

Health Technology Assessment in India: Present status and future perspectives

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ABSTRACT

It is a cause of serious concern since the Health Budget in India is very meager in comparison to International Budget allocation, these results in OUT OF POCKET situation to many patients which are uninsured and falling below the poverty line. Development of Health technology Assessment can solve this problem by utilizing the direct investments to be pooled into the healthcare budget which can result in the maximum utilization of resources to the patients. This is the time of need to develop effective HTA system from the Govt. of India, which can only resolve the catastrophic OUT OF POCKET situations. The value of money and cost effectiveness can only be achieved after the implementation of effective HTA system. In this review, we would be highlighting the current position of HTA in India, the critical need felt by Indian for the effective HTA system and how this is going to be a long way in the development of healthcare sector in India. HTA is valuable tool as it takes into account several factors such as pricing; cost effectiveness, Budget allocations etc.

Keywords: Health technology Assessment, Cost-effectiveness, pricing, India

INTRODUCTION

Health technology assessment (HTA) is "any process of examining and reporting properties of a medical technology used in health care, such as safety, efficacy, feasibility, and indications for use, cost, and cost effectiveness, as well as social, economic, and ethical consequences, whether intended or unintended" Its aim is to inform public decision-making by providing an opinion with supporting evidence, taking account of all aspects of the topic concerned.

Health technology assessment (HTA) is a form of policy research that examines short- and long-term consequences of the application of a health-care technology. Properties assessed include evidence of safety, efficacy, patient-reported outcomes, real-world effectiveness, cost, and cost-effectiveness as well as social, legal, ethical, and political impacts (1).

The International Network for Agencies in Health Technology Assessment (INAHTA) has provided the

following description of HTA: "technology assessment in health care is a multidisciplinary field of policy analysis. It studies the medical, social, ethical, and economic implications of development, diffusion, and use of health technology" (2)

The newly founded society for Health Technology Assessment International (HTAi) defines HTA as "research-based, practice-oriented assessments of relevant available knowledge on the direct and intended consequences of technologies, as well as the indirect and unintended consequences" (3)

HTA can solve numerous medical queries and problems for example cardiovascular problems can be resolved by various techniques like reduction of stress at workplace, cessation of smoking or heart by-pass surgeries.

According to this broad understanding of health technologies, it is obvious that decisions on health technologies are an important part of the everyday business of health services design, management, and delivery in any health system. Health policy-making concerns the application of health technologies both in and on the system and in regards to both clinical and health system policies. (4)

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Importance in Healthcare Management

It is prime objective of HTA to ensure provide value for money to the patients. HTA depends on the outcome research as during healthcare treatment there can be various hurdles like social, institutional objectives, financial constraints which can result in inefficient utilization of the resources. There are numerous innovations but very few of them actually benefit the patients. There is urgent need to identify this research work and get their IPR so that the actual benefit reaches to the patients.

HTA is urgent requirement in a developing country like India, in which large populations are deprived from basic health care facilities. Development of strong HTA as in place in developed countries can go a long way in providing the maximum utilization of health care benefits to people.

An HTA assessment is only useful when it is able to provide sufficient data and at the same time hastens the process of providing access to new research and development to the patients. This is very critical as in present scenario it is happening that even after the discovery of the new innovations; it is taking long time to reach the healthcare system. If the technology is taking long time, it is clear cut indication that the current system is ineffective. Henceforth, there is strong requirement of HTS system which will fasten the process and save number of lives.

An ideal HTA system should be transparent, effective and systematic and unbiased. THE HTA system should be able to provide strong guidelines and able to develop effective assessment of all disease treatment. Different countries have varied climate, cultural background and priorities and therefore, HTA system should be unique for any country.

Pharmacoeconomics principles support the model of development of HTA system. Various Pharmacoeconomics tools such as cost-effectiveness measures [provides the basis for the development of new methods and techniques for the assessment. Assessment model should take into criteria each and every factor such as cost, effective, utilization of

resources, need of the time, social status, economic background etc.

Various Health Awareness programmes at the National level must be started to initiate the development of strong HTA model. Novel techniques and innovation should be incorporated into the HTA model after adequate verification and checking the effectiveness level.

Development of strong HTA Model will not only assist in the development of decision making in the healthcare, but also support the transparency in the treatment of same type of disease in different patients. Maximization of strong HTA system will lead to 100% utilization of existing sources.

HTA system in India

In India, currently there is no formal national HTA program, although there have been isolated attempts by a few groups in this direction. NICE International, an arm of National Institute for Health and Clinical Excellence, UK has held two workshops on evidence based medicine approaches for sensitization about HTA, and the need for clinical guidelines for policy makers and senior clinicians in Southern Indian states. Some work on training of healthcare workers and policy maker sensitization has been done by SIGNET initiative- a collaborative effort with Singapore. It has been reported that in the past, few sensitization workshops with policy makers were held, which were conducted by key functionaries of HTA International (5).

HTAi which has memorandum of understanding with WHO for capacity building of low and middle income countries on HTA, has formed a Developing Countries Special Interest Group, which is currently chaired by Dr Joseph Mathews from Post Graduate Institute of Medical Education & Research, Chandigarh. This could provide a much needed strategic momentum to help establish HTA in India.

The Health industry in India is influenced by various factors such as low expenditure on health budget in India, less health insurance coverage, large number of

population lying in the low income group and High bills of medical care for long term disease.

Public sector healthcare provision in India is inadequate, accounting for only 22% of the total expenditure on health.(6) Furthermore, India's national health expenditure is half that of Sri Lanka and one-third that of China and Thailand, in terms of purchasing power parity per capita.(7) As public expenditure on health in India has remained low (the government plans to raise the percentage to 3% of GDP from 0.95% in 2004 – 2005);(8) expenditures on healthcare are highest in the world. The majority of healthcare spending are out of pocket (OOP) (82.2%), 74.7% of which is spent on medicines. The mean OOP payment as a percentage of household expenditure is 4.8%, rising by income group to 6.5% in the richest 20% of the population.(9) This is a concern because countries that rely most on OOP financing for healthcare, generally have the greatest incidence of catastrophic payments (i.e., expenditure in excess of 10 – 20% of household income to meet healthcare costs).(10)

Many patients in India have been forced below the poverty line due to healthcare expenditure (11) nearly 40% of Indians who were hospitalized in 1995 – 1996 fell into debt on account of paying for hospital expenditures, with nearly a quarter falling below the poverty line as a result.(12) The risk of falling into poverty when hospitalized ranged from 17% in Kerala to double that in Uttar Pradesh and Bihar.(12)

Set against this backdrop, only 3 – 5% of Indians are covered under any form of health insurance,(13) and premiums amount to just 0.3% of total healthcare expenditure.[9] Despite this, research has shown that Indians make informed decisions when presented with options for healthcare insurance coverage.(14) In a study of a community-based health insurance scheme, among a low-income population in Gujarat, reimbursement of healthcare expenditure more than halved the percentage of catastrophic hospitalizations, although the relatively low rate of claims suggests that

members submitted claims for only a fraction of all hospitalizations.(15)

After analyzing this data, this can clearly understood that the HTA system will be a valuable tool in the healthcare development sector. Development of HTA can only provide Value for money. Outcomes research and HTA are widely used to prioritize interventions that represent the most effective use of resources among many competing options in the developed world. In India, states such as Kerala have begun discussions with established HTA agencies from other countries (such as the international arm of the UK's National Institute for Health and Clinical Excellence, NICE), recognizing that these approaches offer the potential to safeguard quality, accessibility, and efficiency within the Indian healthcare system.(16) To this end, the government and the Clinical Epidemiology Resource and Training Centre (CERTC) of Kerala have decided to formalize the development, dissemination, and implementation of best practice guidelines for selected high-priority diseases. This initiative aims to address the disparity in the quality of primary and secondary care between urban and rural settings; the importance of publishing minimum quality standards is even more pressing, now that a system of health insurance has been set up in Kerala.(17)

In a transitional economy such as India, where chronic and non-communicable diseases represent a major public health challenge, choices related to the allocation of healthcare resources are difficult. Health technology assessment methodology offers an equitable and transparent framework, within which these challenging decisions can be made.(18) In this review we describe how tools such as these can be utilized in the development of the Indian healthcare sector, and what considerations are necessary to allow them to be deployed effectively in the context of challenges particular to India. These issues have been discussed at a workshop on the potential for HTA in India, organized by the Public Health Foundation of

India and the South Asia Network for Chronic Disease, held in October 2011, in Delhi.(19)

MATERIALS AND METHODS

Articles were sourced from literature searches in PubMed (<http://www.ncbi.nlm.nih.gov/pubmed/>) and from related articles. Publicly available materials published by the Government of India have also been cited.

Introduction to health technology assessment

Health technology assessment and pharmacoconomics are very well developed in the developed nations like UK, US, Argentina and Canada. The effective Health technology assessment system ensures the timely delivery of latest technology and innovations to the community. Even after low Budget allocation in India, the Health technology assessment system will ensure fair deals to the patient.

In the developing world budget constraints are more likely to preclude the provision of any new interventions above a threshold level of expenditure, regardless of the potential return on that investment. Second, the demographics of many developed nations in the world are stable and the populations of healthcare consumers are well-characterized. Taking into account India's rapid population growth, it becomes clear that the annual cost of providing any new technology is far from static (20).

Out of pocket situation (OOP)

The predominance of OOP payments in the Indian healthcare sector has implications for the application of any nascent HTA initiatives. Experience in countries where HTA is a well-established methodology, such as Canada and the UK, suggests that irrespective of the identity of payers — be they government, insurance companies or private individuals — there is a growing reluctance to pay the high prices associated with new healthcare technologies. Health authorities are demanding increasingly robust demonstrations of the incremental value of novel interventions over the established standards of care. Payers agree to fund the new technologies only when manufacturers have

provided sufficient evidence of 'value for money', which may be defined differently in different countries. It is likely that suppliers of healthcare technologies to the Indian market will have to address these concerns in the future, even if the burden of evidence is less exacting to begin with.

Health technology assessment for pricing and reimbursement decisions

According to an estimate published in 2007, it costs US\$1.3 billion to bring a new drug to market,(21) and the cost of failure in drug development programs has forced prices to unprecedented high levels. There is a need to strike balance between development of inventions and delivery to the patients..

The criteria for determining whether a drug will be included on the NLEM are as follows (22):

- **Essentiality of drugs:** that is, those on the NLEM considered to satisfy the public health priorities of the Indian population
- **Market-based pricing:** the previous system involved a labor-intensive calculation of price, based on complex and variable cost data; market-based pricing uses publicly available data to ensure a simple, transparent process
- **Control of formulation prices only:** to ensure more specific price controls of the medicines used by the consumer/prescribed by the physician.

Furthermore, there will be a fixed ceiling price, below which manufacturers can place their products, to retain competition in the market. The ceiling price will be calculated according to a formula based on the price and strength of the reference formulation, as given in the NLEM. Previously, drug price controls for the Indian market were based on the market share of individual products, defining a minimum profit margin and featuring a cost-based pricing formula.(22)

The concept of the reference formulation echoes the system of HTA in developed countries such as France, where assessment of the incremental value of a new agent compared with the standard of care is used to

determine pricing and reimbursement, within a comprehensive market access framework. Pharmaceutical pricing in India could mirror this approach, if a rigorous clinical and economic evaluation, in the form of HTA, was allied to the proposed reference pricing system. This would enable new treatments across a range of therapy areas to be assessed according to the same procedures, followed by a transparent and consistent system for the determination of prices.

Considerations for health technology assessment in India

Economic evaluation of the benefits of a new technology is based not only on health gain versus monetary expenditure required, but also on its effect on the quality of life of the treated population. The priorities of healthcare resource allocation in the developed world are founded on broadly utilitarian principles (i.e., maximization of total utility in the population, often measured in terms of quality-adjusted life years [QALYs]), which may be at odds with the philosophical and ethical preferences of the Indian population. In one study based in Thailand, many decision-makers, health professionals, and academics rejected the QALY maximization principle by supporting life-saving (but cost-ineffective) renal dialysis rather than the more cost-effective laparoscopic cholecystectomy, which would have resulted in more QALYs for the same level of expenditure. (23)

Furthermore, it is clear that HTA system in various countries are very validated and developed. There is vast cultural and demographic difference between developed nations and developing nations like India. In India, pediatric and geriatric care are given due importance and large funds are allocated in the family for that, whereas in developed nations the budgets are more directed towards the earning and potential members, which lies in the 20-40 age group.

In a review of the quality of existing pharmacoeconomic studies carried out in India, Desai *et al.* recommended a standardized set of guidelines

for these studies, and improved pharmacoeconomic education to produce skilled professionals who can produce high-quality research. (24) There are lot of hurdles in the development of effective for health technology assessment in India ranging from, lack of professional experts, non effective reporting system, low budget allocation. The health technology assessment in India should ensure following objectives:-

- Appraise health interventions and technologies efficiently and transparently
- Develop systems and mechanisms to promote the management of health technology as well as appropriate health policy determination
- Distribute research findings and educate the public in order to make the best use of the results.

Professor David Banda, an expert in the development of international HTA programs, identifies the following priorities for the establishment of a sustainable HTA infrastructure:-

- Interest and commitment from government policy makers
- Ability and willingness to commit public money to HTA
- Support from important stakeholders
- Scientific capability
- Ability to review the literature and search the internet
- Involvement of educators (HTA training program)
- Consideration of workable options, for example, national agency, network, coordinating agency
- A coherent and effective health policy structure — regulation, payment, and the like.

The advent of economic evaluation in healthcare does not mean that future healthcare decision-making will be free of political manipulation or sociological pressures. Other considerations such as total budget size, equity, social solidarity, and protection against catastrophic health expenditure will continue to play a role in the healthcare sector in Asian countries.(25)

However, it is clear that HTA has a role to play in decision-making concerning the future of Indian healthcare provision. As noted by Virgil, 'health is the greatest wealth'; economic productivity and prosperity depend on a healthy population. Although healthcare expenditure may be seen as an economic burden, this philosophy underlines the need to view spending on healthcare as an investment in the long-term economic wellbeing of the population. Indian policymakers can make informed choices as to the most productive use of investments in the health and wellbeing of the nation, by employing rigorous methodologies such as HTA (26).

Future Implications of India

It is clear that HTA methodology discussed in this review article can form the basis of understanding the urgent need for the development of effective HTA system in India. One of the strengths of HTA is that it allows like-for-like comparison of medical, surgical, and public health initiatives. If the system is developed concerning realities of Indian healthcare, as well as the cultural, ethical, and philosophical considerations pertinent to local policymaking, these methodologies can form the basis of decision-making on pricing, reimbursement, and future investments in the Indian healthcare system.

There are number of potential applications for HTA in India including

- Development of Guidelines for public reimbursement of healthcare.
- Advanced pricing strategy for novel drugs.
- Advising national healthcare policymakers to draft clinical trial guidelines to ensure consistency of evidence-based experimentation for maximum efficiency

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