HEALTH TECHNOLOGY ASSESSMENT: SUSTAINING EQUITY IN HEALTH CARE

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Summary

Health technology assessment is both evaluation of a technology for safety and benefits, and, more broadly, a policy research process examining the consequences of a technology. Assessment may combine examination from clinical, epidemiologic, economic and socio-legal perspectives.

Developing from early efforts to support decisions in the development of products and processes, HTA emerged as groups and institutions outside the market demanded better control of technology and its consequences. Advances in health-care research and rapidly-increasing health-care costs spurred speedy establishment of agencies at provincial, national, and international levels, but with notably different structures and purpose, and in the absence of any agreed theoretical basis for HTA.

Generally, HTA seeks to evaluate effectiveness evidence, the benefit of technology use under routine conditions. Appraisal is based on rigorous investigation of the strength and quality of research findings, providing the decision process with an analysis of the weight of scientific evidence specific to a health technology. Systematic review

methodology uses comprehensive examination of literature, mainly randomized controlled trials.

Current modalities augment systematic reviews of published evidence. Strategic HTA is a broadly-based discipline for technology decisions in health care, discussing technological options with societal and political implications. Grounded in critical theory, it explores issues of politics, power, professional authority, and community values. Its principal tool is a comprehensive framework applying consistent key dimensions of policy concerns: Population-at-Risk, Population-Impact, Economic-Concerns, and Social-Context (descriptive of the health problem, and the social, environmental context within which it is defined); and Technology Assessment (reviewing scientific evidence on the problem, and the alleviating technologies or health programs offered). Composite measures for each dimension are developed combining clearly-defined, accurately-measured indices, alongside less specific or qualitative measures.

Given current (and greater future) proliferation of competing options in health-care technologies, systematic, inclusive assessment supported by rigorous evaluative methods will be essential if equity and utility for the population are to be served effectively.

1. Introduction

Health technology assessment (HTA) is a field of evaluative research which examines the relative effectiveness of technologies in health care and their costs. Health technology has been defined as including the drugs, devices, and medical and surgical procedures used in the health care system; and the organizational or administrative and support systems within which health care is delivered. In a narrow sense, evaluation of the technology is for safety and benefits when used under ideal conditions (efficacy evaluation). In a broader sense, however, HTA is the process for policy research that examines the short- and long-term consequences of the technology under review.

The assessment of a technology can combine examination from clinical, epidemiologic, economic, and socio-legal perspectives. These aspects are usually specific to the technology being examined. The analytic frame applied in technology assessment activity may take into consideration any, sometimes all, of the following concerns:

- the safety of the technology a judgment of the acceptability of risk in a specified situation, which may include comment on the quality of provider, or type of facility within which the technology is used;
- the benefit of using a technology or procedure for a particular clinical problem under ideal conditions (efficacy), such as within a study environment in a laboratory or at a teaching hospital;
- the benefit of using a technology or procedure for a particular clinical problem under general or routine conditions (effectiveness), such as in a field situation or within a rural or non-teaching hospital;
- considerations of costs, volume of services, and benefits in terms of cost savings and other factors such as lives saved or serious illness prevented;

• the implications of using the technology in the context of societal norms, and cultural values, and social institutions and relations.

Most health technology falls into one of five categories of application: prevention, screening, diagnosis, treatment (including palliation), and rehabilitation. The application of the technology is particularly important, as the assessment question usually focuses on this aspect. Clear criteria exist for evaluating technologies or health programs for screening, diagnosis, and treatment.

Technologies may be assessed at different stages of diffusion - the process by which a technology enters and becomes part of the health care system. These stages include: emerging, new-to-practice, established, almost-obsolete, and outmoded. The patterns of technology diffusion may be visualized in S-shaped curves of adoption and abandonment, which can be gradual or more rapid depending on intricate dynamics that go well beyond measurable benefits the technology might have to offer. To understand this complex of processes, health technology assessment is necessarily a multi-disciplinary branch of learning.

In addition to incorporating methods and understanding from a wide range of fields, HTA seeks to make sense of the available information about technologies, regardless of its source. Evidence is appraised in detail for its strength and validity, and based on the findings, logical and defensible conclusions about the technology are formulated and presented in reports prepared for decision-makers. Generally, assessment is undertaken to examine the effectiveness of health care, and to provide information in a timely manner for better informed decision-making by policymakers, clinical practitioners, industry, and consumers. Further assessment may be undertaken at various stages of diffusion, to provide a critical re-examination of the technology.

The technology assessment dimension incorporates a particular factor into the decision process: the weight of scientific evidence specific to the health technology. Methodological rigor and the application of rules of evidence to what is known about the technology under consideration arguably provide the best basis for reasoned decision-making.

2. The Development of Health Technology Assessment

Systematic HTA is a relatively recent development of the broader movement for technology assessment (TA) which emerged several decades ago. Between the 1950s and the 1970s, hitherto unquestioned acceptance in the industrialized world of technological change as beneficial and progressive was considerably tempered as technology was increasingly blamed for many problems and unexpected consequences, and for increased lack of control. So, for example, nuclear power led to threat of war, automation led to unemployment, chemicals to pollution, data banks to loss of privacy, and so on. Increasing awareness of the consequences of poor planning led to calls for greater public and social control of the direction of technological development. The effect was the emergence of a more systematic approach toward the evaluation of technologies, and how they should be developed and introduced (Figure 1).

In the first of two phases, TA was adopted by companies, organizations, and narrowly-defined interest groups as a goal-oriented tool. It was originally viewed by industry as an analytic discipline to determine and support decisions on which products and what processes should be developed. As such, TA included tests for safety and efficacy in the form of quality control; and analyses such as program-planning, and budgeting and cost-benefit analysis, to examine economic feasibility of new products. TA was thus the domain of engineers, technicians, and later, economists. In this period, health technology assessment (HTA) fell under the same ad hoc research groupings as all other industrial technology, and was greatly limited in public influence. During phase one, therefore TA and HTA were focused on industrial policy issues.

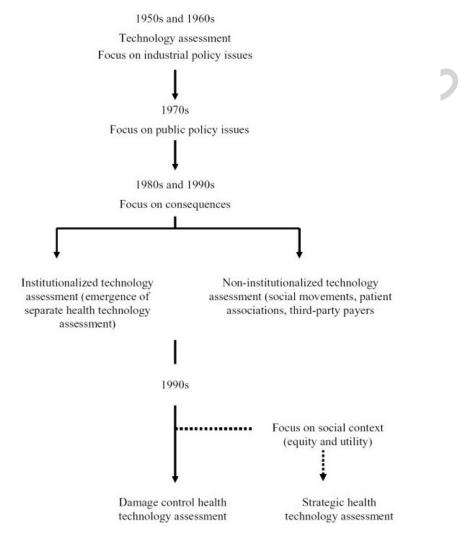


Figure 1: Development of Health Technology Assessment

Phase two is traced to the period when the emphasis of TA shifted to assessment of consequences, especially when these impacted the public purse. Groups and institutions outside the market demanded better social control of technology. A major turning point in phase-two TA occurred in the commercialization of biotechnology, as concern shifted from internal to external issues, and TA became associated with public policy. Public opinion was uncomfortable leaving the direction of such significant

technological change to market forces and policies of laissez-faire, and sent a clear message to this effect through pressure groups and the media. This led to the rapid growth of TA in: (a) non-institutionalized, and (b) institutionalized contexts.

- Non-institutionalized TA and the shift to a more socially-responsive assessment has been attributed to a generalized sense that development should be planned for people. Social movements and pressure groups were key players in the 1980s, their collective purpose being social reorganization. In the health-care sector, there was, for example, the women's health movement, particularly concerned about reproductive health issues including the medicalization of childbirth. Other pressure groups, such as patient associations focussing on a particular disease (heart disease, arthritis and many others) were influential in pressing for technological change. Third-party payers were another active grouping, in their case driven largely by cost concerns. HTA was not, however, an explicit priority of any of these groups, but rather a logical response to issues of particular interest. Thus, no single group developed by itself a comprehensive program of TA.
- It was during the rapid expansion of TA in institutionalized settings that medical or health technology was identified for separately-administered assessment. This occurred almost simultaneously at all levels provincial, national, and international and at an exhilarating rate. Examples ranged from the US Congressional Office of Technology Assessment (OTA) and OECD's special programme for the social assessment of technology, United Kingdom's Parliamentary Office of Science and Technology; and later, the WHO program for regulating drugs and devices, the Foundation for Future Health Scenarios (STG) in the Netherlands, the Swedish Council on Technology Assessment in Health Care (SBU), and the Canadian Co-ordinating Office for Heath Technology Assessment (CCOHTA); followed by the state-level agencies: Basque Office for Health Technology Assessment (OSTEBA); Conseil d'évaluation des technologies de la santé du Québec (CETS), British Columbia Office of Health Technology Assessment (BCOHTA), the Catalan Agency for Health Technology Assessment and Research (CAHTA/AATM), and others.

Several factors precipitated the establishment of separately administered HTA activities: notable in international experience were rapid advances in health-care research and development (accompanied by increased dependency of the medical profession on these advances); the influence of the medical professional heading most national and international efforts (adding physicians to the growing list of TA experts); and, in particular, rapidly-increasing costs in health care. The emerging agencies were, however, quite different in structure and purpose, depending on the local situation. Furthermore, there was never an agreed-upon theoretical basis for assessment. Consequently there were (and are) as many schools of thought and methods of analysis in HTA as there are analysts.

What may be strongly asserted is that TA has never been a neutral tool: it has developed in various forms, shaped by cultural norms and societal values. This need not be regarded as a short-coming, since critical HTA must address the consequences of technology in the context of everyday life, including the realities of dominance, control, and conflicting values. To maintain a useful place in decision-making processes, however, HTA must continue to demonstrate power and validity in its evaluative

methodologies.

3. Establishing effectiveness evidence

The orthodox focal centre of HTA research is aimed at identifying what evidence exists to support the effectiveness of a technology. Effectiveness is defined as the benefit of using technology under general or routine conditions of use, that is, whether in these circumstances, the intervention under consideration is likely to do more good than harm. This is distinct from efficacy. The efficacy of an intervention is established through study of a specific aspect of a given technology under controlled conditions, most desirably the gold standard of double-blind controlled trials. Results obtained under this standard may be suggestive of benefit, but there can be many reasons why the value of a given technology is diminished when applied in real-life situations. For example, practitioner or operator proficiency, patient compliance, or issues of diagnosis, are just some of the factors which mitigate against reproducibility of efficacy findings under routine conditions.

To make an assessment which is of value to policy-makers tasked with concrete health-care choices having significant financial consequences, it is the overall effectiveness that will be in issue. To assist, assessment findings will ideally indicate not only likely short term results, but also some measures of likely long-term benefit. It will also seek to be comprehensive, that is to say, to give an appraisal of practical implications of personnel training and certification, capital expenditures, and broader implications for health insurance or social security.

Given these wide considerations, it is imperative that an assessment adopt rigorous scientific methods if the appraisal process is to produce sound and objectively defensible results. Assessments usually incorporate one or more methods. The preferred methodology is by systematic review, that is, a comprehensive examination of published literature relevant to the technology in question. The principal form of literature required as the basis for appraisal is randomized controlled trials (RCTs), which represent the gold-standard for base measures.

Over recent years, strategies have been developed to identify pertinent published research of this type. Methods for systematic search have been greatly enhanced by modern electronic technical advances, which allow for relatively rapid investigation of standard databases, such as Medline and Current Contents, of peer-reviewed medical literature. To be fully comprehensive, however, literature searches need to identify other sources of research such as government reports, monographs, indices and directories, health newsletters, and other reports which may contain germane material not identifiable through standard databases. Techniques for identifying the more ephemeral publications, sometimes known as 'gray' or 'fugitive' literature, are much less well-developed, but have recently come to be identified as containing important reserves of research material, with the potential to affect assessment findings significantly.

The next step is to undertake a critical appraisal of the identified research material. This process requires the development and application of explicit criteria under which the collected research is surveyed for its strength and quality. Research that has been

conducted using rigorous methods is generally given more weight than research using weaker methods of study. For example, evidence obtained from at least one properly-designed RCT is viewed as stronger than evidence from non-randomized or descriptive studies. An assessment will be more powerful when it is based on meta-analysis (in which findings from several well-designed RCTs are gathered together, reconciled, and subsequently analyzed as a single large study to provide a basis for stronger conclusions), than on reports of expert committees. Systematic evaluation of a technology can draw on research using any assessment method, but currently most technology assessments primarily use synthesis of the literature, expert opinion, and cost-analysis.

Once this process has been completed the assessor is in a position to draw clear and authoritative conclusions about the evidence that exists to support the effectiveness of a technology. The ensuing report should ideally make every stage of the process explicit and transparent, so that other investigators may objectively review both the conclusions and the evidence on which these are based.

4. The Appropriate Role for Health Technology Assessment

Decisions about technologies in health care are made daily by practitioners, administrators and policy-makers. Ideally, these decisions should be based on evidence from comprehensive assessment, that is, information on the safety, effectiveness, costs and the ethical, legal and social implications of the particular technology under consideration. As we have seen, HTA involves systematic evaluation of the properties, effects, or other impacts of health technologies, as broadly defined.

The role governments play in the development and diffusion of technology is clearly an influential one, especially in health care systems with public insurance, but also in mixed or private systems. It spans a wide range of levels of involvement: supporting the development of technologies through funding of research in basic sciences; regulating the marketing of certain technologies and licensing of facilities for the provision of certain technological services; and paying for such services through public funds (medical insurance). Yet, these policy decisions are most often made in the absence of accurate information on the specific, or even general implications of such technological development or diffusion.

Under ideal conditions, a technology should be assessed before diffusion into the social system. However, in the real world, most health technology is adopted before it is examined for efficacy or effectiveness. In fact, the large majority of technological innovations in health care are in use long before any systematic assessment has taken place. Belated assessment (sometimes as late as the second or third generation level) can show technologies to be ineffective, or even unsafe. The costs to the system and society of failure to make comprehensive assessments prior to introduction are sometimes enormous, as was the case with the drug thalidomide for the treatment of nausea in pregnancy.

In recent years, a distinct trend appears to have emerged: HTA as damage control. In addition to the earlier narrow activities of testing for safety, efficacy, and costs, the

damage-control orientation incorporates a subsequent effort to include technical, economic, or social consequences of health care interventions, aimed at anticipating the need for control, through regulation or otherwise. This thinking is based on a rationing perspective, giving centre-place to issues of allocation. The most widely-held (and increasing) perception of HTA is in the 'tool-for-regulation' form.

This standpoint is, however, not entirely appropriate. HTA is currently undertaken by agencies small in number and with resources that greatly limit the scope of their inquiries. The forces which drive the enormous complex of health-policy and care-provision cannot be circumscribed by the efforts of relatively few researchers, however scientifically irreproachable their findings.

In modern conditions, tensions exist between, on the one hand, health-care professionals seeking to do the best for individual patients without regard to constraints of cost and limitations of access, and on the other, funding bodies obliged to accommodate an accelerating demand on tightly-circumscribed budgets. The interplay of competing interests is both inevitable and desirable in an open society. But in such an environment, HTA is not suited for use as a management tool. The regulatory controls that protect the public interest can only emerge from the normal political and fiscal processes that underpin the workings of effective democratically-based institutions.

But while HTA cannot and should not be used as a controlling force, it has increasing potential of great value for all participants in these dynamic processes, namely its ability to develop evidence that is soundly and scientifically based, and to apply comprehensive methodologies so as to assimilate and synthesize data along many relevant dimensions. With such rigorous processes, it has the capacity to assist both the individual practitioner with information on relative effectiveness and safety; and the health-funder with information appropriate to high-quality decisions on resource allocation.

Along this line of development (Figure 1), HTA may serve the population as a whole by making its goal not damage control, but utility and equity (the most good for most people). The following section shows how this can be achieved in practice.

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Biographical Sketch

Dr. Arminée Kazanjian is a Professor at the Department of Health Care and Epidemiology, Faculty of Medicine, University of British Columbia (UBC). Dr. Kazanjian is an internationally recognized Health Services Researcher who has undertaken international collaborations and acted as a consultant to the WHO, World Bank, and UNCSTD. Her work incorporates social epidemiology and health technology diffusion, social and cultural dimensions of care seeking and service provision, and health workforce policy. She is an expert in data linkage of large administrative databases and population-based surveys. A Sociologist by training, Dr. Kazanjian obtained her Doctorate from the Sorbonne in 1977. She was founding Director of the British Columbia Office of Health Technology Assessment at UBC, 1991-2002, and Associate Director, Centre for Health Services & Policy Research, UBC, 1988-2002. Current major areas of research interest include: equitable and quality cancer care for culturally diverse populations, gender and health care utilization, women's health indicators, immigrant health and health care utilization.