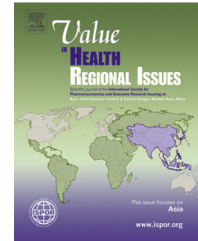




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## Analysis of a Small Group of Stakeholders Regarding Advancing Health Technology Assessment in India

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### ABSTRACT

**Objectives:** This study aimed to explore and understand the perspectives of a small group of stakeholders involved in health technology assessment (HTA) for evidence-informed decision making on policy in the Indian health system. **Methods:** Semi-structured interviews were conducted in April–June 2013 with policymakers, academicians, industry experts, and community representatives in India to understand their knowledge of, position regarding, and interest in HTA. A semi-structured questionnaire was designed on the basis of a World Health Organization framework for evidence-informed health care policy-making. **Results:** Seven key informant interviews were conducted to represent the various stakeholders. Although there is a good understanding of HTA among the national-level policymakers, academicians, civil society representatives, and industry experts, there is lack of knowledge about the subject among policymakers at the lower level. There is a positive perception about producing and using HTA

for decision making among all the stakeholders interviewed. Nevertheless, at the national level, institutions prefer to treat the use of HTA evidence with caution because the capacity for adopting evidence-based tools in the health system is very limited. **Conclusions:** This small-size stakeholder analysis suggests a mixed response in implementing HTA in India. There are, however, factors involved in implementing such tools that can be dealt with using various approaches. Finally, there is a positive view on the national level toward pushing the HTA agenda forward to improve the decision-making process in health care.

**Keywords:** economic evaluation, evidence-informed policymaking, health technology assessment, India, stakeholder analysis.

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### Introduction

Using evidence is one of the most important and rational approaches to health care policymaking; this is especially important in settings in which resources are constrained [1], and health technology assessment (HTA) is an important tool in these situations [2]. HTA has been defined as “a form of policy research that systematically examines short- and long-term consequences, in terms of health and resource use, of the application of a health technology, a set of related technologies or technology related issues” [3]. The goal of HTA is to support informed policymaking, and economic evaluation forms one of the core components of HTA studies.

In many developed countries, HTA plays a key role in improving efficiency in the use of health care resources, especially in the reimbursement for drugs [4]. HTA could potentially also have an impact on policymaking in developing countries such as India, which are characterized by a huge demand for health care, low public sector expenditures, and high private out-of-pocket expenditures [5]. In Asia, Thailand has successfully

used HTA for the market approval process and for establishing a protocol for reimbursement [6]. There is increasing emphasis on the use of evidence-based tools for future investments and for decision making in the Indian health care system [1]. The High Level Expert Group report on Universal Health Coverage by the Planning Commission of India highlights the need for using economic evidence for policymaking in India [7]. Tested tools such as KNOW ESSENTIALS facilitate evidence-informed health care decision making in settings in which resources are limited and in which there is an absence of formal HTA [8]. This is also important in light of the poor quality of economic evaluations in developing countries, where these studies can be misleading in terms of making well-informed decisions [9]. Collaborative initiatives such as SIGNET have been undertaken to build the capacity of Indian health care professionals in HTA [10].

Currently, there is limited understanding about how policymakers perceive such evidence-building tools and whether studies providing evidence based on economic evaluations, such as cost-effectiveness analysis, would be useful in policymaking or program evaluation. Therefore, it is essential to understand the

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different perspectives of various stakeholders, and to see how far evidence-building tools such as HTA are taken into account in decision making. In this study, analysis of a small group of stakeholders was undertaken to understand their knowledge, interest, position, possible (methodological and political) barriers, and other factors affecting the use of evidence in decision making.

## Methods

The study adopts steps recommended by Varvasovszky and Brugha [11] to conduct stakeholder analysis that includes identifying and approaching stakeholders, collecting and analyzing data, and presenting and using findings. Key stakeholders were identified using the World Health Organization (WHO) framework for evidence-informed health care policymaking and also through expert opinion [12]. The framework helps to analyze various constraints on using research for setting priorities, generating and disseminating knowledge, and describing key elements of evidence-informed policymaking in health care. Evidence-informed health care policymaking is an approach to policy decisions that aims to ensure that decision making is well informed by the best available research evidence [13].

The study includes stakeholders who are promoting and producing HTA and also policymakers and other potential users of HTA in India. They include decision makers in government, industry experts, health insurance experts, academicians, civil society representatives, and bodies that provide technical assistance to government. Two key experts (an academician in the area of HTA and a professional worker in the health care industry) from India were consulted to identify stakeholders and subsequently contact them.

A semi-structured interview was designed on the basis of the WHO framework for capacity development for evidence-informed health care policymaking [12]. An initial topic list (Table 1) was designed for interviewing stakeholders, covering topics related to institutional mechanisms, and the capacity and interest of various stakeholders in producing and using HTA. Two experts also helped in reviewing the content of the topic list. This helped to improve the validity of the content and of the study overall. Participants were contacted primarily through e-mails. Interviews were conducted at the participants' workplace in person.

Interviews for which approval for recording was obtained were transcribed. Written notes were taken during interviews for which recording was not permitted by the participant. Because the topic list was related directly to the research questions, the content of interviews was clustered accordingly. This analysis was done using the grounded theory approach [14]. Key points were grouped according to categories of research questions. Useful quotes from the interviews were highlighted for each group of questions and are presented in the findings.

## Results

In total, seven key informant interviews were conducted to represent various stakeholders (Table 2).

### Knowledge and Position of Stakeholders on HTA

Interviews suggest the existence of a basic knowledge and understanding of HTA as a tool for informing decision making. The interviews, however, touched on only some of the four components of HTA, namely, medical, social, ethical, and economic. The decision maker at the state level had only limited understanding of HTA (P3) and believed that only medical aspects are covered by HTA. Regarding the position of stakeholders on

**Table 1 – Topic list for discussion with stakeholders.**

Variables	Topic list
Stakeholder's knowledge and interest for HTA	<ul style="list-style-type: none"> <li>Understanding of HTA in India</li> <li>Level of use of HTA for prioritizing health care intervention</li> <li>Instances of use of HTA or economic evaluations or other evidence-based decision tools used for policymaking</li> </ul>
Stakeholder's position on using HTA in India	<ul style="list-style-type: none"> <li>Positive or negative position to support or reject use of HTA and why?</li> <li>Prospects of using HTA in the current context of the public health systems</li> </ul>
Stakeholder's perception	<ul style="list-style-type: none"> <li>What kind of influence/impact does the research finding have on policy decision making</li> <li>Investments made in enhancing or encouraging the use of evidence such as economic evaluation or HTA</li> </ul>
Existing and emerging factors influencing the use of economic evaluation or HTA	<ul style="list-style-type: none"> <li>Key challenges in utilization and institutionalization of HTA</li> <li>Factors enhancing smooth implementation of HTA at the health systems level</li> </ul>
Stakeholder-specific issues	<ul style="list-style-type: none"> <li>Decision makers: Users of research <ul style="list-style-type: none"> <li>◦ Current process of policymaking and prioritizing in the public health system?</li> <li>◦ Current level of use of HTA in selecting an appropriate intervention drug or equipment</li> <li>◦ Criteria for selection or prioritizing of public health intervention/drug/equipment?</li> <li>◦ Sources of information currently used for generating information to support policy decision making?</li> <li>◦ How HTA can be institutionalized in the current government policymaking process?</li> </ul> </li> <li>Industry/researcher: <ul style="list-style-type: none"> <li>◦ How industry is involved in generating the information for decision making</li> <li>◦ Role the industry and researchers/analyst can play in promoting the use of HTA</li> </ul> </li> <li>Community organization/nongovernment organizations (NGOs) <ul style="list-style-type: none"> <li>◦ Role in pushing the agenda of use of evidence (economic evaluation or HTA) in policymaking?</li> <li>◦ Use of HTA by NGOs in selecting health care intervention for their target populations?</li> <li>◦ How NGOS have institutionalized the process of evidence-based policymaking in their own health care settings?</li> </ul> </li> </ul>
HTA, health technology assessment.	

HTA, government agencies at the national level are pushing the concept of HTA by identifying the roles of different organizations, and developing systems to use HTA.

**Table 2 – Description of stakeholders who participated in the study**

Stakeholder	Participant	Ref.
Decision maker	A secretary for Health Research Department to the Government of India	P1
Decision maker	A director of apex public health technical assistance body to National Rural Health Mission, National Health Systems Resource Centre (NHSRC), Government of India	P2
Decision maker	An executive director of state-level organization, responsible for procuring medical drugs, equipment, and other consumable for the public health systems	P3
Civil society representative	A senior health care researcher at the national level and health care activist working in the area of community health	P4
Academician	A head of health technology unit at the NHSRC	P5
Health insurance expert	A senior health care insurance expert and advisor to the Planning Commission of India	P6
Industry expert	An industry expert who is also working with an international medical device company	P7

So almost two years back, we decided that we will have our own Indian government mechanism (of HTA), and health research governance were both responsibilities of my department in the government. It comes as one of the mandates. Then, alongside debate for 12th plan, a debate was going on; what will the Indian Council of Medical Research (ICMR) do? What will the health research department do? What will the health department do? What will other agencies do for health research? The Planning Commission also felt that such a board (Medical Technology Board) is necessary. (P1)

Even civil society and academics are positive about advancing the agenda of evidence-informed decision making, including HTA in decision making.

As a Senior advisor, I insist that we should advise the Ministry to start an HTA unit and government should have their own institutional structure for doing HTA; otherwise we would keep on getting program guidelines, which are already programmed with their own technology package and the Government of India will only implement these guidelines (rather than questioning package and technology itself). (P4)

### Interest and Influence of Stakeholders on HTA

The analysis reveals that stakeholders have their own organizational interest in promoting economic evaluations and HTA. Apex institutions such as the ICMR have their own mandate to provide good quality assessment for better decision making in public health programs and overall in the health care sector. A national-level think tank to the Ministry of National Health System Resource Centre (NHSRC) also has a keen interest in HTA. Accordingly, there are efforts at the national level to promote evidenced-based decision making.

We have been seized with the HTA issue for the last 2 years. We also want to have a proper HTA mechanism; we want to have a proper institutional system so that ultimately whatever advice we give to government, government hospitals, their doctors or the people who are going to purchase equipment—they do something based on evidence. (P1)

The NHSRC is influencing the HTA domain in India by creating a pool of skilled professionals in HTA and using them in conducting HTA.

We realized that there was not much representation of South-east Asian candidates in international platforms and programmes of HTA, so we devised a national level program in India with almost same faculty as a WHO-sponsored fellowship. We have already trained about 150 people in HTA. The best part is that, having completed this fellowship, these candidate are clubbed into teams and each team prepares an HTA report for our organization. (P5)

### Perspective of Stakeholders on HTA

Stakeholders from academics and technical assistance bodies feel that decisions have always been based on certain criteria, either published evidence or expert opinion. They feel that HTA can formalize the informal decision-making process and might help in creating a system for better decision making. Academics and civil society representatives also expressed similar views.

There is a way of how you look at HTA. By acronymizing the term, you are giving it a specific boundary, a package, a certain existence as a tool or as a discipline or as a domain that it does not enjoy at present. However, there has always been technology assessment. Decisions have always been made about inclusion (of drugs/technology) in programs; regulators, professionals and patients have always made decisions about health issues. HTA brings a certain discipline into each of these processes. (P2)

When asked about the effect of HTA on policymaking, participants expressed the view that HTA is becoming more important in lower- and middle-income countries, due to budget constraints and the need for input in decision making. Even industry and insurance providers are interested in HTA because it promotes competition and provides information on the best possible options.

Government is worried as they have a limited budget, and even this year the annual budget is only 2% more than last year's allocation, though it was supposed to be 25%. In a system where funding health care is not yet based on reimbursement, the utility of HTA and the potential of HTA is far more important. (P5)

Policymakers will welcome this initiative because at this moment they have no choices. They remain under stress due to a limited budget. (P1)

When concerns were raised about sustained investment and establishing a governance model for rolling out HTA programs in a major way, stakeholders felt that not much investment would be required because only trained manpower would be needed; the National Institute of Clinical Excellence (NICE), UK, model could be exploited.

We don't need much investment for HTA programs. The question is how to create a very well-coordinated small structure with good automation. At most, you will have to get consultants. (P1)

The benchmark of how HTA will be done in my understanding is NICE UK, which recognizes and is grounded in the philosophy of sciences. (P4)

### Factors Affecting the Production and Use of Evidence-Informed Policymaking and HTA

A key factor affecting the use of evidence is the availability of a health care data repository for the public and private health system; this is a key requirement for the HTA program. Another factor that affects the use of evidence is policymakers' awareness and knowledge of tools such as HTA and economic evaluation.

Building capacities is first requirement of better understanding of philosophy of sciences. (P2)

The HTA challenge is only one aspect of the need to scale up in terms of human resources. For everything we do here in India, we find a problem with human resources. In comparison with the size of the country and the gigantic problem, the pool of [HTA trained] people is smaller. (P1)

The HTA unit of the NHSRC has included a health systems integration module in its reports, which will make it easier for policymakers to understand and adopt solutions.

In reports on HTA that we publish, we include a health systems integration model and do not leave it in a void. We ensure that these reports reach the desks of the appropriate authorities in charge and tell them that this component could also be a component of your services—for example, a national program for the control of blindness can actually have a mobile eye surgical unit, and how this should function. (P5)

Another important factor that might affect the use of HTA studies is a lack of awareness on the part of public and civil society organizations. Although there have been some interactions between various organizations on the national level, there is a need for wider consultation including regional organizations, state bodies, and so forth. This would enhance acceptance from all parts of society. This would bring about a change in the mindset and ultimately change the approach toward policymaking from opinion based to evidence based.

These are areas where you have to scale up the pool first and change mindset of people. (P1)

Because we don't have patient and users' committees, that kind of consumer awareness is absent. If industry is involved, it becomes a whitewashing mechanism and bureaucracy is created which might have nexus with industry. You also have some civil society group or something which doesn't know the issues, is not equipped to handle them. (P2)

### Discussion

In this study, a small group of stakeholders was interviewed to understand their knowledge of, position regarding, and interest in HTA. Our analysis revealed that most of India's stakeholders believe that HTA should be promoted as a tool for evidence-informed policymaking. The key issue, however, is capacity building for producing and using HTA in decision making. There is a fair amount of knowledge at the national level; however, personnel at the state level have limited understanding of the subject. Stakeholders believe that the use of HTA remains a challenge, even if HTA and economic evaluation studies are produced. Because of a poor understanding of HTA, policymakers, especially at the lower level, are not able to apply the results toward decision making. The HTA unit of the NHSRC has also incorporated a section of health systems integration into its HTA studies, making it more user-friendly.

Although industry is interested in HTA, there is no investment or inclination toward HTA due to limited regulatory mechanisms. Currently, the Drug Controller General of India requires only clinical data, and not economic data, to approve a drug for the market. Accordingly, there is no adequate platform for discussing key issues related to the quantity and quality of economic evaluations and HTA studies. In addition, the limited availability and mostly poor quality of studies hamper the use of evidence by policymakers.

Despite limited use and understanding of HTA, India has already taken steps toward it by starting sensitization and basic workshops on HTA. The NHSRC, Amrita Institute of Medical Sciences and Research Centre, and IIT Chennai have jointly organized 1-week workshops and by 2013 trained around 150 professionals in HTA. The Medical Technology Assessment Board has been established by the Government of India under the aegis of the ICMR. Furthermore, a dedicated unit in the NHSRC is working on HTA. Despite the ongoing dialogue between agencies such as the ICMR and the NHSRC, the need remains for the wider involvement of other stakeholders to ensure success and sustainability. In Thailand, a national-level program called the Health Intervention and Technology Assessment Program has been established and its sustainability is ensured through the involvement of other stakeholders from public and multilateral agencies [15]. Experience from other Asian countries shows that measures such as developing national guidelines for producing economic evaluation studies, creating a database, making the process of using evidence transparent, and educating policymakers and the public can address some barriers to using evidence [16].

Thailand, which has been successful in progressing rapidly toward achieving universal health care, is still struggling in using economic evaluations in setting priorities. The main reasons for this are difficulties in changing the current process for decision making, political acceptability, and organizational structures [17]. Although India is also looking forward to achieving universal health coverage with affordable health care solutions, the country will need to face some of these challenges. Although policymakers are looking at NICE and its integration in distributing health care in the United Kingdom, several contextual differences between the two health systems have to be taken into consideration.

There are some caveats that need be considered in regard to our findings. First, this analysis covers only a very small number of stakeholders. Thus, the opinions of only a fraction of stakeholders might be represented. Further studies are required with a much larger number of stakeholder consultations. The study also captures the present perceptions, knowledge, and interest of stakeholders, and these are subject to change.

In conclusion, this small-size stakeholder analysis suggests that there is potential for HTA programs to be implemented in India. A concerted effort, however, from all stakeholders would be required to build capacities, make investments, and bridge research policy gaps in evidence building. The experience of HTA in countries such as Thailand should be leveraged.

To conclude with a quote from one of the stakeholders:

There will never be perfect solutions. There will be only the best way forward in an imperfect world. (P2)

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