Cost-effectiveness Threshold and Health Opportunity Cost Achieving Universal Health Coverage

SHANKAR PRINJA, THIAGARAJAN SUNDARARAMAN, V R MURALEEDHARAN

With the setting up of the health technology assessment board, evidence from cost-effectiveness analysis will play an important role in decision-making. This raises the fundamental question: How much extra cost per unit of health gained is considered cost-effective? Various approaches for assessing the appropriate cost-effectiveness threshold for India are discussed. A robustly determined opportunity cost of healthcare spending should serve as a proxy for setting up a CET, and it should be used to advocate for greater resources towards achieving universal health coverage.

Shankar Prinja (shankarprinja@gmail.com) teaches at the School of Public Health, Post Graduate Institute of Medical Education and Research, Chandigarh. Thiagarajan Sundararaman (*t.sundararaman@ tiss.edu*) is with the Tata Institute of Social Sciences, Mumbai. V R Muraleedharan (*vrm@iitm.ac.in*) is with the Indian Institute of Technology Madras, Chennai.

Tndia has made a beginning with institutionalising health technology Lassessment (HTA) for contributing evidence to strengthen policymaking with respect to universal health coverage (UHC), for evolving standard treatment guidelines and for generating evidence on value for money for a variety of health interventions and choice of technologies (Downey et al 2017; Prinja et al 2018). While four HTA reports have already been submitted, nearly a dozen others have been commissioned to technical partners (Department of Health Research 2018a). The secretariat for the agency-Health Technology Assessment India (HTAIn)-set up in the Department of Health Research, has recently published the methods manual, which is a practical guide for both technical partners, who are undertaking HTA studies, as well as the users of HTA evidence (Department of Health Research 2018b). However, one of the key issues, which is critical to decisionmaking, has not been yet addressed: what is the cost-effectiveness threshold (CET) that HTAIn should use to judge the interventions that are currently being evaluated or have been evaluated?

In the existing set of HTA studies, as also other previous Indian economic evaluations in health (Prinja et al 2015), researchers have mostly used the World Health Organization's (wно) per capita gross domestic product (GDP) to write the final conclusion of their reports (Marseille et al 2015). However, the problem is confounded by the fact that the who itself has disavowed its earlier guidance on CET for countries (Bertram et al 2016). In the absence of a clear guidance on how to judge the HTA evidence, it becomes even more important to initiate the debate. This article outlines the issue of CET in the Indian context, determines its usefulness in broader debates in HTA as well as UHC, highlights the potential risks and its possible solutions as well as raises the methodological issues to determine the same.

First, the conceptual underpinnings of CET in the context of HTA are defined and its linkage with health opportunity cost is described. It is argued that CET should be understood as the marginal productivity of the health system, and what it could have done with alternative use of the money being considered to be spent in a particular way. Second, the political economy of CET is discussed. This specifically deals with two key questions regarding the purpose of a CET. Should CET be seen as a perverse tool to ration care further in a context with serious underfunding of public healthcare, or as an evidence to advocate for more resources for an aspirational UHC agenda and to simultaneously make the health system more efficient and equitable?

We also present a way of understanding the real purpose of CET, and whether to define a "decision rule" or to "aid in decision-making" by reflecting on the possible consequences of choices that are made. Then, we turn to various approaches that have been described in the literature, identify the practical application of the approaches in different countries, and outline the potential advantages and disadvantages of each of these methodologies. In this, the authors mainly confine their arguments to the classical bookshelf or league table approach, the demand-side approach of willingness to pay and the recently emerging concept of using the health system's marginal productivity as an indication of health opportunity cost. We also identify the areas that need further exploration for research in the Indian context. Finally, the arguments are summarised to make a case for beginning a debate on how to determine a CET for India (HTAIn), and how to articulate the same so that it contributes to the overall aspirations of UHC in India.

Concepts

Economic evaluation is an important component of HTA study. Typically, it involves the measurement of costs and

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outcomes, usually expressed as qualityadjusted life-years (QALY), for the intervention being assessed and its comparator (usually routine care) (Whitehead and Ali 2010; Drummond et al 2015). Finally, the evidence is presented as an incremental cost-effectiveness ratio (ICER), which is a ratio of the difference in costs and the difference in outcomes. This can lead to four different scenarios (Fox-Rushby and Cairns 2005; Drummond et al 2015). First, the new intervention is more effective and less costly than the comparator, in which case the new intervention is a clear-cut choice as against the comparator. Alternatively, if the new intervention is less effective and more costly, then the new intervention would be rejected. The decisionmaking requires some additional guidance when the new intervention, as compared to the comparator, is more effective, but more costly as well. An ICER is thus calculated, which implies the incremental cost which will be incurred for every QALY gained if the intervention is implemented in the health system.

However, the question then remainshow much additional cost per QALY gained is worth the value for money? Any subsequent decision about the costeffectiveness is thus contingent upon this notion of CET. Furthermore, if the intervention is not cost-effective at current costs, then one could undertake a sensitivity analysis to determine how much price reduction could make the intervention cost-effective. However, such evidence generated from HTA, which could be vital for any price negotiation decision, is again contingent upon a CET. In view of this, it seems that a CETwhether implicit or explicit-appears necessary for decision-making.

In the absence of such a CET, decisions could be made without a sound guidance on what may be considered as cost-effective. In such situations, it is more likely than otherwise that costineffective interventions could also find their way for public financing. As a result, it can lead to inefficiency in health systems.

CET and Universal Healthcare

An important consideration while deciding about the use of HTA evidence and development of CET in any country is the overall status of the country's achievement of UHC. Countries like the United Kingdom (UK) or Thailand have already attained a reasonable level of UHC, which provides a comprehensive set of services to the population. All essential services are included, and only a few procedures of doubtful therapeutic merit are excluded (McKee et al 2013; Tangcharoensathien et al 2015). In such a context, the questions which become relevant for HTA evidence include whether newer innovative drugs or devices, or new strategies for the prevention of disease are cost-effective enough to be included, given the overall budget constraints that the country faces and under different prospects of having larger budget in the future. Moreover,



in such a situation, the UK and Thailand governments are already spending about 5% of their GDP or over 10% of the total government expenditure on healthcare (Global Burden of Disease Health Financing Collaborator Network 2017). Hence, HTA evidence serves to guide governments more on getting the best value for any incremental change in allocation to health, especially in view of the rising plethora of new drugs and devices that are flooding the healthcare markets, with very "small" and insignificant incremental gains in health outcomes.

On the contrary, in India, the government spends just about 1% of its GDP on healthcare (Gupta and Mondal 2014). In such a situation, a lot of otherwise costeffective interventions are not funded. Hence, HTA evidence is not needed to demonstrate the cost-effectiveness of expanding the basket of services provided with more essential interventions (whose cost-effectiveness is well-established). but to assess the efficiency of different ways to implement the intervention. For example, population-level screening for hypertension, diabetes, and cervix and breast cancer, which are on the list of wнo's (2017) "Best Buys" for noncommunicable diseases, were introduced very recently in India (Directorate General of Health Services nd). Aptly enough, the HTA projects which have been commissioned recently by the HTAIn reflect this contextual variation. The HTA studies commissioned to evaluate the screening for non-communicable diseases do not assess whether the screening is cost-effective as against "no screening." On the contrary, these studies aim to evaluate the cost-effectiveness of screening in order to identify which method, what population age groups, and what periodicity would be most cost-effective when used to screen for diseases such as carcinoma cervix, carcinoma breast, hypertension and diabetes.

The real issue in considering an explicit threshold in India and similar countries, which have high unmet needs, low coverage of essential services and are trying to advocate for increase in public financing for healthcare, is the tension that CET may be seen as a "ceiling," which may be used to "ration" care. This could deter the efforts of those who rightfully advocate for seeking higher allocations for the health sector. In light of this concern, the framing of this issue needs to be improved. It is important to understand what the CET implies, and what purpose it serves. The fundamental concept is that CET is a notion of the opportunity cost of the current healthcare spending, or the societal willingness to spend on health given its benefits. This implies that if, in the current scenario, public spending on health leads to "X" amount of health gained for every ₹1 spent, then any new intervention recommended should have health gains of more than "X" per ₹1 spent. Alternatively, if the society is willing to spend "X" rupees for every unit gain in health status, then any intervention, which costs less than "X" rupees extra for unit gain in health status, should be considered as costeffective and considered favourably for recommendation. Alternatively, it also signifies the loss of population health for not making the desired investment in healthcare.

However, it also needs to be recognised that this notion of CET should be a "guiding" principle for "aiding" decision and not a "decision rule." It is well recognised that the principle of health maximisation, which is evaluated using costeffectiveness, may not be the sole criteria for policymaking. Instead, other criteria which further contribute to UHC, such as the ability of any new intervention to reduce out-of-pocket expenditure or enhance equity in service utilisation, or improve access and quality of care would also be equally important considerations. The value of CET, when viewed as an opportunity cost, is that it allows researchers to make conclusions based on the value of the incremental cost effectiveness ratio, whether the intervention is cost-effective or not. In addition, it allows decision-makers to evaluate ex ante what would be the impact of their decisions on introduction of new interventions, and whether it will make the health system more or less efficient, given the healthcare spending involved. The CET should thus serve as a "decision aid" to further enhance evidence-based policymaking, rather than merely being a binding factor or a "decision rule."

Determining CET in India

There are three broad approaches to determining the appropriate CET in any country. The first approach, which is also referred to as the "bookshelf" approach, involves evaluating all the interventions, which could be considered for inclusion in a benefit package (Culver 2015). Subsequently, it ranks all interventions in descending order of its cost-effectiveness, from the most cost-effective to the least cost-effective intervention. Finally, one evaluates the budgetary requirements for implementing each of those interventions in the same descending order to finally reach that point where the allocation meets the budget constraint. The value of the QALY gained per unit rupee spent for the last intervention signifies the CET, as we can no longer fund any intervention that is less cost-effective than the last. The advantage of this approach is that while estimating the CET, it not only assesses the cost-effectiveness, but also recognises the affordability in terms of budget constraint. Another important advantage of the bookshelf approach is its very lucid illustration of the concept of CET when represented diagrammatically.

However, the biggest limitation of this approach is that it is highly time- and data-intensive, that is, evidence on costeffectiveness and budget required for each intervention, which could potentially be considered in the benefit package, needs to be assessed upfront. This is a herculean task given the data, information and capacity needs for conducting these evaluations. It is exactly the reason why despite being theoretically robust, zero-base budgeting is rarely practised (Thompson and Pyhrr 1979). So, while it may be wishful thinking in the Indian context, it is not a practical reality. One could aim at using this approach in the long run. Potentially, this approach, in tandem with advocacy from both within and outside the government, could be used to push back on budget constraints.

The second method involves assessment of the willingness of society to pay

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for healthcare interventions. This method is based on the conceptual underpinnings of microeconomics involving marginal costs and benefits. So, while a consumer makes a decision about whether and how much to spend on a product, they are assumed to be perfectly rational-a condition that is often violated in healthcare (Arrow 1963). The valuation of CET for a given individual using this approach is likely to be dependent on their own wealth status. This may not be entirely incorrect as a randomly drawn sample of population should ultimately represent the wealth status of the country and hence, should be representative of the individual country's affordability. Nonetheless, it has the potential to estimate a CET which is much lower than what the government may actually be spending and thus, could lead to inequities.

The third method for assessing CET comprises estimating the "opportunity cost" of current health spending. Through this method, one can measure how much QALYS are gained with every rupee spent in the existing health system. This way, one can evaluate the value of each decision made in the health system in terms of the introduction of new interventions. If the new intervention which is introduced provides more QALYS per rupee spent, then going by the health maximisation criteria, it will result in an improvement in population health. On the contrary, if an intervention which leads to lower QALY gained per rupee spent is still implemented, then the policymakers would need to recognise the potential consequences of those decisions. And, the latter decisions may need to be justified, if other criteria such as improvement in equity, or reduction in out-of-pocket expenditures are overriding the health maximisation principle.

One such attempt to value the health opportunity cost has been done in the UK (Ochalek et al 2018). The study provides empirical assessment of the elasticity of healthcare spending to help

determine CET. A similar cross-country analysis reports the health opportunity cost or CET for India to be one-third of the per capita GDP, much lower than the wнo's earlier guidelines (wно Commission on Macroeconomics and Health 2001: Woods et al 2016). However, there are a few major limitations of this analysis. First, while the valuation of entire consequences are performed in terms of DALYS (daily-adjusted life-years) averted which is the result of entire healthcare spending, only public sector costs are considered. Since nearly 70% of the total healthcare costs in India are private, this would lead to underestimation of true costs, and hence, result in the significantly lower valuation of CET. Second, this analysis uses the elasticity of healthcare spending drawn from a cross-country analysis. This national-level elasticity is then applied at the state level to derive statespecific CETs. In a country as diverse as India, application of a national elasticity estimate in each state evens any effect,

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Gender and Education

Edited by

VIMALA RAMACHANDRAN AND KAMESHWARI JANDHYALA

Education of women and girls in India has been widely debated and discussed since the mid-1900s. While the last century has seen a considerable shift in the status of women in Indian society, gender equality in education continues to be influenced by the economy, society, and culture, the accessibility and availability of formal education, and gender norms. A continued preference for sons across the country plays an important role in determining whether girls are given access to both primary and higher education.

This volume brings together wide-ranging debates that took place in the *Economic & Political Weekly* from 2000 to 2017 on the social, political and economic realities affecting the education of women across the country. It analyses the different axes of inequality; the political, economic and social context of education; and pedagogy and curriculum, through a study of textbooks.

The volume will be critical for students, scholars and researchers of sociology, education, women's studies and development studies, and for NGOs and organisations working in the development sector.

Authors: Vimala Ramachandran • Kameshwari Jandhyala • Aarti Saihjee • Anuradha De • Claire Noronha • Meera Samson • Krishna Kumar

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Mumbai • Chennai • New Delhi • Kolkata • Bengaluru • Bhubaneshwar • Ernakulam • Guwahati • Jaipur • Lucknow • Patna • Chandigarh • Hyderabad Contact: info@orientblackswan.com which state-level organisation of healthcare delivery and governance may have on efficiency. Third, this article measures CET for every DALY averted instead of QALY gained, which is recommended as the outcome measure to be valued in the Indian reference case.

Besides these methodological issues, a fundamental issue with the current supply-side approach is that it is suited for estimating opportunity cost of decisions made in the presence of a fixed budget involving reallocation of budgets between programmes. However, if the new interventions are to be financed by creating additional investment, which will also be more congruent with the UHC vision, then the additional funds will most likely be raised through tax contributions. In such a case, the opportunity cost is more appropriately determined by evaluating the consequences of changes in consumption expenditure as a result of increased tax contributions. Thus, there is both a methodological as well as theoretical angle which justified a need to redo the analysis with much more comprehensive measurement of costs and consequences, and use of local data. Moreover, after the entire analytics, there will be significant role of a consultative process within a wide group of stakeholders to build a consensus around the CET.

Conclusions

HTAIN has been entrusted with the task of evaluating new and existing healthcare interventions for inclusion in health benefit package. The main criterion that is to be used for making decisions is health maximisation, for which cost-effectiveness is used as the tool. However, making decisions based on cost-effectiveness evidence requires comparison with CET. As a result, the HTAIN will eventually need to decide the appropriate CET for India and the appropriate methodology to define it.

The use of a CET will help further improve transparency and accountability in healthcare decision-making. If there is an understanding that any new intervention sanctioned will expand the resource envelope available in public health departments, a CET will not result in any negative effect towards rationing care. If, on the other hand, the new intervention does not lead to an overall budgetary increment, one would require some transparency in understanding what is being sacrificed or withdrawn to pay for the new intervention. But, since new interventions could be expensive and inefficient, an insistence that new interventions have to be based after consideration of its cost-effectiveness in comparison to the CET, and that this CET is close to what Woods et al (2016) have shown, would ensure that investments in health are very efficient. This is an argument that the Ministry of Health often fails to offer when arguing for higher investments from the Ministry of Finance. Moreover, the latter would also feel more confident in supporting fund interventions, which result in higher QALYS gained per rupee spent than the health opportunity cost currently. Thus, CET or health opportunity cost concept can be used to garner more money for health and vice versa, and thus help advance the cause of universal health coverage.

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