

Health-technology assessment: Its role in strengthening health systems in developing countries

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Since the 1900s, there has been rapid generation, continuous innovation and incremental improvement of medical technologies. However, not all innovation and development result in overall health gains, nor does their implementation result in improved cost-efficient solutions. Health systems worldwide need to ensure efficiency and demonstrate value for investment, and when coupled with cost pressures and constrained resources they create a difficult decision-making environment for investing in health technology. To overcome these challenges there is a need to evaluate all technologies and eliminate those that are ineffective and not cost-effective, and that have been superseded. Evaluation should consider the availability of resources as well as the organisational, societal, legal and ethical issues pertaining to the country or the local setting. Starting in the 1950s, the concept of health-technology assessment (HTA) has been developed to generate evidence-based foundations to illustrate the relevant preconditions and consequences when using a health technology. It involves multidisciplinary teams applying a systematic approach that is grounded in the scientific method. The goal is to generate, or synthesise, the highest possible level of evidence to inform the decision-making process about health technologies. HTA offers a simple structure to unify the multiple dimensions (including clinical, patient-related, organisational, economic, ethical and legal aspects) in the consideration of complex problems/questions regarding technology deployment and reimbursement. However, its role has evolved to encompass technologies from inception to obsolescence as well as early awareness and alert systems, reassessment post introduction, evidence briefs and recommendation for disinvestment. HTA is increasingly seen as an innovative way to sustain and improve health systems. This process can contribute towards decision-making information at all levels of the healthcare system, including political, administrative and clinical. It is regarded as a 'way of thinking' to improve decision-making related to the planning, administration and management of healthcare interventions.

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Overview of health technology assessment

According to the World Health Organization (WHO), healthcare technology is broadly defined as the practical application of scientific knowledge to disease prevention, diagnosis, treatment and rehabilitation care.^[1] This includes drugs, devices, procedures and the organisational and support systems within which care is provided. Health technology assessment

(HTA) is the process, usually applied to the field of policy analysis, whereby healthcare technologies are subjected to a review by a multidisciplinary team. HTA studies the medical, social, ethical and economic implications of the development, diffusion and use of healthcare technology.^[2] The objective is to provide a synthesis of the best available evidence to support policy decisions. In doing so, wide stakeholder



engagement is required, including from patients, service users and providers, industry and academic groups. The goal is to substantially improve patient outcomes by supporting investment in effective and efficient technologies/services, which is ensured by HTA processes being grounded in rigorous research methods that are transparent and repeatable, and that account for bias.

Based on Drummond *et al.*'s^[3] framework, one of the key principles is the method of HTA. International organisations and networks, the WHO and individual agencies have developed frameworks and methodological tools to assess a health intervention. HTA guidelines differ among organisations, in areas such as the range of evidence accepted, the methods used and the scoping of topics to be addressed.^[3] However, irrespective of methodology, it is important to clearly show and specify the use and interpretation of different data and their sources.

In the context of HTA, multidisciplinary teams comprise experts from various medical disciplines, including clinicians, epidemiologists, information scientists, biostatisticians, biomedical engineers, public health specialists and health economists. Team structure will depend on the technology being reviewed and the point where the technologies are in their lifecycle. For these resources to produce quality information, they should have the capacity and support to find, collect and analyse information relevant to the specific context.

In many Organisation for Economic Co-operation and Development member countries, agencies have been established to support the HTA teams, and all have the common goal of being key drivers for quality and safety, as well as facilitating and encouraging the best use of resources in health services.^[4] However, an agency's organisational structure and governance needs to reflect the cultural traditions, healthcare systems and fiscal climates of the region or country. Establishing such a structure requires an appropriate institutional and legislative framework, as well as financial resources. HTA bodies may:

- receive public funding only and be established by ministries of health (at national, provincial or regional level)
- receive a mixture of private and public funding
- be independent of governments
- be situated within academia or initiated by organisations of health professionals.

Critical to establishing an HTA mechanism is securing a solid commitment from the decision-makers that HTA

and the findings on clinical evidence, applicability, cost effectiveness and budgetary constraints are embedded in their decision-making process.

Health systems and HTA

According to the WHO,^[1] a health system consists of people, institutions, resources and activities whose main function is to promote, restore and/or maintain health. Acknowledging that not all countries can follow the above definition of a health system, it furthermore states that a modern health system should ideally:

- endeavour to improve the health of the population it serves
- respond to the public's reasonable expectations
- safeguard against the cost of an individual's ill-health.

There are large differences between countries in the way financial resources are obtained and distributed. This extends to differences in services provided by various healthcare professionals, and the organisational structure for their delivery. However, health technologies are common to all countries, and play an important role in achieving the goals of the health system.^[5]

HTA should directly influence policy- and decision-making processes at all levels, i.e. national, regional and local. Where HTA is placed will depend on whether a technology addresses a whole population issue (e.g. funding hepatitis C treatments) or a local issue of service delivery (e.g. imaging services). Key to HTA placement is the power to negotiate a price or authorise the allocation of funds for purchase. Kristensen *et al.*^[6] propose a close relationship between HTA and policy-making (Fig. 1), and consider HTA as a bridge between research and decision-making.

The ideal of HTA is to provide a comprehensive review of clinical evidence, and exhaustive economic, social and ethics analysis requires significant resources

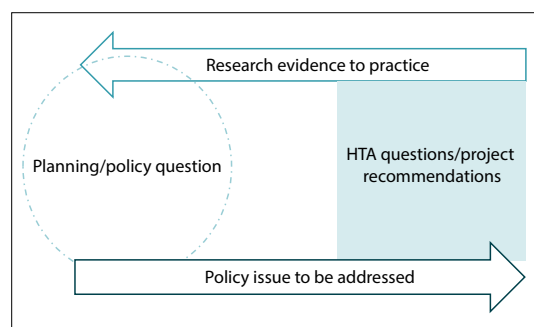


Fig. 1. Adapted from *HTA informing decision-making*, Kristensen *et al.*^[6]



and time. The pace of technology development has required adaption in HTA methods to meet the needs of health systems. Increasingly, assessment is within a framework of potential, risk and cost. These three factors influence the evidence required to support decision-making within a health-system context.^[7] Campbell *et al.*^[7] argue that more evidence is required for high-promise interventions, irrespective of cost, if they are deemed high-risk. In contrast, a technology of similar promise but of low cost and judged to be low-risk requires less evidence. This framework allows the tailoring of HTA to be fit for purpose. This and other efforts to increase pragmatism within the HTA field will extend its utility in strengthening health systems.

Such pragmatism has resulted in many HTA product types; however, all are based on adherence to protocol, transparency and being repeatable.^[8] The products vary by scope, stage in technology lifecycle, promise and risk profile. Furthermore, the actual decision-making (appraisal) can be a part of the same or a separate process. In England and Wales, the National Institute for Health and Clinical Excellence conducts appraisals using the evidence coming from HTA, in a process that leads to guidance.^[9] This is policy-making beyond HTA processes, and even involves a decision endpoint.

Furthermore, HTA products can play a valuable role in transnational collaboration if the product has been appropriately conducted, clearly and precisely documented so that it can be assessed for transparency, timeliness, relevance and appropriate use of evidence.^[10] Indeed, the pace of innovation requires efficient HTA generation and implementation, and this can only be achieved through collaboration both within and between health systems. The need for cooperation and sharing of information across cultures at a global level is evident from the many international networks and societies devoted to HTA. An example is the European network for Health Technology Assessment (EUnetHTA), established for HTA collaboration, which has developed models for sharing HTA reports between countries. This framework is based on nine domains:^[10]

- Current use of the technology (implementation level)
- Description and technical characteristics of the technology
- Safety
- Effectiveness
- Costs, economic evaluation
- Ethical aspects
- Legal aspects
- Organisational aspects
- Social aspects.

Table 1. Characteristics of different kinds of HTA reports*

Characteristics	Full HTA report	Mini-HTA	Rapid review
Describes characteristics and current use of technology	Y	Y	Y
Evaluates safety and effectiveness	Y	Y	Y
Determines cost-effectiveness	Y	N	N
Provides information on cost/financial impact	Y	Y	NA
Discusses organisational considerations	Y	NA	N
Addresses ethical/social and legal considerations	OPT	N	N
Conducts comprehensive systematic literature review or a systematic review of a high level of evidence	Y	Y	N
Critically appraises the quality of the evidence base	Y	Y	NA
Conducts a review of only high-level evidence or of recent evidence, and may restrict the literature search to one or two databases	N	N	O

Y = yes; N = no; NA = not always; OPT = Optionally; O = often.
*Adapted from Merlin *et al.*^[8]

Key to collaboration are the common methodologies and central access to completed reports.^[11] These domains define the 'landscapes of HTA' that should be considered when planning an HTA in Europe. According to EUnetHTA model, an HTA process can be based on different combinations of these domains, e.g. legal aspects may be important in some cases, while domains like effectiveness and safety issues of cost and economic evaluation should be covered in most HTAs. The EUnetHTA framework, although complex, is flexible, and provides clear guidance on the information needed to address each domain and, importantly, suggests resources to acquire the information. It also provides the scaffold to refine the scope of HTA processes to fit the needs of the health system, and it can be readily adapted to fulfil the definitions of HTA products proposed by Merlin *et al.*^[8] (Table 1).

Decentralised HTA to support health systems

The growing acceptance that medicine should be evidence-based has flowed on to the use of evidence within health policy decision-making.^[12] Like clinical care, defining health policy to strengthen health systems should be the domain of those responsible for its implementation. This aligns with the World Bank position regarding investing in health.^[13] The objective is decentralisation, to allow services and health expenditure to be guided by local need and user preferences, as well as increased awareness of fiscal responsibility, and greater accountability and equity

through resource allocation to marginal regions and groups. However, the impact of decentralisation is yet to be fully realised,^[14] partly owing to the complexity of decentralisation and the need to establish local governance systems and develop local capability.^[15] For a local overview of health systems, the implementation of HTA processes can assist in addressing these challenges. However, this requires the training of personnel to conduct assessments and the provision of systems to support the HTA process as well as to facilitate the collaboration and commitment of all those responsible for service delivery.

The drive for decentralisation has increased through advancements in health systems requiring the application of HTA methodologies at the regional and hospital levels. The main challenge to use HTA in hospital management relates to the decision-making arena and the need for rapid decisions. This has contributed to the so-called 'hospital-based HTA'.^[16] The purpose of these HTAs are to evaluate health technologies 'in context', in order to support decisions about the introduction of innovative and new technologies and to improve system efficiency by improving microeconomic efficiency. In 1982, CEDIT (Comité d'Evaluation et de Diffusion des Innovations Technologiques) was one of the first hospital-based agencies in Europe with the aim of supporting hospital managers in the management of technologies by assessing technologies on the principles of HTA.^[16]

In 1994, the Danish National Board of Health, a forerunner of the Danish Centre for Evaluation and Health Technology Assessment, issued a recommendation that a form capturing the HTA philosophy should be completed upon application for hospital devices and equipment. This form contained questions about the technology, the patient, the organisation and financial aspects, and is now recognised as the mini-HTA tool. This model is currently being applied in many hospitals in Denmark, and is also compulsory in the Regions of Denmark's annual collection of early warnings. A study in 2006 by Ehlers *et al.*^[17] to evaluate local decision support tools in Danish hospitals found that mini-HTA reports were already being used in most hospitals surveyed, and that local engagement in the HTA process was important for both the use of the reports and for implementation aspects.

HTA and public health challenges

The WHO defines public health as an organised effort by a society to improve, promote and restore the health of its population.^[1] Assessment of public health interventions poses additional challenges because of the engagement with a diverse stakeholder cohort, including public health professionals, clinicians,

politicians and consumers. These challenges are exacerbated by a lack of standardised methodologies, and difficulties in measuring direct and indirect consequences of the intervention.

Important trends, however, force us to consider assessment of public health interventions. One of these is the growing burden of chronic diseases that accompany the ageing population.^[18] Due to the complexity of the intervention, one must consider the impact across individuals as well as community, organisational and policy levels, measure the effects on intermediate outcomes and examine the effects.^[19] Such methodological challenges are tackled in European Union projects such as INTEGRATE-HTA.^[20] The present trends and challenges in the public healthcare system call for the further development of scientifically based decision-making in public health, and the production of reports which address continuous developments in public health.^[19]

HTA in developing countries

HTA is recognised internationally as a valuable tool for supporting decision-making at all levels of a health service.^[21] This in-depth, scientific, systematic multidisciplinary approach to evaluating health technology interventions has not been utilised generally in the South African (SA) public sector to inform decision-making.^[22]

Poorly made decisions at both macro- and micro-levels in the health sector commit the institutions to current and future costs which they can ill afford. In countries like SA, with transitional economies, HTA is therefore needed especially when scarce resources demand smarter decisions to ensure efficient and effective outcomes and to understand the systemic implications of introducing technologies at all levels of the health system.

As stated earlier, HTA is about bridging the gap between research and policy and planning. It is important that research is done locally to develop the best applicable information to be used in decision-making. Though HTA studies have been conducted in other countries, it is important to consider technology-transfer issues in this context. Health technologies, which include medical devices, are recognised as the main platform for healthcare delivery, and they pose complex challenges in their use. Research and development of these technologies are not as stringent as those for drugs, and the pace of technological advancement outstrips the evidence base, which further complicates their evaluation.^[23] Health technology presents a serious challenge to public health, which faces inequalities, issues of equity and cost-effectiveness. Therefore, understanding the local environment is vital to develop



policies around medical devices, to ensure they can be implemented.

Although evidence of best practice can be obtained from international experience, ignoring the local setting could mean that these practices remain theoretical and not applicable. The majority of the medical devices being used in the SA context are purchased internationally (US, Europe, China and Japan). This has implications for the users in SA, as these devices are researched and developed in these respective countries with systems that benefit users in these countries. An HTA strategy that protects patients from unsafe and ineffective devices is post-market surveillance. This is a problem for users in SA, as these surveillance systems are not in place.

The main hurdle is the lack of use of the HTA framework to support decision-making related to the procurement, use and disinvestment of health technologies in policy and planning in the SA healthcare system. A focus-group discussion with hospital CEOs has shown that HTA is not being uniformly used in the public decision-making process, and identified two main problems:^[22]

- Problem 1 is the lack of use of the HTA framework to evaluate health technologies in the SA public healthcare system.
- Problem 2 is the lack of a health-technology decision support tool to guide decision-makers to ensure the best diagnostic, therapeutic and economic outcomes.

The development and integration of a broad HTA framework in policy and planning, to optimise the management of health technologies in public hospitals, should address these problems to ensure the safe and effective delivery of patient care.

Conclusion

Limited resources raise the necessity of making decisions based upon evidence, and therefore the need to establish a system that supports decision makers. The process of HTA and its implementation will contribute to establishing a balance between equity, quality healthcare and efficiency in need prioritisation, investments decisions, organisational impacts of new and emerging technologies and reassessment of the value of existing interventions. Establishing a formal and institutionalised system of HTA will then result in effective implementation of the recommendations and findings, accompanied by close monitoring of the interventions.

Setting up HTA units can be challenging and time-consuming, and involves close collaboration between a variety of stakeholders, capacity in scientific research and financial resources. At a local level, immediate control over health spending can be achieved through establishing a hospital-based HTA capability. It can start off as a small

committee or unit, and evolve into larger organisational structures serving multiple hospitals. A smaller unit can build on the knowledge generated elsewhere and contextualise it to its own setting, while a large institution may solve complex multidimensional questions. The structure will thus depend upon the decision-making needs and ecosystem, the availability of qualified human resources and available financial resources.

As depicted here, HTA has been widely embraced as a valuable multidisciplinary scientific approach to the evaluation of health technologies. Economics is only one component of technology assessment, and the broader HTA framework that incorporates social and ethical issues lends itself to wider applications, resulting in overall system benefits. HTA will yield valuable information to address deficiencies in our health system. In addition, it will encompass a wider understanding of the overall impact, requiring comprehensive policy considerations, identification of knowledge gaps and the need for research.

The adopting and production of high-quality assessments is directly related to available expertise, experience and skill level, relevant capacity building, communication and implementation of recommendations. Ultimately, to adopt HTA is to embrace a culture of evaluation and accountability, and will contribute towards optimising the management and delivery of healthcare, with improved outcomes for patients, operators and institutions.

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