

DEVELOPING HEALTH TECHNOLOGY ASSESSMENT IN LATIN AMERICA AND THE CARIBBEAN



Organization and Management of Health Systems and Services Program
Division of Health Systems and Services Development
Pan American Health Organization
Pan American Sanitary Bureau, Regional Office of the
World Health Organization

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FOREWORD

Since the beginning of this decade, the majority of countries in the Region of the Americas have been reforming or considering the reform of their health systems and services for the express purpose of promoting equity in health and access to health services, increasing efficiency in the allocation of resources, improving the effectiveness and quality of care, ensuring financial sustainability, and promoting community participation and intersectoral action.

Technology development has played and continues to play an essential role in promoting health and developing health systems and services. Properly evaluation of its introduction and use can contribute to the achievement of the stated objectives.

In the view of the Pan American Health Organization (PAHO), health technology assessment (HTA) is an essential component of the regulatory role of the health authorities and can help to strengthen their leadership.

However, after a promising start, stagnation or even setbacks were noted in the conceptualization and implementation of HTA activities in the late 1980s and early 1990s, in the Region. This occurred at a time when, as a consequence of the reform processes mentioned above, needs were growing and challenges were multiplying.

This document is not a manual on HTA, although the first part includes a section on basic concepts that is primarily intended to clarify the scope of a number of terms generally used in this field. It is a strategic document intended to help modify the situation described above, identifying the conceptual, methodological, and programmatic bases for lending impetus to actions by PAHO and the countries in this field. Its principal audience falls into two categories: first, policy-makers and stakeholders in health systems and services at both the national and subnational levels in the Region; and second, PAHO technical personnel, both at Headquarters and in the field. Added to this are individuals and groups interested in this field (health professionals, university professors, professional associations, members of consumer and user organizations, etc.).

The document consists of two parts: Part One presents a number of basic concepts pertaining to Health Technologies (HT) and HTA, analyzes their importance, and seeks to respond to a number of elementary questions (what, how, when and why are HTs evaluated?, to whom are the results of

HTA directed? and who is evaluated?), and the role of HT and HTA in the programming activities of the World Health Organization (WHO) is described.

Part Two refers specifically to HT and HTA in the Region. It contains a brief analysis of the relations between Health Sector Reforms (HSR), HT and HTA; a description of HT situation in the Region; a description of PAHO program activities with respect to HTA; a strategy proposal for HTA in the Region, and a brief description of the elements that can permit PAHO to develop its technical cooperation in this field.

A working group from the Division of Health Systems and Services Development of PAHO has been given the task of preparing this, coordinated by Dr. Alberto Infante. A first draft was discussed internally in late 1996. Contributions came from participants in two subregional workshops on the methodology and practical application of HTA (Mexico DF, April, 1997 and Santiago, Chile, October, 1997) and a staff members' meeting of the Division of Health Systems and Services Development/Organization and Management of Health Systems and Services (HSP-HSO) at Headquarters and in the field (Antigua, Guatemala, May, 1997), and a panel at the XIII Annual Meeting of the International Society for Technology Assessment in Health Care (ISTAHC, Barcelona, May, 1997) made contributions toward a new version. The third version was distributed to 30 experts in Europe and the Americas. Some of them, listed in Annex A, were invited to a meeting to discuss the document and the results of the survey and to propose modifications (Ottawa, Canada, October, 1997). Finally, the fourth version was discussed again in a new subregional workshop on HTA (Bogota, February, 1998). Summing up, about 200 high level experts and professionals contributed along one a half year.

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HEALTH TECHNOLOGY ASSESSMENT



1.1 INTRODUCTION

Traditionally, most of the decisions on health technologies (defined as a drug, medical device, a software, or equipment, a procedure, a given way of providing care) have been made by health professionals, and, in particular, by physicians. Most of the time, such decisions required information on whether a new technology was actually doing what it was designed to do and whether it produced unexpected results. Even well into the twentieth century, such information was obtained largely through empirical observation. In recent decades, rigorous clinical trials have been introduced in order to determine the effectiveness of certain treatments.

More recently, the circle of those who "need to know" has been widened and diversified. In addition to service providers, that group now includes lawmakers, officials, health administrators, researchers, biomedical engineers, managers of the pharmaceutical industries and medical equipment, and patients and families. The nature of the information requested has also expanded. In addition to information on safety, risks, and the efficacy of HT, information is requested on the effectiveness, the economic implications, the quality of life associated with their use and the ethical, cultural, and social implications of their dissemination¹. In other words, a transition is being made from an assessment based mainly on the needs of HT producers to one that gives priority to the individual and collective needs of HT^{2, 3} users.

Assessment of the result of clinical interventions has always existed. The first recorded clinical trial (for the treatment of scurvy) dates back to the eighteenth century⁴. By the 1960s clinical trials had become a prerequisite for marketing drugs and certain health products. After the creation of the Food and Drug Administration (FDA)⁵ in 1931, HTA strictly speaking received a strong boost in the 1970s with the establishment of the Office of Technology Assessment (OTA) by the U.S. Congress. This was the first public agency created for the specific purpose of generating information in this field. Its first report was published in 1976⁶.

1.2 SOME BASIC CONCEPTS

Technology is understood as the application of empirical and scientific knowledge for a practical purpose. The term Health Technologies (HT) initially referred to “the drugs, equipment and medical devices, medical and surgical procedures, and the organizational models and support systems” necessary for their use in patient care⁷.

Since its formulation, this definition has been expanded to: i) include all technologies used for personal health care (for both the healthy and the sick), and ii) emphasize the importance of the personal skills and knowledge necessary for their use, something not sufficiently explicit in the initial definition⁸. In certain cases, technologies used in environmental care have also been included when their relation to human health has been demonstrated. Nevertheless, the initial definition is the most widely disseminated and accepted.

While acknowledging the importance of the environment related technologies, this document refers basically to those technologies utilized in personal health care (protection against risk, prevention of injury, diagnosis, treatment, and rehabilitation) with priority given to the technologies used in health systems and services⁹. Figure 1 outlines the different levels of action reflected in the application of health technologies.

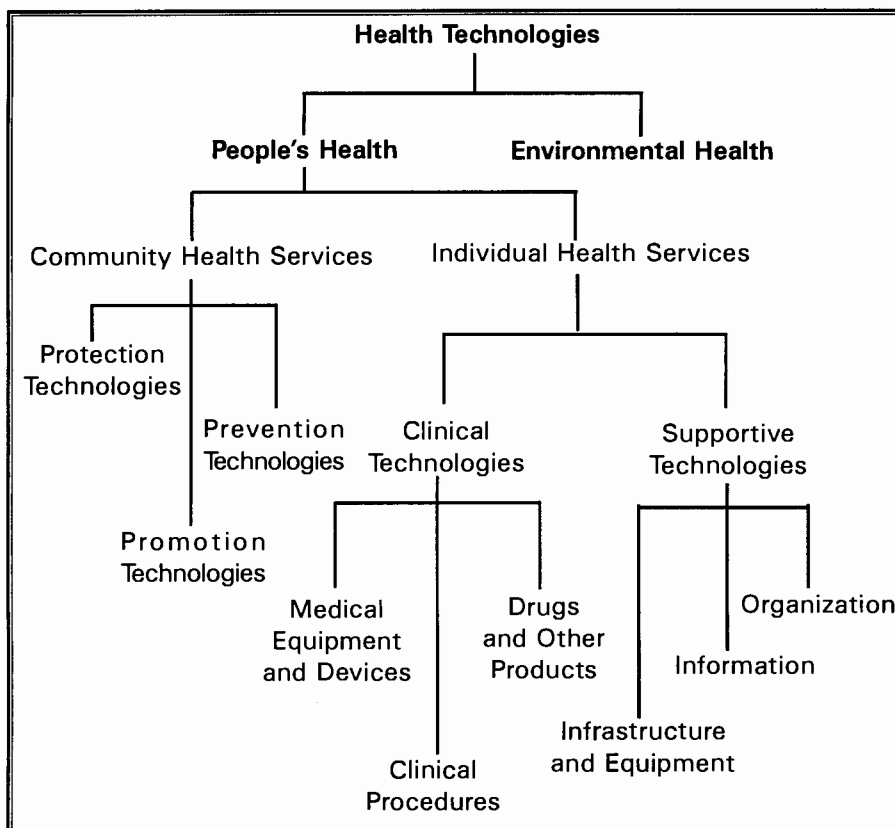
In addition, HTA is the “comprehensive way to research the technical (almost always clinical), economic, and social consequences of HT utilization in the short and the long term, as well as its direct and indirect effects, both desired and undesired. Assessing a health technology makes it possible “to present information on the patient’s alternatives to clinics, patients, and others,”¹⁰ and frequently provides elements that orient strategic decision-making related to health insurance coverage or resource allocation, including the purchase of equipment¹¹.

However, HT is often identified with equipment only (and, more specifically, with expensive, sophisticated and/or new equipment) and HTA reduced to procedures of registration and authorization prior to their use or to maintenance and supervision tasks during their useful life. And although most of the basic concepts of HTA were broadened some time ago to include drug assessment (and, sometimes, radiology and laboratory procedures), this does not happen in the other fields included in the previous definition.

Sometimes there is a tendency to confuse HTA with research. In this regard, it is necessary to bear in mind that basic research seeks to generate new knowledge about normal physiological or pathological processes, and

that applied research uses basic research findings and other sources to design new solutions to problems of prevention, treatment, cure, or rehabilitation¹².

FIGURE 1: HEALTH TECHNOLOGIES



Source: authors

In addition, HTA is increasingly understood as an “analytical process aimed at estimating the value and relative contribution of each health technology to the improvement of individual and collective health, taking into account its economic and social impact.”¹³ That is, HTA is not a speculative or purely academic discipline but a systematic interdisciplinary process whose objective is to effect change¹⁴.

A basic feature is that health technology assessment is carried out in order to *orient decision-making* (by clinicians, patients, financiers and insurers, planners, health service administrators, policy-makers, etc.). It is therefore grounded in the available basic and applied research and a comparison of the divergent views of specialists; it is then placed within the context of cost, opportunity, effectiveness, and acceptability¹⁵. In this regard, it is becoming increasingly important to consider not only the benefits, risks, and costs of

HT for those who now receive it, but also for those who need it but do not receive it.

TABLE 1: SOME BASIC HTA CONCEPTS

Safety:	the expected results of the use of HT greatly exceed(s) the probable risks.
Efficacy:	the expected results are obtained in the expected manner under ideal conditions.
Effectiveness:	the expected results are obtained in the expected manner under practical conditions for the application of HT.
Cost-Effectiveness Analysis:	links the effectiveness of several HT (e.g. expressed in the number of lives saved or the number of disease-free days) with costs (expressed in monetary units) ¹⁶ .
Usefulness:	an HT is useful if the quality of life (measured in objective and/or subjective terms) improves as a result of its application.
Cost-Usefulness Analysis:	links the cost of HT to survival, adjusted by the quality of life.

Source: authors

Since the purpose of HTA is to “promote change” rather than “knowledge for knowledge’s sake,” the strategies for disseminating results and analyzing the factors that promote or hinder the adoption of the conclusions and recommendations are part of the work of those who devote themselves to HTA.

1.3 WHY IS HEALTH TECHNOLOGY ASSESSMENT IMPORTANT?

Over the past 15 years, interest in HTA has been growing in developed countries for one or more of the following reasons:

- ▶ increasingly precise knowledge about the *variability of clinical practice*, which can be attributed to factors such as clinical/epidemiological

diversity, uncertainty, acceptability, accessibility, differences in training and/or incentives, etc. This can lead to professional practices that are inconsistent and possibly inappropriate in certain instances (e.g. the rate that a given surgical or pharmacological procedure is used in two provinces in a country or two cities in the same state can range from 28 to 163 per 100,000 population, even though the models for organizing the services and training professionals are identical)^{17, 18, 19}.

- ▶ evidence of high levels of *uncertainty about the real impact of many of the most widespread diagnostic and therapeutic interventions* on individual and collective health, especially, in terms of reducing suffering, improving the quality of life, or extending life²⁰.
- ▶ the *speed with which new technologies are introduced*, since new possibilities in diagnosis and treatment are evolving very rapidly and pressure from the interests involved (industry, potential users, etc.) is so strong that innovations are often introduced for widespread use well before their real clinical impact, ethical consequences, and economic and social impact can be rigorously assessed²¹.
- ▶ the *incompatibility of many new technologies (particularly diagnostic)* with the old, with its consequences on both patient care (more interventions, greater dehumanization) and the cost of every procedure; this, combined with the trend toward more procedures driven by the aging of the population, would explain to a great extent the growth of health expenditure in many countries²².

The foregoing has created growing concern by society about these issues and led public authorities to search for instruments to determine the degree of individual and collective usefulness of the available health technologies, their cost, the conditions under which they should be introduced, and where their use is considered appropriate.

Thus, there is growing awareness that not everything that is technically possible (that is, safe and effective) is useful (that is, effective and efficient) for bringing about improvements in individual or collective health, and that to control costs without arbitrarily reducing access to health care, we will have to know much more about the safety, effectiveness, and appropriate use of drugs, tests, and procedures²³.

1.4 WHAT AND HOW TO EVALUATE?

HTA essentially considers: i) safety, ii) efficiency, iii) effectiveness, iv) usefulness, v) economic impact, vi) organizational consequences, vi) ethical implications, and vii) social impact. There is an abundance of literature on each of these aspects in both English and Spanish^{24, 25, 26}.

The *method* commonly used to assess a technology, and the first step for all the others, is to consolidate the best available evidence²⁷. To do this, collecting, analyzing and synthesizing information of good quality is needed. This information can be both, primary (content in systematic records and files, and by databases) and secondary (content in originals and/or review works)^{28, 29}.

Among the primary information highlight that provided by demographic and epidemiological statistics, by the surveillance systems (for example, those of compulsory notification diseases, or drugs side effects), by the discharge records information systems and by some specific diseases or clinical situation records (for example, cancer and transplants). Among the secondary information content in originals highlights those provided by descriptive observational studies (for example, case series, or incidence and/or prevalence inquiries) particularly) or by analytical studies (for example, cohort studies and case and control studies), and that provided by experimental studies, particularly controlled clinical trials, as well.

To improve quality information, some strategies of searching have been designed to eliminate or minimize the possible database bias. And to evaluate the quality and, consequently, the weight of the information obtained, different scales have been proposed³⁰.

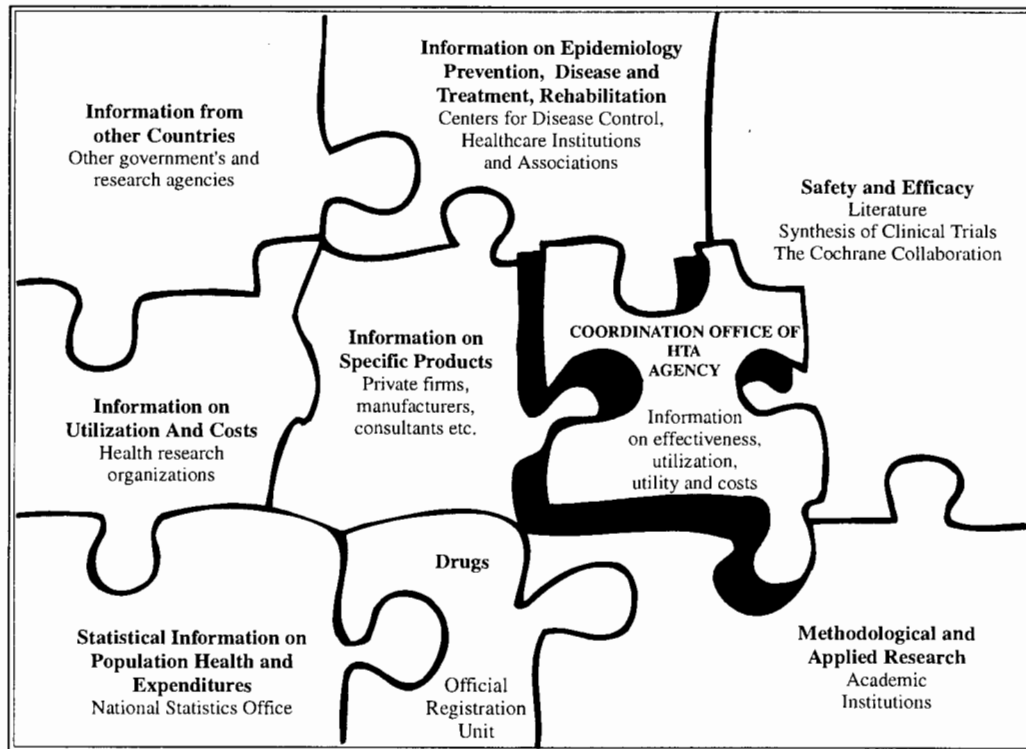
In addition to the previous method there are some others more specific:

- i) the different expert consultation modalities^{31, 32}, (for example, the nominal group technique, the consensus conferences the Delphi method or appropriate indication method);
- ii) the different socioeconomic assessment³³ modalities, and the construction mathematical simulation models.
- iii) the application of Bioethical principles and related international agreements and rules³⁴.

In general, all of them begin after and complete the systematic literature review and synthesis of the best available experience outcomes.

Figure 2 intends to show, in a summarized way, some of the more relevant information sources used in HTA.

FIGURE 2: INFORMATION FOR DECISION MAKERS



Source: CCOHTA (1996), modified.

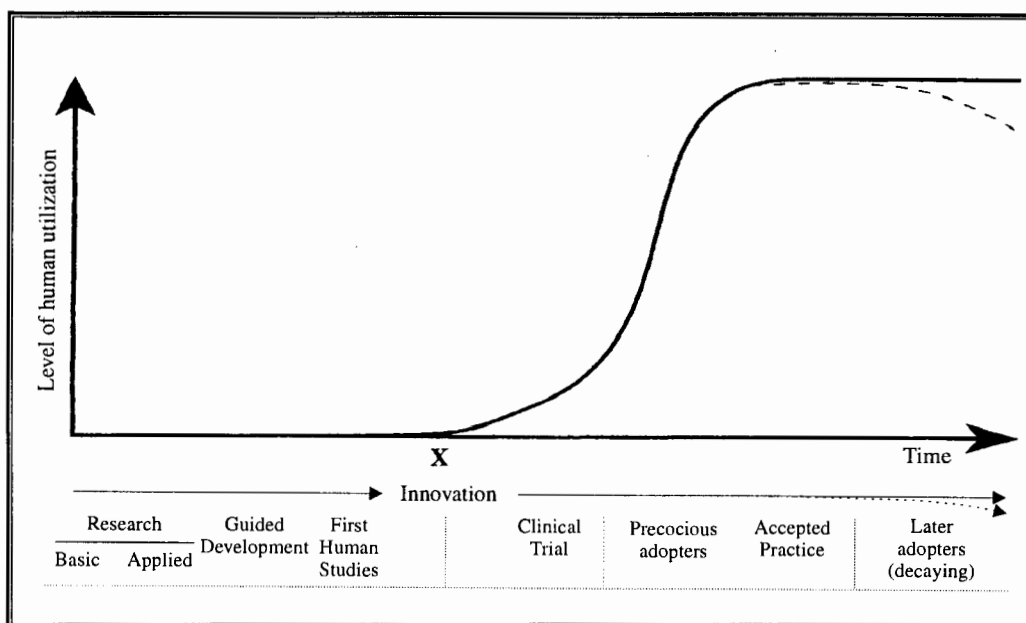
1.5 WHEN TO EVALUATE?

A health technology (or a new application of an existing technology) can be assessed during any phase of its life cycle; that is during the: i) experimental, ii) initial implementation, iii) generalization, and iv) decaying phase (see Fig. 3).

During the *experimental phase*, studies on safety and efficacy in a strict sense are conducted. In this phase a leading role is played by researchers, and groups and institutions involved in HTA are not active. Its results are a prerequisite for proceeding to the next phases.

During the *implementation phase*, it is important to know the effectiveness, clinical usefulness, and foreseeable economic and organizational impact. This is not an experimental phase, but rather a "clinical trial" phase, under conditions that should be carefully established from the scientific, ethical, legal, and administrative standpoint. It is during this phase that agencies and groups responsible for HTA usually become involved.

FIGURE 3: LIFE CYCLE OF TECHNOLOGY



Source: Banta et al. (1981), modified.

Once the implementation phase is over, the area of application of the technology is established, together with the conditions for its dissemination and the mechanisms for monitoring its expected and unexpected effects in the medium and long term. This is what is called *the generalization phase*, which must yield information on how long the technology will be used and, in particular, how it is being used in each individual case. This is a phase that directly involves organizations and groups devoted to HTA.

Finally, during the *decaying phase*, an evaluation is generally done of whether it would be beneficial to replace the technology in question (or one of its applications) with one or more new technologies. This is a phase that also benefits from HTA.

1.6 WHAT IS THE PURPOSE OF EVALUATION?

Agencies and groups devoted to HTA normally try to answer questions coming from one or several sectoral actors. In few occasions, an assessment is made because of their own concern on the relevance of, or the social alarm caused by a specific problem. HTA outcomes are Assessment Reports which conclude with one or more conclusions and one or more recommendations.

Sometimes, these Reports can induce the preparation of Clinical Management Protocols or Clinical Guidelines.

HTA is intended to assist decision-makers in adopting rational decisions concerning three principal issues related to new HTs:

- i) approval for market access;
- ii) approval for their inclusion in the services financed with public funds, and, if appropriate,
- iii) proper dissemination within the health system.

With regard to existing HTs, HTA is intended to orient rational decision-making with respect to three principal issues:

- i) the withdrawal of financing for technologies proven to be inefficient,
- ii) the generalization of new applications of technologies that already exist in the public health system, and
- iii) the withdrawal of technology (or the suppression of one of its indications) from the market (e.g. a drug such as thalidomide because of its side effects)³⁵.

Although the health authorities do not usually have the power to withdraw diagnostic and therapeutic procedures from the market simply because they are inefficient, they can render such technologies obsolete by publicizing their inefficiency (e.g. the number of hysterectomies performed has been reduced considerably in cases where, in the absence of other factors, a table of more restrictive indications has been properly and sufficiently disseminated)³⁶.

However, what the health authorities can do, provided that they have accurate evaluations, is to discontinue public financing to obsolete technologies or those that have not been sufficiently tested and adopt others that meet the appropriate criteria. In this regard, there are numerous examples of underutilized cost-effective technologies³⁷.

Finally, but just as importantly, the results of evaluations are directed more and more toward patients, family members, and the public, in order to promote both the proper use of existing HT (e.g. drugs, self-monitoring methods, or prevention and treatment guidelines) and provide reliable and accessible information that can shed light on discussions about the implications of emerging HT.

1.7 WHO CAN BENEFIT FROM THE RESULTS?

Within the health system, the results of HTA are geared basically towards three levels and four types of actors. The levels are: the macro level (steering role, regulation, public financing, and global evaluation of systems and services); the intermediate level (health insurance and/or health care networks and major providers) and the micro level (clinical practice and self-care by individuals, families and communities). The main actors are the health authorities, managers and decision-makers, health professionals, and the patients and their families.

At the **macro level**, HTA has a decisive effect on regulation and financing. In fact, the health authorities are responsible, to one degree or another, for making decisions that affect:

- i) registration, authorization, and approval of the basic conditions for the use of health technologies (which basically affect drugs and health products);
- ii) whether or not to include such technologies in the coverage of publicly financed health insurance;
- iii) specific financing conditions. This can only be done by using the information produced by the groups and entities involved with HTA.

At the **intermediate level**, the results of HTA have a decisive effect on the content of private financing insurance, the allocation of resources to each level, and models of care. For instance, including (or not) a specific vaccine in a compulsory vaccination scheme, practicing (or not) certain tests for screening of cancer, promoting the oral rehydration therapy, practising (or not) some preoperative routine testing in elective surgery, or including (or not) in vitro fertilization therapies in publicly financed insurance schemes have depended, in many cases, in assessments done with criteria as those used in HTA.

At the **micro level**, health professionals³⁸ using these technologies are interested in knowing in detail the conditions and requirements for their safe, effective, efficient, and acceptable use in different clinical situations, as well as the advantages and drawbacks of the different diagnostic and therapeutic options with respect to a specific process or patient. This is seen in a case where, for example, it is advantageous to replace a technology (i.e. traditional surgical cholecystectomy) that has been exclusive to a medical specialty with another exclusive to a different specialty (i.e. laparoscopic cholecystectomy). This replacement will induce changes in patients clinical management, in professionals training, and in the allocation and resources organization. Moreover, when introducing a new technology induces the development of a

new speciality³⁹; or where a technology used exclusively by a hospital is proven more cost-effective at the primary level or in the patient's home. In both cases, managers and health administrators also wish to identify the problems created and the organizational adaptations demanded by the implementation of new technologies, the useful life expectancy of the technologies, their amortization conditions, and their potential additional applications. Besides, patients and their families wish to be informed, in language that they can understand, of many of the above-mentioned features and, when possible, choose accordingly⁴⁰.

TABLE 2: WHO CAN BENEFIT FROM THE RESULTS?

<ul style="list-style-type: none">▶ Patients and health planners▶ Insurers▶ Providers▶ Health professionals▶ Patients and families▶ Communities▶ Public opinion▶ Industry
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Source: author

Outside **the health systems**, the media and public opinion are showing increasing interest in the results of technology assessments for all reasons cited above. This is particularly evident if the assessment will influence decisions by the health authorities and have a strong ethical, public health, or economic impact.

Finally, at least two more actors are interested in knowing the results of HTA: Industry, which wants to know the results of technology dissemination, since it is one of the most important sources of information for the design of new technologies and/or new applications of existing ones, and the judicial system, which can use HTA reports, and more frequently, the guidelines for clinical practice or the expertise of specialists in litigation resulting from clinical practice.

Increasingly, all of this is leading to the development of conceptual frameworks capable of integrating the different approaches and providing a clear understanding of the phases of the assessment, the studies necessary for each one and, without diminishing their scientific value, of the way to

present results in a manner appropriate to various audiences (for example, researchers, clinicians and patients and their families)⁴¹.

1.8 WHO EVALUATES?

HTs are goods and services for which national and international markets are expanding. Given their nature and the high cost of production, many of these technologies were initially conceived for a world market. This is evident, but not confined to, drugs and diagnostic imaging, laboratory, and surgical equipment. This trend has been reinforced by the growing globalization of markets and the dissemination of rapid communication technologies.

In the developed countries, efforts to assess and regulate the introduction, dissemination, and use of HT are being made at the national and international levels.

At the *national* level, assessment and regulation procedures vary with the characteristics of the health system and sometimes with the science and trade policies of the country in question. In countries where the health systems are largely publicly financed (e.g. Canada, Sweden⁴², Norway, the United Kingdom, or Spain) public agencies devoted to HTA (or agencies with majority public funding) have been created during the past decade. In some cases, these agencies are under the control of the legislature, while in others, the central and/or regional governments. Their actions encompass the three phases mentioned above. These agencies started out by focusing on the most expensive technologies, and, little by little, they have extended their activities to the rest of HT. One of their main achievements has been to include HTA as an essential component of the policies intended to reconcile quality with cost containment. In some countries, there are also academic institutions and private agencies. In virtually all countries, a certain lack of focus in their activities has been noted and a need perceived for more coordination with different groups^{43, 44}.

In Canada, the Council for Health Technology Assessment of Quebec was created in 1988, and in 1989, the Canadian Coordination Office for HTA (CCOHTA), a nonprofit public corporation governed by a council consisting of 13 representatives, each from a province or territory. The Council works with two advisory committees: one on drugs and the other on HT. There are currently HTA organizations in Alberta, Saskatchewan, British Columbia, Ontario, and Manitoba.

In the United States, while the OTA was abolished (1995), the role of the FDA has continued. A large number of private enterprises devoted to HTA (nonprofit or for-profit), have been playing a greater role in scientific and professional organizations, and the approach has been shifting from the "macro" level of regulating the introduction HTs to the more "micro" level of controlling of their utilization. The work of the Agency for Health Care Policy and Research (AHCPR), created in 1989 and part of the U.S. public health service, should be noted. Its mandate is to investigate for patients the results of alternative strategies to prevent, diagnose, cure, treat, and manage certain clinical situations, and it has produced an interesting collection of Clinical Practice Guidelines (CPG). In early 1997, the AHCPR announced a strategy change consisting of creating a center for practice and Technology Assessment (in collaboration with the American Medical Association and the American Association of Health Plans), and supporting institutions and groups that practice evidence-based medicine.

At the *international* level, the ISTAHC has been in existence since 1985. This is a scientific society with open membership that 1,000 individual and corporate members in over 30 countries, representing numerous sectors (universities, industry, insurance companies, health institutions, health professionals, and governments). The ISTAHC promotes international activities, holds an annual international meeting (San Francisco, 1996; Barcelona, 1997; Ottawa, 1998; Edinburgh, 1999) and publishes a journal every four months that is required reference⁴⁵. In 1996, an interest group was formed within the society for the development of HTA in the developing countries and, responding to a PAHO initiative, its Thirteenth Annual Meeting included a panel on health system reform and HTA in the Region.

In addition, in 1993, the International Network of Agencies for Health Technology Assessment (INAHTA) was created, and is currently comprised of members of 22 agencies in the United States, Europe, Asia, and Oceania who meet entrance requirements (commitment to HTA, nonprofit status, supervision by a national or regional government, and at least 50% public funding in the form of subsidies). Its objectives are to share information, avoid duplication of efforts, and promote international cooperation in this field⁴⁶. Since December 1996, it has been publishing an interesting monthly newsletter in both English and Spanish, and in 1997 the result of a first collaborative assessment project was disseminated⁴⁷.

In addition, in 1994, the European Union created the EUR-ASSESS program which, in the three years since its creation, has attempted to standardize concepts and define strategies for the Member States in four

areas: i) setting of priorities; ii) assessment methods; iii) dissemination of results and, iv) health coverage and its relation to HTA⁴⁸.

In 1997, the name of the program was changed and it was extended for one year, during which three "case studies" were done (techniques for the early detection of breast cancer, the usefulness of sonograms during pregnancy, and the predictive value of the PSA in prostate cancer). A decision will be made regarding its future.

In addition, since the early 1980s, a network of centers called "Cochrane Collaboration," in honor of the illustrious clinical epidemiologist, Archie Cochrane, has been growing. Initially devoted to the promotion and control of random clinical trials, it has been expanding its sphere of action to the collection, systematic analysis, and dissemination of scientific information used as the basis for medical practice. At present, centers in the United States, Canada, Australia, Italy, United Kingdom, Spain, and the Nordic countries form part of this network, which publishes an electronically accessible "Cochrane Library" that compiles sources of on various medical areas⁴⁹.

1.9 THE WORLD HEALTH ORGANIZATION AND HEALTH TECHNOLOGY ASSESSMENT

For more than two decades, WHO has been interested in HTA, in some cases in itself, and in others, linking it to the quality of medical care policies.

The Declaration of Alma-Ata (1978) defined primary health care as "essential health care based on practical, scientifically sound and socially acceptable methods and technology ... at a cost that the community and the country can afford..." and it called on governments, academic and research institutions, and NGOs to identify, develop, adapt, and implement technologies suited to the specific needs of populations, and which could be maintained by them⁵⁰.

Since the late 1970s, the WHO "Technical Reports" series has included a growing number of reports prepared by different groups of experts and study committees on the appropriate selection, rational use, and quality control of the various health promotion, disease prevention, diagnostic, and therapeutic technologies.

In 1984, the WHO European Regional Office stated that prior to 1990, all the Member States should have established a formal mechanism to systematically assess the appropriate use of health technologies and verify that they respond to the national health programs and the countries' economic

means⁵¹. By the mid-1990s, most of the countries of Western Europe had met that objective, while the majority of Central and Eastern European countries had not.

Since 1991, WHO has held meetings of experts on HTA (Geneva, 1991; Alexandria, 1993⁵²) and a working group to promote HTA in the developing countries formulated specific proposals in 1994⁵³.

In addition, the 1996-1997 biennial program budget of WHO includes a chapter on "Quality and Health Technologies" which summarizes the activities carried out in this area during the previous biennium, especially with respect to the safety of blood transfusions and blood products; quality control of clinical laboratories; the preparation of standards; radiology, dosimetry, and radiation protection equipment; drugs and biologicals; and traditional medicine⁵⁴. The budget provides for the continuation of many of these activities and the development of new ones such as the promotion of information exchange on emerging technologies; the preparation of guidelines on sound practices for emergency surgery and surgery on the battlefield, early treatment of burn victims, minimally invasive surgery, and the use of autotransfusion, or collaboration with various NGOs in drawing up specifications for different surgical and anesthetic equipment and equipment maintenance and repair⁵⁵.

HEALTH TECHNOLOGY AND ITS ASSESSMENT IN LATIN AMERICA AND THE CARIBBEAN

2

2.1 HEALTH SECTOR REFORM, HEALTH TECHNOLOGY, AND HEALTH TECHNOLOGY ASSESSMENT

Since the beginning of this decade, the majority of countries in the Region of the Americas have been reforming or considering the reform of their health systems and services for the express purpose of promoting equity in health and access to health services, increasing efficiency in the allocation of resources, improving the effectiveness and quality of care, ensuring financial sustainability, and promoting community participation and intersectorial action.

In order to achieve these objectives, reforms are attempting, among other things, to: strengthen the leadership and regulatory capability of governments; extend coverage to those who do not have regular access to basic services and serve population groups with specific needs; redefine the models of care, emphasizing the integrated nature of actions and the deconcentration and/or decentralization of services; organize the delivery of services, defining, where necessary, basic groups based on epidemiological profiles, the availability of resources, strategic options and financial, social, and cultural aspects; increase the number and variety of public and private suppliers; introduce new forms of financing and management for health care facilities and contract professionals who promote quality, efficiency, and satisfaction; and adapt health expenditure to economic realities.

Technology development has played and continues to play an essential role in community health and developing health systems and services. Properly evaluation of its introduction and use can contribute to the achievement of the stated objectives. Latin American and Caribbean (LAC) countries represent one of the most important emerging markets for HT and health authorities, public and private insurers, health professionals, patients, and the communications media and public opinion are gradually becoming more aware of the importance of HT and its evaluation.

In the view of PAHO, HTA is an essential component of the regulatory role of the health authorities and can help to strengthen their leadership. In addition, when well-conceived and well-implemented, HTA can make an important contribution to the proper distribution of resources, to the selection of cost-effective interventions, to greater efficiency and more effective services, to quality assurance in care, and to participation by professionals and patients in decision-making.

However, after a promising start, stagnation or even setbacks were noted in the conceptualization and implementation of HTA activities in the late 1980s and early 1990s, both in the action taken by the Organization and at the country level. This occurred at a time when, as a consequence of the reform processes mentioned above, needs were growing and challenges were multiplying⁵⁶. As it is mentioned later, some signs of revitalization of the interest on these matters are realized in several LAC countries.

2.2 HEALTH TECHNOLOGY IN LATIN AMERICA AND THE CARIBBEAN

As in most developing countries, technological development in LAC has been based largely on the transfer of technologies perfected in the developed countries. In many cases, this transfer has been incomplete, since it was not accompanied by modifications to permit adaptation of the technologies to the organizational, economic, social, and cultural situation of the receiving countries.

In the early 1980s, the scarcity of many basic technologies, the excessive and indiscriminate use of expensive HT, the dearth of policies and standards to regulate the introduction and use of HT, the underdevelopment of support technologies (especially management information systems), and inequalities in access to available HT were some of the more commonly cited problems in the Region⁵⁷.

At the beginning of this decade, the HT situation in LAC was not encouraging.

First, with the partial exception of drugs and diagnostic imaging equipment, there was significant lack of consistent and accessible information on the mechanisms for the introduction, distribution, and use of the most common HTs, even in countries with average or better than average levels of development.

Second, it seemed clear that as a consequence of the economic crisis of the previous decade, the countries were not allocating the necessary funds for the upkeep, maintenance, and replacement of installations and equipments. Thus, studies conducted in public hospitals in Central America and Panama revealed that the buildings were, on average, 30 to 35 years old and that roughly half of the equipment was out of order or malfunctioning. In addition, the countries devoted less than 3.5% and often less than 1% of their current budget to activities related to upkeep and maintenance, since the number of personnel assigned to these tasks was limited and 75% lacked the proper training⁵⁸.

In addition, some countries, particularly medium and low income countries, continued to receive donations of equipment that did not meet an expressed need, was not in compliance with national regulations, or for which adequate organizational or management conditions did not exist or trained personnel was lacking. Or, the equipment was directed to non-priority areas, or its complexity or maintenance costs could not be met with national resources^{59,60}.

Third, equipment availability and use (for example, diagnostic imaging, radiation therapy, laboratories and blood banks) varied widely. Large countries with high indexes of urbanization had sophisticated services, nearly always located in what were often private hospitals in the capital cities, and their indicators for availability, use, and quality were similar to those of the developed countries. Outside of these areas, or in countries with a lower level of development, the situation was considerably worse (for example, only two of the seven diagnostic imaging services visited in one country had dosimetry personnel and four of them had no quality control program).

Fourth, a dual process was noted where drugs are concerned: as a consequence of globalization and subregional integration, the tendency was, on the one hand, to deregulate the conditions governing registration and pricing and, on the other, to promote rational use and improve the quality of pharmacotherapeutic care. According to a survey done in 13 countries in the region, only half of them had agencies that functioned as national drug commissions and where these did exist, they lacked managerial capacity. Only one-fourth of the countries had approved standards for good manufacturing practices. In a very limited number of cases, it had been possible to increase the availability of generic drugs on the market. In addition, rising sales drugs without prescription or in commercial establishments without a pharmacist were noted, and in the public sector, the number of countries with centralized procurement fell, the managerial capacity of the public sector deteriorated, and the number of institutions purchasing drugs not included on the basic lists and the number of countries that established various copayment

procedures rose. Furthermore, the information received by physicians continued to be provided, for the most part, by the pharmaceutical industry⁶¹.

Last but not least, very few assessments of the effectiveness of interventions and/or prevention, diagnostic, therapeutic, or rehabilitation procedures were published⁶².

In 1993, the LAC countries represented a market of close to US\$ 16,000 million for health products, which includes biologicals, drugs, medical devices, and hospital equipment. There is a very great shortage of medical devices in LAC. In 1993, Brazil invested US\$ 7.4 per capita in the purchase of medical equipment and devices, and Mexico, US\$5.5, while Canada invested US\$82, Japan US\$94, Germany US\$108, and the United States, US\$140. Despite the dearth of reference studies, it is believed that the domestic distribution of these products, particularly those involving more modern technology, is inversely proportional to health needs.

The effects of demographic transition (especially increased life expectancy and the predominance of chronic pathologies and accidents) and improved economic conditions in many of the countries are making it necessary and possible to increase expenditure on HT in the years ahead. Governments of LAC countries begin to be aware of this situation as it is shown by the fact that the II Summit of the Americas agenda (Santiago, Chile, April, 1998) includes a specific initiative called "Health Technology linking the Americas"⁶³. Society as a whole must decide and governments must implement measures that steer this increase in expenditure toward more cost-effective and appropriate technologies. HTA should play an important role in this.

2.3 HEALTH TECHNOLOGY ASSESSMENT IN LATIN AMERICA AND THE CARIBBEAN

For some time, HT in Latin America and the Caribbean has been associated with highly complex equipment, and HTA has initially been viewed in terms of mechanisms to increase the supply of Biomedical equipment (in a region where, for more than a decade, there had been a steep decline in operating capacity and purchasing power), as well as all administrative procedures prior to their registration and marketing.

From the early 1990s, HSR processes were proposed in most of the countries of the region. In December 1994, the Summit of the Americas reaffirmed the interest of the governments of the Region in promoting reforms in their health systems that would guarantee equitable access to basic health

services. Despite the importance of the HT in terms of expenditure⁶⁴ and of HTA in terms of effectiveness and efficiency, they were not specifically mentioned in the corresponding section of the Summit's Plan of Action⁶⁵.

The Summit charged PAHO, the International Development Bank (IDB), and the World Bank with organizing a Special Meeting on Health Sector in the Americas. In preparation for this, each country drafted a report on the strategies and initiatives in progress for the reform of their health systems⁶⁶. Except for drugs (which appeared under the heading "establishment of essential drug policies" in 6 of the 37 countries or territories), HTA was not cited as a priority. In addition, of the 103 organizations working with HTA in 24 countries identified in an international survey conducted between 1994 and 1995, only one was a LAC country⁶⁷.

This is probably due to one or more of the following factors:

- ▶ HTA is a relatively new field: the first report on HTA was published by the OTA 20 years ago⁶⁸, and national organizations and agencies devoted to HTA were established in a number of developed countries during the 1980s but not in any LAC countries.
- ▶ from a technical standpoint, HTA is a complex activity that involves knowledge and skills derived from a number of areas: basic and applied research, clinical practice, nursing, epidemiology, engineering, economics, management, etc. In addition, a clear vision of the legal, ethical, and trade implications of HT is usually necessary.
- ▶ in the context of economic liberalization and globalization, HTA can sometimes be perceived as a new form of state interventionism or bureaucracy.
- ▶ In this regard, as the case of drugs demonstrates, the situation in the Region is paradoxical: on the one hand, there is a trend towards a lowering of national trade barriers and, on the other, towards a strengthening of the regulatory role of the public authorities, combined with subregional efforts to coordinate trade policies and the technical and quality criteria for products.

Does all this mean⁶⁹ that HTA is not part of the daily work of health authorities, clinicians, and users? Not at all.

First, because economic globalization and electronic access to information are facilitating the dissemination of both technology advances and the results of their assessment (when they exist) with unprecedented speed⁷⁰.

Second, because a number of international agencies^{71, 72, 73} have been emphasizing the importance of HTA as a way to improve quality, increase

effectiveness, and, through the rationalization of resource allocation, contribute to the reduction of inequities in health.

Third, because, as a recent study demonstrated⁷⁴, the relationship between professional incentives and the proper use of HT is becoming evident in some countries.

Fourth, because users (from both the public and the private sector) have been acquiring a growing awareness of the ethical and legal implications of the use of many HTs.

And, last but not least, because the establishment of "basic packages of cost-effective interventions," one of the strategies used in HSR to allocate resources and increase coverage, has been requiring early (and not always easy) HTA application⁷⁵.

2.4 THE PAN AMERICAN HEALTH ORGANIZATION AND HEALTH TECHNOLOGY ASSESSMENT

PAHO devoted attention to HT and its assessment almost from the beginning. Therefore, as early as 1977, during the preparation of what was known at the time as the Health for All Strategy, the organization helped to prepare and disseminate the concept of "appropriate technologies," linked to those of "expansion of coverage" through "primary care" and "community participation," in the improvement of individual and collective health. In 1983, the Health Technologies Development Unit was established, which integrated the health technologies, essential drugs, biologicals, and laboratory programs. The Unit developed an active publication policy, sponsored several collaborative studies, and brought together various advisory groups.

In 1985, PAHO coorganized an "Ibero-American Seminar on Medical Technology" in Madrid (Spain); in 1989, a case-study on "Health Technology Assessment. Methodologies for Developing Countries" was published⁷⁶; and in 1990, a seminar and international advisory group on "Regulation of Medical Devices" was organized in Ottawa (Canada). The Technology Unit was subsequently restructured, as a result of which the Regional Program on Drugs and Health Technology, was created under the Division of Health Systems and Services⁷⁷.

In the "Strategic Orientations and Program Priorities for Quadrennium 1991-1994" (SOPPs), approved in 1990, technology development was one of the priorities for strengthening the health services, and during the 1995-

1998 period, there has been great concern about the appearance of new technologies, their incorporation into the field of health, and access to information on them. More specifically, promoting cooperation among the countries for the development and use of technology, supporting the formulation of policies on essential drugs, and strengthening the development of laboratory services, are included as specific lines of action⁷⁸. A summary of the activities in Technology and Essential Drugs has been appearing regularly in the Director's reports⁷⁹. And from the mid-1980s, an important effort in the medical equipment and facilities maintenance has been developed. This effort has contributed to originate "technological management programs" in many countries, particularly in the Centro America and Andean Area.

In 1996, a restructuring of the Division of Health Systems and Services Development took place in order to confront a series of new challenges, among them, the processes of HSR and their effect on equity, quality, efficiency, sustainability, and social participation. A document on "PAHO Cooperation in Health Sector Reform Processes" recently appeared. It points out that PAHO activities will be geared, among other things, to strengthening the capacity to assess technologies, drugs, and other critical inputs⁸⁰.

This document is part of that same effort and represents an attempt to help guide PAHO technical cooperation in this field.

2.5 PROMOTING HEALTH TECHNOLOGY ASSESSMENT IN LATIN AMERICA AND THE CARIBBEAN

Strengthening HTA activities in LAC countries is an indispensable component of HSR processes and health services development.

A number of ideas are presented below that can assist both technical personnel in the countries and PAHO professionals who provide technical cooperation in this or another related area.

2.5.1 STARTING FROM OUR PRESENT POSITION

Although in LAC, HTs tend to be associated with expensive and highly complex equipment and HTA, with only the assessment of equipment prior to its registration and marketing, in third-level hospitals in some countries guidelines for clinical practice already exist and physicians and nurses occasionally use them.

The preparation and dissemination of national or subnational guidelines, as appropriate, on clinical practice for the proper management of high impact clinical situations has often been the first step of HTA⁸¹. In fact, its preparation and dissemination requires an in-depth discussion of HT and the establishment priorities in HTA. At this point, the experience with drugs can be used as an analogy. Concepts such as safety, effectiveness, undesirable effects, and cost-effectiveness are more or less the same, and there are many common elements in terms of basic philosophy and work methodology.

2.5.2 LINKING HEALTH TECHNOLOGY ASSESSMENT MORE WITH QUALITY AND EFFECTIVENESS THAN COST CONTAINMENT

HTA and Quality have close relationships. From the HTA side, a decade ago, a well-known report estimated that 20% of total health expenditure was devoted to financing useless or harmful clinical procedures in developed countries⁸². More recently, another report pointed out that 20%-25% of the clinical procedures utilized in the United States were based on inappropriate or dubious indications⁸³. The mere elimination of useless procedures and inappropriate indications could improve quality and effectiveness and reorient health expenditure towards greater cost-effectiveness⁸⁴.

From the Quality point of view the role of HTA can be understood remembering that, technically speaking, Quality of care has two dimensions: the appropriateness of the provided service and the rightness with which an appropriate service is provided. The classical sentence: "Do the right things, right" summarized both dimensions. Additionally, other dimension must be added: patients' opinion, which includes perception, acceptability and preferences⁸⁵.

Nevertheless, Quality of care needs to be measured; but to measure it is necessary having standards of appropriateness; and for elaborating these standards, synthesizing the best available experience, and completing it with one or more of the experts consultation modalities (to assess effectiveness and costs) is required. In addition, patient's opinion (to assess acceptability and usefulness) must be evaluated. In other words, using HTA criteria and outcomes.

2.5.3 HEALTH TECHNOLOGY ASSESSMENT AS A WAY TO LINK PROFESSIONALS WITH MANAGEMENT DECISIONS AND HEALTH SECTOR REFORM STRATEGIES

Linking professionals with management decisions and HSR strategies is a logical sequel to the previous point. Rapid changes in HT and patient

management by physicians, nurses, and other health professionals have helped greatly to vary the methods of care and the distribution of the functions of the various levels (e.g. many techniques and procedures previously restricted to hospitals be applied at the primary level or in the patient's home). All of this strengthens the role of physicians and nurses as "counselors," and of patients and their families as managers and decision-makers. Increasingly, the global effectiveness of health systems is shown as it is: an aggregate of multiple decisions made day to day by multiple actors at the preventive and delivering care levels (physicians, paramedical personnel and nurses)⁸⁶.

Decisions on the orientation of investment in the health sector is a clear example: rarely can policy makers and managers make decisions on new construction, the purchase or replacement of equipment, the approval of new applications, etc., without consulting with groups that represent health specialists. In many LAC countries, the physicians and nurses who belong to these groups are forced to choose between what is "technically possible" and what is "really necessary and useful for each patient specifically." Even where the lack of resources is clear, those in charge of preparing projects in search of external financing need this type of assessment. Some years ago, this situation was defined as "the third revolution in Medicine," a situation characterized by the need for procedures and resources to develop "a permanent critical assessment" of HT, which offers stimulating scientific challenges and great professional responsibility.

2.5.4 HEALTH TECHNOLOGY ASSESSMENT AS AN ESSENTIAL COMPONENT OF THE REGULATORY ROLE OF THE MINISTRIES OF HEALTH

Strengthening the leadership role of the ministries of health is one of the HSR strategies. HTA should be a fundamental component of this strategy. Its implementation will vary from country to country. As mentioned earlier, from the mid-1980s, some developed countries established independent specialized agencies, financed totally or partially with public funds⁸⁷. Others established HTA Committees^{88, 89}, which forged ties with universities and public and private institutions. At the moment, there is no single public agency in the United States specializing in HTA⁹⁰.

The countries of LAC could probably begin (as some have already done) by establishing small units in the ministries of health, which, in turn, could serve as the secretariat of a national committee that would include representatives from universities, basic and applied research institutes, scientific organizations, and other public and private organizations. This Committee, chaired by the minister or his delegated representative, would establish the

priorities and the work plan, as well as the necessary resources, and the Secretariat would work in close contact with a network of scientific organizations, institutes for regulation of drugs or elaborating technical rules, and professional groups in order to carry out the assessments included in the plan.

A few countries that have autonomous "FDA-type"⁹¹ regulatory agencies should consider whether the aforementioned unit should be part of them, should be under the health authority, or should be an independent agency with its own status. One reason to opt for the latter arrangement is the possibility of receiving both public and private sector financing.

In any case, it is becoming clearer that, given the magnitude of the task, in order to be efficient, this type of unit and/or committee must be the tip of a big iceberg made up of many people, groups, and institutions linked by the common notion of basing health care on the best scientific evidence available; that the priorities in the allocation of resources for evaluation projects should be established in a public, objective, and rigorous manner; that in preparing them, rigorous methodologies, compared internationally, should be used; and that the results should be timely and widely disseminated⁹².

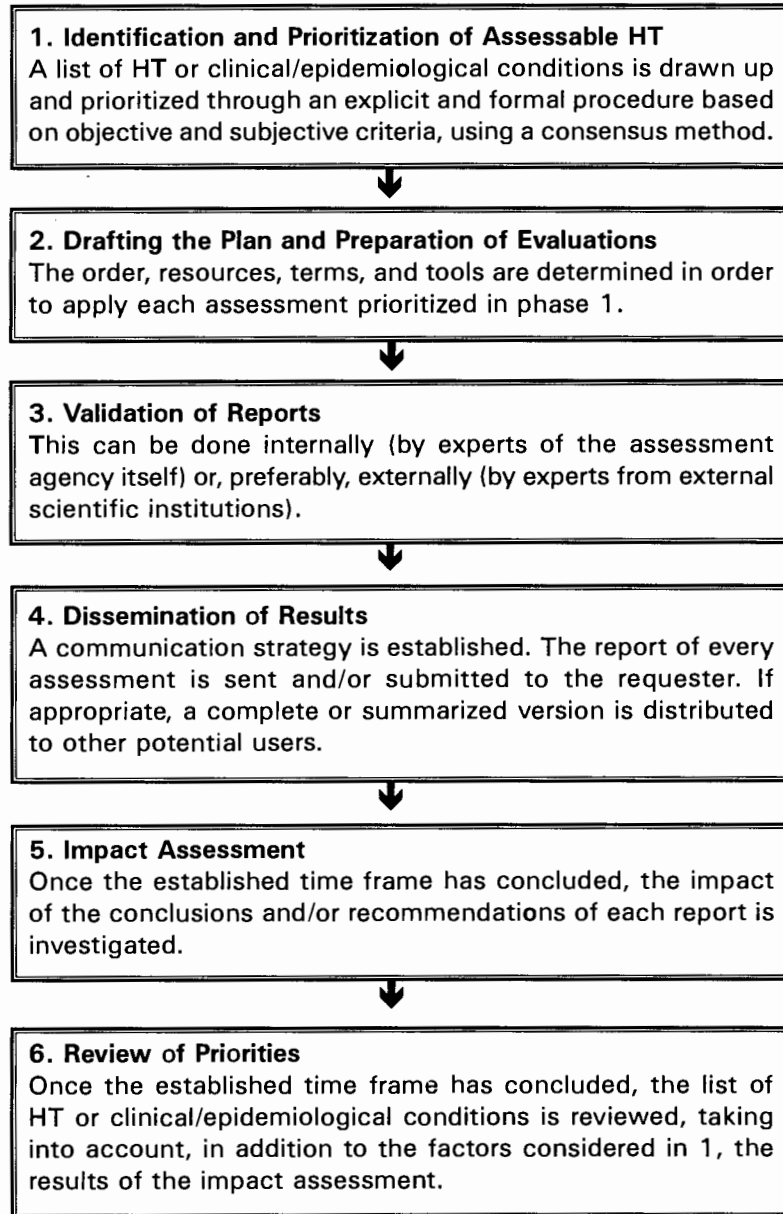
Experience suggests that the unit's initial group should be small, stable, multidisciplinary, independent, highly skilled, and capable of working in close contact with fairly high-level health groups and health institutions in the country.

Since HTA requires time and money, proper organization of resources is a prerequisite for achieving the objectives of the assessment units and/or commissions. Organizing a rapid response to requests from different sources with rigorous⁹³ and acceptable prioritization of health technologies requiring assessment by policy makers within a given time frame poses a significant challenge.

Table 3 summarizes the phases of the assessment process, from the identification and prioritization of health technologies requiring assessment to an evaluation of the impact that the results of the assessments have on health status and/or the operation of health systems and services.

Table 4 includes some general criteria that can be used to prioritize HT that would require assessment. This prioritization exercise is obviously facilitated when the country (or Province, State or Region) has a document describing and prioritizing health problems, and strategies and actions required to cope with them⁹⁴.

TABLE 3: PHASES OF THE ASSESSMENT PROCESS



Source: *Osteba Berriak, n 2*

TABLE 4: GENERAL GUIDELINES FOR PRIORITIZING ASSESSMENTS

1. **Prevalence** of the problem that HT is trying to address (number of persons affected per 1,000 persons) or incidence (number of new cases per 100,000 inhabitants in one year) if the problem is determined to be new.
2. **Toll** taken by the problem in terms of mortality, morbidity, or impeding operations.
3. **Cost** of the problem.
4. **Variability** in terms of the practical management of the problem: significant differences in rates of use of prevention, diagnostic, therapeutic, or rehabilitation procedures.
5. **Risks** arising from HT itself (e.g. serious complications during a surgical procedure or radioactive contamination during a radiological or radiotherapy technique).
6. **Potential** for the assessment recommendations to improve the results obtained from management of the problem.
7. **Possibility** of evaluating the impact of the assessment's recommendations.

Source: Institute of Medicine (IOM), modified

2.5.5 HEALTH TECHNOLOGY ASSESSMENT AS AN IMPORTANT FIELD OF INTERNATIONAL TECHNICAL COOPERATION

Avoiding the duplication of studies in different countries, facilitating the efficient and timely exchange of information and experiences, and making progress with the development of new information in order to improve the operation of the health systems are three fundamental reasons for promoting international cooperation in this field. In the Region of the Americas, this cooperation can be carried out:

Between developed and developing countries

For many reasons, LAC countries should design their own HTA strategies, taking the experiences of Europe, Canada, and the United States into account. The results of the EUR-ASSESS program of the European Union may be particularly important. In addition, some European countries include HTA as an area for cooperation with third countries. The Canadian International Development Agency (CIDA) includes support for efforts to introduce appropriate technologies among its objectives. And, since 1995, the Canadian Therapeutic Product Directorate supports the efforts for organizing medical devices and equipment regulation programs in various LAC countries.

Among the Latin American and the Caribbean countries themselves

This can be achieved by establishing regular channels of communication among the organizations and groups involved in HTA at the regional and/or subregional levels. The example of drugs can be instructive. In May 1994, the governments of the Andean countries signed a Quadrennial Plan (1994-1997) on Strategies, Supply, Regulation, Quality, and Rational Use of Drugs and, in June of that year, the Central American presidents decided to create a free market for 40 essential drugs and to evaluate jointly the operation of several related programs (e.g. indicators of use and regulation of prescriptions and dispensing).

More recently, the regulatory authorities of the countries of four subregions (North America, Central America, the Andean Area, and MERCOSUR) recently began work to harmonize requirements and procedures for the registration of medication. Moreover, in the Andean Area, preparations have begun for the drafting of the Andean Pharmacological Standards for common products in the subregion, and a similar effort is beginning in Central America

In addition, in April 1996, a meeting of ministers of health of "Mercado Común Suramericano" (MERCOSUR) (Argentina, Brazil, Uruguay, and Paraguay) was held to address two subjects: quality and HT. And since 1997, there is a MERCOSUR technical subgroup in charge of, among other things, promoting HT and HTA issues.

Either alone or with other members, PAHO can serve as a facilitator (at both the national and subnational levels), cooperating with countries in the establishment of suitable policies and mechanisms for promoting HTA, which, among other things, includes:

- i) identifying relevant groups and national institutions in this field;
- ii) encouraging the organization of coordinating agencies and/or specific units;
- iii) supporting situation analysis and the identification of needs;
- iv) supporting the setting of HTA priorities;
- v) facilitating coordination with international agencies, groups, and networks⁹⁵;
- vi) organizing workshops and seminars on HTA methodology and practice, and supporting the introduction of HTA in the pre and postdoctoral curricula;
- vii) technical cooperation on regulation, dissemination, and assessment of the use of a number of specific technologies;

- viii) supporting participation in international conferences on assessment of relevant technologies;
- ix) establishing and/or reinforcing the mechanisms for disseminating results and sharing experiences;
- x) supporting evaluation of the impact of the recommendations of assessment reports.

Of course, each country will have to identify its own HTA needs and priorities, as well as the way of organizing the activity that is most appropriate to its characteristics and strategies for development and HSR. In this regard, the experience gained WHO and PAHO in programs such as drugs and vaccines, diagnostic imaging, radiation therapy, radiation protection, clinical laboratories, and blood banks, and appropriate technologies for the primary level serves as an excellent reference and a good starting point from which to forge ahead.

In addition, the support of WHO Collaborating Centers is available in the Region. Work has been done with them in the past and will be stepped up in the future⁹⁶.

However, at the moment the two main constraints in the Region are:

- i) the lack of proper understanding on the part of many policy makers about the importance of HTA and the development of health systems and services and the achievement of the reform objectives (in particular, their relationship to the steering role of the ministries of health) and,
- ii) the absence of a "critical mass" of personnel trained in HTA methodology and practice, continuously working in this field and with appropriate access to national and international information sources.

For this reason, PAHO has begun to work:

- i) with its own resources, organizing workshops on HTA methodology and practice (a national workshop in Havana, Cuba, 1996 and subregional workshops in Mexico DF, Santiago, Chile, 1997, and Bogota, 1998); financing the participation of LAC professionals in international congresses (ISTAHC, Barcelona, 1997 and Ottawa, 1998) and providing advice on the organization of units working with HTA (Cuba, Mexico, and Chile); and,
- ii) as an impartial intermediary among the health authorities (and groups and units in the countries) and other international cooperation initiatives such as ISTAHC and INAHTA.

These two lines of work, together with the others mentioned above, will continue to be developed in the near future.

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37. Among others, the hepatitis B vaccine, the detection of diabetic retinopathy, or thrombolytic treatment following acute myocardial infarction. See, for example, Bloom, B.S.; Frenck, AM: "The Tension between Cost Containment and the Underutilization of Effective Health Services", *Intl. J. Tech. Assess. Hlth. Care*, 12:1 (1996), 1-8.
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53. WHO: "Promoting the Use of Technology Assessment to Improve Health Care in Developing Countries. Report of a Working Group, 30 May-1 June, 1994", Geneva, Tec/ 94.1, English only, distr: limited.
54. Some elements of what is known as "traditional medicine" or "alternative medicine" are useful, and some are not. WHO is encouraging efforts to find remedies and safe and effective practices. However, it does not support any type of "traditional medicine." This must be examined critically, based on criteria similar to the rest of HT. See, for example, WHO: "The World Health Report 1997: Conquering Suffering, Enriching Humanity", Geneva, 1997, p. 94.
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- de Actividades al Honorable Congreso de la República 1996-1997", Bogotá, 1997, pg. 57.
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68. OTA: "Development of Medical Technology: Opportunities for Assessment", Washington DC, U.S. Government Publishing Office, 1976.

69. PAHO/WHO: "Essential Drugs in the New Socioeconomic Context of Latin America and the Caribbean. Principles and Strategies", series HSP/SILOS-42, Washington DC, 1995.
70. "There is a great potential for innovation in the health sector arising from the appropriate use of telecommunication and information technologies. However, it should be pointed out that in many countries, access to basic telephone services and the use of computers in general are still very limited... although there are metropolitan areas that have ... very sophisticated and advanced systems. See: OPS/OMS.HSP-HSO: "Telecomunicaciones en Salud y Atención de Salud para América Latina y el Caribe. Reporte Preliminar para una Reunión de expertos", Washington DC, May, 1997.
71. OPS: "Orientaciones Estratégicas y Programáticas", Washington DC, 1995, págs. 27-28.
72. BID, BIRF, CEPAL, OEA, OPS/OMS, UNFPA, UNICEF, USAID: "Acceso equitativo a servicios básicos de salud: Hacia una agenda regional para la Reforma del Sector Salud", Washington, D.C., Sep. 1995 (mimeographed).
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75. For example, the methodology used in the preparation of "clusters" of interventions, which subsequently defined the new social security system in Colombia. See: Republic of Colombia, Ministry of Health: "La Reforma de la Seguridad Social en Salud", t. I, págs. 113-40, Santa Fe de Bogotá DC, 1994.
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81. IOM: "Setting Priorities for Clinical Practice Guidelines", M.J. Field, ed. National Academy of Press, Washington DC, 1995.

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84. This strategy is generally less complex and more gradual than positively defining "basic packages" or sets of cost-effective interventions and may be more understandable and acceptable to clinicians, patients, and the public at large. In light of the growing diversity of insurance and methods of service delivery, as well as the trade implications of the results of HTA, it may be best (and, sometimes, it is imperative) to involve HT producers and distributors.
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91. For example, in 1992, Argentina created the "National Administration for Food, Drugs, and Medical Technology (ANAMAT)," and in 1993, Colombia created the Institute for Monitoring Drugs and Food (INVINA). Both cases involved autonomous public entities related to the ministries of health, with responsibility for the registration, quality control of food, medication, and health products, and for the ANAMAT "equipment and medical devices."
92. This has been, since its creation in 1993, the work philosophy of the "National Coordinating Centre for Health Technology Assessment" an agency of the National Health Service of the United Kingdom. Since then, 4,300 suggestions for developing "evaluative investigations" have been submitted, 250 of which were selected. Among them, 119 drafts corresponding to 77 thematic fields were ultimately financed. To date, 6 reports have been published and 29 more will be published in the months ahead. See: NHS Executive: "The Annual Report of the NHS Health

Technology Assessment Programme 1997. Identifying Questions, Finding Answers", London, Sep. 1997.

93. See, for example: Henshall, C.; Oortwinj, W.; Stevens, A.; Granados, A.; Banta, D: "Priority Setting for Health Technology Assessment: Theoretical Considerations and Practical Approaches. A paper produced by Priorite Setting Subgroup of the EUR-ASSESS Porject", *Int. J. Tech. Assess. Hlth. Care* 13:2 (1997), 144-185.
94. Since the beginning of nineties, PAHO has been promoting Sectoral Analyses, Health Plans, and Master Investment Plans as valid tools for strategic planning in the HSR processes. These tools could help to national health authorities and other sectoral actors to improve health systems and services performance. See, for example: OPS/OMS: "Lineamientos Metodológicos para la Realización de Análisis en Salud," PIAS, serie Informes Técnicos, n° 6, Washington DC, junio 1996.
95. For this purpose, a PAHO homepage website has been created (<http://www.paho.org/english/hsp/hsptec.htm>) including sections devoted to news, technical documents, links, and more.
96. In June of 1997, the list included: i) Medical Technology and Practice Patterns Institute, Washington DC, USA; ii) ECRI, Plymouth Meeting, PA, USA; iii) University of Ottawa, Ottawa, Canada.

ACRONYMS

AHCPR	Agency for Health Care Policy and Research
CCOHTA	Canadian Coordinating Office for Health Technology Assessment
CIDA	Canadian International Development Agency
ECRI	Emergency Care Research Institute
FDA	Food and Drug Administration (USA)
GPC	Guías de Práctica Clínica
HSP/HSO	Health Systems and Services Development/ Organization and Management of Health Systems and Services (PAHO)
HSR	Health Sector Reform
HT	Health Technology
HTA	Health Technology Assessment
IDB	Inter-American Development Bank
INAHTA	International Agencies for Health Technology Assessment
IOM	Institute of Medicine (USA)
ISTAHC	International Society of Technology Assessment of Health Care
LAC	Latin American and the Caribbean
NGO	Non-Governmental Organization
OTA	Office of Technology Assessment
PAHO	Pan American Health Organization
SOPPs	Strategic Orientations and Program Priorities (PAHO)
WHO	World Health Organization

ANNEX A:

GROUP OF PARTICIPATING EXPERTS IN THE MEETING OF OTTAWA, CANADA

Aiston, Edward: Health Canada, Canada
Asua, José: INAHTA, Spain
Ausejo, Mónica: Observer, Spain
Banta, David: ISTAHC, Netherlands
Battista, Renaldo: ISTAHC, Canada
Bergevin, Yves: CIDA, Canada
Borrás, Cari: PAHO, USA
Conde Olasagasti, José: Ministry of Health, Spain
Dickson, Catherine: PAHO, USA
Glennie, Judith: Observer, Canada
Hatcher-Roberts, Janet: WHO Collaborating Centre, Canada
Hernández, Antonio: PAHO, USA
Hillman, Don: Observer, Canada
Hillman, Elizabeth: Observer, Canada
Infante, Alberto: PAHO, USA
Jadad, Alex: WHO Collaborating Centre, Canada
Jaudin, Rusilawati: Observer, Malaysia
Kagis, Maija: WHO Collaborating Centre, Canada
Leinan, Linda: Industry Canada, Canada
Lemus, Jorge: Ministry of Health, Argentina
López-Acuña, Daniel: PAHO, USA
Macedo, Cecilia: Observer, Canada

Moe, Judith: CIDA, Canada
Muñoz, Fernando: Ministry of Health, Chile
Previsich, Nick: Health Canada, Canada
Rodriguez, Carlos Ivan: Ministry of Health, Colombia
Saraswati, Jeea: Observer, Canada
Sáenz, Antonio: Observer, Spain
Shea, Bev: Observer, Canada
Shields, Chuck: CSIH, Canada
Tarek, Salem: Observer, Egypt
Tombs, George: ISTACH, Canada
Tugwell, Peter: WHO Collaborating Centre, Canada
Weil, Kathleen: Observer, Canada