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Abstract

Health technology assessment and its role in the future development of the Indian healthcare sector

Public expenditure on healthcare in India is low by international comparison, and access to essential treatment pushes many uninsured citizens below the poverty line. In many countries, policymakers utilize health technology assessment (HTA) methodologies to direct investments in healthcare, to obtain the maximum benefit for the population as a whole. With rising incomes and a commitment from the Government of India to increase the proportion of gross domestic product spent on health, this is an opportune moment to consider how HTA might help to allocate healthcare spending in India, in an equitable and efficient manner. Despite the predominance of out-of-pocket payments in the Indian healthcare sector, payers of all types are increasingly demanding value for money from expenditure on healthcare. In this review we demonstrate how HTA can be used to inform several aspects of healthcare provision. Areas in which HTA could be applied in the Indian context include, drug pricing, development of clinical practice guidelines, and prioritizing interventions that represent the greatest value within a limited budget. To illustrate the potential benefits of using the HTA approach, we present an example from a mature HTA market (Canada) that demonstrates how a new treatment for patients with atrial fibrillation — although more expensive than the current standard of care — improves clinical outcomes and represents a cost-effective use of public health resources. If aligned with the prevailing cultural and ethical considerations, and with the necessary investment in expert staff and resources, HTA promises to be a valuable tool for development of the Indian healthcare sector.

Key words: Cost-effectiveness, health technology assessment, India, pricing, reimbursement

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INTRODUCTION

Healthcare in India is characterized by:

- Low levels of public sector expenditure on health
- Low levels of private health insurance coverage
- High levels of out-of-pocket payments for healthcare
- High levels of catastrophic healthcare payments.

Public sector healthcare provision in India is inadequate, accounting for only 22% of the total expenditure on health.^[1] 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.^[2] 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);^[3] private out-of-pocket (OOP) expenditures are among the highest in the world.^[2] The majority of healthcare spending is 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.^[4] 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).^[5]

Many patients in India have been forced below the poverty line due to healthcare expenditure;^[6] 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.^[7] The risk of falling into poverty when hospitalized ranged from 17% in Kerala to double that in Uttar Pradesh and Bihar.^[7]

Set against this backdrop, only 3 – 5% of Indians are covered under any form of health insurance,^[8] 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.^[10] 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.^[11]

Given these statistics, there is a clear need for increased investment in the Indian healthcare sector. However, irrespective of the source of funding or the distribution of public versus private healthcare provision, demonstration of value for money is a growing and global requirement that will no doubt shape future investments in Indian healthcare.

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.^[12] 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.^[12]

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.^[13] 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.^[14]

MATERIALS AND METHODS

Articles were sourced from literature searches in PubMed (<http://www.ncbi.nlm.nih.gov/pubmed/>) and from related articles. The case study presented in this review is based on published literature relating to dabigatran etexilate. Publicly available materials published by the Government of India have also been cited.

RESULTS

Introduction to health technology assessment

Health technology assessment and cost-effectiveness analysis have become established methodologies in many countries of the developed world, where policymakers have come under pressure to provide broad access to healthcare, while faced with 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 consumers of healthcare. Implicit in these assessments is the concept of the opportunity cost of providing one health technology over another and the recognition that upfront investment in public health can be cost-saving over

the longer term. To the extent that the resources invested in healthcare in India are limited, HTA may 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, including:^[15]

- Guiding public reimbursement of healthcare, as in several nations, including Australia, Sweden, and the UK
- Informing the nationwide or statewide pricing strategy for new drugs or drug classes
- Helping national healthcare policymakers to draw up clinical practice guidelines to ensure consistency of provision and evidence-based interventions for maximum efficiency.

However, various aspects of the developed-world paradigm of HTA are not transferable to countries such as India. Healthcare budgets in the developed world often have the flexibility to fund interventions if they promise a certain level of health benefits, whereas, 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.

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,^[16] and the cost of failure in drug development programs has forced prices to

unprecedented high levels. There is a balance to be found between delivering innovation and affordable pricing, particularly in emerging markets such as India, where strengthening of mechanisms for intellectual property protection is a priority. The absence of patent protection for drugs in India, between 1972 and 2005, allowed companies to use alternative non-infringing processes to manufacture generic drugs. Thus, generic versions of many medicines are on sale in India at prices that are substantially lower than their branded equivalents in Western markets.

With continued upward pressure on pharmaceutical development costs, leading to higher prices for drugs in the developed world, agencies in many countries are using HTA methodology to control these trends. However, it is not only Western markets that are seeking new ways of checking the increase in prices of medicines. With the introduction of a new draft National Pharmaceutical Pricing Policy, which promises to extend the proportion of drugs subject to pricing controls from 20 to 60%, it is clear that India is moving toward a Western-style 'reference pricing' approach.^[17] It is now proposed that 348 medicines will be included on the National List of Essential Medicines (NLEM).

The criteria for determining whether a drug will be included on the NLEM are as follows:^[17]

- 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.^[17]

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.

Case study: The new oral anticoagulants

New classes of oral anticoagulants provide an informative case study to illustrate the benefits of economic assessment with regard to innovative health interventions. Warfarin has been the standard of care for many years, for the prevention of stroke, in patients with atrial fibrillation (AF). New orally administered agents such as dabigatran etexilate (dabigatran), rivaroxaban, and apixaban have recently demonstrated their safety and efficacy in these patients and are currently being considered as replacements for warfarin.^[18-20]

Stroke in AF patients is associated with higher mortality and costlier hospital stays than stroke in patients without AF.^[21-23] In clinical practice, in the developed world, patients at moderate-to-high risk of stroke traditionally receive long-term anticoagulation with vitamin K antagonists such as warfarin. However, warfarin has significant drawbacks, including a variable pharmacokinetic profile, which leads to wide inter- and intra-patient responses. Furthermore, the safety and effectiveness of warfarin is dependent on maintaining patients within a narrow therapeutic anticoagulation range.^[24,25] Patients receiving warfarin, therefore, require regular monitoring and dose adjustments.

The new oral anticoagulants have predictable and stable pharmacokinetics and a wide therapeutic margin, without the need for continuous monitoring or frequent dose adjustments. In a major clinical trial, dabigatran was superior to warfarin in terms of the primary endpoint, stroke or systemic embolism (1.11 vs. 1.71% per year; relative risk [RR] 0.65; 95% confidence interval [CI] 0.52 – 0.81).^[18] Secondary outcomes, particularly intracranial hemorrhage (ICH) and hemorrhagic stroke (HS), were significantly less likely with dabigatran, compared with warfarin. The clinical case for dabigatran would seem to be clear, but the relatively high price of the novel oral anticoagulants may be seen as a barrier to use in markets such as India, especially when compared with the current standard of care. However, the price should not be the only consideration. It is in cases such as this that HTA can help to assess the true value of a therapeutic alternative.

To assess the cost-effectiveness of dabigatran, a model was developed to enable comparison with the current standard of care for stroke prevention in AF, in the Canadian

healthcare setting.^[26] Canada has been at the forefront of HTA development over the past 20 years. As such, it serves as a useful example for emerging market economies that may wish to introduce HTA in the coming years. Dabigatran was compared with two warfarin scenarios; one based on clinical trial results and the other reflective of ‘real-world prescribing’, in which patient compliance and time in the therapeutic range were substantially reduced.

This analysis was based on the rates of clinical outcomes relevant to the population under study and used clinical trial results to accurately estimate the likely risk reduction associated with dabigatran compared with warfarin. In addition to the acquisition costs of both alternatives, it also took into account the costs of anticoagulant monitoring required with warfarin and the costs associated with post-stroke disability, that is, mortality, impact on patients’ quality of life, and the long-term follow-up costs of ischemic stroke and ICH/HS.^[26]

The model predicted that the cost of one additional year in perfect health for a patient taking dabigatran would be C\$10,440 compared with trial-like warfarin, or C\$3,962 compared with ‘real-world’ warfarin, both of which were well below the accepted threshold for cost-effectiveness.^[26] In terms of budgetary restrictions affecting healthcare systems in the developed world, these estimates represent a highly cost-effective alternative to the current standard of care for the prevention of stroke and systemic embolism. Naturally, the model inputs would be substantially different in an Indian context; the costs associated with drug therapy and the expected clinical outcomes would be different, as would the costs of treating post-stroke disability. Additionally, the assumptions underlying such a model would require various modifications when applied to an Indian setting, to enable a realistic analysis reflective of the local healthcare systems and cost structures.

Cost-effectiveness analysis in the Indian context

Although HTA is in its infancy in India, there are several recent examples of economic evaluation of healthcare interventions that demonstrate the capabilities of the methodology, and highlight the types of questions it can help to address.

For instance, a recent cost-effectiveness analysis assessed a range of interventions aimed at reducing cardiovascular disease and its risk factors in the Indian setting.^[27] Several secondary prevention strategies, such as the use of aspirin, angiotensin-converting-enzyme (ACE) inhibitors, and beta blockers for people with post-acute coronary heart disease and ischemic stroke, could be provided below an arbitrary cost-effectiveness threshold, based on the average income of individuals in India (US\$1,000 [Rs.45,000] per

disability-adjusted life year [DALY] averted). The DALY is a commonly used economic measure of overall disease burden, expressed as the number of years lost due to ill-health, disability or early death. This study found that treatment of congestive heart failure with ACE inhibitors and beta blockers was also cost-effective, using these criteria. For a similar cost per DALY averted, population-wide health gains can be increased with the use of a combination of hypertension-lowering and cholesterol-lowering drugs in people at high risk of events associated with cardiovascular disease. Coupled with data from recent clinical trials, these conclusions support the existing evidence in favor of the feasibility and effectiveness of such a combination drug treatment.^[27]

Another study found that the widespread use of metformin for the treatment of type 2 diabetes in India could lead to a reduction of approximately 400,000 DALYs at a cost of less than \$130 per DALY averted.^[28]

In addition to enabling health authorities to frame effective policies for the reduction of various widespread chronic diseases, economic analyses such as these can be used to compare the relative effectiveness of several alternative interventions that might be under consideration by healthcare providers, in the publicly funded or private insurance spheres.

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.^[29]

Furthermore, the assumptions on which health-related utilities are based have been validated in the developed-market context and will likely need to be recalibrated for use in populations in the lower income countries, which have different health-related expectations and values. For example, in many Asian cultures the elderly are accorded a great deal of respect and reverence; correspondingly, resources may be preferentially allocated

to them, whereas, in Western cultures preferences tend to favour the young, or the more economically productive members of society.^[15] It is also important that the tools used to determine the utilities of individuals in developing countries are validated and give consistent results across different regions and language groups. In many cultures — both Western and Asian — there is a reluctance to discuss the economic and financial aspects of health and healthcare provision, and this is another barrier that merits consideration.

There are limited resources for carrying out robust economic analysis in India. Along with a lack of trained professionals, there are likely to be data collection and reporting deficiencies in the early years of HTA. 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.^[30]

The experience of Thailand may provide Indian policymakers with a template for development of the infrastructure required to support a healthcare system that accommodates the concepts of HTA in the future. The Health Intervention and Technology Assessment Program (HITAP) is a non-profit organization established in Thailand, in 2007, funded by a range of governmental organizations within Thailand and by international bodies including the World Bank and the World Health Organization (WHO). HITAP was established with the following objectives:^[31]

- Appraise health interventions and technologies efficiently and transparently using qualified research methodology
- 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.

The HITAP has no legal authority to make healthcare resource allocation decisions; its role is strictly to act as an adviser to the Ministry of Health and other national Thai authorities. However, through the revision of the National List of Essential Medicines and the requirement for costs to be considered when licensing medical devices, the role of HTA, as carried out by HITAP, is becoming increasingly linked to government policy.^[31]

Thailand also provides a useful model of the type of evidence that would be required to meet the demands of any new HTA body in India. When HITAP was established, previous academic expertise in outcomes research and cost-

effectiveness evaluation was used as a platform for attracting investment from a range of sources.^[32] Acknowledging the lack of trained experts in Thailand, funds were made available to enable young research professionals to take up Fellowships in Europe, the United States, and Australia, where they learned the skills required to sustain a national HTA organization in the future. Among the first tasks undertaken by HITAP was the development of standard guidelines for health economic evaluation, for use in the Thai setting. These guidelines included the need for studies that addressed the effects and implications of new interventions, programs, and policies that went further than simply health economics and outcomes research.^[32] If and when such programs are introduced in India, there is likely to be a variation in the level of understanding of economic evaluation among healthcare policymakers, and stakeholder education will be required to ensure that the research is interpreted correctly.^[33]

Professor David Banda, an expert in the development of international HTA programs, identifies the following priorities for the establishment of a sustainable HTA infrastructure:^[13]

- 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.^[34] 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.

SUMMARY

It is clear that HTA methodology of the kind discussed in this article can form the foundation of comparative research concerning future investments in healthcare, in markets such as India. One of the strengths of HTA is that it allows like-for-like comparison of medical, surgical, and public health initiatives. With appropriate adjustments made to take account of the clinical and economic 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.

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