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Is health technology assessment value for money? Estimating the return on investment of health technology assessment in India (HTAIn)

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10.1136/bmjebm-2023-112487

► Additional supplemental material is published online only. To view, please visit the journal online (https://doi.org/10.1136/bmjebm-2023-112487).

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To cite: Bahuguna P, Baker PA, Briggs A, *et al*. *BMJ Evidence-Based Medicine* Epub ahead of print: [please include Day Month Year]. doi:10.1136/bmjebm-2023-112487

Abstract

An increasing investment in health technology assessment (HTA) in low-income and middle-income countries has generated greater interest from policy-makers about the value and return on investment (ROI) of HTA. Few studies have, however, quantified the benefits of HTA in terms of its value to the health system. This evaluation aims to quantify the impact and ROI achieved by the HTA agency in India (HTAIn).

A framework developed by the University of Glasgow was used to review three 'hta's commissioned by HTAIn between 2018 and 2020, taking into account the opportunity cost of investing in these processes. Costs included fixed costs for HTAIn and costs for undertaking each 'hta'. Attributable benefits are calculated by subtracting the counterfactual (benefits that might have been realised without an HTA) from realised benefits.

HTAIn sits under the Department of Health Research, Ministry of Health and Family Welfare, Government of India. It was set up to facilitate the process of transparent and evidence-informed decision-making in healthcare in India.

HTA helps decision-makers to understand the consequences of alternative courses of action and to select the options that produce the best outcomes at the lowest cost. Institutionalisation of HTA is seen as pivotal to supporting universal health coverage as a means of supporting a better allocation of finite resources, cost containment and the maximisation of health.

Net health benefits are our measure of value.

The ROI of HTAIn is calculated by aggregating attributable benefits and offsetting them against the costs of investment.

Our findings show that investing in HTAIn yields a return of 9:1, with potential to increase to 71:1 with full implementation of HTA recommendations. Variability of ROI ranged from 5:1 to 40:1 between the different interventions and diseases.

While HTAIn requires financial investment, it is an efficient use of resources. The potential for greater impact and the variability of the ROI between interventions underline the importance of planning for implementation and good topic selection in HTA.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The purpose of health technology assessment (HTA) is to inform evidence-based decision-making in order to promote an equitable, efficient and high-quality health system. Yet, few studies have quantified the benefits of HTA in terms of its value to the health system. Understanding the extent to which HTA is having an impact on financing decisions and providing value for money is important as such institutions can divert resources away from health service provision.

WHAT THIS STUDY ADDS

⇒ This is the first study, as far as we are aware, to quantify the realised and potential return on investment (ROI) of HTA while maintaining its broader value on efficiency rather than cost containment or savings. It is the first study to evaluate the impact of HTA in India (HTAIn). Our results show investing in HTAIn yields a return of 9:1 with the ROI of each HTA ranging considerably. ROI at the systems level could be increased nearly eight-fold if full implementation occurred.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ We envisage the use of this evaluation will help to optimise the impact of HTA in an era of investment and expansion. The study underlines the importance in HTA of planning for implementation and good topic selection. For HTAIn, we anticipate this will contribute to generating political will and continued financial investment in these processes.

Background

Globally, healthcare budgets are under growing pressure, exacerbated by an increasing non-communicable disease burden and a fiscal crisis following the unprecedented COVID-19 pandemic. Value for money is key, especially as there may not be large increases in aid or domestic financing on the horizon. It is more important than ever that governments transparently allocate finite resources based on evidence to maximise health benefit and support universal health coverage (UHC).

Health technology assessment (HTA) is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. Its purpose is to inform decision-making in order to promote an equitable, efficient and high-quality health system.[1] Priority setting in healthcare has long been recognised as a key component of resource allocation[2 3] and over the last three decades, HTA agencies have played a central role in explicit priority setting with the aim of building equitable and efficient health systems. The growing investment globally in HTA, which potentially diverts the use of public funds from front-line healthcare services,[4] has generated greater interest from policy-makers and donors in the value and return on investment (ROI) of HTA.[4 5]

The HTA body in India (HTAIn) was established in 2017. Its institutionalisation has been supported by the international Decision Support Initiative which provided technical expertise and capacity development during its inception and growth.[6] The primary role of HTAIn is to generate evidence to support central and state governments in their healthcare decision-making. The presence of HTAIn has enabled these governments to make more transparent and inclusive resource allocation decisions, conforming to the healthcare priorities of the Indian population.[6] To date, HTAIn has completed over 30 HTAs. Its recommendations have influenced and guided public investments in evidence-based interventions which offer value in terms of cost-effectiveness. Currently, constitutional approval to transform HTAIn from a recommendatory to mandatory body is being considered. HTAIn is well positioned to play a catalytic role in supporting India's aspirational goal for UHC by influencing healthcare decisions at national and state level, engaging with public healthcare providers and generating evidence to inform decisions regarding publicly funded interventions.[7 8] These range from primary care interventions to hospital-based health benefits package. Users of this HTA evidence include India's publicly financed insurance, Pradhan Mantri Jan Arogya Yojana (PM-JAY), a tax-funded national health insurance scheme to cover 100 million families.[9] As the regulatory body for PM-JAY, the National Health Authority has created a Health Financing and Technology Assessment unit which will closely work with HTAIn.

Measuring the impact of HTA is not straightforward, not least in part due to the diversity of structures, functions, capacities and budgets.[4 10–13] With increasing investment in HTA, there is a growing pressure to appraise 'value for money' of HTA to justify the use of finite public resources.[5] Yet, few studies have quantified the benefits of HTA in terms of its value to the health system.[14] Different methodological approaches have been used,[5 15–21] including the use of frameworks.[16–19 22 23]

Evaluations of HTA agencies in several countries have been undertaken[21 24–30] including Austria,[25] Catalonia,[31] Canada,[32] Denmark,[33] Iran,[27] Malaysia,[34] the Netherlands,[24] Poland[35] and Taiwan[26] with some applying the frameworks above.[24 34] While these are encouraging, many are descriptive, for example,[26 35] use a case study approach[32] or qualitative[27 31 33] resulting in a lack of any quantified impact of HTA on health outcomes. While a few do acknowledge the need to account for a counterfactual, this is not done due to methodological challenges[25] or the use of simple before-and-after measures, which do not provide a credible measure of attribution.[36] Financial benefit is generally presented as cost savings, a narrow interpretation of HTA which aims to ensure an efficient use of resources as distinct from being a cost-cutting exercise.

To overcome this research gap, a framework[11 37] was developed by the University of Glasgow (UoG) which is grounded in the use of net health (or equivalently, monetary) benefits (NHB/NMB) as its measure of value. By using NHB (or, equivalently NMB) as our measure of outcome, HTA's broader value on efficiency rather than just cost containment is maintained and allows us to estimate realised and attributable impact. Employing this framework to quantify the ROI in HTAIn at a systems level, we envisage this could help build political support and continued funding for improved healthcare decision-making and resource allocation in India. This evaluation aims to quantify the impact and the ROI achieved by HTAIn by reviewing a set of selected HTA studies commissioned by HTAIn between 2018 and 2020. It will answer the following questions: What are the costs and benefits to the Indian population that could be attributed to the implementation of the selected HTAs undertaken by HTAIn? What is the ROI that could be achieved by HTAIn on the implementation of the selected HTAs?

Methods

The ROI-NHB framework

The framework defines the value of HTA as that of increasing the uptake of cost-effective, that is, net beneficial technologies and decreasing the uptake of non-net beneficial technologies.[11] A technology is deemed beneficial if it produces more overall health than it displaces as a result of its additional cost, diverting resources away from other interventions or services. Net health benefits, a rearrangement of the more usual incremental cost-effectiveness ratio (ICER) or cost per quality-adjusted life-year (QALY), are used as the measure of outcome in the ROI calculations(box 1).

Expressing costs in terms of their health equivalence by dividing through by the willingness-to-pay threshold (λ) for a QALY allows costs (C) and effects to be combined into a single metric. By definition, only technologies which are cost-effective would produce positive NHBs. The advantage of using NHBs (as opposed to the ICER which is a ratio) is that NHBs can be scaled to a population level by the size of the patient population served by an intervention.[38]

Distinction is made between HTA at the systems level and 'hta' as an assessment and/or appraisal of an individual technology (or technologies). We use 'HTA' (capitals) to denote HTA at a systems level and 'hta' (lower case) as an assessment and/or appraisal of an individual technology (or technologies). In order to get to the value of investing in HTA at the systems level, we need to look at what the process is delivering. In other words, we need to quantify the value and impact of individual 'hta's. The impact of an 'hta' is a function of its 'implementation', for example, the adoption of guidance into practice or uptake of a technology, following its recommendation. We also consider the counterfactual, that is, what might the level of adoption or uptake of a technology have been without going through an HTA process. By aggregating the impact of individual 'hta's, we can get to the value of HTA at the systems level (figure 1).

Box 1 Net Health Benefit Equation for ROI

Cost-effectiveness decission rule

$$\lambda > \frac{\Delta C}{\Delta B} \quad (1)$$

Where, λ = cost-effectiveness threshold

ΔC= incremental costs for use of technology compared to alternate use of resources
ΔB= incremental health benefits of technology compared to alternate technology(ies)
Net Health benefits (NHB) equation*:

$$NHB = \Delta B - \frac{\Delta C}{\lambda} \quad (2)$$

Return on invesment (ROI) equation:

$$ROI = \frac{G_1 - C_1}{C_1} \quad (3)$$

Where, GI = the gain from invesment
CI = the cost of invesment

Slotting the NHB metric into the original ROI equation and expressing the investment in term of its health equivalence, we can express the NHB-ROI as follows:

$$NHB - ROI = \frac{[\Delta B - (\frac{\Delta C}{\lambda})] - (\frac{C_I}{\lambda})}{(\frac{C_I}{\lambda})} \quad (4)$$

*Can equivalently be rearraged and expresses as Net Monetary Benefits (NMB)
Source: Grieve, E 2020(11).

Reading from left to right in figure 1, the first column shows the fixed costs (C_{FC}) of investing in HTA. In the next column, we identify the number of individual 'hta's undertaken, numbered 1–K. The third column lists the costs (C) of undertaking each 'hta' which would include personnel time and associated running costs. Moving onto benefits, 'level of technology implementation' relates to the uptake of a technology further to an 'hta' recommendation. Current uptake relates to the number of eligible people receiving the treatment, that is, realised NHBs; full uptake is everyone who is eligible receiving it that is, potential NHBs; and the counterfactual is what we surmise the level of uptake of a technology might have been had an 'hta' not been undertaken. In other words, there might have been some natural diffusion of a technology regardless. This would reduce the overall impact of the 'hta' process. Benefits attributable to the 'hta' are calculated by subtracting the counterfactual NHBs (benefits that might have been realised without an 'hta') from the realised NHBs. The final step is to aggregate benefits and offset these against costs. The cost of investment in HTA, that is, the fixed costs and the costs of undertaking each 'hta' are summed and expressed in terms of their health equivalence by dividing by the willingness-to-pay threshold (λ). As costs and benefits are both expressed in NHBs, they can be directly offset against each other to produce a ROI expressed in NHBs (NHB-ROI).

Data sources

We estimated the NHB-ROI of HTAIn based on a purposive selection of three 'hta's undertaken between 2018 and 2020, representing a mix of technologies in terms of type of intervention (public health and clinical interventions; preventive, curative and diagnostic), disease (communicable and non-communicable) and target populations (general population and gender specific). The 'hta's were chosen in consultation with HTAIn, the Center for Global Development (CGD) and UoG researchers. CGD and HTAIn developed a long list of 13 completed 'hta's and 42 ongoing studies, and a shortlist of 8 'hta's, in no particular order. The agreed shortlist recorded priorities based on their large burden of disease and/or large budget impact, evidence of impact and infectious disease funding priorities. The final 'hta's selected were agreed on by CGD, HTAIn and UoG taking into consideration availability of data, the inclusion of a lifetime economic model and with preference given to those which had been published as a peer-reviewed article. As a pragmatic approach, we considered the benefits of

Fixed cost 'HTA' infrastructure	Number of 'hta's undertaken	Cost of undertaking each 'hta' process	Level of 'technology' implementation		
			Current uptake Realised NHBs	Full uptake Potential NHBs	Counter-factual
Fixed costs	1	Cost 'hta' process$_1$	$NHBs^{CI}{}_1$	$NHBs^{FI}{}_1$	$NHBs^{CF}{}_1$
	2	Cost 'hta' process$_2$	$NHBs^{CI}{}_2$	$NHBs^{FI}{}_2$	$NHBs^{CF}{}_2$
	...	....	....	....	....
	...	....	....	....	....
	...	....	....	....	....
	K	Cost 'hta' process$_K$	NHB_k^{CI}	NHB_k^{FI}	NHB_k^{CF}

Total cost HTA (as expressed in NHBs)

$$\frac{C_{Fc} + \sum_{k=1}^{K} C_k}{\lambda}$$

Total benefit HTA (ΔNHBs)

$$\sum_{i=k}^{K} NHB_k^{CI} \quad \sum_{i=k}^{K} NHB_k^{FI} \quad \sum_{i=k}^{K} NHB_k^{CF}$$

Figure 1 HTA impact framework—INSERT. HTA, health technology assessment; NHBs, net health benefits. Source: Grieve, E 2020(11).

three 'hta's against the annual cost of HTAIn. Using significantly more HTAs would have required a commissioned evaluation or audit to collect the necessary primary data rather than using data from existing sources (as we did here). In India (as indeed, is very common in many countries), data to facilitate such evaluations are currently not routinely collected.

Data were extracted from the economic evaluations carried out as part of the 'hta'. Net benefits were calculated from the incremental costs and QALYs from the economic evaluation results in the HTA reports. We used one gross domestic product (GDP) per capita to value a QALY as used as standard practice by HTAIn.[39]

Actual expenditure for 2019–2020 was used as the cost of investment in HTAIn.[40] (Discounting was not applied to costs or outcomes at the systems level as the time frame of investment is a year). This included staff costs for the HTAIn Secretariat and Resource Centres across India, budgets for commissioned 'hta's, committee and stakeholder meetings, and capacity development. The cost of undertaking an 'hta' was averaged across 2018–2020 to better capture the falling costs per 'hta' year-on-year. Implementation costs associated with each technology were not considered to be part of the cost of the investment in HTAIn. As such, they were not included in the denominator of the ROI equation but were instead netted off against the benefits if the economic evaluation had not already included them. Costs in the HTAIn reports and related articles were reported both in Indian rupees (INR) and US dollars (USD). We have exchanged all into US dollars.

Data on implementation were obtained from the literature[41 42] or expert opinion where data was otherwise not available. For those technologies where roll-out was in a specific state, implementation at that state level only was used in the ROI calculations. We made assumptions on a counterfactual level of uptake, that is, the benefits that might have been realised without the 'hta'. As these benefits are not attributable to the 'hta' process, they are deducted from the realised NHBs. In the base case, we assume realised benefits are fully attributable to the 'hta' but we undertook a threshold analysis on the combined level of implementation and attribution to produce a 'breakeven' ROI, that is, where the return equals the investment cost.

Patient and public involvement

There was no patient or public involvement in this study. This analysis was carried out using secondary data available in HTA reports, commissioned and published by HTAIn.

Results

Selected HTA studies

The selected 'hta's were on Safety Engineered Syringes (SES), Cervical Cancer Screening strategies (CCS) and TrueNat, a rapid molecular test for the diagnosis of infectious diseases (table 1). Cervical cancer is the second most common cancer among women in low-income and middle-income country.[43] As India is promoting national level screening, this HTA was designed to assess the cost-effectiveness of various screening strategies for cervical cancer among women in the age group of 30–65 years. Among the screening strategies assessed, screening with Visual inspection with acetic acid (VIA) 5 yearly and VIA 10 yearly came out to be cost-effective, with VIA every 5 years providing greater health benefits. Screening with VIA for 5 years was thus the recommended strategy for India.[44]

Addressing unsafe injection practices is an important public health agenda as they can lead to the large-scale transmission of bloodborne infections among patients and also to healthcare workers through needle-stick injuries (NSIs). Globally, 16 billion injections are administered each year, of which 95% are for curative care.[45] India contributes 25%–30% of the global injection load, and over 63% of these injections are reportedly unsafe or deemed unnecessary.[46] Safety-engineered syringes are devices designed with advance safety features to prevent reuse and accidental NSIs.[47] Punjab state initiated an HTA in 2018 to support the introduction of SES, replacing the current practice of using disposable syringes for therapeutic care. Three types of SES were evaluated, with reuse prevention syringes found to be cost-effective.[47]

India has the world's highest tuberculosis (TB) and multidrug-resistant TB burden, and due to poor diagnostics at healthcare facilities with low sensitivity and low linkage-to-care rates, over 25% of patients who use the public sector facilities are neither diagnosed nor started on treatment.[48] The 'hta' compared TrueNat and three other TB diagnostic strategies, GeneXpert, Smear Microscopy, Culture.[49] TrueNat was found to be the most cost-effective strategy. Used at the point-of-care in India, TrueNat for TB diagnosis could improve linkage-to-care, increase life expectancy and be cost-effective compared with smear microscopy or Xpert.[49 50]

All three technologies were reported to be cost-effective at one GDP per capita yielding positive NHBs (table 2). Please see online supplemental annex 1 for full workings on population estimates and conversion to NHBs using the threshold.

Actual reported expenditure by HTAIn over 12 months for 2019–2020 was 201.8 million INR.[40] For the purposes of this evaluation, this was taken as the cost of investment in HTAIn. The cost of undertaking each 'hta' was averaged across the first 3 years of HTAIn's operation (2018–2020) to better capture the falling costs per 'hta' year-on-year. These costs were then expressed in terms of their health equivalence by dividing by the willingness-to-pay threshold (λ) (table 3).

Table 1 Intervention classification matrix

Technology	Non/communicable disease (CD/NCD)	Decision-maker	Population	Type of intervention
Cervical cancer screening[44]	Cervical cancer (NCD)	NCD Division, Ministry of Health and Family Welfare, Government of India	Women	Preventative
Safety engineered syringes[47]	HBV, HCV, HIV (CD)	Punjab State Government and National Pharmaceutical Pricing Authority, Government of India	Healthcare workers and general population	Therapeutic
TrueNat diagnostic for tuberculosis[49 50]	Tuberculosis (CD)	Central Tuberculosis Division, Government of India	General population	Diagnostic

Table 2 Calculating benefits and costs of each 'hta'

Technology	Comparator	Incremental costs*	Incremental QALYs	NHB† individual level	Eligible population*	Implementation		NHBs scaled to eligible population‡		
						%	Source	Potential (100% implementation)	Realised (actual implementation)	Attributable
CCS[44]	Visual inspect with acetic acid at 5–10 years	22	0.0260	0.0142	5.62 million	1.9	National level, WHO and NFHS, 2020[41]	79 706	1514	1514
SES[47]	Disposable syringes	35.4 million (Punjab)	20 964 (Punjab)	1966 (Punjab)	Punjab	80.0	Personal communication	1966	1573	1573
TrueNat[49 50]	GeneXpert, Smear Microscopy	166	0.22 (Life Years)	0.131	98 000	82.3	Andhra Pradesh under RNTCP, Jeyashree *et al*[42]	13 057	10 742	10 742

Exchange rate 82 INR to US$1, 12/2022, source: https://www.exchangerates.org.uk/.
*See online supplemental annex for full calculations.
†Converted using WTP at one GDP per capita at USD. See box 1 for equation and online supplemental annex 1 for workings.
‡Figures may vary slightly with rounding.
CCS, cervical Cancer Screening strategies; NHBs, net health benefits; QALY, quality-adjusted life-year; SES, Safety Engineered Syringes.

NHB-ROI individual HTA study

Inserting the potential and realised NHBs from table 2 into table 3, the costs and benefits can be directly offset against each other and expressed as an ROI. At actual levels of implementation, the ROI ranged for each 'hta' from 5:1 to 40:1. If we calculate ROI based on potential benefits, that is, 100% implementation and attribution, the ROI increases. In the case of CCS, given the current low level of uptake, the potential impact is sixty-fold greater.

NHB-ROI HTA systems level

To calculate the ROI at the systems level, the benefits of the three individual 'hta's are summed and offset against the investment costs of HTAIn. As these represent only a selection of HTAIn's output over the evaluated period, the total estimated costs of undertaking the three 'hta's is much less than the total investment costs in HTAIn over that same period. The ROI for HTAIn at the systems level is 9:1 given current levels of implementation and increases nearly 8-fold to 71:1 if potential benefits are realised with full implementation.

A threshold analysis undertaken demonstrates that at significantly lower implementation levels than assumed in the base case, each 'hta' still yields a positive ROI. We found that for SES, the ROI would be positive at a coverage level of at least 13%, which is a sixth of the coverage estimated in the base case. Similarly, the ROI would be positive for CCS and TrueNat at the lower levels of implementation of 1.7% and 34%, respectively (online supplemental annex 2).

Discussion

Our research on estimating ROI of HTAIn has helped to show that priority-setting institutions produce a high ROI through improvements in health system efficiency and could be enhanced through targeting resources on priority topics and focusing on implementation.[51] High upfront costs have been identified as a key reason for discouraging countries from investing in HTA.[52 53] Yet, our findings show that HTA can be expected to generate overall efficiency gains in the health system, even though the 'creation and operation of an HTA body adds another layer of administrative costs to the health sector and may increase expenditure related to the additional use of effective interventions'.[54]

Extrapolating from these three illustrative cases, HTAIn shows a positive ROI of 9:1 but with a wide range of ROI for the individual 'hta's. This is to be expected given the diverse types of interventions, target populations and levels of implementation. Implementation of HTA recommendations is critical to optimise the ROI, and with full implementation of these selected HTAs, there is scope to increase ROI almost 8-fold to 71:1. The variability of the ROI between the different 'hta's underlines the importance of good topic selection. The strategic scale-up of HTAIn and careful selection of HTA topics, for example, focusing on areas with ongoing uncertainty, large budget impact and where the HTA recommendation will be adhered to and implemented, is likely to be pivotal to increasing its ROI further. It should also be noted that the conduct of 'hta's need not involve the same level of resources in all instances. Careful routing of selected topics to different 'hta' processes could further enhance ROI, especially when it is acceptable to leverage international evidence/recommendations in certain situations.[55]

While the empirical evidence of HTA on health systems efficiency is scarce, two recent studies do use quantitative methods to assess the impact of HTA. Kingkaew *et al*[20] model the potential impact of using HTA-based decision rules to produce significant

Table 3 ROI at a systems level

HTAs	HTAIn costs per HTA (INR million)	HTAIn costs per HTA (NHB)	Potential NHB	Realised/attributable NHB	ROI Actual NHB	ROI Potential NHB
CCS	40.36	265	79 706	1514	5.1	300.1
SES	40.36	265	1966	1573	5.1	6.1
TrueNat	40.36	265	13 057	10 742	40.1	48.1
HTAs	Annual HTAIn Costs (INR million)	Annual HTAIn costs (NHB)	Potential NHB	Realised/attributable NHB	ROI Actual NHB	ROI Potential NHB
Extrapoloated ROI	201.8	1324	94 730	13 830	9.1	71.1

CCS, cervical Cancer Screening; HTA, health technology assessment; NHBs, net health benefits; ROI, return on investment; SES, Safety Engineered Syringes.

positive NMB in the Thai health system, with an estimated 8:1 ROI.[56] They note this illustrates the potential impact as they do not consider the issue of implementation and access. RAND Europe conducted an economic analysis of the impact of the HTA research programme in the UK using a similar NMB approach.[21] They found that if 12% of the potential net benefit of implementing the findings from 10 selected studies was realised, it would cover the cost of the HTA Programme from 1993 to 2012. Both these studies highlight the added value of our framework incorporating implementation as this allows us to estimate realised as well as potential impact.

While all the 'hta's selected represent positive recommendations, the framework can also be applied to a 'not recommended' decision as the value of HTA is defined as both increasing the uptake of net beneficial technologies but also decreasing the uptake of non-net beneficial technologies. As it is, all topics completed during the first 3 years by HTAIn (the period evaluated) were found to be cost-effective and consequently recommended.

ROI is about the efficiency of an investment and a valuable metric for funders or governments interested in investing in HTA at the systems level to evaluate if it is a worthwhile use of resources. Given heterogeneity in ROI calculations,[57] a good ROI is one that is entirely transparent in its methods, values health outcomes/QALYs robustly (ie, preference weighted) and acknowledges its limitations. Rather than a financial ROI focused on maximising financial returns, that is, with a preference for cost–saving interventions, we monetarise health using the cost-effectiveness threshold, the value of which in India is one GDP,[39] taken to capture the opportunity cost of healthcare investments. This concept of opportunity costs as expressed through the threshold is central to NHB but is also integral to the NHB-ROI framework. As such, our framework addresses the opportunity costs associated with the capital investment and ongoing running costs required to sustain an HTA infrastructure at the systems level. However, as the resulting ROI is an aggregate of both (the value placed on) health gains and financial costs, we are wary of conveying a 'misinterpreted' message, that is, it is not a typical cash return.[58]

We acknowledge the following limitations in our study. We estimated realised and attributable NHB without analysing primary monitoring data on implementation and relied on secondary and expert sources. We also assume full attribution of the benefits to the HTA recommendation, exploring this assumption in a threshold analysis. Considering these threshold levels are in the main much lower than the implementation estimates used in the base case and that this represents only a small number of HTAIn's studies, it is likely that HTAIn retaining a positive ROI is robust to uncertainties in key parameters.

At the systems level, the counterfactual is what would have happened without an HTA. Ideally, we would find a sector or jurisdiction unaffected by the HTA to make such a comparison, but where randomisation is not possible, quasi-experimental methods can be used to construct a control. A control or comparator is crucial to impact evaluations, as without this, it can lead to erroneous measures and conclusions of impact with attribution which could be wrongly assigned or interpreted. The dominant framework for thinking about causality is underpinned by randomised controlled trials (RCTs) and a counterfactual. However, an RCT is not suited to the evaluation of many complex interventions, including HTA if we think of the process of HTA as a complex intervention itself, that is, the assignment of the population and their outcomes to 'HTA' or 'no HTA' is beyond our control. In order to estimate attributable benefits in the absence of a randomised evaluation, there are different approaches to construct or 'mimic' a counterfactual dependent on the data available.[59 60] For example, interrupted time series or segmented regression utilising routine administrative data to capture time trends in the uptake of a technology.[59 61] The use of routine administrative data in a subsequent analysis could also provide insight on the distribution of costs and benefits. Here, we allocate NHBs proportionately in line with implementation which does not consider how the NHBs are distributed across the eligible population. For example, it may be that difficult-to-reach populations who may have the most to gain are more likely to often be the last to take up the intervention.

There exist multiple sources of uncertainty in the empirical findings both at the level of the individual 'hta's (eg, in the long-term modelling of costs and benefits of a technology subject to robustness of source data and assumptions used in the economic model) and in the overall framework (eg, the reliance of NHBs on threshold values as a representation of the true opportunity costs of resource allocation within a health system and the implications this would have for the ROI). Treating the impact framework parameters probabilistically with fixed underlying cost-effectiveness from the 'hta's would not fully represent uncertainty. Instead, we vary key parameters in a deterministic sensitivity analysis to represent uncertainty in the ROI framework (online supplemental annex).

While we recognise that doing this for all 'hta's in any given context would be impractical, we acknowledge that the extrapolation of ROI at the systems level based on 1 year of costs and the costs and benefits from a small sample means results are necessarily indicative. Given the true benefits would be for all 'hta's undertaken within the evaluation period, we estimate the ROI to be conservative. ROI is frequently used to consider a portfolio of individual investments, and the return is the combination of

what is gained and lost collectively. This relates to the ROI of HTA at the systems level, which we show to be an aggregate of what that system is delivering that is, a portfolio of individual 'hta's. While the 'hta' case studies selected here each show a positive ROI, not every 'hta' needs to produce a positive return for the overall investment in HTA at the systems level to be valuable.

Generalisability of the ROI result is not intended. HTA structures and disease patterns (thus costs and benefits) will differ by context. Indeed, one definition of the value of HTA is 'the perceived worth or benefit of HTA, which may vary according to stakeholder type, local setting and other factors'.[5] We recognise too there are many other important criteria, for example, the distribution of outcomes which is not captured in this metric. There are likely to be many additional benefits stemming from HTA not captured here as the quantitative framework does not consider spillover effects in order to limit the scope. For example, this could include enhancements in governance and changes in attitudes and discourse around the importance of 'evidence'. As such, we are likely to be conservative in illustrating the value of HTAIn. However, while HTA will necessarily take different forms depending on purpose and context, the evaluation methodology is portable and transferable. Qualitative or theory-driven methods[4 11] could be adopted alongside this framework to capture other outcomes from different contexts and perspectives in line with the definition of HTA value above.

Conclusion & policy implications

Our study shows HTAIn represents value for money with a positive ROI of 9:1, increasing to 71:1 with full implementation. While HTAIn requires financial investment, it is an efficient use of resources and offers value for money as a policy tool. We envisage the use of this evaluation will encourage accountability of spending decisions and help to optimise the impact of HTA in an era of investment and expansion through better understanding of HTA's role in delivering health outcomes and value for money at the systems level. As it is understood that final outcomes are already (usually) modelled as part of an HTA, this allows the focus of optimisation to be on selecting the evaluation topic wisely and improving implementation or uptake of HTA recommendations. ROI is contingent on successful implementation of HTA recommendations. It is only when decisions are implemented, and patients receive the health benefits, that the full impact of HTAIn can be secured. HTA evidence uptake by public health sector 'user' departments, as well as the private sector, must be supported to secure implementation and maximise HTA investment return. HTAIn and its generation of evidence to inform decisions of key budget holders such as the National Health Mission, National Health Authority and State Departments can help expedite India's progress towards UHC. This requires reinforcing HTAIn's mandate and role in the health system governance, clarifying the responsibilities of stakeholders and enabling them to support the implementation and scaling up of HTA recommendations. For HTAIn, we anticipate this will contribute to generating political will and continued financial investment in these processes.

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Acknowledgements The authors would like to acknowledge the support received from the health technology assessment in India (HTAIn).

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Funding This study was funded by the Bill & Melinda Gates Foundation (BMGF), INV-003239.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information. All data used in the analysis are shared in main manuscript and supplementary material.

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