# The state of cost-utility analysis in India: A systematic review

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# Abstract Aims: Cost-utility studies are crucial tools that help policy-makers promote appropriate resource allocation. The objective of this study was to evaluate the extent and quality of cost-utility analysis (CUA) in India through a systematic literature review.

**Methods:** Comprehensive database search was conducted to identify the relevant literature published from November 2009 to November 2019. Gray literature and hand searches were also performed. Two researchers independently reviewed and assessed study quality using Consolidated Health Economic Evaluation Reporting Standards checklist.

**Results:** Thirty-five studies were included in the final review. Thirteen studies used Markov model, five used decision tree model, four used a combination of decision tree and Markov model and one each used microsimulation and dynamic compartmental model. The primary therapeutic areas targeted in CUA were infectious diseases (n = 12), ophthalmology (n = 5), and endocrine disorders (n = 4). Five studies were carried out in Tamil Nadu, four in Goa, three in Punjab, two each in Delhi, Maharashtra, and Uttar Pradesh, and one each in West Bengal and Karnataka. Twenty-three, eight, and four studies were found to be of excellent, very good, and good quality, respectively. The average quality score of the studies was 19.21 out of 24.

**Conclusions:** This systematic literature review identified the published CUA studies in India. The overall quality of the included studies was good; however, features such as subgroup analyses and explicit study perspective were missing in several evaluations.

**Keywords:** Consolidated Health Economic Evaluation Reporting Standards checklist, cost-effectiveness, cost-utility, economic evaluation, India, systematic literature review

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# **INTRODUCTION**

There is increasing pressure on the health-care budget due to the rising costs of health care worldwide. Countries such as the UK and Australia have developed a formal health technology assessment (HTA) system to evaluate the drugs and devices for effectiveness, safety, and value for money. It

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is undertaken by specialized agencies such as the National Institute for Health and Clinical Excellence<sup>[1]</sup> in the UK and Pharmaceutical Benefits Advisory Committee<sup>[2]</sup> in Australia. In these countries, cost consideration in medical decision-making has long been in place. The government decides on drug reimbursements based on the HTA agencies recommendations.

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In India, Ayushman Bharat scheme was introduced in 2018 to address health-care needs at primary, secondary, and tertiary levels.<sup>[3]</sup> Such schemes necessitate rationalization of health-care resource use. Cost-utility analysis (CUA) demonstrates the relationship between the cost and benefits of an intervention compared with another intervention and is a useful tool for efficient resource allocation.

The Indian Government has created an institutional setup, HTA in India (HTAIn), under the Department of Health Research to facilitate transparency in the process and evidence-informed decision-making in the field of health.<sup>[4]</sup>

A systematic review of pharmacoeconomic studies from India found that 29 articles focused on drugs were published from 1998 to 2012.<sup>[5]</sup> Another systematic review retrieved 104 records that were published from 1980 to 2014.<sup>[6]</sup> However, no study assessed the extent and quality of CUA of health-care interventions and programs in India. The present study, therefore, aims to fulfil the following objectives:

- a. To describe the frequency and trends in the publication of cost-utility studies, focusing on health-care interventions and services in India
- b. To examine the quality of published cost-utility studies, taking into consideration key methodological issues.

#### **METHODS**

#### Literature search

A systematic literature review was performed using a strategy that combined search terms pertaining to economic evaluations. Following databases were searched for the English language publications – PubMed, National Health Service Economic Evaluation Database, and Cochrane library (Search period: November 2009–November 2019). In addition, gray literature and hand searches were performed to identify the relevant articles. The three conferences, Congresses of International Society for Pharmacoeconomics and Outcomes Research (US, Europe, and Asia-Pacific), HTA International, and Society for Medical Decision-Making were searched for relevant articles in the last 2 years. Bibliographic searches of identified studies were also performed.

#### Study selection

Studies were selected based on the screening and selection process detailed in Figure 1. Two reviewers independently screened titles and abstracts based on the criteria mentioned below:

#### **Inclusion criteria**

Economic evaluations

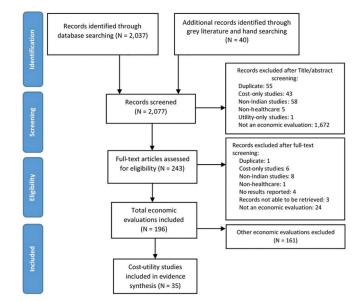


Figure 1: Selection of cost-utility studies for systematic review (original)

- Country: India
- Health-care interventions: pharmaceuticals, medical devices, diagnosis and screening, education programs, and service delivery.

## **Exclusion criteria**

- Duplicate
- In vitro studies
- Cost-only studies
- Utility-only studies
- Non-healthcare interventions
- Non-Indian studies
- Studies with no results or outcomes reported.

Full texts of all the articles included in the above steps were screened based on all the above criteria by two independent reviewers. Disagreement in the screening steps was resolved by a third reviewer.

#### Data extraction and quality assessment

A standard data extraction form was developed in Microsoft Excel. One reviewer extracted the data and another performed the quality check.

Quality appraisal of the included studies was performed using the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) checklist,<sup>[7]</sup> a 24-item checklist to assess the quality of economic evaluations. A score of 0, 0.5, or 1 was allocated for each item on the checklist as follows:

- i. 0: criterion not met
- ii. 0.5: criterion partially met
- iii. 1: criterion fully met.

Total score was calculated out of 24, and then, a percentage score of each study was calculated. The two reviewers discussed any disagreements in the scoring criteria of the studies, and discordances were resolved by a third reviewer.

## RESULTS

#### Search results

Database searching (n = 2,037) and gray literature and hand searching (n = 40) retrieved 2077 articles in total. After screening of the titles and abstracts, 243 studies were shortlisted for full-text screening. A total of 196 articles were found to be economic evaluations, of which 35 were CUA<sup>[8-42]</sup> and therefore eligible for this review [Figure 1].

#### Study characteristics

General characteristics of included studies are briefed in Table 1.

#### Quality assessment

In the absence of a widely accepted method of reporting quality assessment, categories were decided based on the methods from published literature.<sup>[43]</sup> A study was rated excellent if it scored  $\geq$ 85%, very good if it scored between 70% and 85%, good if the score ranged between 55%–70%, and poor if the score was <55%.

Majority of the studies, 65.71% (n = 23), were of excellent quality, 22.86% (n = 8) and 11.43% (n = 4) studies were of very good and good quality, respectively. None of the studies scored <55%. Decision model-based studies had better quality scores than non-model (trial, observational) based evaluations (mean 19.97 [85.70%] vs. 17.55 [81.86]). This may be because these studies clearly defined parameters such as time horizon, discounting, model choice, choice of assumptions, and uncertainty analysis.

The criteria that were the least well addressed in the studies were analytical methods and the choice of the model employed in the studies. Twenty-seven studies did not comprehensively describe the analytical methods supporting their evaluation. Most of the studies, 71.43% (n = 25), did not perform subgroup analysis and hence item 21 on the CHEERS checklist, on characterizing heterogeneity, was not applicable. Other key areas where studies lost points were study perspective (not reported by eight studies), choice of discount rate for costs and outcomes (not reported by 12 studies), and relevance of health outcomes for the type of analysis performed (not reported by 10 studies).

Table 1: Characteristics of cost-utilit	ty studies in India ( <i>n</i> =35)
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Characteristic	Category	<u>n (%)</u>
Publication year	2009-2014	7 (20)
	2015-2019	28 (80)
Lead author's	Foreign	18 (51.43)
institution affiliation	Indian	17 (48.57)
Study design	Model	24 (68.57)
	Trial based	9 (25.71)
	Observational	2 (5.71)
Time horizon (years)	<1	1 (2.86)
	1-5	8 (22.86)
	5-10	1 (2.86)
	$\geq$ 10 but not lifetime	6 (17.14)
	Lifetime	14 (40)
0	Not reported	5 (14.29)
Study perspective	Societal only	13 (37.14)
	Payer only	9 (25.71)
	Both payer and societal	5 (14.29)
	Patient	1 (2.86)
D	Not reported	7 (20)
Discount rate (%)	3	18 (51.43)
	5 10	1 (2.86)
		1 (2.86)
	Not applied	3 (8.57)
Tupo of model	Not reported Markov model	12 (34.29)
Type of model	Decision tree	13 (37.14) 5 (14.29)
	Combination of decision tree and	4 (11.43)
	Markov model	4 (11.43)
	Microsimulation model	1 (2.86)
	Dynamic compartmental model	1 (2.86)
	Not applicable	11 (31.43)
States	Tamil Nadu only	3 (8.57)
States	Tamil Nadu and Delhi	1 (2.86)
	Tamil Nadu and Maharashtra	1 (2.86)
	Goa only	4 (11.43)
	Punjab only	3 (8.57)
	Delhi only	1 (2.86)
	Maharashtra only	1 (2.86)
	Uttar Pradesh only	2 (5.71)
	West Bengal only	1 (2.86)
	Not reported	18 (51.43)
Intervention type	Drug/vaccine	14 (40)
	Diagnosis and screening	7 (20)
	Education program	6 (17.14)
	Medical device	3 (8.57)
	Service delivery	2 (5.71)
	Surgery	2 (5.71)
	Public health program	1 (2.86)
Therapeutic area	Infectious diseases	12 (34.3)
	Ophthalmology	5 (14.3)
	Endocrine disorders	4 (11.4)
	Oncology	3 (8.6)
	Others	11 (31.4)
Sensitivity analysis	Yes	29 (82.86)
	No	6 (17.14)

#### DISCUSSION

Our review yielded 35 cost-utility studies<sup>[8-42]</sup> published from November 2009 to November 2019. A region-wise distribution of the studies was almost equal in Northern, Western, and Southern Indian regions, with seven studies conducted in the Northern region, followed by six studies each in the Western and Southern regions. Only one study was conducted in the Eastern region. The increase in CUA over last few years reflect the increased interest to understand the costs of healthcare interventions relative to benefits.

The systematic literature review performed by Prinja *et al.*,<sup>[6]</sup> identified 30 CUA studies published between 1980 and 2014. However, our search retrieved 35 cost-utility studies from November 2009 to November 2019. This demonstrates that the number of CUA studies has risen in the last decade. However, the number of studies retrieved in our review reveals that CUA in India is still in the embryonic stage. One hundred ninety six economic evaluations retrieved in our searches, when compared with the 1249 papers on cost-effectiveness published in the USA between 1979 and 1990 and 1167 papers published between 1991 and 1996 confirm this observation.<sup>[6]</sup>

Several factors explain this difference in number of health economic evaluation evidence in India and in countries such as the UK. In countries such as the UK and Australia, health economic evaluation is mandatory for most of the new drugs and devices coming to the market. There is no such requirement in India. Another reason for smaller number of economic evaluations could be the lack of professional expertise and specialty courses in the domain of health economics.

There are very limited programs and universities which offer health economics as a specialization. As the number of corporates increase in the space of health economics, we anticipate this to have spillover effects on academia. We believe that the introduction of health economics courses at the graduate and post-graduate levels would be beneficial to promote the development of health economics domain in India.

To the best of our knowledge, this is the first paper synthesizing the evidence on CUA studies in the Indian context. The researchers of this study came from diverse disciplines (pharmacy, economics, and public health) which allowed a comprehensive and independent opinion of the review. Government or pharmaceutical company reports and unpublished research might have been missed. Publication bias could have been introduced in the review due to the inclusion of only published studies. Some CUA studies that included India in their analysis could have been missed as we excluded studies that did not report separate data for India. The variation in study designs, therapeutic area, and the state where the study was conducted leads to heterogeneity among studies and thus limited the comparability of the studies. Finally, a minor limitation of the CHEERS checklist can introduce the possibility of bias. As noted by Gerkens *et al.*,<sup>[44]</sup> the results of the quality assessment of economic evaluation are impacted much more by the assessor than the instrument itself. The mean score of all the 35 studies was 19.21 out of 24. The quality of CUA studies can be improved by educating and including training by conducting workshops for health-care professionals.

#### CONCLUSIONS

Through this systematic literature review, we identified the published CUA studies in India. The overall quality of the included studies was good; however, features such as subgroup analyses and explicit study perspective were missing in several evaluations. There is a need for continued education and training for healthcare professionals in India for generation and reporting of high-quality cost-utility evidence

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#### **Conflicts of interest**

There are no conflicts of interest.

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