

Challenges and limitations to adopting health-technology assessment in the South African context

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Healthcare systems across nations develop in response to the social, economic and political situations of each country. Nevertheless, all health systems cater to the health needs and wellbeing of their population. This is achieved through both the delivery and financing of services to ensure patient access to health services and technologies. However, all countries, no matter whether developed or developing, are faced with finite resources. To achieve the maximum health benefits for the public, decisions need to be made on the organisation of the health-service delivery system, the type of interventions to be offered and the manner of service delivery. There are two distinct parts to a decision-making process: the collection and synthesis of evidence, as part of a health-technology assessment (HTA), and the appraisal of the evidence, framing the recommendations to a given context. HTA is a multidisciplinary study that provides information on the introduction and diffusion of the technology in question, as well as information on price, reimbursement and the appropriate targeting of the technology for effective clinical practice. There are various methods and frameworks available to conduct HTAs. Here, we showcase the European network for Health Technology Assessment (EUnetHTA) Core Model, developed in Europe, that is used fully, partially or adaptively by European countries. As decision-making is the process of selection of the best possible course of action among all the available options, those making decisions need tools to consider multiple factors in a consistent, transparent and reproducible manner, for example, by using multiple-criteria decision analysis. However, it is important to consider that these tools were developed in countries with health systems very different to those of South Africa and low- to middle-income nations, which raises the question of their limitations and the adaptations necessary to fit to the health-system needs of these countries.

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Irrespective of country, policy-makers see the need to govern and manage an ever-expanding diffusion of new and innovative health technologies in national health services.^[1] A health technology may, for example, be a drug, an organisation of services, a medical device or a diagnostic. This demand has led to the advancement of health-technology assessment (HTA) techniques to generate 'fit-for-purpose' reports that present the best available evidence to inform policy-making. HTA is the study of the medical, social, organisational, ethical and economic implications of the development, diffusion and use of health technology. It is a multidisciplinary field of policy analysis, and encompasses the assessment of the quality, safety, efficacy, effectiveness and cost-effectiveness of healthcare interventions and technology. Therefore, tools such as cost-effectiveness analysis and budget-impact models, although still widely used, are not adequate for evaluating a health technology, as their one-dimensional nature is insufficient to capture the typical multiple benefits of a health technology.^[2] The first steps to document HTA methodologies can be traced back to the

seminal work titled *Canadian Economic Evaluation Guidelines* (1st ed. November 1994),^[3] published by the Canadian Agency for Drugs and Technologies in Health. This was followed by a work by Goodman^[4] in the USA, the latest online edition of which was updated in 2014, and one by the Israeli Center for Technology Assessment in Health Care in 1998.^[5] This level of rigour has subsequently been applied by other disciplines, especially in the fields of clinical science, life sciences and engineering science, with a focus on the development of HTA methods that incorporate all aspects of healthcare delivery and health economics. The outcome of these innovations in HTA has been a remarkable increase in the number of HTA agencies and the volume of assessments.

The EUnetHTA Core Model – a standardised approach to HTA

This proliferation of HTA agencies and the consequent multitude of approaches to HTA resulted in the need for the development of common methodologies, to increase the transferability of HTA



reports across jurisdictions. This paved the way for the evolution of the European model, the European network for Health Technology Assessment (EUnetHTA) Core Model,^[6] which is now in its third iteration. EUnetHTA (<http://www.eunetha.eu/about-us>) is a network of HTA organisations across Europe, established with the aim of standardising evidence generation and working jointly towards providing support to policy-makers at national and regional levels. To accomplish this task, the Core Model was developed by EUnetHTA members for its members. The model provides a standard method for evidence synthesis, structured and presented in a standard format.^[7]

The model is divided into nine domains (Fig. 1) representing the use, consequences and implications of the health technology in question. A domain is divided into several topics, and each topic is further divided into several issues. Each issue covers a specific area and is divided into separate questions, the responses to which provide an assessment of a health intervention.^[7] An assessment element is a combination of a domain, topics and issues (Fig. 2). A by-product of this development is a simplified rapid-HTA model^[8] that is currently being used in various countries.

The challenges of introducing HTA

Using Italy as a case study, what were the challenges that needed to be addressed in adopting HTA and the EUnetHTA Core Model for decision-making and policy development? In Italy, the first steps

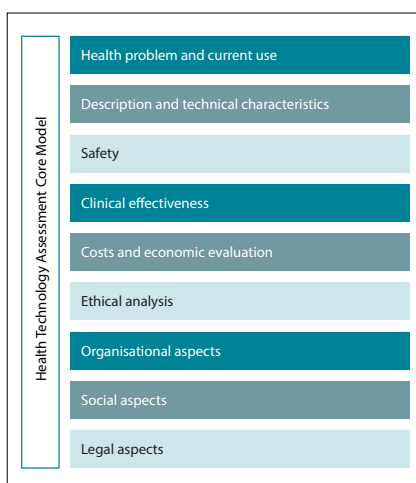


Fig. 1. Domains of the EUnetHTA Core Model.

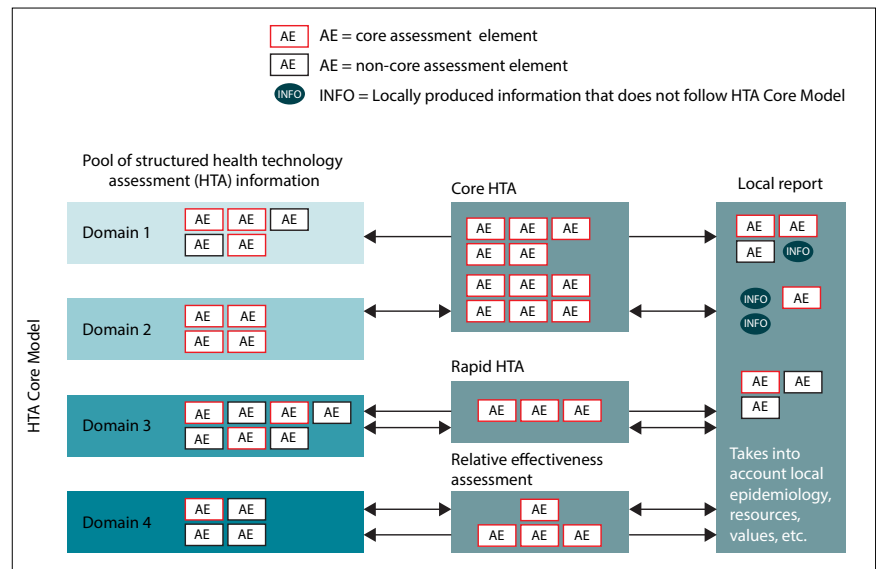


Fig. 2. EUnetHTA Core Model implementation scheme (adapted from the presentation by Finn Børllum Kristensen, Director, Secretariat for EUnet-HTA, Croatia meeting, 2010). (HTA = health-technology assessment).

towards HTA can be traced back to the initiatives of the National Institute of Health in the 1980s, when the effectiveness and safety of large equipment was considered from a technical viewpoint.^[9] This was followed by the introduction of the National Health Plan in 2006, and the founding of the National Agency for Regional Health Services (AGENAS), a technical scientific agency which oversees the uniformity of services offered to citizens by various regional health services. To date, there has been limited uptake of HTA, mainly due to the fragmentation of the 21 regional health services. What can be learnt from the Italian experience? In brief, the factors that hinder the introduction and further development of the HTA methodology, the sole purpose of which is to serve the policy- and decision-makers,^[10] can be classified as being organisational, scientific and material.^[11] These limitations need to be assessed and addressed if the introduction of HTA in Africa is to be a success.

Organisational challenges reside in developing an awareness in policy- and decision-makers that HTA exists, and then educating them on the strengths and weaknesses of the tool. Conducting HTA, and the use of decision-making tools such as multiple-criteria decision analysis (MCDA), are not alternatives to making decisions about where healthcare funds

are spent. Our experience shows that there is a misconception that HTA is a substitute for the decision-making process, rather than a tool to assist in making decisions, and this needs to be overcome for the effective introduction and use of HTA. In addition, another major organisational issue is capacity building to develop and retain a core group of experts capable of conducting HTA. There are abundant training courses; however, there are few opportunities for the mentoring of staff to adopt HTA within the context of their health service. The International Network of Agencies for HTA (<http://www.inahta.org/>), through its mentorship programme, provides a potential avenue to gain the necessary experience. These programmes are being supplemented by emerging postgraduate qualifications that are grounded in the practical application of skills for technology assessments – for example, the HTA programme at the University of Pretoria.

Capacity building aside, another common issue facing new HTA agencies in the low- and middle-income countries (LMIC) setting is staff retention. This was highlighted by attendees at workshops at the Rome meeting of the Health Technology Assessment International Society^[12] and that conducted for the National Department of Health (South Africa, SA) held in Pretoria (24 - 25 November 2017). Attendees highlighted



the fact that in many LMIC settings, the HTA agencies are seen as training platforms for subsequent employment in the medical device and pharmaceutical industries, with the primary driver for this movement being salary considerations. Organisationally, the aspect of staff retention needs to be addressed through competitive salaries and clear career pathways.^[13]

The scientific limitations reside in the wide variety of HTA methodologies, the complexity of the methods and the absence of an overall judgment (of 'accept' or 'do not accept') being made at the end of the assessment process. Variation in method is overcome by adopting the EUnetHTA Core Model. However, the model is very rigorous, and it requires significant resources to complete the lengthy and complicated process of preparing a full HTA report. This left room for the creation and use of simplified HTA templates, from the Danish mini-HTA^[14] to various hospital-based models.^[15]

Given the rigour of the HTA Core Model, and the detailed guidance it proffers regarding how to identify the best available evidence for a given technology, there was a move to develop a simplified rapid-HTA model which is based on the Core Model.^[8] This has now been achieved, and the rapid method is currently being used across Europe. For those new to HTA, the rapid-HTA method that is built on the solid foundation of the Core Model 3 provides the novice practitioner of HTA or a new HTA agency with a clear methodology to follow. Importantly, adopting this standardised approach allows benchmarking against expert practitioners and established agencies.

Restrictions on the use of HTA

To date, the application of different HTA methodologies, which are often applied with varying degrees of pragmatism, has been problematic,^[16] as the variation in methods makes a comparison of the HTAs carried out on the same health technology extremely difficult. This is further complicated by variation in health services and social context, and the underlying burden of disease within a given population. Adopting a reference model, as happened across Europe with EUnetHTA's Core Model 3, does address some of these restrictions based on methodology. Similarly, it is difficult to fully apply the results of a HTA across different models in health services (e.g. universal v. mutual), and in different regions (e.g. Africa v. Europe). Aside from different regional contexts, different healthcare payment systems for performance in the delivery of care create an additional barrier to adopting existing HTA reports.^[17]

It seems that these barriers to the applicability of HTA reports across jurisdictions make it counterintuitive to proceed with a single model. However, it is only through the adoption of common methodologies that the potential for reuse of existing HTA reports can be considered and achieved. Certainly, the use of common methodologies will assist HTA practitioners in determining what is common and relevant to their setting, to provide shortcuts for rapid assessment and ensure that evidence is representative, while limiting bias to a minimum.

We suggest that the EUnetHTA Core Model 3 be used as the reference standard for developing a variant of HTA that is Africa-centric. The Core Model is complicated (9 domains, 134 elements),

as it tries to capture all the nuances between different dimensions, different points of view and different actors (it is multiprofessional). To reduce the number of elements of the model would require a careful appraisal of the domains and assessment elements to eliminate those that are not relevant to the African context, and thereby give greater weight, sensitivity and depth of knowledge to the elements that are relevant. The challenge and potential restriction to adopting HTA within Africa is to adapt the Core Model in a non-arbitrary manner.

Theoretically, this approach is promoted by EUnetHTA in Fig. 2. A major goal of the collaboration between the Charlotte Maxeke Medical Research Cluster (CMeRC, SA), the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) and Università Carlo Cattaneo (LIUC, Italy) is to refine the rapid version of the EUnetHTA Core Model 3 to be contextually relevant to SA, as well as to other African countries.

Finally, a quantitative approach, such as MCDA, could support the use of the HTA-based decision model. The introduction of a healthcare technology is based on risk-benefit evaluation.^[18] MCDA is applied to decisions with multiple objectives, and can be used to appraise different alternatives with conflicting criteria.^[19] MCDA techniques need to be carefully constructed, with appropriate training of users. The process requires decisions to be broken into domains, and the application of the EUnetHTA model, i.e. its nine domains. The participants in the MCDA process must weigh the importance of each domain against the technology being analysed, for example, pathologies with many therapeutic alternatives compared with pathologies with few or no therapeutic alternatives. Then, based on the best available evidence as presented in HTA reports, each domain is judged and given a numerical value that is adjusted by the assigned weight for each domain as pertaining to the technology under review. Adopting tools such as MCDA applies a similar level of rigour, transparency and reproducibility to the use of HTA reports as to that applied to their generation.

Conclusion

Countries with limited resources, such as those in Africa, have been challenged by the continuous influx of new and innovative health technology, whether voluntarily or involuntarily. Policy- and decision-makers are in need of reliable, timely, transparent and rigorous information to support their decisions on the prioritisation, selection, utilisation, diffusion and disinvestment of health interventions, leading to better outcomes for patients and the public. Equity among citizens is still a very important value. Standardised and detailed methodologies such as the EUnetHTA Core Model provide a framework for collecting, synthesising and sharing information. As stated, decision-makers are faced with multiple alternatives and multiple factors influencing these decisions, which situation requires a robust and quantitative approach to the appraisal process, as provided by the MCDA tool. It is to be noted that the authors are working on the adaptation of the model to the SA context, to enable the production of reports suitable for the context.

As to the limitations on the uses of HTA methodology, perhaps

the main limitation lies within governance at the meso-level of the healthcare service, i.e. provinces and districts, and healthcare providers. At this level, chief directors (and politicians too) see discretionary allocation of resources to be important for the strategic operation of healthcare services. The challenge is to ensure that HTA informs such allocation of funds so that all patients receive healthcare that is deemed safe and effective.

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