



HTA Toolbox for emerging settings: Best practices and recommendations

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Abstract

Objective: This article describes a Health Technology Assessment (HTA) toolbox that aims to improve the decision-making processes by providing information on best practices, practical experiences and recommendations on HTA. The toolbox is targeted to emerging settings, with emphasis on Central, Eastern and South-Eastern Europe (CESEE) and Region of the Americas.

Methods: The development of the Toolbox was based on a literature review, two surveys of key informants (e.g., government officials, decision-makers), case studies of three health technologies and additional search in the websites of governmental institutions. In addition, further insights provided by ADVANCE-HTA research partners, survey respondents and the participants in four workshops were employed to contextualize the Toolbox contents.

Results: This Toolbox has five chapters. Each chapter discusses the conceptual background to its topic, presents real-life applications of HTA, and provides tools and recommendations to facilitate the application of HTA to support the decision-making process.

Conclusions: The entire Toolbox provides guidance, resources, tools and recommendations at each stage of the HTA process. Although this Toolbox was designed to assist decision-makers from the CESEE and the countries in the Region of the Americas, it is also useful for everyone who is interested in HTA in any setting where the use of HTA is incipient, or where significant gaps on the implementation of HTA exist.

Keywords: Comparative Effectiveness Research; Capacity Building; Europe, Eastern; Europe; Latin America.

INTRODUCTION

With a growing number of countries making efforts to improve the quality of care, health technology assessment (HTA) is attracting considerable interest worldwide. HTA is perceived as a reliable and acceptable priority setting tool that can assist policymakers and health managers in achieving more efficient, sustainable and equitable health systems. In particular, HTA can improve the allocation of resources, guide the development of health policies, and directly contribute to evidence-based decisions. Internationally, the Pan American Health Organization and the World Health Organization have called member states to adopt and strengthen HTA systems, as well as share information and expertise at local and regional levels^{1,3}.

Developing appropriate methods for conducting HTA has received significant attention, but the need for proximity between those conducting HTA and decision-makers remains in debate. Furthermore, HTA involves a multidisciplinary process, which bridges the gap between science and politics, and increasingly employs more complicated techniques⁴. Lastly, but no less important, resource-limited settings face additional drawbacks to using HTA, including lack of expertise, local data and funding⁵.

Although a number of instruments to assist those interested in the adoption and correct application of HTA have been developed in the last few years^{6,7}, no comprehensive tool focused on emerging settings in the use of HTA has been devised as yet. Bearing in mind the problems faced by low- and middle-income countries, the European Commission's Seventh Framework

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Programme (FP7) ADVANCE_HTA project has among its aims to support the implementation of HTA in emerging settings⁸. Thus, one of its sub-projects involved the development of an HTA Toolbox targeted to emerging settings, especially those of Central, Eastern and South Eastern Europe (CESEE) and Latin American and the Caribbean (LAC) regions.

The aim of this Toolbox is to improve the understanding of the HTA process and to contribute to the institutionalization of HTA, from topic selection to the implementation of related decisions, considering other key elements such as social values and participation of different stakeholders.

METHODS

This *HTA Toolbox* was developed using the following sources:

- A literature search of different databases for HTA, toolkits or similar instruments. Results yielded were incorporated where relevant.
- Two surveys of key informants (e.g., government officials, decision-makers) focusing on the use of HTA in the decision-making process and on the capacity to conduct HTA, respectively⁸.
- Three case studies of the decision making of three health technologies^{9,10}.
- Comments and contributions of ADVANCE_HTA research partners.
- Comments provided at four ADVANCE_HTA capacity-building workshops (Mexico, November 2014; Chile, September 2015; Poland, September 2014 and 2015), where participants contributed from their experiences, reflections and practical recommendations⁸.
- Information yielded from institutional websites.

The Toolbox development process was iterative throughout, and every chapter was drawn from the combined knowledge and expertise of all persons involved. Furthermore, specific reviews of the literature, active search of particular information on Ministries of Health and HTA units websites were conducted in order to collect the latest trends and provide resources to enhance particular subjects.

RESULTS

The primary audience of this Toolbox consists of decision- and policy-makers, and professionals directly or indirectly involved in the allocation or prioritization of health resources and technologies, with a particular interest in learning the advantages and potential use of HTA as a process, its main instruments and results. The Toolbox is divided into five chapters:

I. Healthcare system and HTA: within three topics, it offers a general view of 1.- health services and universal health coverage; 2.- HTA and; 3.- examples of the use of HTA in the decision-making process. In the first topic, authors briefly describe the universal health coverage conditions and definitions followed by priority setting, a challenge for every healthcare system in the world once demand for health outweighs the supply of resources allocated to its finance.

In the second topic, “What is HTA and its use” authors provide decision-makers with general information on HTA and how it can be used in the decision-making process. Also, a set of barriers to the implementation of HTA, and at different levels were identified and made available in the tool. Lastly, the third topic addresses the functioning of HTA systems in a selected sample of countries, and identifies the main agencies/institutions involved in the HTA process.

II. Building the HTA function: the second chapter offers several examples of types of HTA agencies or bodies and their performance. Based on previous studies, the authors proposed to classify those organizations based on their HTA nature or primary purpose in two groups:

- 1.- organizations that had HTA function incorporated/ integrated and
- 2.- organizations that have been set up primarily to conduct HTAs (arm’s length).

Based on the HTA functionality, the organizations can play the role as advisory (providing reimbursement or pricing recommendations), regulatory (responsible for listing, pricing and reimbursement) and/or coordination (responsible for coor-

inating HTAs). A list of HTA organizations found in LAC and CESEE countries and how the process is implemented at the HTA agencies.

In order to assist in the harmonization of methods and information sharing, a selection of HTA networks are also shown. An extensive review of HTA networks worldwide was made and detailed examples are presented in the Toolbox, considering that the different networks focus on different types of HTA products. Finally, understanding that HTA definition includes an ethical dimension and that is expected that the HTA full report incorporates ethical aspects, the authors decided to compile recommendations, examples, and tools to aid in the analysis of social and ethical values in the third topic of this chapter. It is important to mention that both the patient perspective and citizen participation are also covered in this Toolbox. Examples of countries that already deal with these issues are also provided. Critical issues such as transferability and judicialization, an increasingly common phenomenon among LAC countries which carries with it considerable ethical and budgetary implications, are discussed with practical examples.

III. HTA products: in two main topics,

- 1.- the types of studies or evidence to inform decision-making; and
- 2.- the structure and contents of a typical HTA report are described. The first main topic offers:
 - i- documents to support decision-making;
 - ii- guidelines and
 - iii-transnational HTA. Briefly, the authors list and describe the main documents needed to be included in an HTA report and also provide the decision-maker with examples.

An extensive search on websites of Ministries of Health and HTA units/ organizations was made in the Region of the Americas and CESEE countries in order to list the countries and institutions that have economic evaluation guideline available.

The fact that countries often use reports from other settings to help in their decision-making is discussed in “Transnational HTA”⁹. Opportunities and problems with transferability of HTA reports providing decision-makers with best practice to address this issue are also covered here. Key elements to read and understand the different typologies of reports and structures of each one with hyperlinks to relevant repositories are given in the topic “Structure and Content of a HTA Report”.

IV. Beyond HTA: focuses on multiple criteria decision analysis (MCDA) as a tool to facilitate priority-setting and decision-making. MCDA is a set of methods that systematically and explicitly addresses a wide range of criteria to aid decision-making where more than one criterion is relevant, sometimes maybe even conflicting. Since the use of MCDA is increasing in the health sector, it is shown as a promising tool. In those countries only a Russian methodological guideline was found¹¹.

V. Implementation of the decisions: it has three topics:

1. Evidence informed practice guidelines;
2. Disinvestment/reinvestment decisions;
3. Monitoring and evaluation.

In the first topic, the authors discuss the methodological aspects for the development of guidelines and also the adaptation of guides. A hyperlink to guidelines repositories is also provided in the Toolbox, such as WHO guidelines.

Disinvestment/Reinvestment decisions are addressed in the second topic where authors also offer resources of interest and some countries examples and initiatives such as the NICE “do not do” recommendations. Lastly, the monitoring and evaluation of HTA impact is briefly discussed in the last chapter of the Toolbox, which includes definitions and initiatives.



DISCUSSION

This Toolbox is the result of several studies and reports that have been produced during three years under Work Package 6 of the ADVANCE-HTA project, funded by the European Commission. With this Toolbox we got beyond previous works on gathering of information regarding HTA by focusing on data, recommendation and examples available of particular interest in CESEE and Americas countries.

The methodology used in its development is the strength of the Toolbox. The entire process was iterative throughout its development and relies on the knowledge and expertise of all authors and institutions directly involved and widely distributed through the region of the Americas and Europe. PAHO, as Secretariat of RedETSA, counted on its members to provide the most updated information and examples available in order to enrich and improve this Toolbox.

The material is provided currently only English and this can be understood as an important barrier since it is focused on LAC countries, where the majority are Spanish speakers, and CESEE, with great language diversity.

The document is designed to offer a brief definition and concept of HTA, and the reader could learn more by following the provided hyperlinks. Although this Toolbox was designed to assist decision-makers from the CESEE and LAC countries (whom have some barriers to understand the

HTA approach)¹², it is also likely useful for everyone who is interested in HTA in any country where the use of HTA is incipient, or where limited resources and capacity-building opportunities exist. This Toolbox has a particular emphasis on those key resources that are relevant to resource-limited settings^{6,7,13-15}, providing a repository of selected links, tools and sources in a succinct and useful manner. For example, an effort has been made to include open-access softwares and documents, so that all interested users can freely access them. In addition, attempts to provide uncomplicated but cutting-edge tools such as OpenMarkov (www.openmarkov.org) and EpiData (<http://www.who.int/chp/steps/resources/EpiData/en/>) have been made.

Since the standards to perform HTA have undoubtedly improved over the last years¹⁵, the dissemination and use of this Toolbox may contribute to increasing the use and understanding of HTA in emerging settings. Any Toolbox will always be a work in progress, and our intention is to continue enriching and improving with the experience of its use. The Toolbox is available on the Internet (<http://www.easp.es/hta-Toolbox/>) and the readers can make comments online and propose the inclusion of new examples, initiatives or tools. Furthermore, the authors encourage all Toolbox readers to directly contact the corresponding author through e-mail should they have suggestions for improvement.

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Conflict of interest

The authors report no conflict of interest.