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Health technology assessment in India: The potential for improved healthcare decision-making

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ABSTRACT

Health technology assessment (HTA) is a multidisciplinary approach that uses clinical effectiveness, cost-effectiveness, policy and ethical perspectives to provide evidence upon which rational decisions on the use of health technologies can be made. It can be used for a single stand-alone technology (e.g. a drug, a device), complex interventions (e.g. a rehabilitation service) and can also be applied to individual patient care and to public health. It is a tool for enabling the assessment and comparison of health technologies using the same metric of cost-effectiveness. This process benefits the patient, the health service, the healthcare payer and the technology producer as only technologies that are considered cost-effective are promoted for widespread use. This leads to greater use of effective technologies and greater health gain. The decision-making process in healthcare in India is complex owing to multiplicity of organizations with overlapping mandates. Often the decision-making is not evidence-based and there is no mechanism of bridging the gap between evidence and policy. Elsewhere, HTA is a frequently used tool in informing policy decisions in both resource-rich and resource-poor countries. Despite national organizations producing large volumes of research and clinical guidelines, India has not yet introduced a formal HTA programme.

The incremental growth in healthcare products, services, innovation in affordable medical devices and a move towards universal healthcare, needs to be underpinned with an evidence-base which focuses on effectiveness, safety, affordability and acceptability to maximize the benefits that can be gained with a limited healthcare budget. Establishing HTA as a formal process in India, independent of healthcare providers, funders and technology producers, together with a framework for linking HTA to policy-making, would help ensure that the population gets better access to appropriate healthcare in the future.

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INTRODUCTION

An evidence-informed affordable healthcare prioritization mechanism in low- and middle-income countries (LMIC) such as India is essential for achieving the aspirational goal of universal healthcare.[1] Considering the increasing costs of healthcare interventions, diagnostics and devices, their formal assessment is a cornerstone in informing current health policy in India. Priority setting is crucial in an increasingly constrained economic environment and, while India has the capability to invest more in healthcare, the challenge is to set priorities in a rational way so that any extra investment yields increased health gain.[2] Health technology assessment (HTA) has emerged as a national-level formal process that does influence priority setting and is now considered to be a successful mechanism.[3]

WHAT IS HTA?

HTA is the multidisciplinary study of the clinical, social, ethical and economic implications of healthcare interventions, their diffusion and use.[4] Over the years, HTA has expanded from the merely technological level (such as single drugs, devices, diagnostic technologies) to an individual or patient level (clinical interventions to improve health of patients), population level (public health interventions to improve the population's health) and policy-making level.[5,6] HTA consists of appraisals using well-established evaluative techniques of systematic review, meta-analysis, clinical trials, epidemiology and economic evaluation including the application of incremental cost-effectiveness ratios.[7] In some countries, such as the UK, HTA also commissions primary research in areas where the existing evidence is too limited to make any appraisal of the cost-effectiveness of a technology. Other countries also use systematic methods to examine the ethical and social implications of various technologies.[8]

HTA is usually undertaken by specialized agencies or national organizations. Among the early adopters were the USA's Agency for Healthcare Research and Quality (AHRQ), Sweden's SBU, Spain's Catalan Agency for Health Information, Assessment and Quality and the United Kingdom's (UK) HTA programme.[9] In the UK, the National Institute for Health and Clinical Excellence (NICE) has been successful in going beyond HTA by providing clinical guidance, care pathways and implementation plans in a legally binding manner.[10] Such frameworks for ensuring that HTA is capable of influencing health policy must be developed alongside HTA agencies.

Among LMIC, there are established HTA programmes in several countries including Brazil, Mexico, China, Democratic Republic of Korea and Thailand.[11,12] In particular, Thailand's Health Interventions and Technology Assessment Program (HITAP) has had a major impact since its inception in 2007, which includes the development

of an optimal policy for prevention and control of cervical cancer and the creation of an essential drug list. Such has been its success that it is now supporting the efforts of the National Health Security office's 'Universal Coverage' health package.[13] In the Philippines, 'Phil-Health' has helped to inform reimbursement decisions,[12] Iran's Health Technology Assessment Institute is working towards appropriate health technology licensing, utilization and evidence-informed decision-making[11] and in Republic of Korea, HTA was made mandatory for decision-making on drugs and healthcare reimbursement since 2008. In Brazil, since mid-2011 new health technologies can only be listed for funding within the publicly funded health system provided they are approved by the Commissao Nacional de Incorparacao de Technologias (national HTA organization).[3] In Mexico, HTA has been institutionalized as the National Centre for Technological Excellence in Health (CENETEC) within the national government and has helped establish a programme for evaluation of medical technologies.[11] In Columbia, an HTA institute will provide recommendations for inclusion of medical technologies in public health programmes.[3]

An evaluation of Thailand's HITAP suggests that cost savings from HTA-based recommendations adopted by the Ministry of Health has far exceeded cumulative operating costs.[14] Evidence from Europe (EUnetHTA programme) suggests that 70% of HTAs have had a beneficial but variable impact on health policy, depending upon the type of professionals groups and settings.[15]

The 16th World Health Assembly, 2007 urged Member States to emphasize the establishment of systems for assessment of health technologies.[16] Health Technology Assessment International (HTAi), the discipline's international scientific organization, is the technical partner of WHO in capacity building with a focus on LMIC.[17]

POLICY PRIORITIES AND ROLE OF EVIDENCE IN THE PROCESS

The gap between the production of scientific evidence and its use to inform the decision-making process has been acknowledged globally[18] and is pronounced at levels of policy integration in India.[19] An examination of health policy-makers in the UK and Canada concluded that systematic reviews can promote effective policy-making by identifying relevant information for decision-making.[20] The review also identified major barriers as to why systematic reviews did not translate into policy; they include policy-makers' negative attitudes towards scientific evidence, lack of skills and expertise among administrators and decision-makers, lack of perception of the relevance of the research, and the use of technical vocabulary or scientific jargon.[20] A Pan American Health Organization study has pointed out that there is need for policy-makers to have research findings reported in a condensed and integrated manner.[21]

To address the gap, 'evidence briefs' are produced by the Cochrane Collaboration for policy-makers (SUPPORT summary for systematic reviews)[22] and evidence briefs by the health evidence network of the WHO.[23] In addition, the WHO has formed a network for bringing evidence to policy called EVIPNET which coordinates dissemination of briefs from other Health Evidence Networks such as SURE (Supporting Use of Research Evidence).[24]

HTA EFFORTS IN INDIA

Current state of affairs

A National Health Research System (NHRS) was envisioned in 2007, where all research agencies across multiple ministries and sectors would identify priority areas of research and promote public health.[19] However, the report of a working group on health research identifies that establishing such interdisciplinary committees for prioritization would continue to be a *priority* during the 12th plan period.[25] The Planning Commission has accorded due importance to setting up a 'Technology Assessment Board similar to Office of Technology Assessment in some countries', and has recommended formation of a Medical Technology Development Board.

Despite some attempts to introduce Indian policy-makers to HTA by NICE International, UK, there is to date no formal national HTA programme in India.[11] Some attempts have been made to provide training by a joint initiative of Singapore and India for senior healthcare managers and training of trainers.[26] The current efforts of its HTAi's Developing Countries Interest Group[27] have yet to yield substantial results towards any formal HTA mechanism in India.

HEALTH SYSTEM-WIDE CHALLENGES AND REFORM PROCESS

The intrinsic challenges within the Indian research scenario that impair optimal development of health services research include inadequate research infrastructure and funding, shifting policy priorities, weak intersectoral linkage and lack of overall health research culture in India with poor recognition of the importance of such research by policy-makers.[19] However, perhaps the most crucial obstacle to introducing HTA is that presently 71% of the total healthcare market in India is private.[28] The Indian government plans to increase its share of healthcare expenditure from currently 1.4% of gross domestic product (GDP) to 3% of GDP.[29] In tune with the government's commitment, the Planning Commission constituted a high-level expert group on universal healthcare coverage with a mandate of developing a framework for providing easily accessible and affordable healthcare to the Indian population.[1]

The new reforms, when implemented, are expected to have far-reaching impact on the health system, including the pharmaceutical and reimbursement mechanisms in India and hence the need for resource allocation mechanisms such as HTA. For example, the publicly funded social health insurance schemes for those living below the poverty line, *Rashtriya Swasthya Bima Yojna* (RSBY), and other such state government-funded schemes such as *Arogyashree* in Andhra Pradesh are further increasing the government's share as a purchaser of goods and services in healthcare, by creating large risk pooling mechanisms. The budgetary allocation to programmes such as RSBY are steadily on the rise from ₹2979 million (US$ 71 million) in 2011–12 to ₹10 960 million (US$ 210 million) for 2012–13.[30,31] Greater commitments in terms of healthcare will be required from the government in coming years and it is important to make optimal allocation decisions to maximize the utility of funds and their related impact. Despite the higher out-of-pocket spending, the development of large risk pools funded by government, which are likely to get even larger if universal healthcare is implemented, makes it imperative to consider adaptation of formal HTA mechanisms to inform policy in India.

DECISION-MAKING MECHANISMS IN INDIA RELEVANT TO HTA

Healthcare decision-making in India is complex, owing to shared responsibilities between the Central and state governments. The policy process in India is led by the Planning Commission which uses 5-year plans to identify areas of priority. An 'approach paper' outlining the objectives, strategies including the alternative feasible

scenarios, macroeconomic and broader policy considerations is prepared in consultation with multiple organizations involved in care and delivery and state chief ministers. The National Development Council (NDC) then considers the merits of the approach paper for approval, which is then sent to the state government and Central ministers for preparation of respective 5-year plans.[32]

The national healthcare policy is determined by the Ministry of Health and Family Welfare (MoHFW) and its four main departments––Health and Family Welfare; Ayurveda, Unani, Siddha and Homeopathy (AYUSH); Health Research (DHR, comprising the Indian Council of Medical Research (ICMR) and its research centres); and the Department of AIDS Control. Each of these is headed by a Secretary to Government of India. Other government agencies include the Director General of Health Services (DGHS) which provides technical advice on medical and public health matters and implements healthcare services.[33] There are 19 vertical programmes in public health which are also centrally administered, and despite the focus to integrate local decision-making (at the states), the parallel programmes have tended to institutionalize rigid approaches for planning of health facilities without extensive considerations of local priority.[34] Owing to the public–private nature of healthcare, relative autonomy of states, and existence of both vertical and horizontal programmes and linkage to development programmes, healthcare decision-making in India varies across the states. However, the national health policy envisages that in key areas of public health importance, the Central government will take a key role with active participation of state governments.[35] We focus here on mechanisms in health research at the national level relevant to the implementation of HTA.

With regard to health technology management, the DHR (formed in November 2008) has a mandate to translate innovations into products, encourage innovations related to diagnostics, treatment methods and prevention (e.g. vaccines) as well as introduce innovations to the public health service through health systems research and formulation of evidence-based policy.[36,37] The ICMR has also been involved in health technology management through commissioning research but has not yet addressed other functions of assessment.

The three complementary functions of technology regulation, assessment and management must be interlinked for a coherent response,[38] but there are gaps in India due to the minimal regulation and assessment infrastructure in major areas of public health importance such as pharmaceutical products and medical devices.

ORGANIZATIONAL CHALLENGES AND GAPS

What appears to be lacking in India is a forum for collaboration and formal sharing of information from health research to inform policy and clinical decision-making. There are many potential stakeholders: the ICMR, the Planning Commission and its working groups, the National Commission on Macroeconomics and Health, Regulation of Drugs and Therapeutics, the National Health Research Management Forum,[19] and the DHR. The latter has a mandate for the formulation of evidence-based policy and promotion of innovations to develop health technology[36] but it does not currently envision formalization of assessment of health technologies. The DHR aims to generate the evidence-base for optimum health systems and health services and it plans to do this by (i) learning from the global evidence base; (ii) adapting learning from global experiences to national priorities; (iii) providing priority setting platforms; and (iv) ensuring true interdisciplinary approaches across various themes including economics.[19] The limited capacity in health economics, statistics, mathematical modelling, evidence synthesis, policy analysis or health-related ethics is recognized; DHR intends to build further human resource capacity in the 12th Plan.[25]

A CASE FOR HTA IN INDIA

In India, a coherent public policy response, integrating evidence of effectiveness and costs of interventions is needed. Evidence-informed decision-making might have helped in the case of an human papillomavirus (HPV) vaccine trial in India which was stopped due to unexpected deaths, which were later found not to be related to the vaccine.[39] The vaccine has been studied in 27 000 women in 33 countries globally, is licensed in 60 countries and considered effective.[40] The need is obvious for HPV vaccination in India where cancer of the cervix is the leading cause of cancer mortality (17%) in Indian women aged 30–69 years.[41]

HTA for novel, low-cost devices is also needed. A low-cost affordable baby warmer for premature babies was introduced without any formal evaluation requirements and resulted in deaths of babies.[42] However, there is good Indian evidence to support keeping the baby warm by the mother (kangaroo nursing); an even lower cost intervention than a baby warmer, is effective.[43]

Recently, the Indian high-level expert group reporting on universal healthcare coverage envisaged and recommended the creation of a 'NICE-like agency', which could 'critically evaluate the evidence needed for decision-making on new vaccines and drugs needed in the public health system',[1] and a similar recommendation has been proposed by the working group on health research to create an office of technology assessment.[25] The implementation of one or other of these recommendations has the potential to improve overall decision-making and healthcare in India.

POTENTIAL FOR HTA IN INDIA: TWO EXAMPLES

In this section, we examine the relevant key institutional mechanisms to highlight gaps in their mandate and we attempt to provide an overview of how HTA could inform policy for better resource allocation in two illustrative areas, drugs and insurance.

Pharmaceutical products

It has been estimated that the Indian pharmaceutical market will grow to US$ 20 billion market by 2015 from US$ 6.3 billion in 2005.[44] Incremental market growth of a similar scale is also projected in well-regulated markets such as the UK, Japan and Canada, but unlike in those countries, in India the major challenge of regulating this growth has not been met.

In India, there are multiple bodies involved in the regulation of drugs. The Central Drugs Standard Control Organization (CDSCO) has the responsibility for approval of new drugs.[45] The approval mechanism is headed by the Drug Controller General of India (DGCI) in accordance with the Drug Control Act and permission for marketing is given only after evaluation of evidence by the company and submission of reports of phase 3 clinical trials.[46] The National Pharmaceutical Pricing Authority (NPPA) of the Ministry of Chemical and Fertilizers is a statutory body responsible for regulating, monitoring and revising prices of drugs and updating the list of drugs under price control.[47]

However, there are major recurring themes that have been widely discussed but remain unresolved, such as inadequate information about costs and benefits of new and existing drugs, counterfeit drugs, elimination of ineffective drugs and combinations and the establishment of a centralized national drug authority.[48,49] The latter has not yet been formed. The existing

organizations—CDSCO and NPPA—have their own remits for drug approval and pricing. Even with a new proposed National Drug Authority, responsible for overall regulation, no agency has the responsibility for the combined clinical, cost-effectiveness, policy and ethical perspectives for new and existing drugs. HTA has a strong track record in aiding decision-making for reimbursement in drugs globally;[12] an Indian HTA agency would be expected to achieve the same.

India has granted her first compulsory licence for a patented drug (sorafenib) for treating hepatocellular cancer to be manufactured in the country.[50] While making drugs available is a welcome measure, it takes no account of the effectiveness or cost-effectiveness of the drug. Sorafenib does indeed have some beneficial effects on hepatocellular cancer but has been rejected for general use in other countries. In the UK for example, NICE concluded that 'Sorafenib does not provide enough benefit to patients to justify its high cost, even when special considerations were applied.'[51] If India had an HTA programme, use of a compulsory licence grant would have been considered in terms of its cost-effectiveness before making a decision. Countries such as Thailand have successfully evolved a compulsory licensing policy using their HTA programme.[52]

Other LMIC, including Argentina, Brazil, Columbia, Israel, Mexico, Philippines, South Korea and Thailand, use HTA to inform pharmaceutical reimbursements. These countries use various methods to achieve price control; the Philippines uses parallel importation of inexpensive branded drugs from other countries (mainly India and Pakistan),[53] while other countries use inputs from HTA agencies to guide reimbursement processes for their national formularies.[12] In India there is no comprehensive mechanism to provide pharmaco-economic data. The development of an Indian HTA agency could fill this gap, helping to set priorities and hence effectively guide the creation of an Indian drug formulary or modification of the national essential drug list in a cost-effective, clinically efficient and transparent manner.

Health insurance

The state government health insurance schemes have problems in negotiating the care provided, prices of packages of care determined arbitrarily,[54] and the pricing process is not transparent. Wide variations in prices negotiated, premiums charged and coverage exist which are not determined by local variations in patterns of disease. For example, the Central Government Health Scheme (CGHS) gets ₹16 000 million to cover 3.2 million people, while *Arogyashree* gets ₹12 000 million to cover 71 million people, reflecting differences in the coverage for tertiary care.[54] As healthcare payers, health insurance has a role in supporting the development of HTA as they will benefit from processes that inform evidence-based resource allocation and allow them to control inflation in the premiums charged to individuals and to government.

HTA can help firstly, by determination of a package price of cost-effective and safe interventions and hence help in cost-savings in the already resource-limited environment. This would indirectly help strategic purchasing (negotiating price from providers being in large risk pool), achieving technical efficiency (how much to buy), and allocative efficiency (which services to buy). Secondly, HTA can provide evidence of effectiveness of interventions, aid regulatory bodies such as Insurance Regulatory Authority and governments, to exercise better regulatory control over insurance implementing organizations and help standardization of rates of packages by third party administrators.

CORE REQUIREMENTS FOR HTA PROMOTION IN INDIA

There are three core requisites for setting up an HTA agency: local data, local technical expertise and local institutions.[55] The WHO's Disease Control Priority Project[56] provides relative cost-effectiveness of interventions but there is a need to generate local cost-effectiveness data and willingness-to-pay thresholds for effective local implementation. Presently, there is a need to build a core interdisciplinary team with skills in clinical medicine, health economics, clinical epidemiology, information technology, and evidence synthesis. In India, as elsewhere, there is a need to bring knowledge translation for health policy to the fore. Building capacity in collecting high-quality routine health data suitable for audit, and inculcating a culture of audit among health service providers is an essential prerequisite to aiding uptake of HTA and to evaluating whether recommended interventions, products and clinical guidelines are followed.[57] The human resource capacity strengthening used in Thailand comprised mentorship and hands-on training in centres of excellence[13] and could be evaluated for adoption to an Indian setting.

The need to set up a formal HTA structure and a dedicated HTA organization is essential, initially at the national level, preferably within public policy. It has been widely acknowledged that to bring evidence into decision-making local HTA organizations are of paramount importance, particularly in LMIC.[3,55] India has a much evolved system for healthcare governance, but the remit of organizations involved in health policy decision-making is divergent and there is lack of coordination among organizations. This is illustrated by the decision-making landscape in India in pharmaceuticals, minimal regulatory control over publically funded health insurance mechanisms and ad-hoc policy planning processes which are reactive in most circumstances. Hence, there is a need for an inter-agency organization which can have interactions with state governments, various ministries, third party assessors, regulatory organizations, health insurers, drug reimbursement mechanisms and programmes, agencies involved in basic and translational science research, industry, civil society and patient groups to come together to identify and determine health priorities and use of relevant interventions based on robust evidence in a transparent manner with a legally accountable mechanism. The key issue will be to arrive at a consensus and the overall aim is to make best use in terms of health gain of the population of finite healthcare resources available.

CONCLUSION

In summary, HTA has emerged globally as a powerful tool for institutionalizing the use of evidence in decision-making for health policies.[3] It is now prudent to adapt appropriate HTA strategies in India to contextualize global knowledge, support transparent and accountable decision-making, and promote health equity.[58]

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