

# Health technology assessment: A potential roadmap for India

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## ABSTRACT

**Background:** With the signing of the sustainable development goal document, India has embarked on the ambitious task of achieving Universal Health Coverage (UHC) by launching the National Health Assurance Mission (NHAM). However, India has not been able to meet many targets of the previous millennium development goals. **Objectives:** This article discusses the potential role of health technology assessment (HTA) for achieving UHC in the context of limited public health expenditure in India. **Materials and Methods:** Secondary literature review was conducted to review the existing HTA structures in different countries. In addition, key informant interviews were held with senior representatives (current and previous) of the National Institute of Healthcare and Clinical Excellence (NICE), Scottish Medicines Consortium (SMC), and evidence review group members from the University of Liverpool. **Results:** There are many potential applications for HTA in India and other low and middle-income countries. However, there are numerous contextual differences between India and other countries for adopting HTA and it is important to identify these differences and plan accordingly. **Conclusions:** The challenge for HTA in India is two-fold: data challenge and decision challenge. An incremental data to decision model based on the field practicum model of the Tata Institute of Social Sciences is recommended with the future objective of creating regional HTA hubs in India.


**KEY WORDS:** Health Technology Assessment; Sustainable Development Goal; National Health Assurance Mission; Millennium Development Goals

## INTRODUCTION

Global commitments, like the earth, seem to be moving in a circle. First, there was the Alma Ata declaration of 1978 with one goal-health for all (HFA), 12 global targets and 19 indicators, which India committed to, but could not achieve. Then, the millennium development goals (MDGs) were created with 8 goals, 18 targets and 48 indicators, which still remains a pipe-dream for India. And now, we have the

sustainable development goals (SDGs) with 17 goals, 169 targets and the number of indicators yet to be finalized. Universal health coverage (UHC), which is goal 3 of the SDG, has been on the agenda for some time now. Hence, the big question is that when India could not even reach the previous relatively less ambitious targets of HFA and MDGs, how can we achieve UHC?.

Of the total 5% gross domestic product (GDP) expenditure on health, public health expenditure in India is a dismal 1.2% of GDP with a fragmented health-care system comprising public and private players. India has committed itself to the ambitious task of UHC by launching the National Health Assurance Mission (NHAM). The Ministry of Health, India estimates that the UHC roll out would cost USD 26 billion over the 4-year period (2015-2019),<sup>[1]</sup> which means approximately USD 6.5 billion/year for 4 years. Interestingly, the USD 6.5

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billion required per year to achieve UHC is actually only 0.28% of India's GDP, which is estimated at USD 2.25 trillion by the World Bank.<sup>[2]</sup> Hence, although India has been widely criticized for its very poor public expenditure on health, these figures suggest that the money required to achieve UHC is well within the current public health expenditure hovering around 1% of GDP. Yet, India is a long way from achieving UHC. Hence, the problem is not the amount of money spent, but the inefficient way in which it is spent that is preventing India from achieving the objective of UHC. Therefore, it becomes very important to improve efficiency through prioritizing resources using evidence to get the maximum value for the money spent. Unfortunately, current decisions of prioritization in India are not evidence-based or evaluated on cost-effectiveness. For efficient allocation of resources, there has been a global movement toward health technology assessment (HTA) as a tool for priority setting. In India too, there is a movement toward creating structures and mechanisms for HTA as a tool for creating better decisions for better health.

HTA is the systematic evaluation of properties, effects and/or impacts of health technologies and interventions. It covers both the direct, intended consequences of technologies and interventions and their indirect, unintended consequences.<sup>[3]</sup> Technology, by definition, has a wide scope and can simply be summarized as a way of doing something and hence could include any procedure, equipment, drug or organizational form. In a simplified form, HTA is a meeting of science and politics. The science of economic evaluation is the starting point for developing the objective evidence on which a deliberative process is initiated, which incorporates the views of various stakeholders before arriving at a final decision.

This study reviews literature published on existing HTA structures in different countries. In addition key informant interviews were conducted with senior representatives of the National Institute of Healthcare and Clinical Excellence (NICE), Scottish Medicines Consortium (SMC), and evidence review group members from the University of Liverpool. The HTA model in UK was chosen since it represents one of the most comprehensive ways of conducting HTA and its application.

## MATERIALS AND METHODS

Secondary literature review was conducted to review the existing HTA structures in different countries. In addition, key informant interviews were held with senior representatives (current and previous) of the NICE, SMC, and evidence review group members from the University of Liverpool.

## RESULTS

HTA analyses have become established methodologies in many developed countries worldwide, where policymakers

are under pressure to provide broad access to health care, while facing increasingly limited resources. To varying degrees, the developed nations have incorporated economic evaluation of incremental value into the processes by which new drugs and medical technologies are made available to health-care consumers. The opportunity cost of providing a certain health technology over another is implicit in these assessments and upfront investment in public health can be cost-saving over the longer term.<sup>[4]</sup> Since the resources invested in healthcare in India are limited, HTA could be a means by which future healthcare expenditure in India can be allocated fairly and efficiently.

There are many potential applications for HTA in India and other low and middle-income countries. These include prioritization of services for public health-care spending, developing benefit package for public reimbursement, forming a nationwide or state wide pricing strategy for new drugs or drug classes, helping health-care policymakers to form clinical practice guidelines to ensure consistency of provision and evidence-based interventions for maximum efficiency.<sup>[5]</sup>

However, there are varied contextual differences between India and other countries for adopting HTA and it is important to identify these differences and plan accordingly.

There are two key dimensions of challenge in India. One is the data challenge and the other is the decision challenge. There are 3 major types of data challenges in the Indian context. The first challenge is poor quality and quantity of information. There are very few economic evaluation studies in India. Moreover, these studies are prone to bias because of the poor quality of data used and deficient reporting systems. The second data challenge is poor capacity for economic evaluation in India. There are very few health economists in India as compared to other disciplines which make the analysis of data even more challenging. The third data challenge is the absence of guidelines for conducting economic evaluation in India, unlike those in most developed countries and some Asian countries (South Korea, China, Thailand and Taiwan).<sup>[6]</sup> The absence of a standard methodology is one of the major barriers that hinders the use of economic results and affects transparency and quality of evaluations.

In terms of decision challenge, the first challenge is the political culture and attitude of decision makers in India. Historically, decision-making in India has been based on the power of voices of stakeholders rather than on objective decision-making. Resource allocation is inherently political and politics influences the use of economic evaluation for resource allocation. Decision makers in India can perceive themselves as losers (like in Thailand),<sup>[7]</sup> if economic evaluation were to be used for making decisions because their power and authority would be transferred to researchers. In addition, health professionals in India, like in Japan,<sup>[8]</sup> may

consider a loss of clinical autonomy if the method was used for health-care rationing. The pharmaceutical industry is another big player in the Indian healthcare sector and is a big influencer of the political decisions.

The second decision challenge is the lack of understanding of economic evaluation among users. Experiences from Japan,<sup>[8]</sup> Korea, and Thailand<sup>[7]</sup> suggest that decision makers had difficulties in understanding the terminologies used in economic evaluation. Consequently, its application for decisions was limited.

The third and a more universal decision challenge lies in the ethical dimensions of such decisions. Utilitarianism, on which economic evaluation is based, is not the only ethical principle that can be used to make a justified health resource allocation. Ethical considerations are complex and multifaceted, especially when decisions have to be made between providing life-saving/cost-ineffective interventions and non-life-saving/cost-effective interventions.<sup>[9]</sup>

To add to the complexity, health is a state subject in India and hence, having a centralized structure for HTA will not be operationally feasible. Furthermore, drugs and drug pricing fall under the Department of Pharmaceuticals, which is under the Ministry of Chemicals and Fertilizers and not under Ministry of Health. In India, 65% of medical devices and technology are imported and hence applicability of HTA to medical devices is limited. Therefore, drugs and medical devices cannot be the starting point for HTA in India as we do not have the systems in place for including them in the HTA process. A possible starting point would be to look for “wasteful” public health expenditure (for example public funding of renal dialysis centers in all district hospitals or using public funds for paying for cardiac stents, etc.), analyzing the opportunity costs of such expenditures and providing evidence for better cost-effective options. In other words, the first step toward HTA in India should not aim at prioritization but rather deprioritization of decisions of the state that are not evidence-based and consume significant amount of public resources.

## DISCUSSION

A model to address this challenge in India is the data to decision (D2D) model. It is an incremental model with steps to be undertaken in an incremental manner. The model is as follows:

### Step 1: Skill Development and Ensuring Ownership

This step has two key stakeholders: The data people (researchers) as well as the decision people (policy makers, bureaucrats, etc.). For the researchers, it is important to develop capacities for conducting economic evaluation, developing standard guidelines and creation of an economic

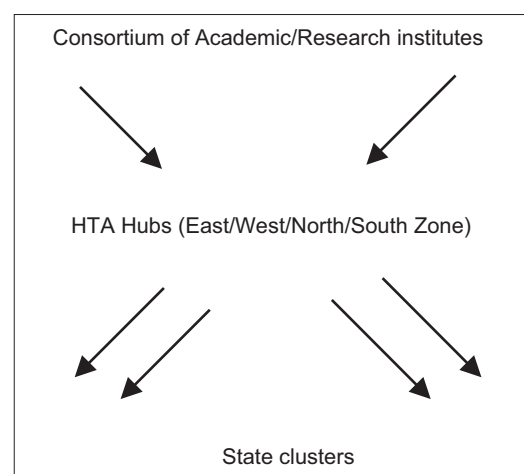
evaluation database. Simultaneously, education and awareness generation are needed among the decision makers to ensure their participation and create ownership and transparency in the process.

There are some researchers/faculty in India, who are trained in health economics at institutes like Tata Institute of Social Sciences (TISS) in Mumbai, which conducts postgraduate courses on health economics and economic evaluation. Training other faculty and researchers in these institutes would help in developing the capacity of the data people. Once this is done, these institutes and researchers can engage with the state governments through the hub and cluster model (below) to create the education/awareness programs, participation, and ownership of the state governments.

### Step 2: Structure Development and Operational Modality: The Hub and Cluster Model

Each HTA hub is a network of one or two academic research institutes wherein the data people have been trained and skills and capacity are available for doing the economic evaluation required for the HTA process. Each hub can be given the mandate to rollout the HTA process in its respective zone/region in India. A cluster of 2-3 states/zone can be identified for engagement by these HTA hubs (Figure 1). The process of engagement would follow the principles mentioned above.

Each HTA hub will be involved in research and evidence generation as well as training and policy advice. Engagement of respective state health departments is critical for the success of this model. It would be easier for regional academic/research institutes to engage with the state governments for two reasons. One, these institutes have already worked with these state governments and established a reasonable level of understanding, credibility, and acceptance within the states. Two, health being a state subject in India state-level decisions on health is much better implemented.



**Figure 1:** Hub and cluster model for health technology assessment in India

Creating the academic network or consortium would have its own challenges including individual personality issues, power relations and institutional relationships. However, HTA itself may act as a strong binding force to bring these academic institutes together and create the critical mass required. Furthermore, since many of these institutes conduct their own postgraduate/doctoral/post-doctoral programs on health economics and economic evaluation, it will lead to a cascading effect of these trained researchers being able to further train younger minds enrolled in these institutes and create a pool of good health economists in the long run from which the country can benefit.

The greater challenge is to convince the state health systems/government decision makers to participate, accept and implement the recommendations from the HTA hubs. Furthermore, the extent of autonomy provided to these institutes is critical. Hence, existing autonomous research and academic institutes across India are a good starting point for this exercise. The acceptance of the HTA process by the states as a tool for decision-making is extremely important or else India will end up with a pool of well-trained health economists who do not have an opportunity to apply or use their skills.

### Step 3: Prioritization of Topics for HTA

The topic selection has to be done with the consensus of the respective state government to ensure ownership of the process by the state. Some of the focus areas at this stage for topic selection could be interventions with high cost/budgetary burden, interventions likely to improve health outcomes but not widely accepted and interventions with significant adverse effects and ethical impact. For example, the recent union health budget proposed opening of renal dialysis centers in all district hospitals of India. The cost of implementing this one decision is estimated to surpass the National Health Mission budget.<sup>[10]</sup> However, an alternative public health intervention to screen for risk factors and prevent renal diseases (such as diabetes and hypertension) would cost much less. Hence, a possible use for HTA in India could be to reprioritize previous decisions using economic evaluation. The potential applications or questions for which HTA can be used in the Indian context would include prioritization of services for public health-care spending, developing benefits package for public reimbursement, providing information on drug pricing and developing clinical guidelines.

After topic selection, a pilot study needs to be conducted to create legitimacy, validity, and credibility of the process.

### Step 4: The HTA Pilot-Field Practicum Model at TISS

One potential D2D model developed by the Centre for Health Policy, Planning and Management at the TISS in Mumbai is worth exploring. The model called the "Field Practicum"

is an innovative and cost-effective method of engaging state policy makers and researchers to address public health issues with timely and reliable evidence. The model, through a consultative engagement process, creates a sense of ownership of data by state decision makers and presents the evidence in the form of a policy brief.<sup>[11]</sup> There is potential for this model to be engaged for using economic evaluation to inform decision-making, which could be the first step toward creating a process and system for HTA in India.

### Step 5: Pilot Review, Necessary Changes and Rollout

The pilot study needs to be reviewed to identify areas of improvement. Based on the results of the pilot study, a roll out of the HTA process across India can be planned.

## CONCLUSIONS

While it is absolutely clear that priority setting for decisions is an efficient way to deal with scarce resources, the Indian context should be kept in mind. Countries that started using economic evaluation techniques for priority setting did it at a time when they already had achieved or were close to achieving UHC through robust public health interventions (which had already proven to be cost-effective). In India, we are nowhere close to achieving UHC. Hence, we need to tread slowly, cautiously, and steadily. In our enthusiasm for applying these economic evaluation techniques, we should be careful that it does not become a tool for the state to further decrease the public health expenditure, which is already very dismal. Furthermore, the HTA process is attempting to bring a new (and perhaps alien!) way of decision-making in India. Hence, it is extremely important to gain the trust and confidence of the decision makers in this process right from the beginning.

As a first step, it is important to do a pilot study to ensure validity, credibility, legitimacy, and acceptance of the process. Hence, perhaps the first topic to be selected should be an issue for which robust data is available and can be done quickly. The field practicum model of TISS can be used to do the pilot study. Once this is done, the scope of this process can be extended. If we spread ourselves too thin at an early stage, the battle will be lost even before it has begun!

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