Resources for Health Technology Assessment

Summary

This paper describes the important role that health technology assessment (HTA) can play in decisions about health policy and practice in developed and developing countries. It describes the present state of HTA around the world and the potential for and extent of international collaboration. It places HTA as a tool among others, in the broad challenge of bridging the know-do gap in health care management. It goes on to analyze the resources required to improve the conduct and use of HTA in developed and developing countries, and describes the role of Health Technology Assessment International (HTAi) and the International Network for Agencies of HTA (INAHTA) and their wish to work in partnership with other organizations to promote the use of HTA around the world.

HTA as a tool for knowledge translation

One of the most important challenges to improving the quality of health systems worldwide is the need to establish mechanisms for transferring knowledge to action, (i.e., for bridging the "know-do" gap). Such mechanisms require the involvement of many different constituencies, all of whom are committed to achieving evidence based health policy and practice. The HTA community, with its agencies, associations, and researchers, has developed its role around contributing to this effort.

HTA, in its original form, was restricted to the assessment of new "technologies". However, over the years, its focus has expanded to address questions from all levels of decision making in health care (see Figure 1). Today, HTA is about assessing interventions on 4 levels: 1) the technology level (i.e., single drugs, devices, diagnostics etc.), 2) the individual/patient level (i.e., clinical interventions that aim to improve the health of individual patients), 3) the population level (i.e., public health interventions that aim to improve the health of the population, mainly through preventive measures), and 4) to a lesser extent, the policy level (i.e., the ways in which we organize, legislate and finance the health system). As such, it has become an integral part of the knowledge chains that exist on each one.

HTA aims to "globalize the evidence, localize the decision"[1], and, therefore, involves 2 steps. The first comprises a systematic synthesis of the *global* evidence base (i.e., systematic reviews). The second involves an appraisal of this evidence within a *local* or jurisdictional context, engaging local experts and decision makers who play important roles in the dissemination and utilization of the intervention. It may also include an examination of the intervention's potential impact on the higher population and policy levels.

[1] Eisenberg JM. Globalize the evidence, localize the decision: evidence-based medicine and international diversity. Health Affairs 2002;21(3):166–8.

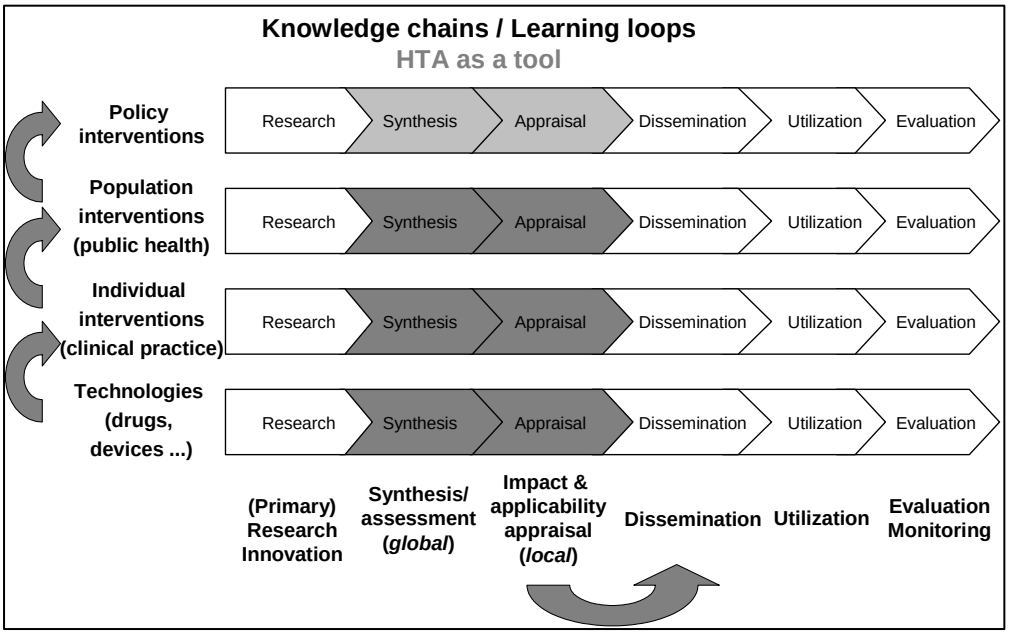

Figure 1. Knowledge chains/learning gaps in HTA

We hope that this puts HTA into perspective and demonstrates its usefulness as a tool for knowledge translation. Below is a more detailed description of HTA.

Background

Around the world, diverse questions about health care arise, such as:

- How should drug reimbursement schemes be organized and financed?
- How should best practice hypertension treatment guidelines be implemented in the health services?
- How effective is screening mammography for early detection of breast cancer in women under the age of 40?
- What is the current evidence on the effectiveness and costs of diagnosis and treatment of back pain?
- What technologies are effective in reducing pregnancy-related maternal mortality in low-resource countries?
- What are the safety, effectiveness, and cost-effectiveness of antiviral therapies for influenza?
- What combination of malaria control interventions is most effective in sub-Saharan Africa?
- What is the effectiveness of implantable cardioverter defibrillators in patients with previous myocardial infarction and left ventricular dysfunction?

In all countries, demand for health care exceeds the resources available to fund it. Rapid innovation and diffusion of health technologies, while offering potential improvements in access and outcomes, bring great challenges for priority setting, resource allocation, patient care choices, and other policies and decisions. Health ministries, physicians, hospital managers, and others are faced with the need to choose between alternative interventions for a given disease, between treating a disease or preventing it in the first place, and/or between treating one disease as opposed to another. Such decisions require the interpretation of existing, often incomplete evidence by different types of experts. They also call for systematic, unbiased, and transparent methods.

What is HTA?

HTA is the systematic evaluation of properties, effects or other impacts of health care interventions. The main purpose of HTA is to inform decision making in health care, including decisions made at the individual or patient level, the level of the health care provider or institution, or the regional, national and international levels. HTA may address the direct and intended impacts or consequences of interventions, as well as their indirect and unintended ones. HTA is conducted by interdisciplinary groups using explicit analytical frameworks and drawing from a variety of methods.

As described above, HTA is context specific, with findings for one health care setting, patient population, or country not necessarily being valid in another.

HTA overlaps or helps to inform other types of health care inquiry, such as clinical epidemiology, evidence-based medicine, health outcomes research, clinical engineering, and health economics. Its role in clinical decision-making is directly related to the field of evidence-based medicine, which refers to the use of current best evidence from scientific and medical research and the application of clinical experience and observation in making decisions about the care of individual patients.

Health technology

The application of HTA has evolved to embrace many forms of technology/ (interventions), including the physical nature, how it is applied, and its lifecycle stage. Health care technology refers to drugs, biologics, devices, equipment, supplies, medical and surgical procedures, support systems, and organisational and managerial systems. HTA addresses the different applications of an intervention, including prevention, screening, diagnosis, treatment and rehabilitation. It is not a one-time evaluation. Rather, it may be applied throughout the lifecycle of a technology, from the design and investigational stages, to standard or established use, and to obsolescence or disposal.

HTA can inform different types of decisions

HTA is used by different types of health care decision-makers, including:

- Regulatory agencies who must decide whether to permit the commercial use of a drug, device or other technology

- Health care payers (health care authorities, insurance companies) who must decide whether technologies should be included in the list of services or benefits (i.e., covered) and, if yes, the extent to which they should be reimbursed (i.e., how much to pay)
- Clinicians and patients who must select appropriate health care technologies which best meet a particular patient's clinical needs and circumstances
- Hospitals, clinics, and other health care organisations who must decide whether or when to acquire or use certain technologies
- Health authorities who plan to undertake public health programs (e.g., vaccination, screening, and environmental health programs)
- Health care product companies who must make product development and marketing decisions.

What does HTA assess?

HTA may involve the investigation of one or more properties, impacts, or other attributes of health technologies or applications. In general, these include: safety, efficacy and/or effectiveness, technical properties, economic attributes or impacts, and social, legal, ethical, or political implications. The extent to which these are addressed depends upon the purpose of the HTA. Nonetheless, the design of an HTA should consider the potential for any of these impacts to affect the practical use of an intervention in health care.

Safety is a judgment of the acceptability of risk (a measure of the probability of an adverse outcome and its severity) associated with using an intervention in a given situation. Efficacy and effectiveness both refer to how well it works to improve patient health, usually based on changes in one or more pertinent health outcomes (mortality, morbidity, quality of life). Of course, an intervention that works under carefully controlled conditions or with carefully selected patients under the supervision of its developers does not always work as well in other settings or as implemented by other practitioners. In HTA, efficacy refers to the benefit of using a technology for a particular problem under ideal conditions, while effectiveness refers to the benefit of using a technology for a particular problem under general or routine conditions (e.g., by a physician in a community hospital for a variety of types of patients). Technical properties can include performance characteristics and conformity with specifications for design and manufacturing, as well as the technology's reliability, ease of use, and maintenance needs.

Health technologies can have a wide range of microeconomic and macroeconomic attributes or impacts. Microeconomic aspects include costs, charges, and payment levels associated with individual technologies, as well as comparisons of resource requirements and outcomes (or benefits) of technologies for particular applications, such as cost effectiveness, cost utility, and cost benefit. Examples of macroeconomic impacts of health technologies are the impact of new technologies on: national health care costs, resource allocation among different health programs or among health and other sectors, employment, competition, and others.

A variety of interventions raise social, ethical, and legal concerns that are often subject to cultural, social, economic, and national differences. Depending on the context, such technologies as genetic testing, contraception, organ transplantation, and life-support systems for the critically ill challenge certain societal norms and standards. Allocation of scarce resources to interventions that are expensive, inequitably accessible, or non-curative raises broad social concerns. The need to assign values to the length and quality of human life when weighing costs and benefits of health technologies can be controversial.

The properties, impacts, and other attributes assessed in HTA pertain across the wide range of types of interventions. Thus, for example, just as drugs, devices, and surgical procedures can be assessed for safety, effectiveness, and cost effectiveness, so can malaria control programs, smoking cessation programs, and electronic medical records systems.

Methods

HTA draws upon a diverse group of methods that can be grouped into two broad categories. Primary data methods involve collection of original evidence, ranging from more scientifically rigorous approaches, such as randomised controlled trials, to less rigorous ones, such as case studies. Integrative methods (also known as "secondary" or "synthesis" methods) involve assessing evidence from existing sources, particularly from reports (usually from peer-reviewed published literature) of primary data studies. These can range from quantitative, structured approaches such as meta-analyses or systematic literature reviews to informal, unstructured literature reviews. Cost analysis methods can involve either or both primary data methods and integrative methods. Most HTA programs rely on integrative approaches, placing greater emphasis on evidence derived from the more rigorous methods. Some HTA programs do collect primary data, or are part of larger organisations that collect primary data.

It is not always possible to conduct an assessment using evidence from the most rigorous types of studies. Indeed, health care decisions and policies often must be made in the absence, or before completion, of definitive studies of direct relevance to a particular policy or health care decision in a given country or health care setting. There are various helpful frameworks and general guidelines for conducting HTA, however there is no standard methodological approach. HTA programs must rely on different combinations of methods subject to their financial resources, time constraints, and other factors.

But HTA programs are increasingly transparent regarding their approaches for searching the literature for potentially relevant evidence, using explicit inclusion and exclusion criteria for identifying the relevant evidence, and applying criteria for rating the methodological quality of individual studies and the strength of findings based on the full body of relevant evidence. HTA processes and reporting must be designed explicitly to avoid any sources of bias or potential conflicts of interest.

Finding the Evidence
Successful HTA requires assembling relevant evidence. For very new technologies, this information may be sparse and difficult to find; for many technologies, it can be profuse, scattered and of widely varying quality. The type of technology and the properties or impacts of interest should be incorporated into a systematic search strategy of appropriate information resources. Among those used more often in HTA are: databases of the published peer-reviewed literature such as MEDLINE/PubMed, EMBASE, CINAHL, and SciSearch; the Cochrane Review Databases, including the Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Trials; Database of Abstracts of Reviews of Effectiveness; HTA Database; and NHS Economic Evaluation Database. A comprehensive guide to information resources useful for HTA is the HTAi Vortal (www.htai.org/vortal).

Expertise
Given the variety of impacts addressed and the range of methods that may be used in an assessment, multiple types of experts can be involved in HTA. Most countries, agencies and programs aim to develop a core staff that is familiar with HTA. These staff may have been trained originally in such areas as medicine, epidemiology, biostatistics, health economics, and health information resources. Depending on the topic and scope of assessment (the technology and impacts of interest), this core staff with methodological and process competence can draw upon other experts with content and context knowledge, who might include any of: physicians, nurses, dentists, and other clinicians; managers of hospitals or other health care facilities; allied health professionals; pharmacists; biomedical and clinical engineers; lawyers; social scientists; ethicists; decision scientists; communication specialists; and patients and patient affairs representatives. Depending on resources, time constraints, and the need for certain types of expertise, HTA agencies often rely upon outside experts or commission certain parts of assessments. However, the HTA agency remains responsible for the quality and findings of its HTA reports.

Differences among lower- and higher-resource countries
Whether within or among countries, HTA should be context specific. Although it originated in and has been used mostly in the wealthier nations, health technology assessment is increasingly used in low- and high-resource nations to provide findings to inform health care policies and decisions. Further, there is increasing international sharing of HTA expertise, information, methods, and findings. It is also an aim among HTA agencies and scientists in the developed countries to assist low-income countries by "adopting" future local HTA activities and helping to build up local expertise.

For many health care interventions, the medical evidence on safety and effectiveness is applicable across populations in different communities or countries. Indeed, evidence used in HTA is rapidly and easily shared around much of the world. However, the desirable or acceptable levels of safety, effectiveness, cost-effectiveness, and other attributes of a technology, as well as acceptable tradeoffs among these, may vary in different communities, countries, or other circumstances. As such, in HTA, it can be useful to "globalise the evidence, localise the decision."

The impacts of a technology are mediated by the context of health care setting, delivery, financing, maintenance, and personnel. For example, in any country, the technological costs of concern are not just the purchase price or capital acquisition costs, but the recurrent, maintenance, replacement, and disposal costs. Too often, technologies fall into disrepair and go unused because these latter costs cannot be met. For example, the World Bank reports that its major investment in medical equipment has been unsatisfactory, as nearly one third of sophisticated medical equipment remains unused and more than one quarter had a downtime of more than 25% due to insufficient maintenance capacity.[2]

Certainly, implementing health interventions in developing countries that have been proven in wealthier nations has been difficult and often disappointing. Conducting HTA and seeking to transfer findings from one country to another should recognise what can be great differences in:

- Epidemiological environments (e.g., relative prevalence of communicable vs. noncommunicable disease; acute vs. chronic disease)
- Physical environments
- Financial resources
- Health care financing and distribution mechanisms
- Cultural acceptance of health care interventions
- Values for personal choice, efficiency, and equity
- Technology maintenance capacity
- Civil and health care infrastructure
- Skilled human resources
- Training and education
- Regulatory environment
- Health professional standards
- Profitability of health care markets (e.g., for technology companies).

International Collaboration in HTA

Informed health technology decision-making is of greatest importance where resources are particularly scarce and the disease burden is high. However, low-resource countries find it difficult to support viable HTA programs. Aside from coping with resource constraints, it is important to close the "know-do" gap in HTA. It is the aim and vision of international

[2] World Health Organization. Medical devices and equipment. Global alliance on healthcare technology. Accessed September 2005. http://www.who.int/medical_devices/collaborations/technology/en/index.html

collaboration to help close this gap, particularly by sharing information resources, expertise, training, and opportunities for practical experience.

Health Technology Assessment International (HTAi) was founded in 2003, with a mission to support and promote the development, communication, understanding and use of health technology assessment around the world as a scientifically based means of promoting the introduction of effective innovations and the effective use of resources in health care.

Toward its mission, HTAi organizes an annual meeting, which is structured around an extensive and diverse HTA program, and distributes the *International Journal of Technology Assessment in Health Care.* Further, it is developing or engaged in other ways to support information exchange, scientific methods, expertise, ideas, experiences in HTA, including: a website (www.htai.org), newsletter, meetings devoted to particular topics or regions, education, exchange of expertise, special interest groups, and travel grants/scholarships. HTAi is a society for individual members, as well as organisational members and sponsors, whose contribution furthers work that supports the mission of the society. HTAi recognises the importance of building strategic relationships with other international bodies in health care, including the WHO and its regional offices for promoting the development and use of HTA globally.

HTA agencies have collaborated in developing HTA methods, information resources, training programs, and other ways of strengthening the field. Shared interests among the growing number of agencies involved in HTA led to the formation of the International Network of Agencies for Health Technology Assessment (INAHTA, www.inahta.org). INAHTA members comprise 41 agencies in 21 countries. Public sources account for at least half of the funding for each INAHTA member agency, and all agencies are affiliated with regional or national governments. Among other resources, INAHTA members contribute information about their completed and ongoing HTA reports to the HTA Database.

Partnership
HTAi welcomes the opportunity to work in partnership with other agencies to develop resources for promote the use of HTA around the world.