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Original Research

Essential Medicines List and Health Technology Assessment. Two complementary strategies to prioritize medicines in health systems

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Abstract

This article describes two strategies for incorporating medicines into national health coverage programs: the use of the WHO Essential Medicines List (EML) as a model for National Medicines Lists, and the implementation of Health Technology Assessment (HTA). We also put forward the main challenges that countries face, both in normal situations, as well as under financially restrictive conditions or during health or environmental emergencies Historically, high-income countries have used the HTA as a tool for incorporating medicines into their healthcare system, and low- and middle-income countries (LMIC) have followed the WHO EML. However, in recent years we have observed an increase in the use of HTAs in LMIC as well as the use of EMLs under special circumstances in high-income countries. Although both strategies partially share their basic methodological core, they differ in the procedure of selecting health problem, in using modeling procedure for economic assessment and in their final outcomes.

The goal of this article is to evaluate the validity of the concept of essential medicines (EM) in times of increasing use of the HTA, and the need for relying on both strategies when making evidence-based healthcare decisions.

Keywords: List of Essential Medicines; Health Technology Assessment; low- and middle-income countries; health decisions

INTRODUCTION

Challenges in the context of national health systems

Equitable access to health services and products is a global priority and is considered an essential human right. At a global level, healthcare systems face new challenges due to demographic changes, and scientific and technological development, with increased numbers of new, high-priced medicines, variable benefit/risk balances, and asymmetry in the available information to prescribers and users [1]. Twenty-five percent of global healthcare expenditure is spent on medicines and in low- and middle-income countries, these costs are primarily financed by individuals and households[2] as the main source of funding, especially in low and middle-income countries[2]. The World Health Organization (WHO) Model Essential Medicines List (EML) has served as a model for the rational selection of medicines placed on the market since 1977[2] .

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There is also a growing demand for recently emerged, high-priced medicines and other healthcare technologies (HTs), which are generally intended for low-prevalence pathologies, which is why health technology assessments (HTAs) have become relevant in Latin American and Caribbean (LAC) countries. The HTAs assesses the properties, effects and/or impacts of Health-related technologies, considering not only the medical dimension, but also the social, ethical and economic ones[3]. Considering these two strategies for the assessment and selection of medicines, what is the best way to use them within the framework of a healthcare policy4, is the main question we want to address[4].

The aim of this article is to analyze the validity of the concept of EM and EML in the face of the growing use of the HTA approach to decide about the incorporation of medicines into national healthcare systems coverage programs."

Essential medicines

According to the WHO, EM are those necessary to cover the priority health needs of countries, selected on the basis of diseases' prevalence, and that are relevant for public health, counting with evidence of efficacy, safety, qualityand suitable cost-effectiveness ratio. The term "priority health needs" has not been clearly defined, as there is no metric for a specific prevalence to define it unequivocally.

Since 1977 the EML has been reviewed and updated biannually by an experts committee including members from different countries. This List is proposed as a model procedure for countries to prepare their own National Lists (NEML), to guarantee the availability of medicines, considering their particular health

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needs, especially in low- and middle-income countries [5]. For more than 20 years, EMLs have also been implemented in high-income countries [6].

The Experts Committee follows a transparent process to undertake each reviewing task according to applications received by the WHO. This reviewing process ensures the committee to be free of conflict of interests with the pharmaceutical industry, focusing its analysis on the epidemiological profile of the relevant pathology to which the medicine is intended for, and comparing the medicine's efficacy, safety and cost-effectiveness with alternative treatment options already available in the market [5].

High-priced medicines were initially not incorporated into the EML. However, since 2002, instead of being a prerequisite, "affordability" became a goal to be pursued during the selection process.

As an example of this new trend, 12 antiretroviral medicines for HIV/AIDS were included in the WHO-EML, regardless of their high cost, implying that these products should be made affordable in their countries for all patients who need them. Over the last few years, other medicines with high relevance for public health were incorporated, even, if necessary, only for a small percentage of the population. Such was the case of drugs for treating hepatitis C, or yet theexample of imatinib, which is effective to cure neoplasms that affect less than 0.001% of the global population annually. The percentage of "orphan" medicines that is medicines for rare diseases, in the EML increased from 1.9% to 14.6% between 1977 and 2021[7]. The price of high-cost orphan medicines was not a reason to rejecting its entry into the EML, as were instead limited clinical evidence or uncertainty about the magnitude of its net benefit[7].

Health Technology Assessment

HTA assesses the properties, effects, and the direct and indirect consequences of new technologies, providing evidence to inform policy-making about health care technologies, both for individuals and institutions. This approach uses explicit methods to determine the value of a health technology at different points of its life cycle, and can assess the pertinence of coverage, reimbursement and other decisions. In HTA, a specific medicine is analyzed considering evidence of quality, safety, efficacy and cost-effectiveness, although medicines with low or moderate quality evidence are sometimes also recommended[4].

In contrast to the EML model, in the HTA framework, the criteria to identify the topic, the selection process, and the prioritization of the health technology to be assessed, are variable, and independent of the health relevance of the problem[8]. The professionals, who are responsible of defining which technology is prioritized for assessment, are commonly located outside the HTA department. If the prioritization process does take place within the structure, it is carried out by committees, medical services or management staff. At a global level, the main promoters of most HTAs are health ministries or health insurance organizations[9].

In Latin America and the Caribbean (LAC), out-of-pocket health expenditure is above 30%[10], which makes it necessary to systematically evaluate the value of HTAs in order to make coverage decisions. In this context, HTAs allow the allocation of scarce available resources to improve the efficiency and equity of the health systems[11].

Implementation of EMLs around the world

Currently, more than 137 countries use EMLs[12,] including 87.2% of LAC and 75% of which have of the countries have EMLs, and 75% of them, have governmental regulations for their implementation in healthcare services[13]. In these countries, the health authority is the one who prioritizes the medicines to be included in their EML, taking into account either the prevalent pathologies and/or in some cases, specific health needs of particular regions or special populations in the country.

High-income countries such as Australia, Sweden, New Zealand, and France have lists based on the concept of EMLs. This was initiated aiming to control the costs of subsidized medicines, and then began to demonstrate advantages in preventing shortages and ensuring quality healthcare. In the US, due to the 2020 pandemic, in the face of medicines shortages a presidential executive order was issued for the FDA to develop an EML. In Canada, a recommendation to develop an EML exists in order to ensure access to medicines that are necessary for the entire population, and in 2023 a listing of drugs used in ophthalmic-related medicines was published, based on the WHO EML[14].

Implementation of HTAs around the world

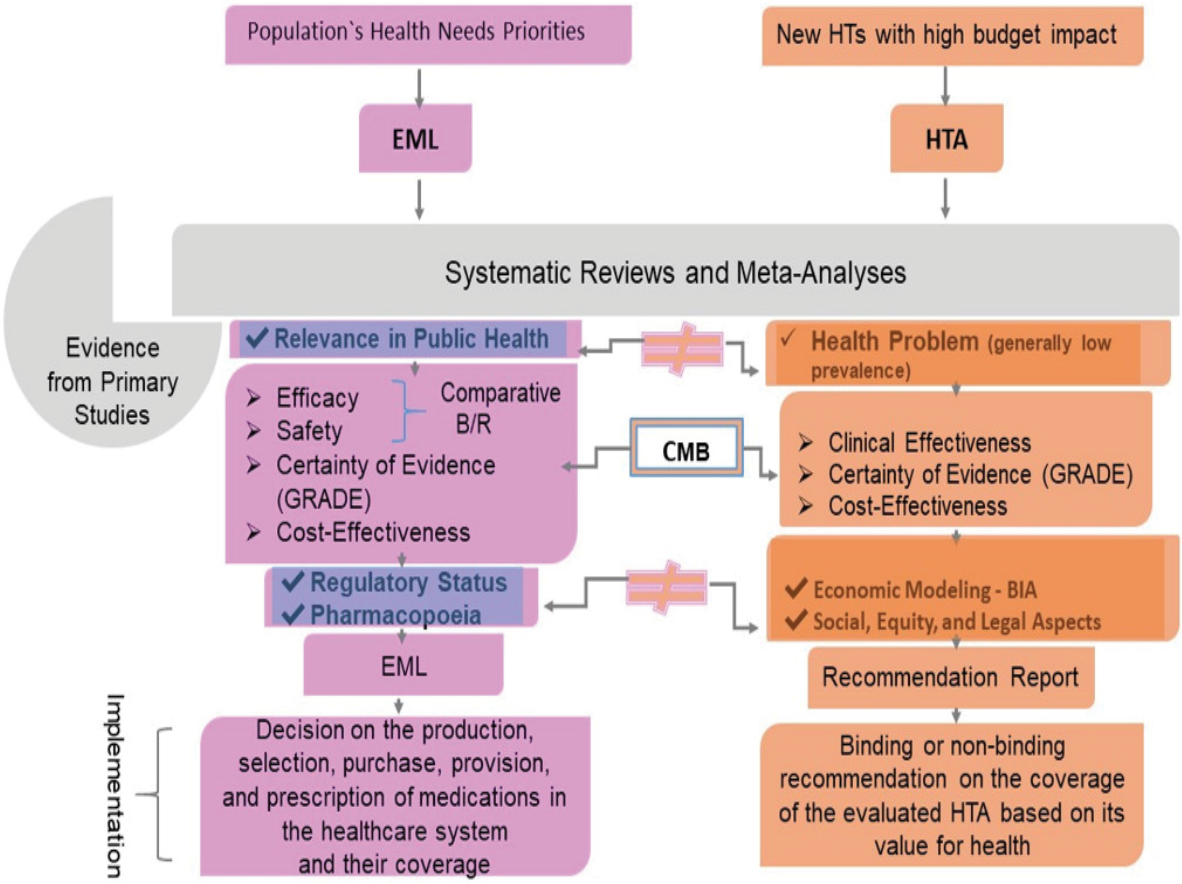
HTAs, which are more closely linked to innovations, can be used in contexts where the implementation of a strategy to incorporate new medicines is being put forward. In European countries such as England, Germany, France and Sweden, as well as in the USA, the HTAs were adopted by organizations that were specially conceived to evaluate and incorporate new drugs, and to make coverage decisions[4]. These countries have not used the WHO EML as a model. A different landscape is observed in LAC. Since 2012, there has been a growth of HTA agencies, promoted by the Pan American Health Organization (PAHO). The level of institutionalization of HTAs varies considerably throughout the region. On the one hand is Brazil, which has adopted a systematic HTA process, which is binding for decision-making in the health system while on the other hand, countries such as Nicaragua, Bolivia and Haiti, HTAs are not yet part of their political agenda[11]. Between these two extremes, there are countries at different stages of institutionalization of the HTAs. Colombia and Mexico have functioning HTAs, but their recommendations are not binding for coverage decisions of high-cost drugs. In Chile, HTA has been used to inform high-cost coverage decisions, but it has not been institutionalized to update the Universal Health Benefits Plan. In Costa Rica and Colombia, "consideration of HTA recommendations is neither mandatory nor systematic."[11]. In Argentina, CONETEC conducts HTAs since 2023 in the framework of the National Ministry of Health, but only one provincial Ministry of Health (Mendoza) has developed an official HTA agency during 2024.

EML and HTA: two evaluation strategies for the inclusion of medicines in healthcare systems.

The two evaluation strategies above discussed have different methodologies, objectives and outcomes. On the one hand, the evaluation to prepare national EMLs, is intended to promote access and affordability to medicines needed for prevalent health problems with public health relevance and that are prioritized by the national health authorities. On the other hand, the objective of HTAs is to provide decision-makers evidence-based information about the direct and indirect health and economic consequences of adopting the new technology. In HTAs, the selection and prioritization of the health technology to be evaluated is generally independent of the relevance of the health problem, as said before, often being connected to new high-priced medicines necessary for a low-prevalence health problem. Both evaluation procedures partially share a basic methodological core: the evaluation of the efficacy and safety of the health technology with its benefit/ risk balance (clinical effectiveness) and cost-effectiveness, compared to available alternatives, including the analysis of the certainty of the evidence (GRADE).

But both approaches also differ in important ways: in HTAs, central aspects of the economic evaluation involve budgetary impact assessment andthe utilization of modeled procedures, which are instead not considered when incorporating medicines into EMLs and also in their targets and outcomes In contrast, information regarding the regulatory status of the medicines and their presence in the Pharmacopoeia is also considered when generating EMLs, which are topics not contemplated by the HTAs. The impact that both approaches have on public health is different. In the case of the EMLs, they are not only useful as a model for the process and as a product, they constitute a tool for medicines policy to promote access and rational use of the medicine for fulfilling most of the population needs, with a legal framework that guarantees their use in the healthcare system. EMLs also guide countries by providing a list of necessary medicines that can be produced locally and that play a very important role in pandemics or other health emergency situations. On the other hand, the HTA provides information to assess about the coverage of new high-priced medicines conditioned by market developments, to generate recommendations that may or may not be binding for the healthcare systems (Figure 1).

Figure 1. Essential Medicine List and Health Technology Assessment



BIA: Budget Impact Analysis; B/R: Benefit-Risk Balance (clinical effectiveness); HTA: Health Technology Assessment; EML: Essential Medicines List; CMB: Core Methodological Basis; HT: Health Technologies

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Some experts believe that medicines' prioritization is in transition from the EML model to the HTA model[4], pointing out that, in contrast to the global model provided by the WHO EML the processes and standards for HTA vary between countries. Research about the impact of HTAs, has neglected the evaluation of their effectiveness in drug prioritization, cost containment, and in ensuring access to, and appropriate use of, drugs that meet the needs of the population – which are, in fact, the main objectives of the essential medicines strategy[15,16].

In our opinion, the concept of essential medicines and the EML remains valid for all countries, regardless of their income level. HTAs are also needed in order to incorporate new technologies into the healthcare systems. These are not mutually exclusive strategies, but rather complementary approaches to guide the incorporation of medicines into the healthcare systems. Both of them are necessary to take the best evidence – based health related decisions.

Research in context

Both the Essential Medicines List (EML) and the Health Technology Assessment (HTA), represent important tools for prioritizing medicines in healthcare systems worldwide. Historically, these approaches originated in specific contexts: the EML was widely used in low- and middle-income countries, while HTAs were developed in high-income countries. However, in recent years, low- and middle-income countries have also adopted the HTA methodology while high-income countries have incorporated the principles of the EML, especially in situations of health-related crises or emergencies. This study analyses how these two tools can complement each other to address challenges in allocating resources and access to medicines in healthcare systems

Evidence before this study

Some authors point out that in many countries, the prioritization of medicines for their incorporation into the healthcare systems, is transitioning from the EML model to the HTA model. However, the acquisition, availability and accessibility of medicines, remains an ongoing challenge for many healthcare systems. Limited research has been done on how these two approaches might coexist or complement each other.

Added value of this study

This study makes a contribution by comparing the methodology and objectives of EMLs and those of HTAs, highlighting their differences and complementary roles in healthcare related decision-making process. Unlike previous analyses that have generally focused on each strategy in isolation, this work integrates examples from both high- and low-income countries, demonstrating the practical relevance of both approaches. This paper also challenges the notion that EML and HTA are mutually exclusive, highlighting their simultaneous use to promote evidence-based healthcare policies.

Implications of all the available evidence

The findings of this study highlight the need for comprehensive health policies that use both EML and HTA to optimize resource allocation and improve access to medicines. Decision-makers should recognize the validity of the concept of essential medicines, especially to ensure affordability and address prevalent health problems. At the same time, HTA should be used to evaluate innovative, high-priced technologies aimed at small population groups, ensuring that their healthcare systems should no transition from one to the other because both are necessary.

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