP	MULTIPLE, NECESSARY TIME DELAYS BETWEEN	SINGLE	MULTIPLE, NECESSARY TIME DELAYS BETWEEN	MULTIPLE, AS REQUIRED BY INDIVIDUAL
NORMAL MODE RANGE	EQUALITY TO CHAIRMAN CONTROL (FLEXIBLE)	EQUALITY TO CHAIRMAN CONTROL (FLEXIBLE)	PRESENTATION (DIRECT)	EQUALITY TO MONITOR CONTROL (STRUCTURED)	EQUALITY TO MONITOR CONTROL, OR GROUP CONTROL AND NO MONITOR (STRUCTURED)
PRINCIPAL COST	COMMUNICATION	TRAVEL, INDIVIDUAL TIME	TRAVEL, INDIVIDUAL TIME, FEES	MONITOR TIME, CLERICAL, SECRETARIAL	COMMUNICATION COMPUTER USAGE
OTHER CHARACTERISTICS	TIME-URGENT CONSIDERATION EQUAL FLOW OF INFORMATION TO AND FROM ALL CAN MAXIMIZE PSYCHOLOGICAL EFFECTS	FORCED DELAYS EQUAL FLOW OF INFORMATION TO AND FROM ALL CAN MAXIMIZE PSYCHOLOGICAL EFFECTS	EFFICIENT FLOW OF INFORMATION FROM FEW TO MANY	FORCED DELAYS EQUAL FLOW OF INFORMATION TO AND FROM ALL CAN MINIMIZE PSYCHOLOGICAL EFFECTS CAN MINIMIZE TIME DEMANDED OF RESPONDENTS OR CONFEREES	TIME-URGENT CONSIDERATION EQUAL FLOW OF INFORMATION TO AND FROM ALL CAN MINIMIZE PSYCHOLOGICAL EFFECTS CAN MINIMIZE TIME DEMANDED OF RESPONDENTS OR CONFEREES

ized so that the sum of all scores was 100. A chi-square test comparing the expected versus the real scores for each problem refuted the hypothesis that the panelists could not distinguish the importance of the problems at a 0.1 level of significance.

Further analysis of the scores indicated that rural and urban panelists perceived health needs differently (Table 3). In addition, when the panelists were separated

Table 2. Health needs of a population in central Texas (USA), as perceived by 103 panelists.

Code	Problem	Rank
1	Underutilized and duplicated facilities and equipment	7
2	Absence of effective preventive medical and dental health programs	3
3	Lack of physicians (either shortage or poor geographic distribution)	2
4	Poor coordination of health-related social services (mental health, welfare, social security, public health, and education)	5
5	Lack of knowledge on the part of the public of available health services and/or how to gain access to these services	6
6	Inaccessibility to health services due to location of facilities or lack of transportation	8
7	High cost of health care	1
8	Lack of personal concern and understanding between the patients and those who provide health services	10
9	Inadequate emergency care	4
10	Lack of health care personnel other than physicians	9

Source: Shoeman and Mahajan (68).

Table 3. Health needs as perceived by rural and urban panelists.

Problem code	Rank order given by	
	Rural panelists	Urban panelists
1	9	3
2	6	2
3	2	4
4	3	6
5	7	7
6	8	8
7	1	1
8	10	10
9	4	5
10	5	9

Source: Shoeman and Mahajan (76).

into health providers and nonproviders, important differences in their perception of health needs were detected (Table 4).

As this study indicates, the Delphi approach can be a flexible tool for collecting preliminary information and formulating hypotheses that can then be investigated by more detailed experimental designs.

3. Analytic hierarchy process

As described by Ramanujan and Saaty (80) and by Saaty (81), the analytic hierarchy process is an attractive technique for structuring the process of choosing

Table 4. Health needs as perceived by health care providers and nonproviders.

Problem code	Rank order given by	
	Provider	Nonprovider
1	3	10
2	7	3
3	2	2
4	4	5
5	5	9
6	8	8
7	1	1
8	10	7
9	6	4
10	9	6

Source: Shoeman and Mahajan (76).

among a number of alternatives. Instead of the assignment of ranks or grades, the method works by multiple comparisons between paired alternatives.

Given a problem with n alternatives, paired comparison leads to $(n - 1) \times (n/2)$ decisions. It is reckoned that individuals cannot compare more than 7 ± 2 elements simultaneously, so $n = 9$ alternatives is the generally accepted maximum at each level of the hierarchy (81). Although this limitation can restrict the usefulness of the analytic hierarchy process in some cases, the technique can still be applied to a wide range of problems in HTA. One of the main advantages of this technique is that it allows an assessment of the consistency of the expert judgments, making possible some degree of control on the quality of the estimations.

The hierarchical structure of the technique takes into account the interdependence among different elements of a health program or technology. When every element of one level is related to every property in the next higher level, the hierarchy is said to be "complete." In most cases, however, hierarchies are incomplete.

The hypothetical small-scale example described below illustrates the use of the analytic hierarchy method in health care.

Assume a health service is to receive some additional funds to purchase new technologies or extend coverage of technologies already in use. Since the demand for additional services is greater than the available resources, it is necessary to establish priorities for the use of these funds. After some preliminary analysis of critical areas, the following alternatives are selected:

T1—One X-ray machine;

T2—A surgery theater for emergency care;

T3—An education campaign about oral rehydration (target population: 200,000);

T4—A strengthened measles vaccination effort (move from 80% to 90% coverage);

T5—Free distribution of contraceptives (5,000 families/month);

T6—Three obstetrical ultrasonographic scanners.

The following criteria are to guide the selection process:

H—health impact;

C—costs;

R—availability of human resources.

Other criteria would certainly be considered in a real-life situation, but these three properties will suffice to illustrate the method.

Figure 8. Hierarchical representation of the problem of establishing priorities for technological choice among a number of alternatives, using the analytic hierarchy process.

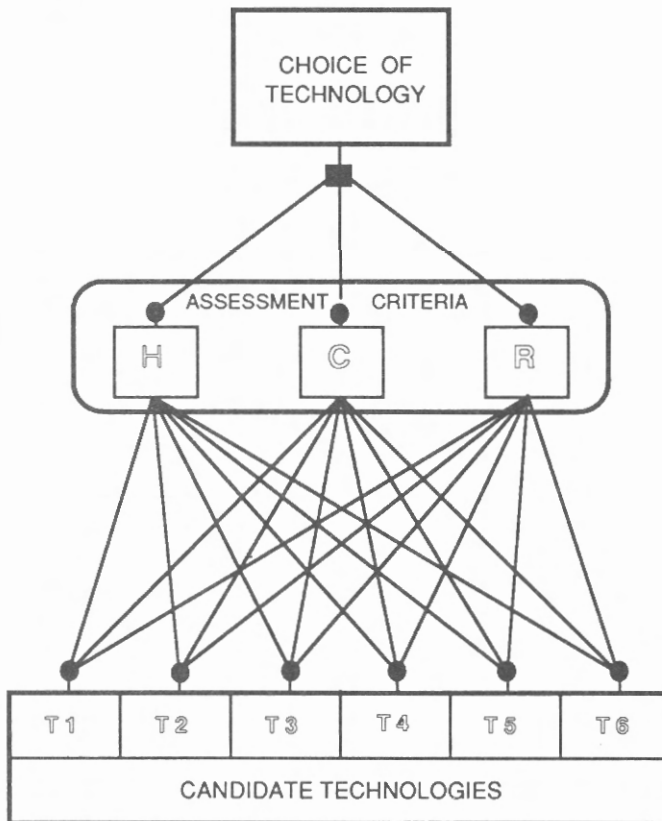


Figure 8 represents the relationship of the individual technologies to the assessment criteria described above. In this case, the hierarchy is complete because each criterion applies to all the candidate technologies.

The process involves establishing priorities at each level and projecting the results of this ranking onto the level immediately below. In the example shown in Figure 8, paired comparisons are first done between the assessment criteria H, C, and R, in an attempt to determine their relative importance for selecting between the alternatives T1 through T6. For this purpose Saaty (81) developed a "scale of importance" (see Table 5).

Therefore, if an expert strongly believes that, for the conditions considered, H has well-established dominance over C, then he or she would represent this assertion by placing coefficient $a_{hc} = 9$ in the comparison matrix:

	H	C	R
H :		9	
C :			
R :			

Table 5. Scale of importance of criteria used in analytic hierarchy process.

Importance	Definition	Explanation
1	Equal importance	Two attributes contribute identically to the objective
3	Weak dominance	Experience or judgment slightly favors one attribute over another
5	Strong dominance	Experience or judgment strongly favors one attribute over another
7	Demonstrated dominance	An attribute's dominance is demonstrated in practice
9	Absolute dominance	The evidence favoring one attribute over another is definitively affirmed
2,4,6,8	Intermediate values	Where further subdivision or compromise is needed

Sources: Ramanujan and Saaty (80), and Saaty (81).

In the inverse paired comparison (C:H) the coefficient is considered to be $1/9$; the complete matrix might be as illustrated below:

	H	C	R
H	1	9	5
C	$1/9$	1	$1/3$
R	$1/5$	3	1

Each criterion will have a normalized priority weight calculated by dividing the sum of its row by the sum of all coefficients:

Assessment criteria	Priority weight
H	0.726
C	0.070
R	0.203

In addition, the consistency of judgments is assessed by a “consistency ratio” (CR) given by:

$$CR = \frac{\lambda_{\max} - n}{(n - 1) CI \text{ random}}$$

where n is the dimension of the matrix and λ_{\max} is the largest eigenvalue of the matrix (80, 81); CI random is the average value of $(\lambda_{\max} - n) / (n - 1)$ for highly inconsistent matrices made up of random coefficients. Values of $CR < 0.10$ are acceptable and indicative of consistent judgments. Higher values suggest that judgments should be revised.

For the above matrix of assessment criteria, $\lambda_{\max} = 3.05$ and $CR = 0.043$, since, for matrices with $n = 3$, $CI \text{ random} = 0.58$ (81). This CR value indicates that the pairwise comparisons are highly consistent.

Next, moving to the lower level, paired comparisons of the technological alternatives T1–T6 are done with regard to each of the assessment criteria. The priority weights are calculated as they were for each assessment criterion, and the resulting matrices might look like the following:

Health Impact (H) (W = 0.726)

	T1	T2	T3	T4	T5	T6	Priority weight
T1	1	$\frac{1}{3}$	$\frac{1}{7}$	$\frac{1}{5}$	$\frac{1}{5}$	3	0.062
T2	3	1	$\frac{1}{3}$	$\frac{1}{5}$	$\frac{1}{3}$	5	0.125
T3	7	3	1	2	5	7	0.317
T4	5	5	$\frac{1}{2}$	1	3	8	0.285
T5	5	3	$\frac{1}{5}$	$\frac{1}{3}$	1	5	0.184
T6	$\frac{1}{3}$	$\frac{1}{5}$	$\frac{1}{7}$	$\frac{1}{8}$	$\frac{1}{5}$	1	0.025

Costs (C) (W = 0.070)

	T1	T2	T3	T4	T5	T6	Priority weight
T1	1	3	5	7	1	$\frac{1}{5}$	0.265
T2	$\frac{1}{3}$	1	3	2	$\frac{1}{3}$	$\frac{1}{3}$	0.108
T3	$\frac{1}{5}$	$\frac{1}{3}$	1	$\frac{1}{5}$	$\frac{1}{3}$	1	0.047
T4	$\frac{1}{7}$	$\frac{1}{2}$	5	1	$\frac{1}{7}$	$\frac{1}{3}$	0.110
T5	1	3	3	7	1	$\frac{1}{2}$	0.239
T6	5	3	1	3	2	1	0.231

Human Resources (R) (W = 0.203)

	T1	T2	T3	T4	T5	T6	Priority weight
T1	1	5	9	7	7	3	0.392
T2	$\frac{1}{5}$	1	5	5	3	1	0.175
T3	$\frac{1}{9}$	$\frac{1}{5}$	1	$\frac{1}{3}$	3	$\frac{1}{7}$	0.055
T4	$\frac{1}{9}$	$\frac{1}{5}$	3	1	$\frac{1}{5}$	$\frac{1}{7}$	0.054
T5	$\frac{1}{7}$	$\frac{1}{3}$	$\frac{1}{3}$	5	1	$\frac{1}{5}$	0.077
T6	$\frac{1}{3}$	1	7	7	5	1	0.246

The overall priority weights are determined by adding the products of the weight of the assessment criterion times the weight calculated for that criterion for the individual technology:

Technology alternative	Overall priority
T1	0.142
T2	0.132
T3	0.244
T4	0.225
T5	0.165
T6	0.084

According to these results, programs T3, T4, and T5 would be favored; more refined planning could then be pursued. As with the Delphi method, the estimations of the coefficient based on the "scale of importance" should represent a consensus or average of the responses of several participants.

Although only two hierarchical levels were included in the hypothetical situation described here, real problems can be represented by many more levels. It is also possible to adopt a multilevel structure that circumvents the limitation of $n \leq 9$ at each level (80).

4. Consensus conference

In both the analytic hierarchy process and Delphi method, information is obtained from groups of experts, either by means of comparisons of paired alternatives or questionnaires, and the result is some form of ordinal scaling of elements. But this attractive feature of these methods is also their limitation. In many cases the existing knowledge about a subject cannot be organized into discrete estimations or paired comparisons.

The Technical Consensus Development Conferences, organized by the U.S. National Institutes of Health (NIH), constitute one attempt to improve knowledge about current medical practices and their utilization patterns. These conferences have emphasized technologies that are controversial owing to insufficient or inadequate information about their effectiveness and/or safety. The conferences' format is a meeting of a panel of experts from a wide range of fields related to the topic under analysis. These experts are asked to present evidence and formulate recommendations regarding a set of predetermined subtopics (2).

An important example of this mechanism was the Cesarean Childbirth Consensus Development Conference which took place at the NIH in 1980. A task force

was convened that included 19 panelists who were asked to develop a consensus and give recommendations on the following points (82):

- i) Why and how have cesarean delivery rates changed in the United States and elsewhere, and how have these changes affected pregnancy outcome?
- ii) What is the evidence that cesarean delivery improves the outcome of various complications of pregnancy?
- iii) What are the medical and psychological effects of cesarean delivery on the mother, infant, and family?
- iv) What legal and ethical considerations are involved in decisions about cesarean delivery?

The task force assembled a large amount of data, analyzed it, and circulated a detailed report prior to a two-day meeting, in which the public participated and the main conclusions and recommendations of the report were discussed. Because of the unusual format of the conference—in which a task force prepared the basic document and then also acted as the consensus panel that attempted to integrate the resulting information—the NIH and National Institute of Child Health and Human Development (NICHD) Directors set up a special review panel to analyze the consensus report as well as the strengths and weaknesses of the process. The review panel had some reservations about the dual role of the task force and some criticism of the time allotment for public participation at the conference, but it agreed with the final report and the main conclusions of the task force.

NIH has organized a large number of such consensus conferences covering a wide variety of topics, such as brain diseases in the elderly, breast cancer, therapy for burn care, postmenopausal estrogen treatment, and others (83). Although adopting different formats, many other institutions and professional organizations are performing similar activities in attempts to rationalize the existing information and knowledge in their particular fields (21). The Pan American Health Organization developed its first consensus conference on chronic terminal renal insufficiency in 1988.

C. SYNTHESIS AND LITERATURE REVIEWS

Literature reviews have always constituted an important method of synthesizing information, frequently on controversial subjects in the case of the biomedical and health sciences. This technique is particularly important in developing countries because of the difficulties and limitations involved in performing direct studies. In addition, scientific literature pertinent to health problems and conditions in the developing world is harder to come by than equivalent data for developed countries; therefore, reviews can disseminate information that would otherwise be lost to many interested parties. In general, when resources for experimental studies become available, a sound literature review is invaluable as a source of

baseline knowledge that has accrued from previous work and an indication of the pitfalls that may beset any future investigation.

The process of reviewing previously published studies is one way to synthesize information in order to shed light on controversial issues surrounding a technology and provide data essential for improved decision-making. Similar objectives are achieved by enlisting expert opinion (Section B above) and by meta-analysis (Section F), which some authors also refer to as “synthesis.”

Literature reviews are more informal than consensus conferences. They can be performed by a single investigator who can introduce biases through his or her selection and interpretation of the material.

The contribution that can be made by good literature reviews is illustrated by two recent studies. The first, by Thacker and Banta (84), criticized the entrenched practice of episiotomy on the basis that there is no clear evidence for its efficacy, while it can clearly accentuate postpartum pain and discomfort and lead to serious complications. The review called for a carefully designed controlled study of the benefits and risks of this procedure. The second study, by Fraser (85), reviewed the literature on 12 selected perinatal procedures and concluded that in most cases no sound evidence could be found that these procedures and technologies have a causative relationship to declining maternal and fetal mortality rates. Both studies point out the difficulty of establishing the effectiveness of health technologies because of the multifactorial nature of health problems and the strength of tradition in medical practice. (Techniques for dealing with multivariate information are considered in the next section, and methodologies for the evaluation of effectiveness in Section F of this chapter.)

D. MULTIVARIATE ANALYSIS

1. Overview

In biological and social systems, phenomena that are governed by a single variable, or even a small number of variables, are the exception rather than the rule. Health is a supremely multidimensional phenomenon, and any of its basic dimensions (biological, social, psychological) depend upon a complex interaction of a large number of variables. Accordingly, the outcome of pregnancy (86, 87), the incidence of cancer and cardiovascular diseases (88, 89), and changes in infant mortality (90, 91) have all been shown to have multiple determinants. Many other areas of interest in HTA are also influenced by many factors. The total cost of a technology, its rate of diffusion, the availability of required health personnel, and its effectiveness are just a few examples.

In the past, investigators have dealt with the problem of multidimensionality by adopting appropriate research designs, such as contingency tables or cause-effect relationships, that yield more manageable data. The methods adopted involve either some form of control of confounding, or randomized designs (Section F).

Although this approach has yielded scientific progress and invaluable knowledge, it should be recognized that it is error-prone and self-limiting in its application to HTA. Apart from the classic methodological errors that can be introduced by inadequate research designs, the practice of limiting the number of variables in a study has been responsible for much confusion and many controversies in assessments of the effectiveness of technologies or health programs. First of all, different researchers select different variables, thereby making it impossible to compare studies. Secondly, even when the same variables are considered, the controlled variables might be different or controlled at different levels, e.g., the socioeconomic status of different populations. This problem is not entirely resolved by randomization, especially when the sample size is small. Finally, a third limitation is that investigators, by reducing the number of variables, become trapped in a vicious circle of cause-effect relationships and are never able to identify an overall model representing the majority of interactions.

To meet the objectives of HTA, more multivariate studies are needed in order to go beyond the stage of identifying which variables *can* cause an effect to the stage of distinguishing the different *intensities* of such effects. With this refinement, it should be possible to perform cost-effectiveness studies of multiple technology alternatives—an important requirement of HTA in developing countries (Chapter III). Another potential contribution of the application of multivariate techniques to problems in developing regions would be the incorporation and study of regional characteristics and differences, which could provide information useful for improving the spatial allocation of health technology.

Multivariate analysis represents a group of techniques for quantifying degrees of association in complex systems and alleviating some of the problems discussed above. Although a large number of methods are described in the literature, this review will be limited to a few classic statistical multivariate techniques that show promise for HTA. Some other methods for dealing with multivariate data, such as modeling and decision theory, are described in later sections. These techniques can be used in other areas of HTA, such as evaluations of effectiveness, safety, cost, or social impact.

2. Techniques for reducing the dimensionality of data

The difficulty the human mind has in dealing with a large number of variables and the economy imposed by limited analytic resources require a parsimonious representation of the problem or system under study (92, 93). Consequently, the first step in dealing with multivariate data is to reduce the number of dimensions of the problem without introducing limiting assumptions or discarding critical data. Some techniques useful for this purpose are principal component analysis, factor analysis, and multidimensional scaling. In general, these techniques should be applied prior to cluster and multiple regression analyses, which examine the interdependence among variables.

Given n variables, each one represented by k data points, principal component analysis attempts to identify possible associations and redundancies among these variables in order to reduce their number to $m < n$ derived variables.

Rigorously speaking, **principal component analysis** corresponds to a linear transformation in which the initial n variables are transformed into another n variables called the *principal components*. This transformation is based on the properties of the covariance or correlation matrix of the original data. In principle, no reduction in data is obtained as a result of the calculation of the principal components. However, they present two properties that can be used to further reduce the dimensionality of the problem:

- 1) The principal components constitute an orthogonal set of variables.
- 2) Each principal component tends to concentrate the maximum variance of the data along its axis or dimension; the largest amount of the total variance is accounted for by the first principal component, with each subsequent principal component accounting for less variance, in decreasing order (94).

Because of the second property, it is usual in practice to find a large percentage of the total variance concentrated in the first few components. Therefore, abandoning the remaining components will not incur significant error. Additionally, because of the first property, we know that the components retained are orthogonal, or independent. This means that they are uncorrelated ($R=0.0$), thus representing truly different dimensions of the problem. Some applications of principal component analysis only attempt to estimate the dimensionality of a given set of data. In other cases, like the construction of multidimensional indicators, the principal components whose variance is judged to be significant are adopted as the new variables that describe the phenomenon of interest. The latter approach is more frequently pursued by factor analysis, as will be discussed later.

One example of the use of principal component analysis is identification of the main dimensions in a set of 15 causes of death used as health indicators for 59 Brazilian towns in 1980 (95). The cumulative percentage of variance resolved by each of the first 10 components is given in Table 6; the first four components account for almost 70% of the total variance.

The results shown in Table 6 indicate that a small number of indices derived from the 15 mortality indicators can represent a large share of the total variance, that is, they can explain a considerable fraction of the differences in health levels observed among the 59 towns (95).

Classic **factor analysis** is carried out along the same lines as principal component analysis, but begins with the assumption that each original variable is influenced by many factors, some of which also influence other variables in the set (common factors), while others are unique to a variable:

$$X_i = b_{i1} F_1 + b_{i2} F_2 + \dots + b_{ik} F_k + c_i U_i$$

Table 6. Principal component analysis of 15 health indicators corresponding to different causes of death in 59 Brazilian towns in 1980.

Component	Cumulative % of the total variance resolved by components
1	29.4
2	48.5
3	59.6
4	68.9
5	77.0
6	82.3
7	87.3
8	90.4
9	93.0
10	95.2

where X_i is the original variable, F_k are the common factors, and U_i is the unique factor. The coefficients b_i and c_i are the loadings (96).

Although factor analysis can also be regarded as a linear transformation of the original set of n variables, it differs markedly from principal component analysis in some respects. First of all, the number of common factors is arbitrary and needs to be estimated prior to the application of the method, usually by principal component analysis. Secondly, the rationale of the method is to maximize the total variance of the common factors, under the condition that they represent orthogonal variables. Finally, the values of the common factors and their correlation to the original variables can be modified by a number of different "rotations," which can be visualized by the spatial rotation of a three-dimensional reference system (Cartesian axis) in the case $R=3$ common factors. The objective of the rotations is to align some of the factors with certain original variables, thus facilitating their interpretation (94).

Analysis of the loadings of the principal components on individual mortality indicators in the Brazilian urban data suggested that three main common factors were present, according to the following model:

$$X_i = b_{i1} H_1 + b_{i2} H_2 + b_{i3} H_3 + c_i U_i$$

The results of this factor analysis confirmed the predominance of the three common factors H_i . The analysis of loadings by correlation indicates that each factor is associated with a coherent group of individual indicators as follows:

H_1 = "preventable deaths," associated with indicators:

- mortality at ages 1-4
- mortality at ages 5-19

- infant mortality
- mortality from infectious diseases
- mortality from diarrheal diseases

H_2 = "preventable deaths," associated with indicators:

- mortality at ages 50–64
- mortality from cardiovascular diseases
- mortality from neoplastic diseases

H_3 = "social diseases," associated with indicators:

- mortality from traffic accidents
- mortality from violence

The correlation coefficients demonstrate the independence of these indices:

	H_1	H_2	H_3
H_1	1	0.12	0.12
H_2	0.12	1	0.34
H_3	0.12	0.34	1

The conclusion is that for these Brazilian towns, the three dimensions H_1 , H_2 , and H_3 are independent and are sufficient to explain most of the variance expressed by the 15 individual mortality indicators.

Both principal component and factor analysis require that variables be expressed in numerical terms for the computation of a correlation matrix. An attractive alternative for reducing the dimensionality of a problem is **multidimensional scaling** (97), in which the data used can be either numerical or ordinal. This technique is particularly useful for examining social impact data (see Section E), which is generally difficult to express in numerical terms.

In multidimensional scaling, the observations or "objects" are characterized by a similarity measure, which can take the form of correlation coefficients, difference scores, estimations of similarity, or some other system. The similarity measures are transformed into Euclidean, metric distances by an arbitrary function of the ordinal similarity or proximity scale. The suggested dimensions of the data are obtained by minimizing a quadratic error function, which is usually called a "stress function." Several special computer programs have been written for this purpose (97). Besides identifying the "true" dimensionality of the problem, multidimensional scaling also attempts to interpret its structure by a spatial representation of the data along meaningful axes. Since spatial representations are usually limited to two or three dimensions, problems with much higher dimensionalities are not suitable for analysis by this method.

3. Cluster analysis

Cluster analysis has some similarity to multidimensional scaling, but it is considered separately here since it can also be useful for classification, measures of association, and pattern recognition.

As the name implies, cluster analysis attempts to group observations or variables that share common features or have some degree of similarity. Each observation in the data set, be it a patient or a technology, is regarded as an “object” that is described by the variables considered. As an example, a group of technologies can be described by their cost, expected lifetime, and surface area they required in the hospital. If each technology is represented by a point in a three-dimensional axis system, it is possible to use the distance between points as a measure of similarity. Other indicators of similarity, such as correlation coefficients, are also adopted (93, 98, 99). The points closest together or with the highest correlation coefficients are most similar and therefore should constitute a cluster.

Several different criteria can be adopted for establishing a new cluster, such as joining individual observations or collapsing two small clusters to form a larger one (hierarchical clustering). The most common methods are the following (93, 98):

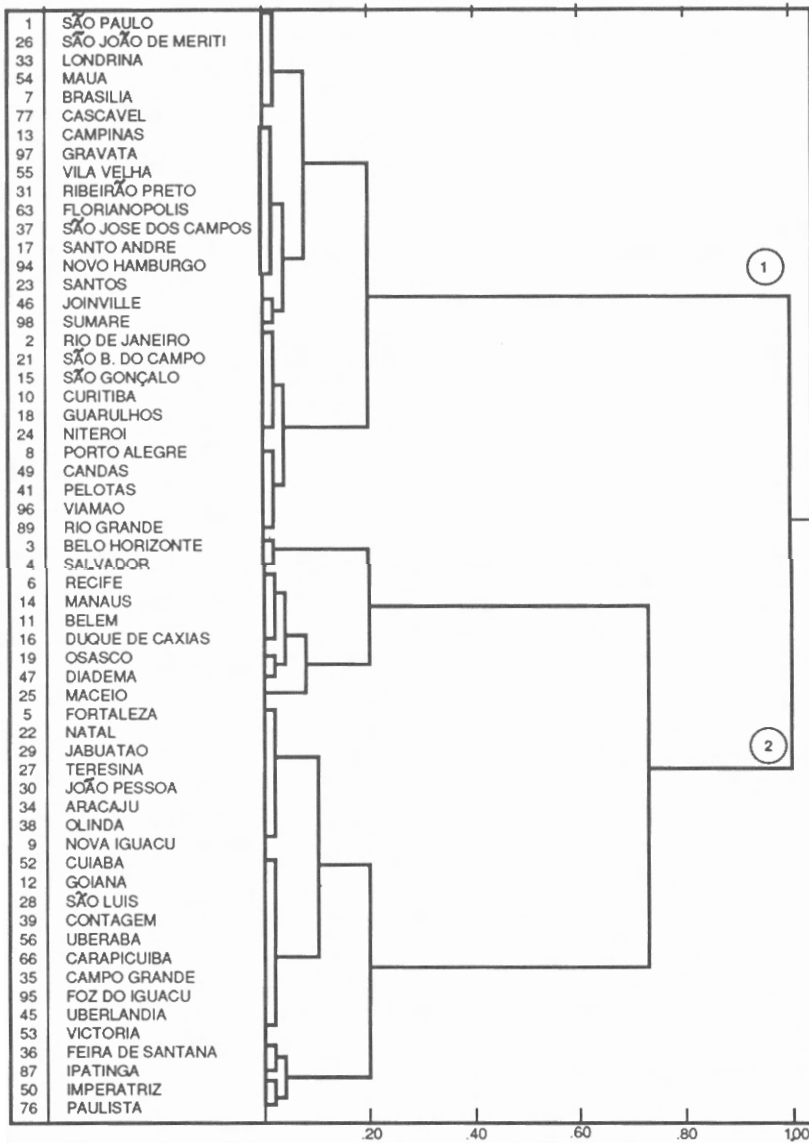
- 1) nearest neighbor (or single link): a new cluster is formed on the basis of the distance between the two closest members of each previous cluster;
- 2) furthest neighbor (complete link): a new cluster is formed on the basis of the distance between the most distant pair in previous clusters;
- 3) group average: a new cluster is formed on the basis of the average distance between all pairs of entities in each cluster;
- 4) centroid: a new cluster is formed on the basis of the distance between the center of gravity of the individual clusters;
- 5) median: the median of the distances between all the elements of two clusters is used to determine which new clusters should be formed;
- 6) Ward’s method: new clusters are formed by optimizing the minimum variance within clusters (98, 99).

Unlike multidimensional scaling, which uses a spatial representation, cluster analysis uses “fusion trees” (the merging of smaller clusters into larger ones) to represent the hierarchical process. One advantage of cluster analysis is that the statistical significance of each new cluster can be assessed by a number of different approaches, notably Mountford’s B-statistics (100) or Akaike’s information criteria (101).

Cluster analysis can be used with the Brazilian mortality data for the 59 towns to identify similarities between towns and to indicate whether further analyses would discern similarities between different groups of towns (95). Using the previously identified health indices H_1 , H_2 , and H_3 (pp. 48–49), cluster analysis with

Ward's method yielded the fusion tree represented in Figure 9. Mountford's B-statistics show that most clusters are significant at the 1% level (100). Detailed examination of Figure 9 reveals that towns in the same region generally end up in the same cluster. This finding is quite interesting, since only mortality data were considered in the cluster analysis.

Figure 9. Cluster analysis of health indices H_i for 59 Brazilian towns in 1980. Group 1 represents better health conditions as expressed by smaller values of H_1 , H_2 , and H_3 .



When the clustering operation is performed on variables rather than observations, the main dimensions of the data set can be determined from the number of final significant clusters, and an indication is given of which variables can be collapsed into summary indices.

4. Modeling

After a multivariate problem is reduced to more manageable dimensions and redundant variables are eliminated, quantitative relationships should be established between the dependent or observed variable(s) and the explanatory or independent variables. This operation is generally described as "input/output modeling," and the techniques generally used for this purpose are multiple regression and path analysis.

In **multiple regression**, the output or dependent variable y_i is expressed as a linear combination of the independent variables x_{ij} :

$$y_i = a_1 x_{i1} + a_2 x_{i2} + a_3 x_{i3} + \dots + a_n x_{in}$$

From the covariance matrix of $[y_i, x_{ij}]$ it is possible to compute the coefficients a_k which, similar to simple linear regressions, represent the slope of the relationship between y_k and x_k when all the other variables remain constant.

As a first approximation, most relationships considered can be described by linear equations. However, important nonlinear relationships are sometimes present, such as saturations and sigmoid curves. The same formulations can still be adopted by substituting for the x_{ij} values an adequate nonlinear function such as $(x_{ij})^2$ or $\log(x_{ij})$. In this case, though, care must be taken with the statistical assessment of the significance of the regression and slope coefficients, since $(x_{ij})^2$ cannot be assumed to have a Gaussian distribution.

When many (for example, more than eight) independent variables are employed, not all of them may indeed affect the output. One way to tackle this problem is to start the regression process with only one explanatory variable and then proceed by adding one variable at a time. At each step, statistical tests are performed to detect the point at which further addition of variables has no significance to the overall correlation coefficient. The squared value of the resulting correlation coefficient represents the fraction of the variance of y_i that can be explained by the set of significant explanatory variables.

In addition to statistical tests to determine the significance of the regression results, it is always advisable to plot the residual values between the real data points y_i and the equivalent Y_i predicted by the regression equation. Frequently, the residual plot indicates trends and nonlinearities that can then suggest improvements in the regression equation.

Louise Russell (27) performed an innovative study of technological diffusion in hospitals by using a modified multiple regression approach to allow for dichoto-

mous variables. In this case, the dependent variable was the fraction of 2,772 hospitals that already had a technology such as intensive care units, electroencephalography, or diagnostic radioisotopes (see Figure 4, p. 13). This variable ranged between 0 and 1 and can be interpreted as a probability. A large number of explanatory variables were considered. Table 7 lists some of the independent variables that were found to be significant in the case of diagnostic radioisotopes, and their contribution to the probability of the hospital having the technology.

In simple or multiple regressions, the association between the dependent and independent variables is symmetrical, implying that it is impossible to state which variable is the cause and which is the effect unless other information is available. Fortunately, in many situations temporal relationships can help to establish the direction of causal influence; in other cases obvious asymmetries are present, such as in the relationship between pollution and mortality.

Path analysis is a technique for clarifying probable directions of influence by working with partial correlation coefficients. To understand how the technique

Table 7. Probability that a hospital had cobalt therapy by 1975.

Characteristic (explanatory variable)		Contribution to probability	
Number of beds			
100-199		+ 0.051	
200-299		+ 0.164	
300 and over		+ 0.469	
Medical school affiliation		+ 0.114	
Residents per 100 beds			
1-9		+ 0.007	
10-19		+ 0.076	
20 and over		+ 0.169	
Percent of doctors in general practice			
under 20		- 0.052	
20-29		0.0	(Ref.) ^a
30 and over		+ 0.012	(NS) ^b
Percent of population white			
under 85		- 0.041	
85-94		0.0	(Ref.)
95 and over		+ 0.054	
Percent growth in population 1950-1970			
under 35		0.0	(Ref.)
35-59		+ 0.039	
60 and over		+ 0.023	(NS)
Summary statistic			
	R ²	0.351	
	corrected R ²	0.342	
	F value	38.9	
	degrees of freedom	38/2733	

Source: Adapted from Russell (25).

^aReference condition in relation to which the other two categories should be interpreted.

^bNot significant.

works, assume that y is the dependent variable and x and z are two of the independent variables. The correlation coefficient between y and x is R^{yx} and $R^{yx.z}$ is the partial correlation of y on x , holding z constant. A significant statistical difference between R^{yx} and $R^{yx.z}$ is suggestive that the path of influence of x on y passes through z , or

$$X \rightarrow Z \rightarrow Y$$

The difference $R^{yz} - R^{yz.x}$ can be tested to determine which of the associations is more likely.

Using the principles of path analysis, Goldsmith (102) analyzed the infant mortality (M) in England and Wales from 1928 to 1938 as a function of the following socioeconomic variables:

- H = index of crowded housing
- U = index of unemployment
- P = index of poverty
- F = proportion of women employed
- L = latitude

Goldsmith's results are shown in the path diagram in Figure 10, which indicates the probable directions of influence. This model reveals information that could not be obtained by classical multiple regressions. For example, it was observed that unemployment has minimal direct influence on infant mortality, the primary effect of this variable being through housing and poverty.

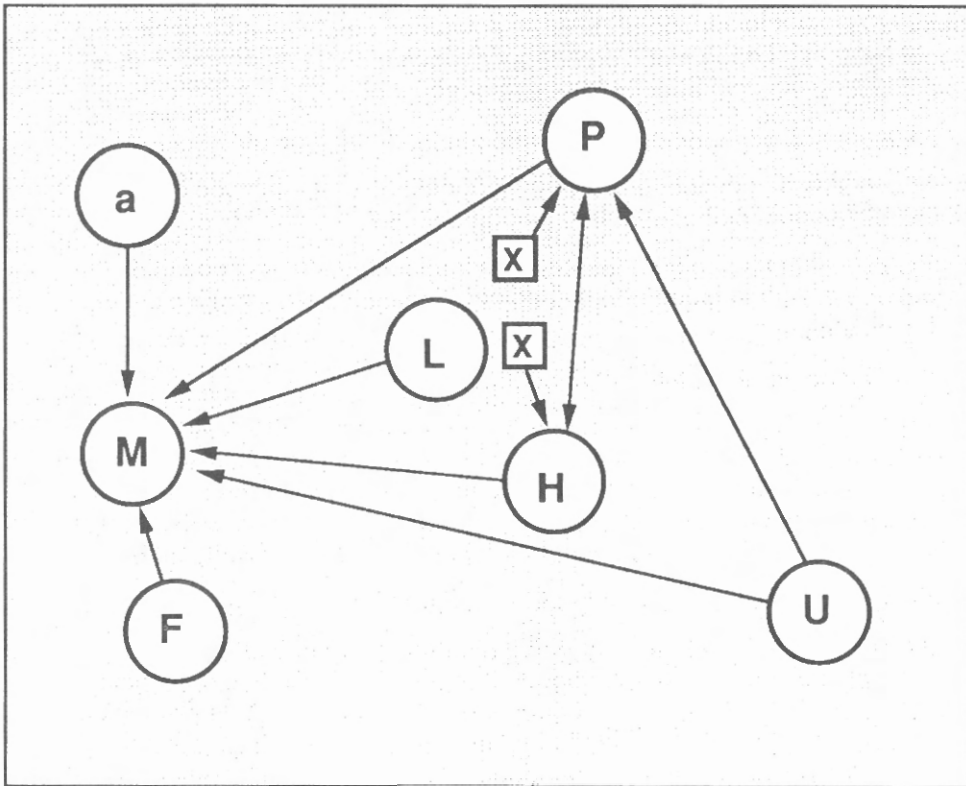
E. EVALUATION OF SOCIAL IMPACT

1. Overview

As discussed previously (Chapter II, Section C.5), evaluating the social impact of health technologies represents the most difficult and challenging task for HTA. One problem involves the difficulty of measurement and modeling inherent in the social sciences (14, 103). Second, since the values and ethics of a society are dictated by culture, it is usually impossible to generalize findings from one country, or even one area, to another. A third difficulty is that health technologies can lead to a wide range of impacts that vary in intensity and affect different population groups. For these reasons, there is no ideal methodology for evaluating social impact; the methodology employed must depend on the technology itself, the objective of the study, and the population and area affected.

Assessing social impact is the aspect of HTA that has the most in common with general TA, and much can be gained by examining methodologies that have been used in technology assessments outside the health care sector. Some of these tools (such as expert opinion, literature reviews, and multidimensional scal-

Figure 10. Path diagram for infant mortality. Modified from Goldsmith (102). ("x" represents implausible paths suggested by partial correlations; "a" represents all other influences. See text for other symbols.)



ing) have already been mentioned. Other technology assessment techniques will be described in this section, with attention given to how a particular assessment can be oriented toward the priorities of HTA for developing countries.

2. Technology-oriented HTA

Impact studies relative to a given technology are usually restricted to the identification of potential impacts and/or an evaluation of the acceptability of negative impacts. Some studies may suggest strategies to minimize impacts of concern. Up to the present, most studies have been purely descriptive and make use of direct observations (104, 105), literature reviews (3, 24, 85, 106), interviews (107, 108), or questionnaires (109) directed to the individuals affected.

Attempts to identify potential impacts of a new technology can vary in their degree of formality. "Brainstorming" gathers experts in different fields in order to

stimulate ideas that can be useful in mapping out the terrain to be covered by more thorough methods. This is a suitable approach for fulfilling step three of Coates' model for general technology assessment (Chapter I, p. 5).

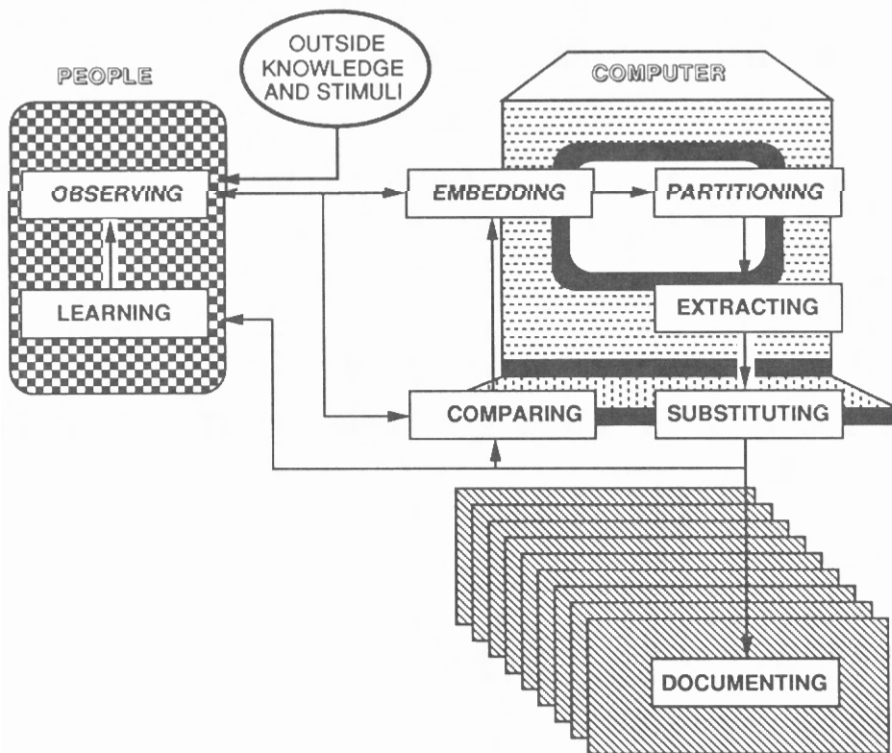
Impacts can also be identified through well-posed questions such as those proposed by the U.S. Office of Technology Assessment (21). A sample of questions that can be applied to most technologies is given below:

- What are the implications of the technology for the patient?
- What will be the quality of life of the patient who has been treated? Normally active? Moderately restricted? Physically impaired?
- What psychological effects can be anticipated? Guilt (because of high financial and social costs to family, etc.)? Anxiety? Feelings of dehumanization or dependency?
- What are the implications for the patient's family?
- What will be the costs to the family? How will the new technology affect family structure? Will there be any physical dangers to the immediate family? Will the device or procedure be psychologically acceptable to the family? Will active cooperation or assistance of family members be necessary on a continuing basis? How will the new technology affect individual and family budgets?
- What are the implications for society in general?
- Will the technology change the demographic characteristics of the society? For example, can changes in sex ratios or age distribution in the population be anticipated? Will the new technology affect reproductive capability of patients and thus change the genetic pool and the prevalence of genetic disease? Will use of the new technology by an individual create threats to the environment that are properly the concern of the entire society?
- Will introduction of the new technology challenge important beliefs and values of the society about birth, gender, bodily integrity, personal identity, marriage and procreation, respect for life, right to life, right to die, responsibility for each other? Will introduction of the new technology result in changes in these values?
- Will the technology alter any basic institutions of society (e.g., schools, recreational facilities, prisons)?
- What are the implications for the legal and political systems?
- Will problems of justice, access, or fairness arise? Will they lead to litigation?
- Will the manufacturer be liable for damages resulting from failure of the technology? Will liability extend only to damage of the individual or will it cover environmental effects as well?
- Will use of the new technology require changes of the definition of death or suicide?

A more formal tool for detecting potential impacts is the technique of **interpretative structural modeling**. Malone (110) gives a useful summary of the technique, and Lindstone *et al.* (111) review a number of computer programs developed for structural modeling.

Figure 11 is a representation of this process. Individuals or groups are asked to develop an *element set*, which is a list of items considered important in a given context. These items can be viewed as nodes of a network; the objective of interpretative structural modeling is to connect the nodes by means of a set of *diagrams* (directed graphs) showing the interrelationships between the elements. With the help of a computer program, the process also produces *relational statements*, which can be expressed in plain English and which indicate the expert's perception of some of the relationships between the elements. The advantage of the technique is that a given set of relationships can be expanded by the computer by logical inference. After a model is produced (Figure 11), it can be inspected by the group and repeatedly modified until it becomes acceptable. As Lindstone *et al.* (111) emphasize, use of a computer in such analyses is only ad-

Figure 11. Block diagram of the interpretative structural modeling process. Adapted from Malone (110).



vantageous when complex systems or a large element set is involved. Thus far, the authors are not aware of any health technology assessment in which this tool has been employed to identify potential impacts, but there are undoubtedly many situations where it could be useful.

One technology that leads to a large number of social impacts is renal dialysis. Table 8 lists some of the impacts or "psychological costs," as identified by Abt (112). On the other hand, by analyzing data and interviewing 859 patients with end-stage renal disease, Evans *et al.* (108) concluded that these patients perceive their quality of life as only slightly below that of the general population. These authors evaluated "quality of life" by two objective indicators (functional impairment and ability to work) and three subjective indicators and found that quality of life was highest for those in home dialysis, followed, in order, by those in continuous ambulatory peritoneal dialysis and in-center hemodialysis. In addition, comorbidity, an important determinant of the objective quality of life, was not a significant factor in the subjective quality of life indicator.

The study by Evans *et al.* (108) sheds some light on the impacts at the individual level of different technological alternatives for treating end-stage renal disease, but does not address the stresses they cause for the family or society. Other investigators have dealt with these aspects mainly from an economic perspective (112, 113).

Table 8. Psychological costs of renal dialysis, as identified by Abt (112).

Treatment	Psychological costs
Home dialysis	Discomfort Disrupted professional and work relations Loss of community contributions and participation Segregation Isolation and discrimination Infantilization Loss of leisure time Reduced aesthetic quality of life Inconvenience Immobility Dependence Limitation of normal activity: work, social life, sex, recreation Family conflict Loneliness Loss of self-esteem Anxiety Worry and depression
Hospital dialysis	All of the above, plus: <i>More</i> loneliness <i>More</i> limitation <i>More</i> inconvenience, reduced use of home environment

3. Problem-oriented assessments

The requirement that multiple technological alternatives be considered for the solution of specific health problems in developing countries (Chapter III) poses additional difficulties regarding the evaluation of social impacts. To discover which technology represents the best response, it is necessary to establish some kind of scale or unit of measurement to rank the alternatives under consideration. When a single type of impact, such as psychological effects, is considered, the ranking can be based on descriptive information. In practice, however, the social impacts of technology are never unidimensional; they cover multiple areas of society and affect many dimensions of an individual's "social space." Consequently, methodologies must allow comparisons of technological alternatives that cause multiple social impacts.

The need to deal with multidimensional social impacts has been recognized by the U.S. Office of Technology Assessment (21), which developed a scheme for classifying social impacts using the matrix shown in Figure 12. Impacts are classified by their type or nature (rows) and by the parties they affect (columns) (Figure 12-I). A separate description (Figure 12-II) is given of each particular impact and can include an estimate of its potential intensity.

Although the approach proposed by the Office of Technology Assessment can help unravel the complex structure of social impacts of a technology, it still does not allow ranking of multiple alternatives, except in very particular circumstances. To circumvent this problem, Panerai and Attinger (114) developed a scaling procedure in order to rank technological alternatives involving multidimensional social impacts. The method has been applied to the assessment of 300 technologies in the area of perinatal care.

The scale consists of 19 subareas of potential impact distributed at three distinct levels: individual, community, and general society. As shown in Table 9, a weight W_i corresponds to each subarea of impact, and the total impact of a technology n can be expressed by the social impact index SI_n , given by:

$$SI_n = \sum_{i=1}^{19} W_i \cdot C_{ni}$$

where the values of C_{ni} are classification coefficients reflecting the impact of technology n on subarea i . For simplicity, the initial test of this scale adopted C_{ni} values of either -1 (negative impact), 0 (impact absent, indifferent, or undetectable), or $+1$ (positive impact). The weights W_i are an interesting feature of this approach because they allow the analyst to introduce his or her own priorities, concerns, and values by choosing numerical values that emphasize some subareas and downplay others. This possibility is particularly important because it gives the model enough flexibility to accommodate requirements imposed by widely differing scenarios in developing countries. The rankings produced by this ap-

proach, and the corresponding SI_n values, are given in Table 10 for some of the perinatal care technologies considered.

Currently, the use of scaling to evaluate social impact in HTA should be regarded as a technique that requires further testing and validation. It is clear that this approach combined with expert opinion and multivariate analysis techniques can be useful to enhance the quality of the data and the strength of the assessment.

Utility theory, a possible alternative to scaling for ranking the impacts of multiple technologies, will be discussed in Section J of this chapter.

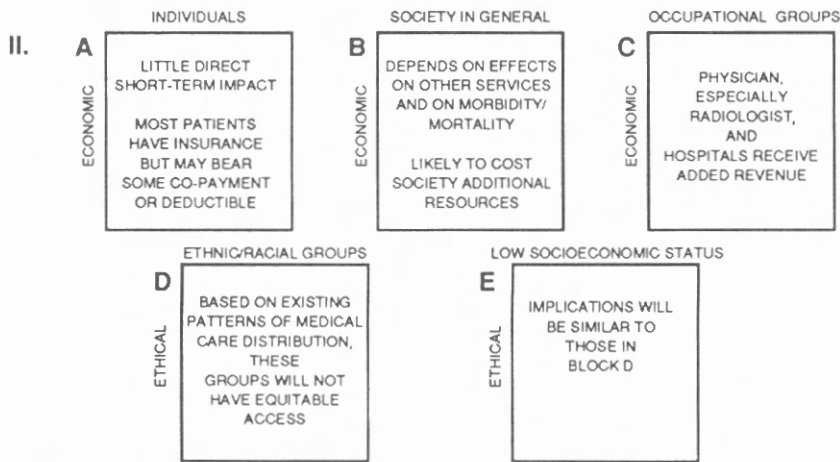
Figure 12. Scheme for classifying the social impacts of health technologies. Adapted from Banta *et al.* (21).

I.

AFFECTED PARTIES TYPE OF EFFECT	INDIVIDUAL PATIENTS	FAMILY/FRIENDS	SOCIETY IN GENERAL	SUBGROUPS OF SOCIETY						
				OCCUPATIONAL/INDUSTRIAL	ETHNIC/RACIAL GROUPS	RELIGIOUS AFFILIATES	LOW SOCIOECONOMIC STATUS	AGE GROUPS	IDEOLOGICAL COHORTS	OTHER SUBGROUPS
ECONOMIC	A		B	C						
LEGAL										
POLITICAL										
PUBLIC ADMINISTRATIVE										
CULTURAL										
ETHICAL/MORAL					D		E			
RELIGIOUS										
ON HEALTH CARE SYSTEMS										
RELATED TECH. SYSTEMS										
EDUCATION										
PHYSICAL ENVIRONMENT										
HOUSING										
NUTRITION										
OTHERS										

I) Classification of some impacts of CT scanner according to parties affected and type of effect.

Figure 12—Continued



II) Description of individual impacts classified in Figure 12-I.

Note: The letters of the blocks (A–E) refer to cells of the matrix. Vertical and horizontal descriptions for each block refer to the matrix's row and column headings. The possible social implications given are meant to be merely illustrative, not exhaustive, and are not the result of a full assessment.

Table 9. Subareas included in overall index of social impact.

Unit affected	Subarea	Weight
Individual	Quality of life	W_1
	Impact on education	W_2
	Economic impact	W_3
	Changes in life-style	W_4
	Psychosocial well-being	W_5
	Patient satisfaction with care	W_6
	Humanization of care	W_7
	Promotion of self-care/responsibility	W_8
	Impact on family	W_9
Community	Accessibility to health care	W_{10}
	Economic impact on community	W_{11}
	Effects for underprivileged groups	W_{12}
	Sense of community and mutual help	W_{13}
Society	Impact on economic development	W_{14}
	Environmental impact	W_{15}
	Impact on value system	W_{16}
	Effect on social tensions	W_{17}
	Ethical questions raised	W_{18}
	Impact on societal structure	W_{19}

Table 10. Ranking of perinatal care technologies according to scale of social impact (SI index), based on 19 subareas of potential impact.

Technology	SI index
Campaign to reduce teenage pregnancy	68
Food supplements	62
Delivery of home-care kit for the newborn	61
Access to telephone	58
Enforcement of asepsis	52
Physical examination and history	43
Skin test for tuberculosis	35
Recording uterine height	22
Papanicolaou staining for cervical smear	14
Genetic counseling	7
Doppler ultrasound	1
Psychological testing	- 4
Local anesthesia	- 10
Rapid surfactant test	- 17
Culture for bacteria in amniotic fluid	- 22
Amniotomy	- 30
Isolation of infected newborn	- 38
Cesarean section delivery (emergency)	- 41
Fetal stress test (FAD or oxytocin)	- 46
Epidural block	- 55
Cervical cerclage	- 61
Cesarean section delivery (programmed)	- 67
Forceps	- 68
Vacuum extractor	- 70

Source: Data supplied by Panerai and Attinger (114).

F. EFFECTIVENESS AND SAFETY

1. Overview

Most health technology assessments and literature about HTA have concentrated on effectiveness and safety. In general, these aspects of a health technology can be evaluated by commonly used methodologies. Since a volume devoted to these methodologies exists (115), they will be reviewed only briefly.

One important problem that arises when effectiveness and safety are evaluated is the different units of measurement adopted by different investigators (2, 48). Independent of differences in the basic concepts of effectiveness and safety (Chapter II), it must be recognized that, like social impact, they are multidimensional variables, since the health benefit of a technology can be manifested by duration of life (length of survival), physiological capacity, absence of pain, psychological condition, and so on. Different technologies and health problems will lead to the use of different units of measurement, but the multidimensional nature of health benefits should not be forgotten. The major problem is that lack of uniformity of measurement makes it impossible to compare different technologi-

cal alternatives, especially when they pertain to different domains such as prevention, diagnosis, or therapy.

The largest group of technologies that have been evaluated is made up of therapeutic agents such as drugs and surgery (2). For these technologies, it is common to use length of survival as the measure of effectiveness. In cancer research the fraction of patients surviving five years after intervention is frequently adopted as a standardized measure (52). The limitation of measures based solely on duration of survival is that they do not take quality of life into account. To circumvent this problem, Weinstein and Stason (116) have proposed the use of quality-adjusted life years (QALY) as a better measure of effectiveness in most cases. This index is the product of the length of survival multiplied by a parameter that reflects the quality of life for each fraction of the period of survival considered. This multiplying factor assumes a value of 1 for states of perfect health and zero for states which are equivalent to death, such as permanent coma. Intermediate states of less than perfect health can be assessed from the patients themselves by using utility theory (see Section J) (53).

Considering that other benefits of health technologies, such as a reduction in hospital stay, can be accounted for by the cost factor in a cost-effectiveness analysis (116), the QALY index appears to be an attractive measure of effectiveness. It can be used to improve current evaluation practices and augment the ability to compare different technological alternatives.

Subsequent sections of this chapter will deal with estimating effectiveness, mainly as it relates to costs and the allocation of technological resources. The most common methodologies for estimating effectiveness and safety are reviewed below.

2. Randomized controlled trials

Randomized controlled trials represent the paradigm of methodologies for evaluating effectiveness and safety because they take into account the difficulty of controlling for the many characteristics of patients that can influence the outcome of treatment or utilization of other health technologies.

In randomized controlled trials, patients are randomly allocated to either a "treatment group" (exposed to, for example, a new diagnostic technology), or a "control group," which is exposed to an old technology or a placebo. Randomization is important in order to distribute equally between the groups patients of different ages, sexes, races, places of residence, and socioeconomic classes, since such characteristics can affect outcome. Above all, randomization can minimize the effect of variables and conditions (such as a virus infection, enzyme deficiency, or genetic trait) that are unknown at the time of the study.

Different randomization techniques can be adopted (44). The most common procedure uses a random number table or shuffled presealed envelopes. Whatever

the scheme adopted, it is essential to assign the patient to a group before he or she is seen by the doctor, to minimize the possibility of physician bias.

Bias can also be introduced by the patient's expectations (placebo and Hawthorne effects) or by those of the investigators in charge of evaluating outcome. *Blinding* is a technique for minimizing bias by making either the patient ("single-blind") or both patient and doctor ("double-blind") unaware of which type of treatment is received. This approach is particularly suited to drug evaluations, but it is difficult or even impossible with many other technologies.

Although randomized trials represent the ideal tool for assessing effectiveness and safety, they present several limitations, the most important being ethical and another being duration of the study.

Ethical complaints have been increasingly raised against some randomized controlled trial designs, either because they subject patients to uncomfortable or even risky procedures or because they deny patients in the control groups the health benefits of the best technology. The former problem is illustrated by the acceptance of "sham" surgery (44) and by the absence of informed consent, which was associated with most surgical trials in the past (117). The latter argument is based on physicians' views that it is unethical to deny the benefits of technologies, many of which may have never been properly evaluated, to the placebo group. Nevertheless, this argument has been criticized by many authors who have concluded that it is even more unethical to use a technology of unknown benefit in a large population than to conduct a randomized controlled trial to evaluate it in a small population.

Randomization can only counteract prognostic factors effectively if the number of patients, or sample size, is adequate. The larger the sample size, the higher the cost of the study. In general, what sample size is adequate depends upon the distribution of the observed variable in the population (variability of the outcome measure) and the significance level adopted for accepting or rejecting the initial hypothesis (118). Therefore, the quality of the study, manifested by the level of significance of the Type I (alpha) and Type II (beta) error levels and the intensity of the effect that can be detected, is improved by adequate sample size and minimization of biases caused by differences in professional skills, experience, and infrastructure (119).

Finally, the duration of a randomized controlled trial is of concern because, as a large-scale operation, it commonly requires about two years for completion. It is not unusual that the technology being evaluated becomes obsolete before the end of the study (119).

An example of the role that randomized trials can play in establishing the truth about the benefits of a health technology is the case of hyperbaric oxygen treatment for cognitive deficits in the elderly (44). An article in the *New England Journal of Medicine* (1969) reported that repeated exposure to pure oxygen in a hyperbaric chamber enhanced the cognitive functioning of patients with organic brain

syndrome. Five subsequent studies confirmed this finding, but only one used a control group. In the meantime, due to extensive news media coverage, the procedure was widely publicized and a number of special centers in the United States began offering to treat memory loss in the elderly using hyperbaric oxygen, and charged fees as high as \$5,000 for 15 days of treatment. In 1975 the National Institute of Mental Health (NIMH) conducted a randomized controlled trial that failed to confirm any benefit of hyperbaric oxygen treatment for cognitive problems in the elderly in a number of subgroups studied. This result was instrumental in stopping health insurance carriers and Medicare from reimbursing for the cost of this procedure. In this case, a timely and well-conducted assessment blocked the spread of an ineffective technology before it became protected from evaluation by hypocritical attitudes and large economic interests.

In light of the problems and priorities of developing countries, randomized controlled trials are prohibitively expensive and would require a level of organization and commitment to research that is not generally available. For many health problems, obtaining adequate sample sizes is difficult because of the small number of centers that are equipped with personnel and physical resources to perform this type of study. For these reasons, developing countries must employ methodologies that are more appropriate to their possibilities and needs.

3. Other methodologies

Several nonrandomized designs can be used in HTA, although each can introduce errors and biases that can lead to wrong conclusions about the effectiveness of a technology (43, 73). Unfortunately, initial evaluations performed following the innovation stage usually fall in this category (21).

Investigators frequently use historical controls to test the effectiveness of a new procedure. In this approach, a group of patients receiving the new treatment is compared with a similar group that received another treatment in the past. The possibilities for biases are obviously very large because, as observed by Moses and Brown (43), time changes all things—including professional skills, knowledge, and the diagnostic armamentarium available for patients of the more recent group (119). As pointed out by the OTA (44), “the problem of using historical controls is not the existence of bias *per se*, but the impossibility of detecting, measuring, or removing it.”

Studies adopting historical controls are more common than randomized controlled trials in developing countries. In the Philippines, Clavano studied the effects of the mode of feeding on infant mortality and morbidity, using data collected on 9,866 births almost equally divided between two distinct time periods (120). During period I (January 1973 to March 1975), there was no explicit policy on breast-feeding and only 40% of the babies were breast-fed. The second period, April 1975 to April 1977, corresponded to the introduction of explicit breast-feeding and rooming-in policies. During this period, breast-feeding rose to 87%,

the remaining 13% of infants being fed either a mixture of formula and breast-milk or exclusively formula. Analysis of the pooled data showed that 97% of both the morbidity and the mortality occurred in the mixture- or formula-fed group. Although many conditions, including the patient population, may have changed over this four-year period, the intensity of the observed differences between groups and the large sample size lend reliability to the conclusion that breast-feeding is healthier for babies than formula.

Series or sequential observations constitute another kind of study frequently found in the literature. This method is extremely weak for estimating effectiveness, but it can be useful in detecting safety problems of a technology (42, 43). In an example of this approach, Steel and co-workers (54) observed 815 consecutive patient admissions to the general medical service of a university hospital. They recorded iatrogenic illness in 36% of these patients; in 9% of the persons admitted it was considered major, in that it was life-threatening or produced considerable disability. One of the main sources of incidents was exposure to drugs. Similar studies, although of limited accuracy and sensitive to the influence of sample bias, could prove effective in pointing out areas of concern regarding the utilization and safety of health technologies in developing countries.

Other approaches to the evaluation of safety and effectiveness include case-control epidemiologic studies, surveillance, and cross-sectional studies (43, 73).

4. Meta-analysis

Meta-analysis is one of the techniques usually regarded as "synthesis," since it brings together information and data accruing from a large number of previous studies. The difference between meta-analysis and literature reviews is that in the former, a new statistical analysis is performed on the pooled data of the individual studies, yielding averaged and more robust results. Pooled "P-values" can be obtained from different studies using Fisher's procedure, which does not require a common structure among the studies (43).

Villar and Belizan performed a meta-analysis of methods used in the diagnosis of intrauterine growth retardation (121). They analyzed the results of 83 individual studies that had employed different techniques for detecting intrauterine growth retardation, and recalculated their positive predictive value (PPV) at a constant prevalence rate, since this factor is known to markedly affect the PPV. Table 11 presents their findings of the best results for each method when only studies with sample sizes above 100 are considered.

For developing countries, meta-analysis represents a creative approach for improving the confidence level of results of groups of studies with small samples, or for adapting the results of investigations performed under differing regimens, for example, by correcting for predicted rates of compliance to therapeutic or preventive technologies.

Table 11. Meta-analysis of the positive predictive value (PPV) of diagnostic methods for intrauterine growth retardation, corrected for a prevalence rate of 10%.

Method	PPV (%)
Risk factors	19
Symphysis fundal height	48
Risk factors and clinical indices	69
Ultrasound measures	51*
Amniotic fluid volume (ultrasound)	73
Fetal movements	38
Urinary estrogen	20
Estrogens and pregnandiol	30
Oxytocin challenge test	48
Nonstress test	23

*Average of results from three dimensions.

Source: Adapted from Villar and Belizan (121).

5. Information technologies

Diagnostic and information systems do not contribute directly to patients' health unless they have an impact on preventive or therapeutic procedures. Such impact is not easy to study, and diagnostic technologies are often evaluated only in relation to their precision (sensitivity, specificity, positive predictive value, etc.) in detecting a disease or other health condition. Ideally, diagnostic tests, equipment, and information systems (such as bedside monitoring computers) should be evaluated by randomized controlled trials, in which their overall benefit could be easily measured. Unfortunately, very few such trials have concentrated on diagnostic technologies.

The lack of objective evaluation studies of information-handling technologies is unfortunate for developing countries, since frequent innovations and high-cost diagnostic technologies spread rapidly (29) and consume a significant fraction of the countries' health care resources. Studies that seek to evaluate the impact of an information technology on patients' outcome or on the population's health should be encouraged and widely disseminated.

In this context, Banta and Thacker (122) reviewed the evidence concerning the benefits of electronic fetal monitoring (EFM) during labor. The technique was developed initially for monitoring high-risk births, but is now used in 50% of all deliveries in the United States (40). The method consists of the continuous measurement of fetal heart rate, coupled with fetal scalp blood sampling. In most cases, measurement of intrauterine pressure or external measurement of uterine contractions is also performed. Regarding precision, EFM presents a sensitivity ranging from 28.6% to 62.6% and a specificity ranging from 77.7% to 93.2%

when the Apgar score (the sum of points given to rate the condition of a newborn 60 seconds after birth) is used as a measure of outcome. This means that the false-negative rate can be as high as 47.4% and the false-positive rate can reach 84.6% (112). In relation to its impact on therapy, use of EFM has been shown in randomized controlled trials to increase the rate of cesarean section. Regarding outcome, the results of randomized controlled trials and a large-scale study indicate that the impact of EFM in lowering intrapartum and neonatal mortality is limited to high-risk patients.

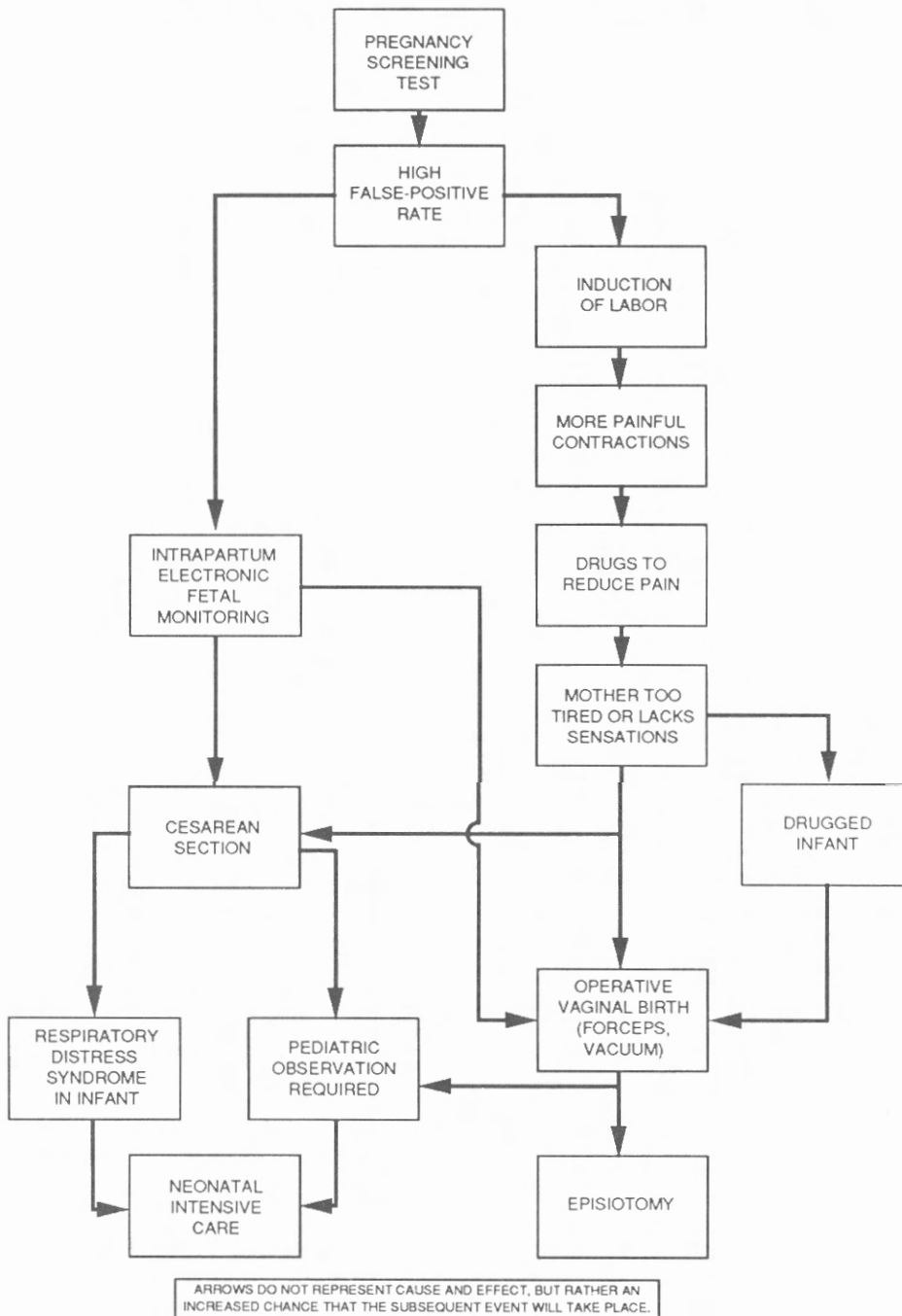
The absence of definite benefits is not restricted to EFM. Grant and Mohide (123) reviewed the evidence concerning the nonstress antepartum test to detect pregnancies at risk. Although many authors have claimed that the method has a predictive value as high as 45% for fetal distress during labor and sensitivities as high as 96.7% for predicting perinatal death and morbidity, different results were observed in four randomized trials. One study allocated patients randomly to groups to be monitored or not monitored, while the other three monitored all patients but randomly concealed the results from the obstetrician. In all four trials, however, the number of stillbirths was higher in the treatment (or reported) group and the number of neonatal deaths of normal fetuses was not significantly different between the groups. Again, the conclusions indicate a procedure whose ineffectiveness can be disguised by figures showing high diagnostic accuracy.

Some diagnostic technologies are not only ineffectual in improving patient outcome, they are also risky and, in many cases, represent a serious safety hazard. For example, Banta and Thacker (122) observed that electronic fetal monitoring presents high risks for both the fetus and the mother. In 0.3% to 4.5% of cases, scalp abscesses are produced by scalp blood sampling. Other common hazards and sequelae are hemorrhage, prolapsed cord, osteomyelitis of the skull, sepsis, and disseminated herpes infection. *EFM represents an increased risk for the mother* because it leads to higher probability of a cesarean section and of accidents involving lacerations from electrodes and uterine perforations with the catheter. In addition, a much higher rate of maternal infections has been observed in conjunction with EFM (122).

This characteristic of *induced risk* is not limited to EFM but can also exist with the most simple and noninvasive tests, which, by giving finite false-positive results, cause normal individuals to be subjected to unnecessary and risky procedures (124). Figure 13, based on Wagner (125), represents a typical chain of events induced by diagnostic tests in pregnancy, showing how a false-positive result can lead to a negative outcome of labor.

In summary, diagnostic technologies and monitoring systems, which are increasing in number, complexity, and cost more rapidly than other types of technology, should receive special attention regarding their *net* health benefits, and investigators should become aware that in many cases measurements of diagnostic accuracy can be misleading in this regard.

Figure 13. Possible chain of therapeutic interventions produced by screening and diagnostic tests with a finite false-positive rate. Adapted from Wagner (125).



G. COST ESTIMATION

Estimating the true costs of a health technology can be as difficult as measuring its effectiveness. A theoretical framework for assessing costs does not exist; most studies are empirical, and their conclusions depend upon the objectives of the assessment and who performs it. Accordingly, an assessment performed by a hospital administration would consider different costs than a similar assessment performed by a public health authority. In either case, it is important to appreciate that in economic terms, the true cost of a technological resource is its *opportunity cost*, which is its value in another use. However, due to, among other things, the imperfect market structure of health care, opportunity costs are not easily measurable (56).

The following three approaches to cost estimation are commonly found in the literature:

- 1) Charges—The amount charged by physicians and hospitals for delivering a technology is often taken as an approximation of its real cost. The shortcoming of this approach is the extremely variable profit margins adopted by different health providers and produced by different types of technology, e.g., drugs versus radiology. For hospital technologies, an additional distortion is introduced by *cross-subsidization*, whereby excessive rates charged for some services cover the insufficient income obtained from other hospital departments and technologies. In Latin America and the Caribbean, the phenomenon of cross-subsidization is of concern because of the unrealistically low reimbursement rates adopted by the Social Security System for some technologies and services. For all these reasons, the use of charges to approximate costs should be avoided whenever possible.
- 2) Aggregate costs—In many instances, the economic costs incurred by a technology can be estimated from an aggregate figure such as the public budget for a vaccination campaign, the cost of treatment of a disease (in problem-oriented assessments), or the internal budget allocated to a hospital service such as cardiac surgery. This aggregate cost approach has the advantage of eliminating the need to account for individual item costs. However, there are several limitations: for example, indirect costs are frequently not included; costs for technologies other than the study objective might be included; and the method is suitable only in certain circumstances.
- 3) Accounting—Accounting for all items that can contribute to the economic cost of a technology, although tiresome, is still the most usual and favored approach to the problem of cost estimation. The general philosophy is to identify and quantify all inputs used, and to evaluate the opportunity cost of individual resources.

Weinstein *et al.* (53) present a classification of costs as shown in Table 12. The same authors call attention to the need to carefully separate items that should go on the cost side from those that should be regarded as benefits. Accordingly, if treatment for hypertension leads to longer life and a higher probability of devel-

Table 12. Classification of costs associated with a health technology.

Type of cost	Example
Production costs	
Direct	Equipment acquisition and improvement Professional and nonprofessional labor Materials and supplies
Indirect ^a	Rent/building depreciation Space preparation and upkeep Utilities Support services Administrative services
Induced costs (and services)	Tests added or averted Treatments added or averted

^aAlso includes patients' time, productivity losses, and transportation.

oping cancer, the cost of treatment needs to be properly documented. On the other hand, additional years of survival should be counted as a benefit. Some of these problems will be discussed again in relation to cost-effectiveness analysis (see Section H, below).

The major problem with the accounting method is that some indirect costs are intangible, and frequently their assessment requires making educated guesses (56). The use of extreme values (maximum/minimum) for these costs can give an idea of the sensitivity of subjective estimations. Because of the guesswork involved, many analysts delete some items from the account list altogether. However, Warner and Luce (56) advocate a different approach in these cases. They suggest that items that are difficult to evaluate should be kept in the background, rather than abandoned, and should be brought into the discussion when the final results of a cost-effectiveness analysis are considered or when a decision involving the technology is going to be made.

The accounting approach for estimating the cost of a technology can be illustrated by the work of Banta and Thacker (122) referred to above (Section F.5). These authors estimated the total cost of electronic fetal monitoring (EFM) for the United States in 1977–1978, assuming that this technology was used in 50% of all deliveries, a figure confirmed by recent surveys (40). With 3.2 million deliveries per year, and EFM adding \$50 to the cost of each delivery, the aggregate estimation of the total cost of equipment and services is \$80 million. Randomized controlled trials suggest that the technique is responsible for 96,500 additional cesarean sections, each one at an added cost of \$2,300. Consequently, \$222 million is required to pay for the (induced) costs of cesarean deliveries associated with EFM. The costs of different complications produced by EFM are included as indirect costs in Table 13.

In comparison to the total cost of \$411 million, the authors observe that during the same time only \$80 million was spent annually in the U.S.A. for all public and private childhood immunization programs. This comparison is a good example of the role of cost estimations in decision making and formulation of policies

Table 13. Estimated total financial costs of electronic fetal monitoring (EFM) in the United States in 1977–1978.

Item	Cost (in millions)
Direct costs of EFM	
Equipment and services	\$ 80
Neonatal morbidity—scalp abscess	\$ 5.6
Maternal morbidity—infection	\$ 11.1
Induced cost of cesarean sections	
Equipment and services	\$222
Neonatal morbidity—respiratory distress syndrome	\$ 10.7
Maternal morbidity—infection	\$ 44
Indirect cost of cesarean sections	
Neonatal mortality	\$ 34.2
Maternal mortality	\$ 3.4
Total	\$411

Source: Adapted from Banta and Thacker (122).

regarding health technologies. A more accurate use of cost data, however, is to couple them with estimations of the health benefits accruing from the use of the technology. As observed by Warner (126), “the true social cost of a capital-embodied technology, or of any medical care, cannot be evaluated in an output vacuum.”

H. COST-EFFECTIVENESS ANALYSIS

Before discussing cost-effectiveness analysis, it is necessary to distinguish between *it* and a related but rather different approach, which is cost-benefit analysis. In the latter, all outcomes are evaluated in economic or monetary terms. This entails the difficult task of placing a monetary value on life, physical incapacity, pain, and suffering, an exercise frequently opposed because of its intangibility and its unethical implications. As a consequence, cost-benefit analysis is usually regarded as unsuitable for the assessment of health technologies. It is even less desirable for use in developing countries because it could accentuate the prevailing socio-economic disparities and inequities by placing value on years of life gained or lost according to local wage earnings and morbidity patterns. In consideration of these constraints, this discussion will be limited to cost-effectiveness analysis.

Adopting the methodologies discussed in Sections F and G of this chapter, independent estimations of effectiveness and cost are obtained: the former in quality-adjusted life years or other measure, and the latter in dollars per year or the total cost in dollars of a health campaign. Typically, the value arrived at is x quality-adjusted years of life per dollar. This figure is meaningless in isolation; it must be compared with the value for a reference or alternative technology to be useful to the decision maker. The solution is that cost-effectiveness analysis inherently assumes a reference condition, or a technology to which results are compared. In most cases the reference technology represents an alternative for addressing the

same health problem as does the technology under study. Other situations exist, however, in which this is not necessary; an excellent example is the controversy of free health care for all versus preventive campaigns that reach only privileged groups (127).

Many situations exist in which the costs incurred in the delivery of the technology and the benefits resulting from it are separated in time, sometimes by intervals of 30 years or more, as in the case of some preventive and screening technologies. Conversely, some technologies can produce immediate benefits, but result in future induced costs of much greater magnitude.

Economic theory states that calculations of future monetary earnings and losses should be corrected for the amount the principal could generate if invested at market rates during the period of time considered. This correction is called *discounting* and should be performed even in the absence of inflation since it represents the opportunity cost of investing the money. Similarly, health benefits, such as additional years of life, have different value for people depending on whether they are received immediately or at some future time. For this reason, effectiveness is *also discounted*, usually at the same rate as capital. This correction permits the worth of costs and benefits to be compared at the same point in time. A strong argument for discounting effectiveness measurements, such as quality-adjusted life years, is that if an additional year of life can be obtained now for \$1,000, investing the money for one year at annual rates of 10% would yield \$1,100 and 1.1 years of additional life one year later. This shows that \$1,000 used at the present will correspond to one year of additional life now, or 1.1 years one year later (116).

The main difficulty with discounting is choosing what discount rate to adopt. In general, values between zero and 10% have been used, and mostly rates between 4% and 6%. One argument for using rates below the market value is that funds for health and social programs should not be given the same opportunity cost as money from the private sector, because they promote the general interest of society and the well-being of future generations (56). Russell argues that discount rates should be standardized at 0%, 5%, and 10% in all cost-effectiveness analysis, and any other rates the analyst decides to use should also be standardized, to facilitate a comparison between different studies (128).

Russell's proposal—to perform several cost-effectiveness analyses using standardized discount rates—relates directly to the subject of *sensitivity analysis*. In most cost-effectiveness analysis, critical parameters such as prevalence of disease or the cost of support services are sufficiently uncertain to jeopardize confidence in the final conclusions of the study. By considering a *range* of values for these uncertain parameters, the *sensitivity* of our results to particular values can be tested. In many cases it is reassuring to observe that the conclusions will not change even if the parameter reaches absurd values. In other situations, a *threshold* value for the parameter can be identified, beyond which the preference for technology A must be switched to technology B (129).

Berwick and Komaroff (130) performed a cost-effectiveness analysis of a screening program to detect lead poisoning in children, a condition that can cause serious learning and mental disabilities, by measuring blood lead levels. The efficiency of such a program depends critically on the prevalence of lead poisoning in the population, as can be observed by the sensitivity analysis performed by those authors (see Figure 14). This result indicates that at very low prevalences the costs per case averted are quite high, and it could be argued that use of other technologies might present greater benefits for the same amount of money. However, for prevalences above 2%, the cost is dramatically reduced and, since many inner city areas have much higher prevalences, this conclusion would favor the promotion of lead screening as a cost-effective program.

Sensitivity analysis is a powerful tool to increase our confidence in the results of a cost-effectiveness analysis, and it can help the analyst identify aspects of the problem that need further investigation or more accurate data.

Very few studies in the literature have addressed the question of evaluating multiple technological alternatives, which is a high priority for developing countries in connection with problem-oriented HTA. One important contribution on this subject is a review paper by Weinstein and Stason (131) on cost-effectiveness of

Figure 14. Net dollar cost per case averted by lead screening, as a function of lead poisoning among children. Adapted from Berwick and Komaroff (130).

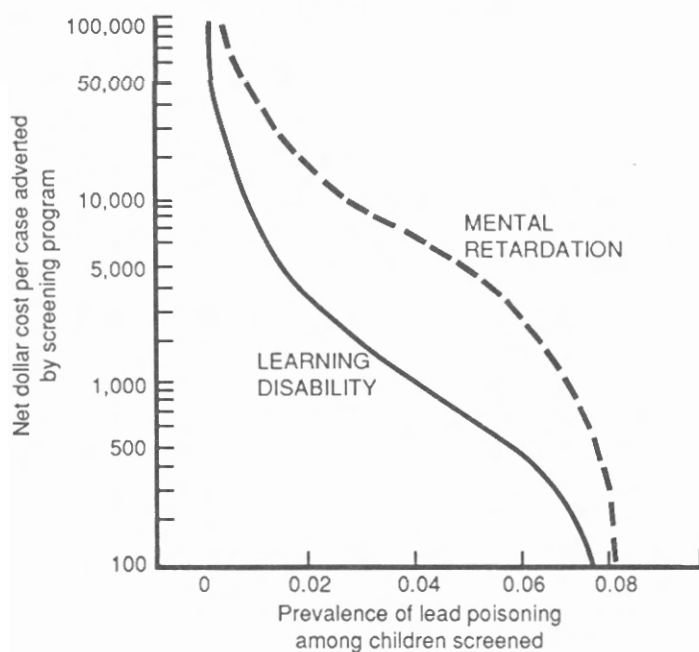


Table 14. Cost per quality-adjusted life year (QALY) of survival for different interventions to prevent or treat coronary heart disease.

Intervention	Cost per QALY (in 1984 dollars)
Coronary artery bypass surgery for left main disease and very mild angina	\$ 4,000
Beta-blockers in recent myocardial infarction	\$ 4,200
Coronary artery bypass surgery for three-vessel disease	\$ 7,000
Control of hypertension—treat diastolic pressure (DP) of 105 mmHg	\$ 12,000
Screening and dietary interventions in 10-year-old children targeted by family history	\$ 15,000
Coronary artery bypass surgery for two-vessel disease and severe angina	\$ 25,000
Control of hypertension—treat DP of 95 mmHg	\$ 26,000
Control of hypertension—screen and treat DP of 95 mmHg	\$ 27,000
Mobile coronary care unit	\$ 35,000
Selective coronary care unit admission (20% risk of myocardial infarction)	\$ 40,000
Coronary bypass surgery for one-vessel disease and severe angina	\$ 40,000
Drug treatment of hypercholesterolemia in adult men	\$126,000
Selective coronary care unit admission (5% risk of myocardial infarction)	\$190,000
Coronary bypass surgery for one-vessel disease and mild angina	\$470,000

Source: Adapted from Weinstein and Stason (131).

different interventions in coronary heart disease, which is an increasingly serious health problem in many developing countries (6, 66). These authors adopted the quality-adjusted life years of survival after intervention as a measure of effectiveness, and calculated all costs in dollars relative to 1984 values. The results of their review and estimates are given in Table 14, in increasing order of cost per quality-adjusted life year of survival. Although these interventions involve different conditions and patient characteristics, the large differences observed in the cost of additional survival years show the great importance of this line of work in deciding the optimal allocation of health resources. Given that some of the parameters and data contributing to the results shown in Table 14 are imprecise and might change with time or according to the study population, and given the more than 100-fold difference observed in benefit-for-dollar between some of the interventions, the argument is strong in favor of more careful evaluations and objective decision making regarding the incorporation and utilization of health technologies. In fact, a laissez-faire attitude and failure on the part of public health officials to take appropriate measures in the face of evidence of wide differences in cost-effectiveness would represent inappropriate use of scarce public resources.

I. RESOURCE-EFFECTIVENESS ANALYSIS

The optimal technological solution to a health problem might prove impossible to implement in a developing country because of lack of key health personnel or adequate maintenance capabilities. The resource limitations of developing coun-

tries require an adaptation of classical cost-effectiveness analysis, with its implicit assumption that once a certain amount of money is available, it can be quickly translated into a variety of resources needed to support the technology's operation.

One way of dealing with the lack of resources is to include into the cost side of the analysis the real amount that would be required to correct local deficiencies. Accordingly, a cost-effectiveness analysis of a technology that must be delivered by physicians in regions where they are in short supply should account for the costs of medical education or assume professional fees sufficiently high to guarantee doctors' permanent commitment. Similar reasoning would apply to electricity and hospital facilities. Although feasible, this approach would lead to inflated costs, which could distort the results of the study. By requiring that key resources be supplied, the technology or health program would have large secondary benefits (for example, provisions of electricity) which would be difficult to evaluate. Unfortunately, implementing the best technological alternative may require considerable time for the development of the necessary infrastructure, which is incompatible with the "impact" solutions required for most health problems in developing countries.

An alternative approach proposed by Panerai and Attinger (144) identifies the type of resources required by different technological alternatives. This approach has been called resource-effectiveness analysis and is illustrated by the diagram in Figure 15.

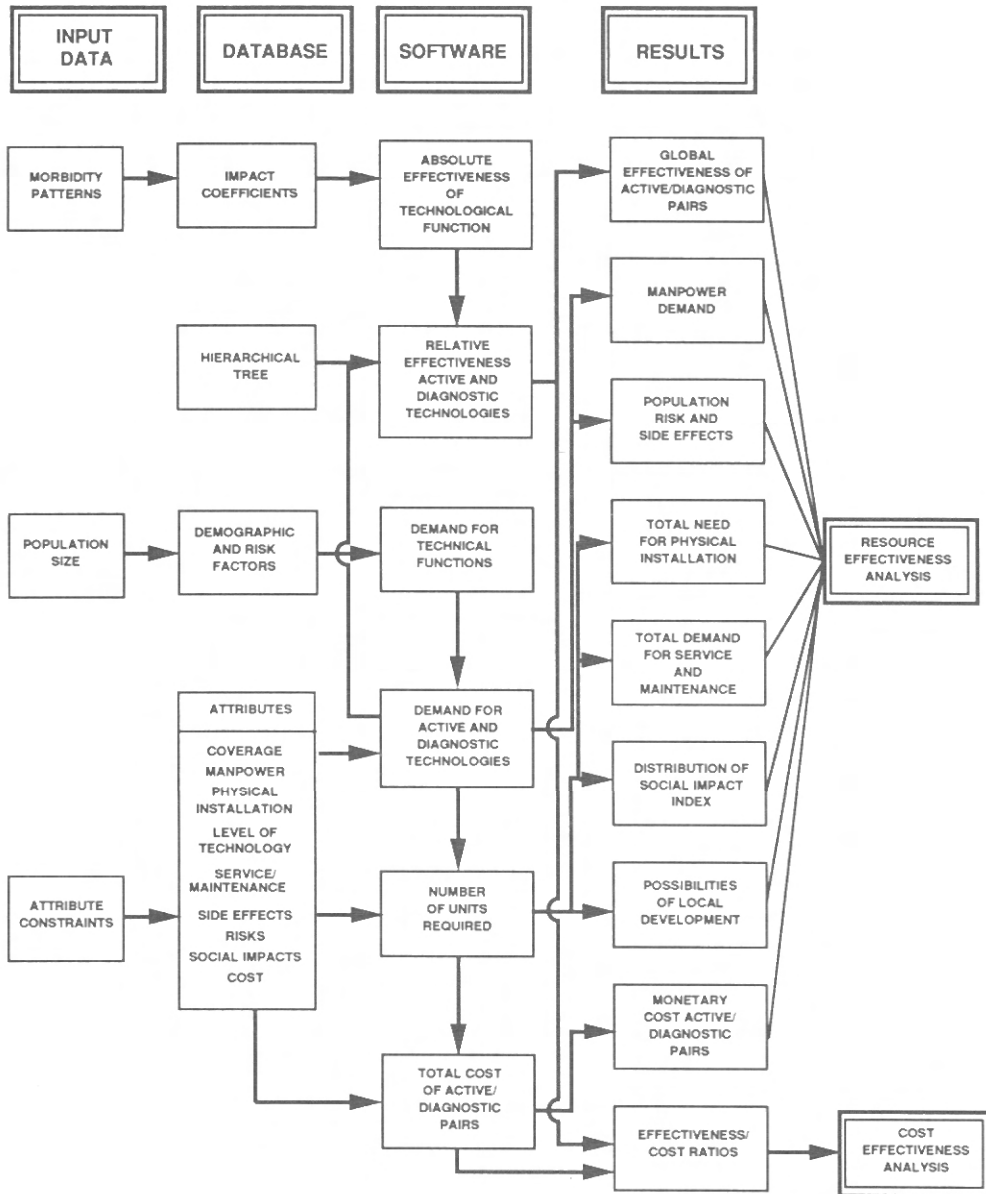
Resource-effectiveness analysis is particularly suited to HTA when there are multiple alternatives. Its objective is to improve the allocation of health technologies that can contribute to the mitigation of a given health problem. This approach examines the demand for different resources separately, and adds up the findings for each type of resource required (e.g., manpower or physical installations) to obtain profiles of total resources demand corresponding to the particular "technological package" selected. Alternatively, as will be discussed in Section K of this chapter, it should be possible to start from the resource profiles and compute the optimal technological solution for the region concerned on the basis of effectiveness and total resource cost.

The objective of resource-effectiveness analysis is to support the development of solutions that make optimal use of the resources already available in a region. The implicit assumption is that such solutions will be much more appropriate, since they will not represent a strain on the resource pool which could provoke abrupt and disruptive social changes.

J. DECISION ANALYSIS

Decision analysis involves a class of models that can help clarify the problem of choice under uncertainty (53). The method was initially applied to problems involving the clinical management of individual patients, where the uncertainties

Figure 15. Information flow in resource-effectiveness analysis of perinatal care technologies. Reproduced from Panerai and Attinger (114).

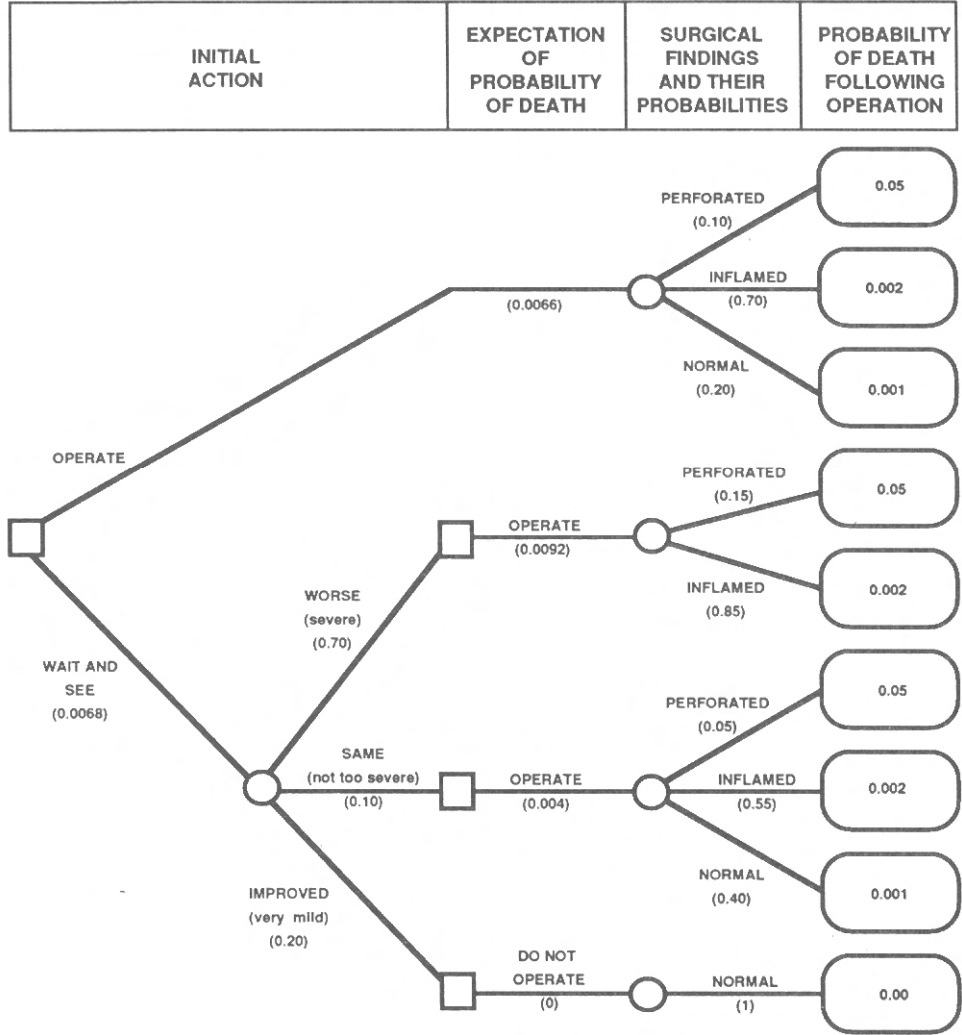


related to diagnosis and treatment make its use extremely appealing. More recently, it has been recognized that decision analysis can also be useful in dealing with public health problems (132) and, undoubtedly, in the evaluation of health technologies (52, 53, 133, 134). A review paper by Krischer shows that many appli-

cations of decision analysis have been devoted to health care policy evaluation (135).

A simple example can illustrate the principles and potential of the decision analysis method. Figure 16 represents the decision-tree for the problem of patients suspected to have appendicitis. The decision involved is whether these patients should undergo surgery immediately, or should remain under observation for some time before a decision to operate is made.

Figure 16. Appendectomy decision-tree for patients suspected to have appendicitis. Adapted from Pliskin and Taylor (136).



The first option, immediate appendectomy, involves a small risk for the patient and the possibility of unnecessary surgery. The option of waiting and observing the patient may avoid the unnecessary surgery, but there is a risk that the appendix will perforate, leading to a much higher risk of death. The tree represents the several options (out of decision nodes: \square) and outcomes (out of chance nodes: \circ). As shown in Figure 16, if the decision is to operate, there is a 20% chance that the patient does not have appendicitis ("normal"), a 70% chance that the appendix is inflamed, and a 10% chance that it is perforated. The outcome of interest is patient survival, and the probabilities of death for each case are represented as 1/1000 (surgical mortality in normal patients), 2/1000 (mortality with inflamed appendix), and 50/1000 (mortality with perforated appendix). These probabilities, prevalences, and incidence rates are obtained from hospital records or represent experts' estimates.

The decision sought is the one which will minimize the probability of death and maximize the chances of survival. To obtain the indication of which branch ("Operate" or "Wait-and-see") will lead to the minimum mortality, we operate backwards, from right to left, obtaining the *average probabilities* at each root branch. Accordingly, if the decision is to operate, the average probability of death is given by:

$$0.10 \times 0.05 + 0.70 \times 0.002 + 0.20 \times 0.001 = 0.0066$$

or 6.6/1000. Similarly, if the surgeon waits, observes the patient, and then decides whether or not to operate on the basis of the patient's later condition, the probabilities of death for three outcomes (worse, same, improved) will be 9.2/1000, 4/1000, and 0/1000, respectively. Thus, the average probability of death for the *decision to "wait-and-see"* is:

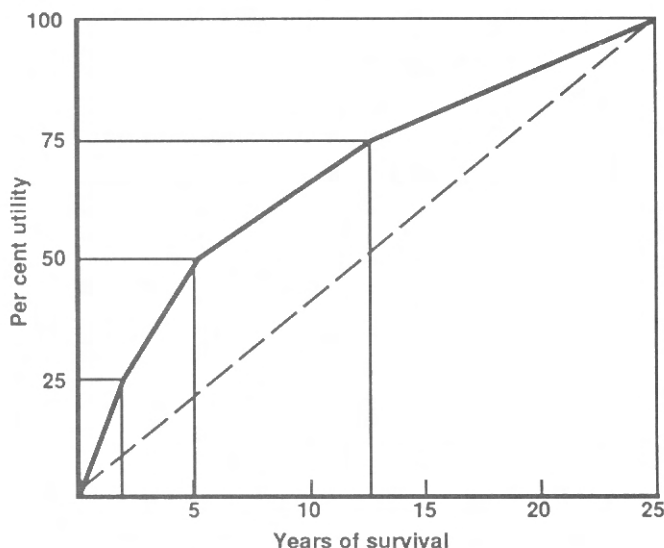
$$0.0092 \times 0.70 + 0.004 \times 0.10 + 0 \times 0.20 = 0.0068$$

Therefore, in this situation the probabilities are essentially the same and, *on a population basis*, it seems to make no difference if the surgeon operates immediately or waits and observes the evolution of the case.

The example presented in Figure 17 allows a discussion of the advantages and limitations of decision analysis from the standpoint of HTA in developing countries. One advantage is that decision analysis is a tool that can yield very accurate answers to problems involving choices where uncertainty exists, a frequent situation when diagnostic and therapeutic technologies are involved. In addition, the modeling process is relatively simple and it can be used in conjunction with sensitivity analysis, thus yielding a better understanding of the role of different parameters.

The disadvantages of the method are, first, that realistic representation of many problems of interest results in decision trees with an unmanageable degree of complexity, and, second, that the method requires an enormous amount of de-

Figure 17. Utility curve for years of survival in lung cancer. Modified from McNeil *et al.* (52).



tailed data, such as probabilities and prevalence rates, which are extremely difficult to obtain in developing countries. Notwithstanding these difficulties, decision analysis is a promising technique for dealing with many problems in HTA, especially in situations involving combinations of technologies.

Utility theory is a technique usually associated with decision analysis. Its objective is to elicit the patients' preferences for different outcomes or states of health (53). Two different health states are chosen to define the extremes of a utility scale. In one example, related to treatment of lung cancer (52), these limits were chosen as immediate death (following surgery), which was rated at a utility of zero, or 25 years' survival, which corresponded to a utility of 1.0. Considering that radiation therapy does not involve any risks of immediate death, patients were asked to choose between a number of years of assured life with that treatment and a lottery with a 50% chance of death and a 50% chance of surviving 25 years. Although we might expect that 12.5 years would be the average figure at which the choice would shift away from the lottery, in reality most people at risk of lung cancer would prefer 5 years of sure life to the lottery, indicating that, in general, individuals are *risk-averse*. The 50% gamble defines the point of 50% utility, because on an average people would survive $(0 + 25) \times 0.5 = 12.5$ years. Other gambles could be presented to the patients corresponding to a utility curve as represented in Figure 17. The utility scale (ordinate) represents a utility of zero for immediate death and 100% for a survival of 25 years. The 50% utility point is obtained as the certitude equivalent to a 50/50 lottery between death or 25 years' survival. The 25% and 75% points represent the same gamble when the 50%

utility (5 years) is used as the upper or lower extreme option, respectively. The dashed line represents the behavior of risk-neutral individuals. The actual results (curved line) indicate that individuals are generally risk-averse.

The usefulness of the curve in Figure 17 for decision analysis is to translate the different lengths of survival accruing from different alternative treatments (e.g., for lung cancer) into their real utility for the patients. Using this principle, McNeil *et al.* (52) observed that although surgery for lung cancer resulted in a better long-term survival compared to radiation therapy, the typical 10% mortality associated with surgery affects its utility for patients who, most commonly, are risk-averse. As a consequence, it would be expected that 71% of 60-year-old patients, and 100% of 70-year-old ones, would choose radiation therapy instead of surgery, according to the utility curves in those populations.

The importance of utility theory in conjunction with decision analysis, and the determination of realistic scales of outcome, is obvious. Utility theory can have many other applications in HTA, for example, in the estimation of appropriate values for the parameter (zero to one) that is multiplied by length of survival to yield quality-adjusted life years (see Section IV.F.1). This parameter can be identified with the relative utility that different states of health have for the individual. To illustrate this point, Table 15 lists the utility of several states of health for the general population and for dialysis patients.

Another potential contribution of utility theory would be the establishment of appropriate utility scales for weighing multidimensional social impacts. This possibility has not yet been widely pursued by investigators.

Decision analysis can be an important methodology for HTA. Previous sections have emphasized that evaluations of diagnostic technologies are usually limited in their accuracy and fall short of determining the technology's real contribution

Table 15. Mean utilities of different states of health for the general population and for dialysis patients.

State of health	Utility
Perfect health	1.0
Tuberculosis	0.68
Mastectomy for breast cancer	0.48
Depression for three months	0.44
Home dialysis for life:	
as rated by general population	0.39
as rated by dialysis patients	0.56
Hospital dialysis for life:	
as rated by general population	0.32
as rated by dialysis patients	0.52
Death	0.00

Source: McNeil and Pauker (137).

to outcome. By using decision analysis, it is possible to relate the accuracy of a diagnostic test to the decisions and outcomes stemming from the therapeutic technologies that are employed to treat a given health problem.

The use of decision and utility analysis to assess the impact of a diagnostic technology can be illustrated by the work of Pauker *et al.* (138) on the role of amniocentesis in the detection of Down's syndrome.

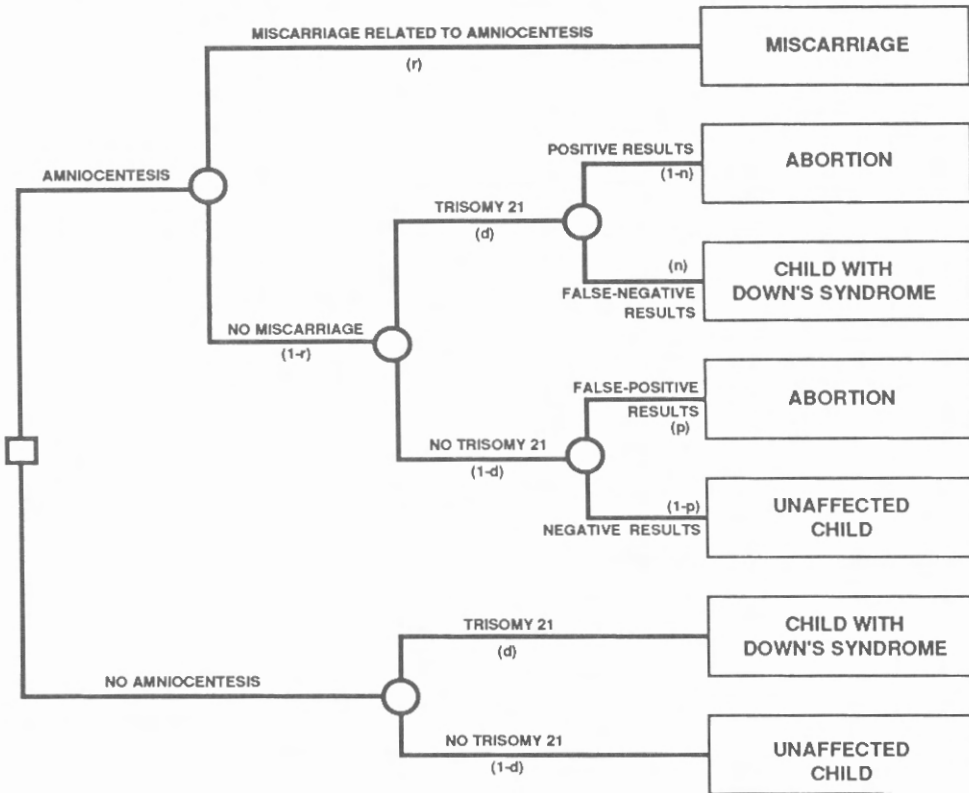
In women above 35 years of age, the risk of Down's syndrome (trisomy 21) increases rapidly, reaching a probability of 4/1000 for women aged 45 years. Amniocentesis can detect the occurrence of trisomy 21, but it entails a small risk of inducing miscarriage and can present both false-negative and false-positive results. Faced with a positive result, the expectant parents might decide to terminate the pregnancy. Figure 18 represents the decision-tree corresponding to the decision of whether to perform an amniocentesis or not, followed by several possible outcomes represented by chance nodes. Four possible outcomes are considered: miscarriage, abortion, child with Down's syndrome, and an unaffected child. A problem with the abortion outcome is that there is a small chance that a normal child would be aborted because of a false-positive amniocentesis result.

A utility analysis is performed to estimate the parents' attitudes towards the four outcomes considered. In this case a "cost scale" was adopted, with a cost of zero for the case of an unaffected child and a cost of 100 for the case of Down's syndrome. This cost scale is not meant to represent the economic and monetary costs associated with the outcomes, but rather reflects their emotional and psychological impacts. The cost of miscarriage is assumed to be equivalent to the cost of elective abortion. Given this assumption, the utility analysis concentrates only on the cost of abortion or miscarriage relative to the utility scale endpoints adopted. A typical population presents large variations in attitudes, corresponding to a mean cost of 25 with a standard deviation of 25 on the scale of zero to 100.

The decision-tree in Figure 18 allows several sensitivity analyses to be performed. Of special interest is the relationship between the accuracy of amniocentesis and the final decision of whether or not it should be performed. Since the risk of Down's syndrome increases rapidly with maternal age, this variable must be considered, as represented in Figure 19. In a reference condition where the risk of miscarriage after amniocentesis and the false-positive or false-negative rate are both one in 200, the proportion of women who should receive amniocentesis (taking into account the parents' utility curves) increases from just over 10% for women of 30 years of age to about 70% at age 40. However, if the accuracy of amniocentesis is increased (fivefold reduction of the false-positive and false-negative rates), the percentage of women who should receive the test does not increase in the same proportion—it increases approximately 10% uniformly for all ages. Finally, when both the safety and accuracy of amniocentesis are reduced, the indications for the test fall, reaching less than 50% for women 40 years of age.

The work of Pauker *et al.* (138) illustrates how decision and utility analysis can be

Figure 18. Decision-tree for amniocentesis in a population at high risk of Down's syndrome (trisomy 21). Adapted from Pauker *et al.* (138).



d = probability of disease (trisomy 21)

r = probability of miscarriage after amniocentesis

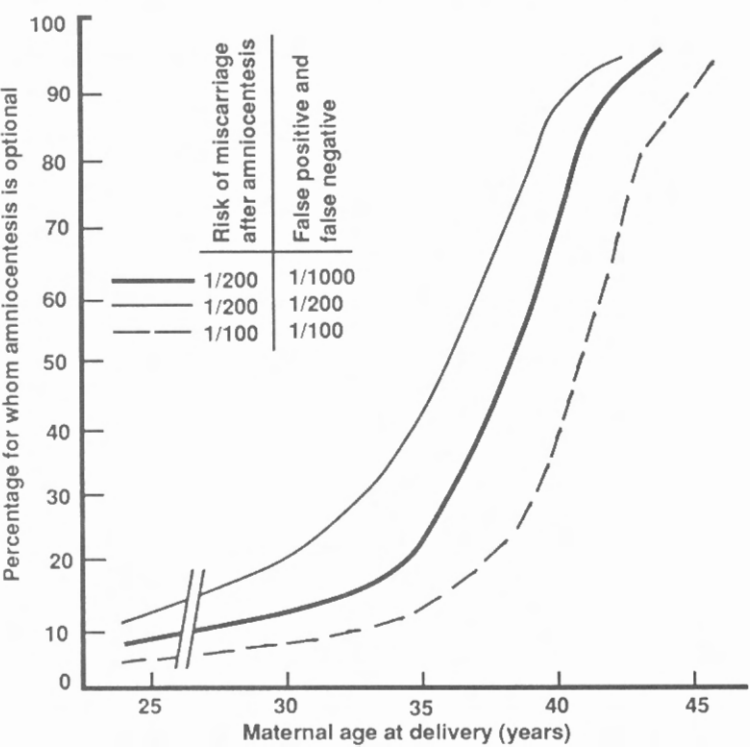
n = false-negative rate of amniocentesis

p = false-positive rate of amniocentesis

combined to advance one's knowledge about the implications of cost and accuracy of diagnostic technologies in relation to their real impact on therapy and health outcomes. By using the population's fertility curves as a function of age and the area under the curves in Figure 19, it should be possible to estimate the net marginal benefit to the population of technological innovations that increase the safety or accuracy of amniocentesis for trisomy 21.

Unfortunately, many real-life problems involve decision-trees of unmanageable complexity and cannot benefit from decision analysis. As described below, operations research is a more general set of techniques which can be of value in some of the problems that cannot be managed by decision analysis.

Figure 19. Proportion of a population for which amniocentesis would be appropriate considering the parents' attitudes towards abortion, as estimated from utility theory. Adapted from Pauker *et al.* (138).



K. OPERATIONS RESEARCH

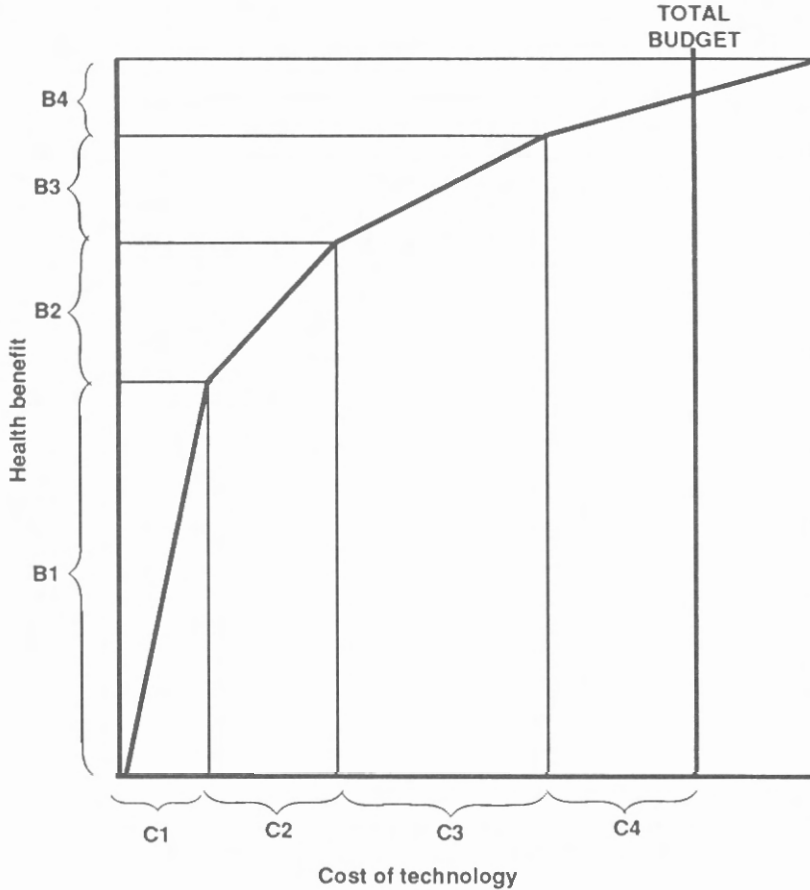
Operations research comprises a set of mathematical techniques concerned with the efficient allocation of scarce resources. Strictly speaking, decision analysis is one of these techniques, but this section will consider another important sub-group known as mathematical programming. The principles and scope of these techniques can be illustrated using the data presented by Weinstein and Stason (131) and reproduced in Table 14 (see page 75).

When a number of technological alternatives T_i present different cost-effectivenesses, the maximum health benefit within a limited budget can be attained through sequential allocations for these technologies in decreasing order of cost-effectiveness (139), as represented in Figure 20. In this case, a very simple “mathematical program” can be formulated as follows:

maximize benefit: $\Sigma b_i = b_1 + b_2 + b_3 + \dots$

within budget constrained to: $c_1 + c_2 + c_3 + \dots c_i = C_t$

Figure 20. Sequential allocations of health technologies in decreasing order of cost-effectiveness to maximize the total benefit when resources are limited.



This would maximize the total benefit obtainable with the subset of technologies considered, but limited to a total cost C_b , representing the resources available. The solution to this problem represents the *optimal allocation* solution.

Unfortunately, real problems are seldom as simple as the hypothetical example depicted in Figure 20. One of the main difficulties, which we have considered previously (Section I, above), is that resource limitations do not apply only to the total cost of the technology; several components, such as physical installations, manpower, and population distribution, must be taken into account. Consideration of the limitations imposed on different types of resources leads to multiple constrained equations, and a general mathematical program can be expressed as:

[illegible]

where x_1, x_2, \dots, x_n might represent the number of different types of technologies considered. The first equation is a generalized *objective function* where Z represents the total health benefit or a related variable; $f(\dots)$ is a function that relates Z to the individual technologies. The optimization program might involve the maximization of Z or its minimization, for example, if the latter represents a total mortality. Similarly, $g_1(\dots)$, etc., are functions that reflect the loadings of technologies x_1, x_2, \dots, x_n on different kinds of resources whose maximum availability in each case is r_1, r_2, \dots, r_m .

Operations research and, more specifically, mathematical programming, have been applied extensively to health care problems (140–142), but with the emphasis more administrative than patient-oriented (143). Although the impact of these approaches to health planning has been limited, either because of the inadequacy or oversimplification of the models proposed, mathematical programming should be kept in mind as a tool with a considerable potential for HTA. Chen and Bush (144) have shown the flexibility of the mathematical programming approach to the problem of establishing the optimal allocation of a countywide tuberculin testing program versus a statewide phenylketonuria (PKU) screening program. The latter involves a blood sample taken from every newborn to detect a biochemical defect that causes mental retardation unless treated by means of a special diet (144). In each case the authors have broken down the target population into 22 modules with different age, ethnic, and regional characteristics, and have estimated the costs associated with each module. An elaborate measure of health status that accounts for differences in quality of life and the transition probabilities between different functional levels was adopted as a measure of outcome or effectiveness. Instead of ranking the different “modules” according to the algorithm illustrated in Figure 20, Chen and Bush (144) adopted a dichotomous integer programming (DIP) model. In this case a module is either selected or not (dichotomous model), and its population cannot be fractioned (integer solution). Moreover, the DIP approach allows consideration of interdependencies among the activity modules due to technical, administrative, and political factors, as well as the total budget constraint (144). Assuming a total budget of \$350,000, the optimal solution indicates that two activity modules should take place for tuberculosis screening and four modules for PKU screening. Since the activity modules reflect the population distribution, among other factors, Chen and Bush’s approach represents an ingenious solution to the more general and difficult problem of modeling the spatial distribution of the population and health facilities (145).

L. MODELING AND SIMULATION

Models are expressions of our perception and understanding of reality. They can be constructed either physically, as in the “mock-up” of an airplane prototype, or abstractly, as in the conceptualization of the laws of production and consumption incorporated into economic theory. In either case, models contribute to research and development by two main mechanisms. First, they invite comparison with reality, which discloses their gaps and imperfections and leads the researcher to ask fundamental questions such as “What is missing? What is wrong?” In this sense *modeling* guides the process of inquiry and, therefore, it does not matter if the models are perfect or complete, as long as they serve to stimulate the investigator’s curiosity and insight. Second, models serve as surrogates for reality in a myriad of manipulations that are not feasible in the real system for economic, ethical, legal, or practical reasons. This application of models can only be realized if they perform with a certain degree of accuracy in relation to the phenomena they are supposed to describe. Destructive testing of mock-ups and forecasting of the impact of alternative energy systems are examples of the use of models for *simulating* events that might take place (20).

In HTA, modeling and simulation are already being used in connection with some screening and preventive technologies (43, 146, 147), but they clearly present a much broader range of potential applications (20, 148–150).

In his studies of cervical cancer screening, Luce (146) adopted a sophisticated model of disease staging involving 13 health states (Table 16).

A cohort population (women 30–39 years old) is initially assumed to be at stage H1. Its evolution through the sequence of multiple stages is followed, and its natural evolution is compared with that under different screening policies to determine their impact. The transition from one stage H_i to the next stage H_{i+1}

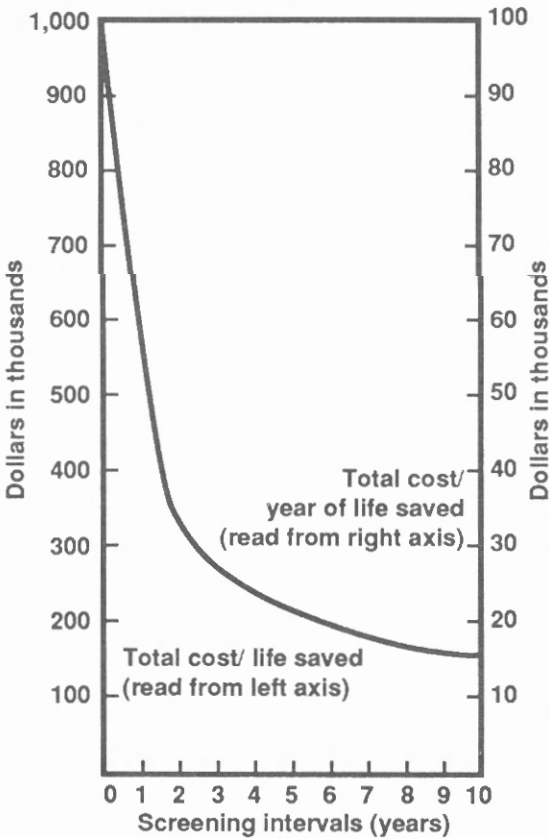
Table 16. Stages of disease process in cervical cancer.

Code	Condition
H1	Normal
H2	Reverted normal—having regressed from a previous state of dysplasia
H3	Dysplasia
H4	Carcinoma in situ
H5	Invasive carcinoma of the cervix
H6	High-risk, disease-free
H7	High-risk, dysplasia
H8	High-risk, carcinoma in situ
H9	High-risk, invasive carcinoma
H10	Hysterectomy
H11	Emigration
H12	Death due to cervical cancer
H13	Death due to all other causes

is described by a “transition probability” that is only dependent on the preceding stage, a process known as a “Markov chain.”

By simulating the process of population aging and different screening policies in relation to the interval of time between Papanicolaou tests, Luce (146) arrived at the cost-effectiveness curve shown in Figure 21. His results indicate that, from the standpoint of society, the optimal screening interval would be around eight years. Intervals below five years lead to a very rapid growth in costs for either a fixed number of lives saved or total number of years of life saved. However, the same study indicated by sensitivity analysis (i.e., simulation) that the optimal interval can change from six years at a discount rate of 0% (see Section H) to eight years at a rate of 12%. This sensitivity of cost-effectiveness in relation to

Figure 21. Cost-effectiveness ratios of different screening policies for cervical cancer in a cohort of women aged 30 to 39 years, assuming a discount rate of 10%. Adapted from Luce (146).



the discount rate follows from the time lag separating the screening costs from the health benefits and survival advantage resulting from early detection of cervical cancer.

A different kind of model has been proposed by Panerai and Attinger (151) for predicting the health impact and allocation policies for perinatal care technologies. The basic structure of this model is represented in Figure 22. The effectiveness of most technologies used in perinatal care is expressed by the potential impact of 43 "technological functions" on perinatal mortality, as estimated by a Delphi technique (Section B.2 of this chapter). The technological functions proposed represent utilization of a set or "package" of individual technologies for such purposes or objectives as "family planning" or "management of toxemia." Different scenarios are described by the prevailing risk factors and mortality profile as well as the existing infrastructure and demographic characteristics of the local population. Another important element of the model is a database containing information about several attributes of perinatal care technologies, such as cost, dependence on health personnel, risks, and physical installation require-

Figure 22. Block diagram for general model of technology assessment and resource allocation in perinatal care. Reproduced from Panerai and Attinger (151).

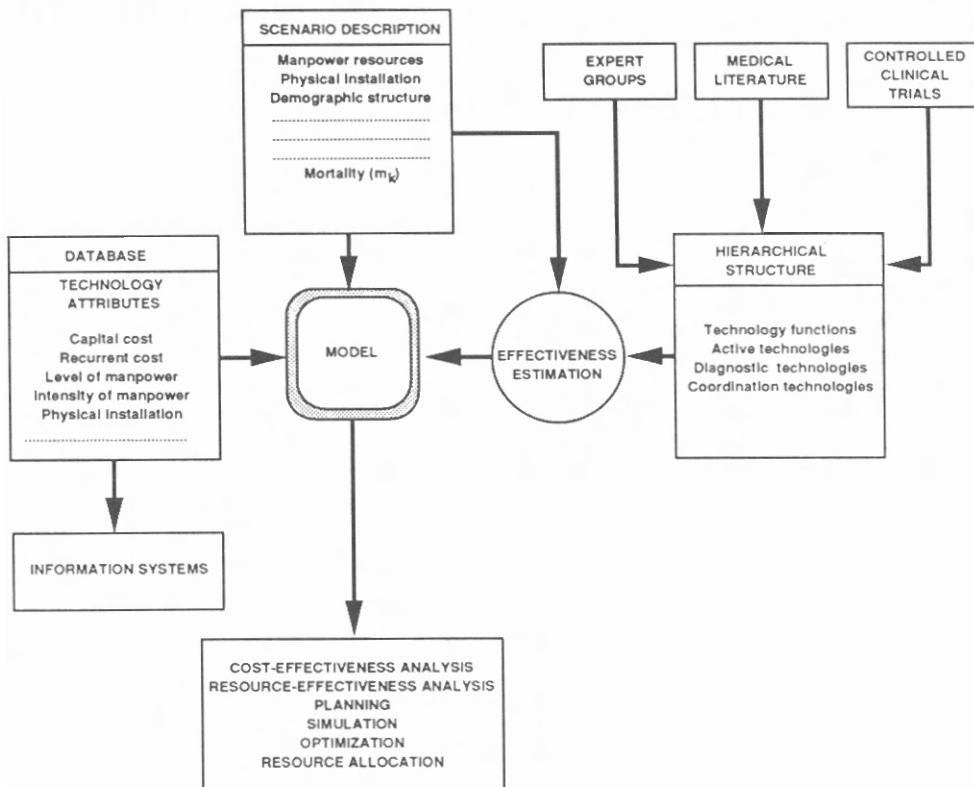
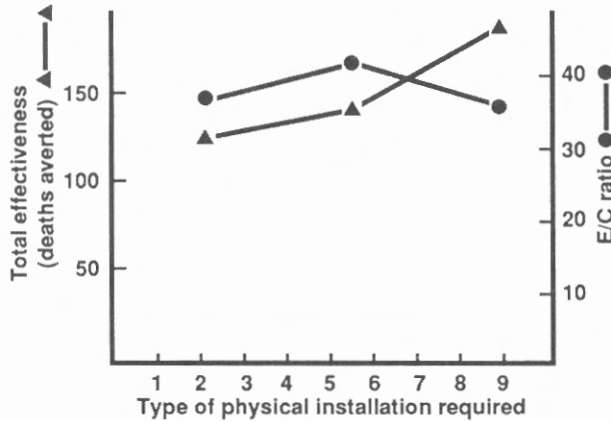


Figure 23. Simulation of the effect of graduated differences in quality of physical installations on the effectiveness/cost ratio and total mortality averted. Reproduced from Panerai (152).

[Quality of physical installations is expressed on an ordinal scale from "0" (no installation required) to "9" (complete surgical theater).]



ments. This information is essential for the allocation model. In addition, the database can be used in isolation as an information system about perinatal care technologies.

The core of the model represented in Figure 22 is the manipulation of the effectiveness, cost, and other information for different purposes such as cost-effectiveness analysis, resource-effectiveness analysis (Sections H and I), resource allocation, planning, and so on. The feasibility of the structure proposed has been tested in the resource-effectiveness analysis (Figure 15, p. 77) of perinatal care technologies in developing countries (152). Although most of the data required by this model still need to be collected so that individual technologies can be classified using simple ordinal scales to represent their main attributes (151), it is possible to perform simulations of the impact of infrastructure on perinatal mortality and cost-effectiveness of prenatal care, as shown in Figure 23. As constraints are imposed on the quality of physical installations, the total number of deaths that can be averted is reduced, but the cost-effectiveness remains unchanged because different technological packages are selected for each situation (152).

Both Luce's and Panerai and Attinger's models manipulate large amounts of data and require the calculation of many equations. For these reasons, they require the use of a computer for their most efficient implementation, but should not be labeled "computer models" because they can also be tested manually. The computer is not their *raison d'être*; it simply enhances their power and scope. This is important to bear in mind, since a prevalent misconception is that computer-based models are independent of the investigators' program design.

Chapter V

Technology assessment and education

A. PRACTICE OF TECHNOLOGY ASSESSMENT

The increase in the number of technology evaluation papers published in the United States has been rapid, as is shown in Figure 24 (83).

Such articles are also becoming more prevalent in developing countries. In Latin America, for example, Guillermo Llanos (153) identified 1,474 articles on evaluation of health technologies among more than 40,000 medical references analyzed. This production is distributed by years and countries as shown in Table 17. Articles from countries not listed were either not included in the Latin American Index Medicus, the principal source of citations, or were not classified under headings searched during this study. Table 18 shows the breakdown of articles according to type of study performed.

Although these data appear to indicate that the Latin American experience with this subject is substantial, as Table 18 shows, a high proportion of the papers are epidemiologic studies, such as clinical trials and case studies to evaluate drugs.

Only recently has some concern emerged for strengthening research capabilities for evaluating technology. This interest is reflected in some publications of the Pan American Health Organization, which include Spanish translations of English works on the topic (61, 72, 154-158).

In 1985, a research project was begun in seven countries in Latin America to analyze the process of technological development, covering the areas of technological policies, supply, utilization, and the effects of technology. Although this research is designed to provide a broad overview, protocols are being suggested to evaluate the cost, effectiveness, utilization, performance, and access to technology, topics that are of high priority for policy formulation. It is possible that the evaluation of technology in developing countries is purposefully concerned more with the general picture and less with micro-efficacy, cost, and safety of specific technologies, in contrast to the emphasis in developed countries.

If, as is beginning to become evident, investment in technology is concentrated at the tertiary care level, in the capitals, and in the private sector that covers a small proportion of the population, it is improbable that governments will be interested in supporting evaluation of that technology. On the contrary, the most interest is reserved for technology that is highly usable and effective and that

Figure 24. Publication of health care technology evaluation papers in the United States, 1966–1978.

[Papers deal with cost-effectiveness analyses (CEA) and cost-benefit analyses (CBA).]

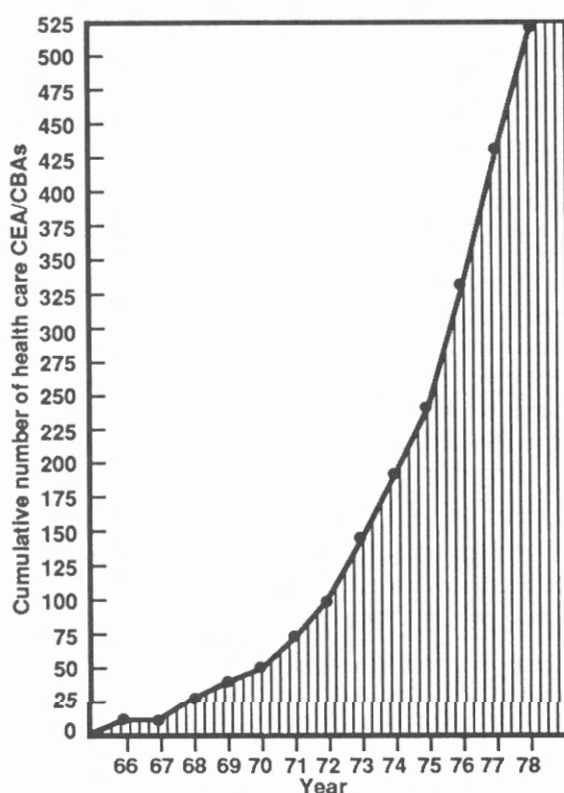


Table 17. Articles on evaluation of health technologies, published in Latin America between 1978 and 1982.

Country	1978	1979	1980	1981	1982	Total
Argentina	10	4	7	25	27	73
Brazil	209	158	144	145	144	800
Central America/Caribbean	4	2	1	8	5	20
Chile	6	4	19	27	30	86
Colombia	7	8	15	17	20	67
Cuba	1	26	32	—	—	59
Mexico	30	27	43	65	96	261
Uruguay	4	13	2	12	7	38
Venezuela	14	11	3	1	5	34
International	5	7	4	8	12	36
Total	290	260	270	308	346	1474
% of total	19.7	17.6	18.3	20.9	23.5	100.0

Table 18. Classification of articles on health technology assessment published in Latin America between 1978 and 1982, by type of study.

Country	Case study	Case-control study	Follow-up study	Controlled clinical study	Total
Argentina	62	8	2	1	73
Brazil	715	44	4	37	800
Central America/Caribbean	18	2	—	—	20
Chile	79	13	10	6	108 ^a
Colombia	127	21	1	8	157 ^b
Cuba	50	6	2	1	59
Mexico	208	35	4	14	261
Uruguay	35	2	—	1	38
Venezuela	26	4	4	2	36
International	26	4	4	2	36
Total	1346	139	31	72	1588
% of total	84.8	8.7	2.0	4.5	100.0

^aIncludes 22 articles from 1983.

^bIncludes 17 articles from 1983 and 73 from 1974–1977.

addresses problems of importance to the major population groups. From this perspective, it is more important to evaluate the cost-effectiveness and impact on overall health indicators of more complex technological functions. Although this does not preclude the evaluation of recent and high-cost technology, the emphasis, at least in evaluations carried out with public funds, will probably be on technological functions that affect broad segments of the population.

Currently, the methodology to support these evaluations is weak. Its further development will be necessary in order to deal with broad cultural, social, economic, and political variables.

B. TRAINING OF RESEARCHERS AND PRACTITIONERS

Health technology evaluation in developing countries largely reflects the influence that the teaching of epidemiology has had on medical and public health education. Epidemiologic methods, as Llanos points out (153), are being employed to evaluate technology. Epidemiology courses at the undergraduate and particularly the public health master's degree levels have encouraged the use of statistical analyses. However, examination of the work carried out reveals that serious limitations exist in conceptualization, design, and analysis. A large proportion of the evaluations are done with poorly defined samples and weak designs.

One remedy to the problem would be to modify epidemiology courses to strengthen training in design and use of the most frequently applicable methodologies. At the same time, it would be advisable to provide continuing education specifically directed toward those researchers who are already involved in evaluation work. These two strategies will succeed in strengthening both current evaluative expertise and that of the future.

These changes are not sufficient, however. Additional efforts must be made to expand the community of researchers involved in evaluations. These efforts should focus on three different groups. The first is specific professional health personnel, such as physicians, dentists, pharmacologists, and nurses, among others, so that the ability to evaluate technology critically is widespread within each profession and specialty. Important steps have been taken in this direction for professionals in the field of maternal, child, and family health in the Americas.

Meetings for these professionals held from 1984 to 1986 dealt with prenatal care technology, delivery care technology (159), and the design of research proposals that take into account behavior and culture in the analyses of maternal and child health technological innovations and policies. Similar efforts have been initiated in the Americas for technologies related to chronic diseases (160, 161) and dental health (162). These projects should stimulate evaluative activities on the part of the professionals who use the technologies and who thus have an influence on new developments and innovations and on their dissemination.

A second group toward which training and education should be directed consists of hospital administrators and health services and system planners. This smaller but important group should be trained to use information from assessments as well as to perform and/or support evaluation projects, though it is probable that the evaluations will be carried out by more specialized professionals. Currently, a large proportion of administrators and planners have not had specific training opportunities in administration; consequently, they should be provided with training through nonconventional methods, such as independent study programs. Training in technology assessment methodologies, particularly those with broad applications, should be included in health administration instruction programs. As these programs are located in public health schools, public administration and business schools, service institutions (social security, ministry of health), and institutes and specialized associations that already collaborate, such interdisciplinary cooperation should be easy to arrange. At present, the Association of University Programs of Health Administration (AUPHA) and the Pan American Health Organization are working to arrange the introduction of technology assessment into health administration programs. This task should not be complex since all these programs already include courses in quantitative methods, statistics, computation, political science, engineering, and practically all the disciplines that are required for this training.

The third group is made up of public-policy makers and other opinion leaders whose input helps forge policy. This large and multisectoral group is critically important, and a different strategy is required to reach its members. A variety of ways should be sought to gain access to these persons, in order to sensitize them to technology-related problems and train them to use and interpret technology assessment information and to formulate and analyze public policies in light of processes of health technology development. Decision making takes place in science and technology councils, ministries of science and technology, and specialized offices in this field in every sector. Universities and rector councils, re-

search institutes, associations of producers, and scientific and professional associations should be among the targets of this third effort.

So far the discussion has dealt with the human and institutional dimension of training for technology assessment. It is also necessary to discuss the repertoire of methodologies. This document has emphasized available methodologies within the frame of reference of the technology life cycle. This framework helps clarify the process by which knowledge is applied to solve problems and the instances in which evaluation is required. But the framework can also be expanded to include other phenomena and ways of thinking about the technological process and the discipline of technology assessment. Other documents exist that address this broader vision of the process of technological development from the standpoint of basic human needs, the theory of dependency, criticism of the overall effects of the technology, and other intellectual constructs.

The different methods of technology assessment described in the preceding chapter vary in their usefulness to the three target groups—clinicians, administrators, and policy makers. Some methods are more appropriate for obtaining information on the effectiveness, performance, or results of the technology in question, and thus are most useful to health professionals who need to decide whether to employ that technology. Administrators, whether they are concerned with a single hospital or a regional health system, require more integrated data on the cost-effectiveness and public health benefits of a technology. This type of information is also useful at the policy formulation and evaluation level, but it is insufficient. To policy-makers, the social cost and overall social, economic, political, and ecological impacts of a technology are the priority concerns.

C. SUPPORT FOR ASSESSMENT PROJECTS

Technology assessment activities are generating a body of knowledge that is being compiled and disseminated. The Office of Technology Assessment of the United States has carried out significant work in this field, as have other groups and institutions identified in a recent publication from the National Academy of Sciences of the U.S.A. (163). In developing countries, information is scattered and is neither pulled together nor reviewed to determine the state of the art in a given field. Thus, to the low level of production of evaluative works must be added the problem of their reduced dissemination and the researchers' limited access to references.

Under these conditions, national and international support for technology assessment projects should encourage exchange and collaborative works. The World Health Organization, through its regional office in Europe, and the Pan American Health Organization have given impetus to the idea of collaborative works based on common protocols. Although the progress is just beginning to be seen, it indicates that efforts are being made and strengthens the idea of cooperation between research groups. The experience in maternal and child health described

previously demonstrates that collaborative projects involving a network of cooperation among countries are feasible.

An advantage derived from intercountry collaboration is that it makes possible intercountry comparison of factors influencing the utilization of a technology and their association with costs and policy variables, on the one hand, and with the technology's impact on individual and collective health, on the other. This comparative analysis improves the analytical capacity of the methodologies employed, which frequently are deficient in their treatment of policy variables, such as the influence of reimbursement systems, investment projects, financing systems, and others whose effects need to be examined.

D. USING THE RESULTS OF ASSESSMENTS

Little evidence exists as to what influence the information derived from technology assessments has at the three decision-making levels described above. In the same way that a new diagnostic technology may provide information that would modify the treatment regimen indicated by a traditional medical diagnosis, information from a technology assessment can have an impact on decisions about technology selection and distribution. Russell and Banta (164) examine the options of direct and indirect control of technology, giving a good perspective on the relationship between assessment information and certain types of decisions.

Persons engaged in evaluative research should clearly specify the needs and priorities that influence them in the design of their projects. It must be understood that since technology assessment is an instrument of policy analysis, discussion of research styles is necessary and justified.

Traditionally, research activity has been perceived as isolated, independent, and protected from the contentious world of policy making. This idea should be reconsidered and contrasted with a style of research in which decision makers interact with researchers and the latter transcend the role of generators of information and become participants in the processes of change that can be derived from their research.

E. POLICY FORMULATION CHALLENGES

The complex challenges facing developing countries can be transformed into opportunities through development strategies. One fundamental factor is science and technology, the utilization of which presents opportunities for both economic development and social change.

For example, the Latin American market for technological products, in the form of drugs, biologicals, and medical devices, is estimated at \$10 billion annually, which provides an opportunity for economic development centered on technological capacity in the health field. The social impact of technology can be increased substantially if policies, investment plans, and investment and expenditure bud-

gets earmark highly effective technology for distribution to communities with the greatest health needs and to services to which large population groups have access. Today, domestic and international market forces, along with other political factors, have acted to concentrate technology so that the opposite situation prevails.

F. CONCLUSIONS

Both the users of data obtained from technology assessment and the researchers, who respectively represent demand for and supply of the information, share the responsibility of promoting HTA activity and the training of evaluators. Educational institutes need to commit resources and generate training opportunities for health technology evaluators, and to train decision makers to interpret and utilize the information that emerges.

International agencies have the opportunity to support and facilitate collaborative research between groups in different countries. The knowledge that is generated should be made accessible and be widely disseminated.

To promote interaction among research groups, collaborative projects must be designed. Both health professionals and decision makers at the administration, planning, and public policy levels should be involved in formulating priorities and in mobilizing national and international resources.

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Assessing the effectiveness, safety, cost, and social impact of health technologies assumes particular importance in developing countries, since proper application of new technologies has the potential to greatly improve health status and the delivery of health care, while their inappropriate use can waste scarce resources. This publication presents an overview of how technology assessment methodologies that were developed in the industrialized nations can be applied to address priority health concerns in developing countries and what problems may hinder these assessments. Using results obtained in actual assessments as examples, it illustrates the most important methodologies and their advantages and disadvantages. Training for personnel who perform technology assessments is also considered. This publication is intended for the professional who has a sound knowledge of evaluative techniques and would like to apply that knowledge to health technologies.



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