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Review article

Developing Health Technology Assessment to address health care system needs

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ABSTRACT

This article discusses the development of Health Technology Assessment methods and HTA institutions, in regards to meeting the information needs of all levels and fields of health policy-making. On the one hand, HTA needs to expand and develop its methods. Although health products and health care services have been its preponderant focus to date, HTA should develop to increase its focus on the “technologies applied to health care” (i.e. the regulatory and policy measures for managing and organizing health care systems) and on policies in non-health care sectors. Such a knowledge synthesis for health policy should not necessarily be called HTA or conducted by narrowly defined HTA agencies. However, the trends observed in several European HTA agencies indicate the recognition of these development needs. Countries embarking on HTA should not consider establishing separate agencies for HTA, quality development, performance measurement, and health services development, but should rather combine these functions and goals into a common knowledge strategy for evidence-informed decision-making on health care and the health system.

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1. Introduction

Health Technology Assessment (HTA) is the “multidisciplinary field of policy analysis that studies the medical, social, ethical, and economic implications of development, diffusion, and use of health technology” [1]. Using the health system as a starting point, this article first provides a

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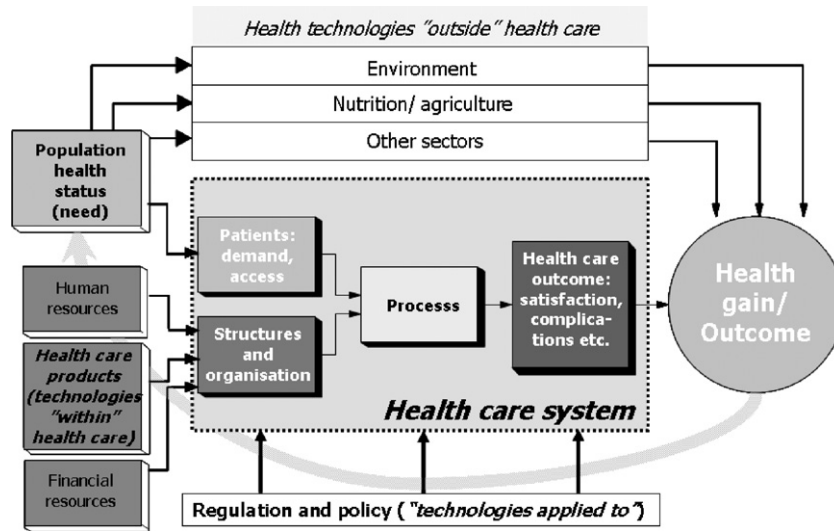


Fig. 1. An input–throughput–outcome model of the health care system in relation to the different types of health technologies.

view of the concept of “health technology”. A brief description of the related information needs of decision-makers is followed by a discussion of possible future developments of institutions involved in producing HTA, from the perspective of health care system needs.

2. Health technologies in the health system

A *health system* consists of all the people and actions whose primary purpose is to improve health [2]. This definition covers a variety of professions and institutions and a broad range of activities dedicated to the promotion, restoration and protection of health. A health system includes health care of ailing individuals, ranging from informal care provided by relatives to highly specialized medical care. It also includes actions targeting whole populations, such as educational campaigns and public health laws that are intended to protect a population’s health (e.g. environmental protection, workplace safety, or water policies). Health systems encompass both individual and population services, in addition to activities aimed at influencing the policies and actions of other sectors, in an effort to address the social, environmental, and economic determinants of health [3]. Contemporary health systems show different degrees of complexity, integration, and co-ordination, which reflects a diversity of socio-political conditions and a varying amount of available economic resources. Notwithstanding this diversity, modern health systems generally pursue the fundamental goals of improving the health of a population, responding to the wishes and expectations of individuals, and providing financial protection against the costs of ill-health [2].

In most countries, the majority of resources available for addressing health system goals are committed to the organization and delivery of preventive, curative, rehabilitative, and palliative health services. These services constitute the *health care system*, which can be defined as the arrangements, individuals, and institutions through which personal health services are provided, organized,

and controlled [4]. The health care system is characterized by a formal structure, whose governance, finance, scope, and content are defined by law and regulations, and its purpose is to deliver health services in the primary, secondary and tertiary sectors, as well as at home, to a defined population [5].

It can be described in the form of an input–throughput–outcome model (Fig. 1). This simplified model illustrates how the health care system contributes to the production of health through the processing of two types of inputs: risk-related input and resource-related input [6]. The first input is based on the health status of a population (e.g. incidence and prevalence of disease and disability). The second represents the financial, human, and technological resources a society devotes to health care.

According to this model, technologies ranging from machines to linguistic and intellectual tools [7] play an important role in the health care system. Health technologies have been defined as the “drugs, devices, and medical and surgical procedures used in medical care, and the organizational and supportive systems within which such care is provided” [8].

Since the health care system embraces more than medical care and is only part of the wider health system, health technologies, therefore, may include the wide range of interventions used in diagnosis, treatment, health promotion, and any other interventions applied with the aim of improving the performance of the health system, thus ultimately the overall health of a population [9]. This article differentiates between three types of health technologies [10]:

- (1) Health care products like drugs, devices, and procedures that can be provided *within* the health care system as it delivers health services. These technologies correspond with the technology input in the model illustrated in Fig. 1 (“Health care products”). We call them “technologies within” the health care system.

- (2) Interventions *applied to* the health care system, in order to organize access, service delivery, payment of providers, etc. corresponds with regulatory and policy measures on “patient demand/access,” “structures and organizations,” “processes,” and “health care outcomes” in Fig. 1. We call them “technologies applied to” the health care system.
- (3) Interventions that promote and protect health *outside* the health care system (corresponds with other sectors policy fields in Fig. 1). We call them “technologies outside” the health care system (e.g. educational services, social services).

Health systems can address major health problems through the combination of these three forms of health technologies. For example, cardiovascular disease can be addressed by providing effective clinical interventions (e.g. aspirin, coronary artery by-pass graft), by reorganizing the methods of providing health care (e.g. disease management programmes, payment of providers according to quality targets), and/or acting outside the health care system, such as on the environment (e.g. through smoking bans, stress reduction programmes in the workplace, etc.).

According to this broad understanding of health technologies, it is obvious that decisions on health technologies are an important part of the everyday business of health services design, management, and delivery in any health system. Health policy-making concerns the application of health technologies both *in* and *on* the system and in regards to both clinical and health system policies.

Following the model proposed by Lomas et al., decisions on these types of health technologies require information on both context-free and context-dependent issues [11]. For technologies applied *in* the health system, context-free issues refers to the questions of whether a technology works and is safe, whereas content-dependent issues refer to questions related to whether that intervention can work in a given context and how it can achieve its optimal effects. However, for many technologies applied *to* the system (e.g. organizational models), the question of whether the intervention works, and even the design of the intervention, is also essentially context-specific.

Policy-makers base their decisions on different sources of information. Evidence from research is one among several other factors and it is not even the prevailing source [12]. Expert and professional opinion, political judgment, the interpretation of values and traditions, and views from stakeholders and contingencies are all relevant inputs in the decision-making and the formulation of policy. Lomas et al. [11] refer to these forms of information as “colloquial evidence”, opposed to information emanating from the application of scientific methods. Since evidence from research on contextual factors is frequently limited, or sometimes entirely lacking, decision-makers most often consider colloquial evidence when compiling information on context-dependent factors [12].

The question is how should HTA further develop in order to respond to these information demands. On the one hand, HTA needs to expand and develop its methods. On the other hand, this paper argues for an expansion of the types of interventions assessed, which, in turn, also calls for further

methodological development. These two expansions may be mutually beneficial.

3. Expansion of methodological approaches

HTA is defined by its aim: to provide input to decision-making in policy and practice [13]. Its intention is to facilitate the consideration of research knowledge by those involved in the decision-making and policy-making processes. Metaphorically, HTA is a systematic knowledge synthesis that “bridges” the gap between scientific knowledge and decision-making [14] and, therefore, HTA is a tool for knowledge management [15]. The HTA-process begins with the identification of a problem facing decision-makers (i.e. their information needs), which is translated into questions amenable with scientific research. These steps lead to an assessment report containing a sound and systematic analysis of the relevant research and information, which is written in a language accessible to the intended target audience [13,16].

Ideally, an assessment is a summary of context-free and context-sensitive issues because both types of information are relevant for decision-makers in the policy-making process. HTA is, by definition, a multidisciplinary activity concerned with both types of issues [1]. That is, HTA should provide an assessment of a technology’s potential effects on health, in addition to an evaluation of its social and ethical implications and the organizational requirements for its application.

However, HTA has mainly focused on context-free issues to date. Several analyses of HTA reports show that the majority of worldwide assessments from the past 15 years have examined the safety and effectiveness of a technology, in addition to considerable analysis on economic issues, such as budget impact and cost-effectiveness. However, approximately only 30% of the assessments considered context-dependent aspects like organizational, social, and ethical issues [17–19]. These empirical findings demonstrate a discrepancy between what HTA claims to be and how it is actually applied in practice. Nevertheless, a recent evaluation suggests an increased focus on context-dependent aspects [20].

HTA has predominately concentrated on the analysis of available research, which, to some extent, may explain this discrepancy. The systematic review of research, particularly regarding clinical and economic aspects – is the most common methodological approach in the field of HTA [21]. The systematic review approach is adequate to uncover gaps in the evidence in any research field; however, it has no capacity to fill the gaps when primary research is lacking.

HTA, however, does not have to be limited to synthesizing available research [22]. Its methodological approach can also include the collection and analysis of primary data driven by policy-relevant research questions. As a part of HTA, primary research allows closing knowledge gaps and can be especially relevant for the assessment of context-dependent issues. Therefore, HTA has the option of conducting more primary research in an effort to effectively respond to the need for information on context-dependent issues, when evidence gaps are found.

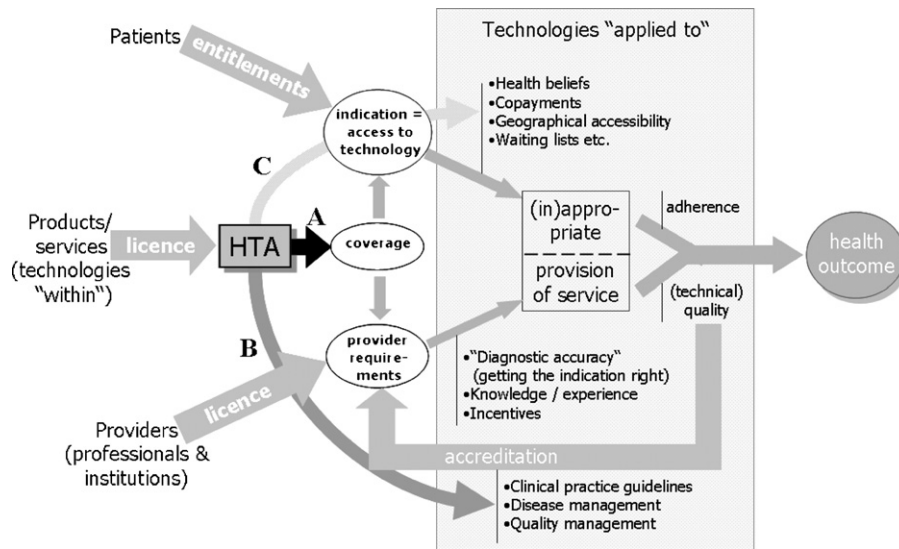


Fig. 2. Place of HTA in the health care system: current emphasis of coverage decisions (A) and expanded roles (B and C).

Some HTA programmes already invest considerably in the funding of policy-relevant primary research [23]. In England, for example, the National Coordinating Centre for HTA coordinates and manages research (i.e. pragmatic trials) to inform decision-making in the National Health System. The recent developments, through which the coordination of the English HTA programme and the Service Delivery and Organisation Programme have been brought together at the National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre (NETSCC), may strengthen this type of research further. Similarly in the Netherlands, primary research that is relevant to the health system is funded within the HTA programme framework, which includes a research program on cost-effectiveness and one on the implementation of research that focuses on the optimal incorporation of cost-effective technologies. In Denmark, primary research is also conducted within the HTA programme, not only to assess the effects of particular technologies on health, but also to analyze patient preference and acceptability issues, which are increasingly being assessed using empirical data from qualitative health research.

HTA must clearly identify socio-political aspects as one of its areas of analysis, independent of whether primary research is conducted for context-dependent issues. Socio-political examination requires approaches other than clinical epidemiology and health economics. Some HTA agencies already employ researchers with a background in ethics in an effort to achieve sound, ethical analysis in their assessments [24,25]. The HTA model recently developed by the European Network for HTA acknowledges both the relevance of predominantly context-dependent issues and the methodological spectrum required to adequately approach these issues [26].

HTA will need to continue developing to provide sound assessments of context-dependent issues in order to transfer research knowledge to the decision-making process, for example, on patient and provider preferences, ethi-

cal challenges, and socio-political issues. If HTA does not improve its responsiveness to context-dependent issues, colloquial evidence will remain the main source of information for decision-makers and HTA will fail to establish a robust bridge over this particular knowledge-action gap.

4. Broadening the scope

HTA has developed significantly and probably achieved its greatest impact on decisions related to the availability and reimbursement of health care products and services [27,28]. In European countries, these coverage decisions generally develop into highly formalized processes, with the use of HTA being enforced by law in France and Germany, for example. Two major implications may result from reducing HTA to decision processes related to the coverage of health care products and services. First, this implies a predominant focus on issues of effectiveness, cost, and cost-effectiveness. However, according to the model presented in Figs. 1 and 2, entering health care products into the health care system is only one of several inputs in the production of health. The organization and delivery of health care is a complex matter, which requires additional types of decisions. Decisions must be made regarding the setting in which the intervention is to be delivered (primary/specialized care and outpatient/inpatient care), the resources necessary to ensure access to products and services, and the means of achieving the optimal results from them. For instance, a decision to implement mass screening for breast cancer requires the screening programme to be designed and organized in detail, including educational campaigns and the assurance of equitable geographical and socio-economic accessibility. HTA may determine how the technology should be provided (arrows B and C in Fig. 2), therefore, it can contribute to achieving a “community effectiveness” as close as possible to the efficacy suggested from clinical trials. In contrast the coverage process refers

exclusively to whether the technology will be provided or not (arrow A in Fig. 2).

Second, limiting HTA to coverage decisions tends to obscure the potential role of the HTA approach in the assessment of technologies applied to the health care system as a whole, such as interventions that organize access, service delivery or payment of providers, and aim to improve quality. Surveys of HTA reports suggest that this kind of interventions has rarely been an object of assessment [17,18]. Similarly, the assessment of public health and health promotion interventions outside of health care (e.g. traffic safety policies) has played a very limited role in the work of HTA agencies [29]. It appears that HTA covers health technology first and foremost in its narrowest sense (e.g. drugs and clinical interventions used within the health care system) rather than the broader meaning described above. Therefore, it is limited to a clinical policy-making tool, rather than being applied to health policy-making in general. This discrepancy adds to the methodological discrepancy identified earlier. In accordance with Ham et al. [30], we argue that since health systems are increasingly demanding evidence-based decisions from health care providers, policies related to the organization of health care delivery should also be informed with the highest quality of evidence. In our view, interventions targeting the health care system, as well as interventions beyond the health care system, should be assessed in terms of their capacity to improve health and any social and ethical consequences they may cause. The expansion of the breadth of evaluated technologies is one of the issues on the HTA development agenda [31].

Covering such “technologies” within a broader scope requires the consideration of research designs other than those typically used to assess clinical effectiveness [32]. Traditionally, this is the domain of those concerned with health services research and health policy and systems research. Thus, it is debatable whether such efforts should be labelled HTA, as the term may alienate health service and system researchers. Nevertheless, HTA’s rigorous and transparent way of synthesizing research evidence should clearly be followed when addressing health system questions. Particularly in health system reform, there is a need for multidisciplinary assessments, despite the associated methodological challenges [33].

Both the methodological expansion and the broadening of the scope of assessed technologies require the development of HTA agencies, employing more social scientists, ethicists, and policy analysts. Otherwise, the credibility of broad-based assessments will be challenged, either due to methodological or content shortcomings. The consolidation of the scientific basis of HTA is essential to increasing its relevance and addressing future challenges [31].

5. Institutional/structural expansion

The recent developments of European HTA institutions reflect the above mentioned considerations. For example, the Norwegian Knowledge Centre for the Health Services (NOKC) was established in 2004, through the merging of

the Norwegian Center for HTA, the HELTEF-Foundation for Health Services Research and the Health Services Research Unit at the National Institute of Public Health. NOKC has a mandate to conduct knowledge syntheses for all types of health related interventions. It is also involved in quality improvement by monitoring performance and safety and by participating in the development of clinical guidelines. Through this approach, NOKC links the ideas of evidence-based practice with those of outcomes and quality improvement and, more recently, with patient safety movements. In Belgium, the Federal Health Care Knowledge Centre (KCE) was established in 2002 with a mandate to support health services policy- and decision-making through its work encompassing “classical” HTA reports, the development of clinical guidelines, and health services research. In Ireland, the Health Information and Quality Authority (HIQA), established in 2007, is mandated with assessment tasks that support decision-making in the Irish Department of Health. It is also responsible for setting standards for health and social care facilities (e.g. hygiene and infection control standards) and for inspecting such facilities. In Scotland, the NHS Quality Improvement Scotland (QIS) is a merger of five institutions and its purpose is to ensure that knowledge is used to promote improvements in the quality of healthcare. It is responsible for setting standards of care, providing advice and guidance on effective clinical practice, and scrutinizing the performance of the health system. Finally, the English NICE (National Institute for Health and Clinical Excellence) has recently been asked to identify performance indicators and set standards, thereby further expanding its role, which was already increased when it integrated with the Health Development Agency in 2005.

These institutions illustrate a tendency to converge the production of HTA reports, health services research, and quality assessment related activities under the same institutional roof. This is also observed in several other European countries and adds to the traditional involvement of many HTA agencies in the development of clinical practice guidelines. These developments reflect the recognition that the knowledge needed to manage the health care system in an evidence-based manner transcends classical HTA reports. Knowledge needs include, but are not limited to, research on the needs and demands of patients and providers as well as data on the quality of care, which, in turn, requires a definition of evidence-based standards and indicators. Classical HTA reports are vital for the improvement of health services but evidence from research on the organization and delivery of health services is at least as relevant [34]. These tasks and research traditions may profit from the institutional proximity to the culture of HTA, with its declared intention of acting as a knowledge broker within the health system and supporting the health services by collecting, analyzing, and disseminating useful knowledge.

It has been proposed that the evaluation of HTA organizations be on the agenda for future HTA development [31]. An important question to be addressed here will be how HTA professionals and organizations react to the institutional developments and relocations within the health system.

6. Final remarks

If the ambitions of the HTA community are to be met, the HTA approach needs to continually develop and expand. HTA will need to increase its focus on regulatory, financial, and policy measures for managing and organizing health care systems, in addition to addressing policies in other sectors beyond health care. Furthermore, it will also need to conduct more primary research and, in general, to incorporate other fields of research in order to respond to context-dependent issues.

It may be that a stronger emphasis on *policy analysis* of clinical technologies in HTA may provide opportunities to increase the use of systematic research syntheses in *analyses of policies* (or policy options). Thus, common terms like *evidence* or *knowledge synthesis* may be more pragmatic. In other words, the call for expansion of the methodological approaches in HTA may lead to an increase of the analysis of the technologies applied to and outside the system.

Countries embarking on HTA, including both low- and middle-income countries, should not consider establishing completely separate agencies for HTA, quality development, performance measurement, and health services development, but should rather combine these agencies into a common knowledge strategy for evidence-informed decision-making in the health services and the health system.

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