BMJ Open

Protocol for estimating the willingness-to-pay-based value for a quality-adjusted life year to aid health technology assessment in India: a cross-sectional study

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To cite: Chugh Y, Jyani G, Trivedi M, *et al*. Protocol for estimating the willingness-to-pay-based value for a quality-adjusted life year to aid health technology assessment in India: a cross-sectional study. *BMJ Open* 2023;**13**:e065591. doi:10.1136/bmjopen-2022-065591

► Prepublication history and additional supplemental material for this study are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-065591).

Received 11 June 2022
Accepted 27 October 2022

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ABSTRACT

Introduction To ensure that the evidence generated by health technology assessment (HTA) is translated to policy, it is important to generate a threshold value against which the outcomes of HTA studies can be compared. In this context, the present study delineates the methods that will be deployed to estimate such a value for India.

Methods and analysis The proposed study will deploy a multistage sampling approach considering economic and health status for selection of states, followed by selection of districts based on Multidimensional Poverty Index (MPI) and identification of primary sampling units (PSUs) using the 30-cluster approach. Further, households within PSU will be identified using systematic random sampling and block randomisation based on gender will be done to select respondent from the household. A total of 5410 respondents will be interviewed for the study. The interview schedule will comprise of three sections including background questionnaire to elicit socioeconomic and demographic characteristics, followed by assessment of health gains, and willingness to pay (WTP). To assess the health gains and corresponding WTP, the respondent will be presented with hypothetical health states. Using time trade off method, the respondent will indicate the amount of time he/she is willing to give up at the end of life to avoid morbidities in the hypothetical health condition. Further, respondents will be interviewed about their WTP for treatment of respective hypothetical conditions using contingent valuation technique. These estimates of health gains and corresponding WTP will then be combined to ascertain the value of WTP per quality-adjusted life year.

Ethics and dissemination The ethical approval has been obtained from the Institutional Ethics Committee (IEC) of Postgraduate Institute of Medical Education and Research, Chandigarh, India. The study outcomes will be made available for general use and interpretation of HTA studies commissioned by India's central HTA Agency.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The threshold generated by this study will be based on 21 640 observations of willingness to pay (WTP) per quality-adjusted life year (QALY), which will be the largest study to be conducted so far.
⇒ Our study uses different health conditions for the estimation of WTP/QALY and these conditions have been chosen such that a spectrum of mild, moderate and severe conditions is presented to respondents so as to estimate how WTP changes with severity of conditions.
⇒ Choice of time horizon is an important predictor of WTP estimation and there exists huge variation in the choice of time horizon in different estimations. Our study will extrapolate the health gains for the remaining life of an individual based on the age and life expectancy followed by eliciting the corresponding WTP so as to get realistic estimates of the value of one additional QALY.
⇒ Given the huge cultural and geographical variation in India, there exists a risk of the interviews being susceptible to the interviewer's effect.
⇒ Respondent fatigue may set in due to the exhaustive interview process, which might impact the WTP estimates in the latter part of the interview.

INTRODUCTION

Increasing healthcare costs and limited resources warrant the need for evidence-based priority setting followed by efficient resource allocation. Such decision-making, in turn, requires careful consideration, given the availability of competing healthcare technologies and the associated opportunity costs for allocating resources to a given intervention. Consequently, the use of health technology assessment (HTA) and economic evaluations has gained importance worldwide as a tool to guide the sustainable allocation of resources.[1–3]

HTA encompasses a wide range of analyses including economic evaluations that aim to generate evidence on the cost-effectiveness and budget impact of medicines, devices and health programmes.[4] HTA aims to improve allocative efficiency wherein the cost and outcomes of different interventions are evaluated. To make a comparison of different

interventions, it is important to have a common summary measure that is comparable across all interventions. If we measure the outcomes with anything else except quality-adjusted life year (QALY) (such as life years gained), we fail to account for morbidity. QALY solves this problem as it combines the effects of health interventions on mortality and morbidity into a single index, and thus provides a common currency to enable comparisons across different disease areas. Therefore, a utility-based index is the recommended and is the most widely used method for reporting economic evaluations.[5] Moreover, many HTA recommendatory bodies including that of India, the US Panel on Cost-Effectiveness in Health and Medicine and the National Institute of Health and Clinical Excellence have endorsed the use of QALY for their 'reference case'.[6–8]

HTA has been widely used to guide policy decisions in India and in the world. To interpret the outcome of such analyses, that is, the incremental cost-effectiveness ratio (ICER), a benchmark is required, which indicates the maximum amount of money a decision-maker is willing to pay for generating an additional unit of health gain. This is commonly known as the cost-effectiveness threshold (CET).[9 10] Generally, if the ICER (with effectiveness often measured in QALYs gained or disability-adjusted life years averted) is less than the CET, it implies that funding the intervention will maximise population health for a given cost and vice-versa.

However, there lies an uncertainty around the estimate of CET that should be used to judge the interventions that are under evaluation. Earlier, the WHO's Commission on Macroeconomics and Health suggested the use of 1–3 times GDP per capita as the threshold.[10] Nevertheless, the revised guidance by WHO on the interpretation of threshold criteria reveals that such criteria are not decision rules but just a guide to policy-makers to assess value for money.[11] In addition, WHO recommends that an intervention should also be assessed in terms of affordability, budget impact, fairness, feasibility and any other criteria considered important in the local context.[11] Therefore, to make decisions regarding the cost-effectiveness of interventions in the Indian context, there is a need to generate a CET value against which the outcomes of HTA studies can be compared. In the absence of such a benchmark, it is not possible to make decisions regarding the potential cost-effectiveness of interventions.

There are different schools of thought on what the threshold is likely to represent. One is that the threshold should reflect the society's monetary valuation of health gains and the other is to assess the opportunity cost resulting from the disinvestment required to adopt new technology. The former represents a demand-side CET, which corresponds to the consumption value of health. Contrary to this, the latter refers to the supply-side valuation of CET which is based on estimating the opportunity cost of current health spending wherein each decision made in the health system can be evaluated in terms of the introduction of new interventions. Apart from these two, one can also use league tables which rely on attaining the largest health impact for the given budget, where one can compare the ICERs across the available interventions.[9 10]

Given the organisation of health systems in India, interventions with different modes of financing may have different approaches to be considered appropriate for the valuation of CET.[12–14] This is because, where some interventions require additional resources to be generated, other interventions might be funded via reallocation or displacement of resources from existing programme budgets. Further, in quite a few new interventions, even a mix of reallocation and additional generation of resources could be employed for financing. In addition, a heterogeneous mix of payers exists in the Indian healthcare system. Therefore, another important consideration lies around who finances a given intervention. Consequently, the maximum value that the decision-makers attach to the health benefits might differ in each case. More importantly, India is still striving to achieve Universal Health Coverage (UHC) for which advocacy around increased resource allocations to health are likely to be imperative. In such a scenario, where the budget for health is in its expanding phase, valuation of societal preferences or the demand-side approach was considered the preferred approach for estimation of CET whereby the budget-setting process can also be informed by the preferences of the public.

In India, public spending for health still lags when compared with population needs and a large proportion of the population continues to pay out of pocket (OOP) to access quality healthcare.[15 16] Therefore, sustainable and efficient resource allocation is imperative. The use of HTA for decision-making and for that, estimation of a robust CET will ensure that there is neither under-spending nor over-spending of resources. Among others, the evidence on cost-effectiveness is one of the important criteria on which the recommendation for funding a health technology is based. We do acknowledge that other criteria such as the extent of unmet needs for healthcare which a given health technology aims to address, the latent demand for healthcare services, equity considerations, the potential of reducing (OOP) expenditure and other ethical and social aspects are also important considerations. Therefore, the Government of India has committed to institutionalising HTA as an integral component of evidence-based priority setting in healthcare and as a result, HTA in India (HTAIn) was institutionalised with the main objective, among others, to generate evidence regarding the cost-effectiveness of health technologies.[17–19] Thus, the availability of CET is pivotal to precisely using the evidence generated by economic evaluations.

With this background, the present manuscript delineates the methods that will be used for the development of a willingness-to-pay (WTP)-based CET for India. The proposed research will not only generate evidence in the form of an explicit CET value, which has been empirically

assessed in the Indian context, but would also lead to a greater commitment of the Government of India towards investing in health technologies that are found to be cost-effective and designing health programmes to make them cost-effective.

METHODS AND ANALYSIS

Study setting

The current study is planned to be conducted in six states of India. These states have been selected to ensure a good mix of income, health status and geographic location to ensure the selection of a sample that is representative of the Indian population. The states thus selected are—Haryana, Uttar Pradesh, Gujarat, Odisha, Tamil Nadu and Meghalaya. A similar criterion was used for the development of a EuroQol- 5 Dimension (EQ-5D) value set for India, which is the largest 5-level version EQ-5D (EQ-5D-5L) valuation study conducted so far worldwide.[20 21]

Sample size

We estimated a sample size of 5410 using the following formula[22]:

$$N = \left[\frac{Z_{\alpha/2}\, V}{\Delta}\right]^2 D,$$

where N is the required sample size, $Z_{\alpha/2}$ is the confidence interval (CI) statistic which is estimated as (1–α) % corresponding to 1.96 for 95% confidence level, and V is the coefficient of variation set at 2. With the design effect (D) which is set at 1.5 and the desired maximum fractional error in the mean (Δ) approximated to 7%, the required sample size is 4704. Further, to account for non-response and resulting incomplete interviews (15%), the sample size was increased to 5410. This sample will be achieved collectively by the 6 selected states, which implies 902 interviews to be conducted per state.

Sampling approach

The sampling strategy has been designed in a way so that the sampled population closely represents the composition of the Indian population. To ensure this, a multistage sampling strategy that has already been implemented to develop the EQ-5D value set for the Indian population would be used.[21] The sampling has been done in five stages (figure 1). First, the states will be selected based on a composite criterion, which includes indicators related to the economy as well as the health status of the population. Based on the gross state domestic product and infant mortality rate, all the states were grouped into six categories and one state was chosen from each group to ensure a good representation of their geographic location.[23 24] Second, two districts from each state will be selected using a stratified random sampling approach. The Multidimensional Poverty Index (MPI), comprising of three indicators, education, health and living standards, will be used to stratify the districts.[25] The districts will be categorised into high MPI and low MDPI districts followed by a selection of one district randomly from each stratum using a simple random sampling approach.

Third, primary sampling units (PSUs) will be chosen from each district, corresponding to villages in rural areas and census enumeration blocks (CEBs) in urban areas. Using the '30-cluster sampling approach' which is a standard approach for various public health studies and government surveys, 30 clusters or PSUs will be selected from each district. The number of rural and urban PSUs will be determined based on the population share in the given district using population proportional to size principle.[26] Fourth, households will be selected within the PSU (village/CEB), and for this, we will first fix the sample size for each PSU, followed by a selection of households within the PSU using systematic random sampling. Given our sample size, the sample for each PSU comes around 15. Finally, the eventual step is the selection of respondents from each household. To ensure randomness, we propose to select a respondent (more than 18 years of age) in a household whose birth date is most proximal to the date of the interview. To ensure equal participation of both males and females, block randomisation based on gender will be done. The data collection will be initiated by 15 October 2022 and is planned to be completed by 30 April 2023.

Valuation methods

The study interview will include three sections and the respondents will be interviewed in a face-to-face setting using the computer-assisted personal interviewing (CAPI) technique. First, the respondents will be asked questions about their sociodemographic and socioeconomic profile followed by questions on self-reported health using EQ-5D-5L and the EuroQol Visual Analogue Scale (EQ-VAS). EQ-VAS is one of the direct and simplest techniques wherein respondents rank their health based on their perspective.[27] The respondent will be asked to mark his/her rating for health on a scale of 0–100 which is a 20 cm

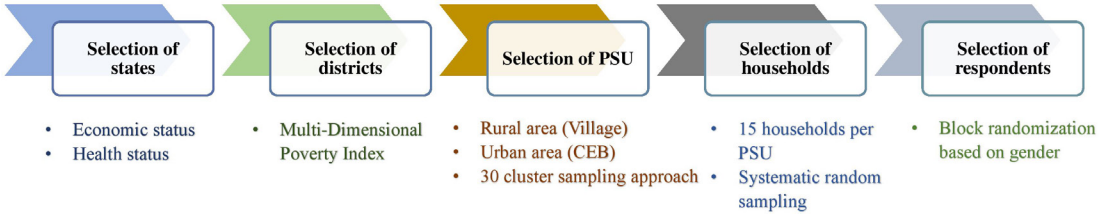

Figure 1 Approach to sampling for estimation of cost-effectiveness threshold. CEB, census enumeration block; PSU, primary sampling units.

vertical line having clearly defined endpoints, where '0' denotes the worst health state and '100' denotes the best health state from the perspective of the respondent.

To generate the estimate for WTP per QALY, we will need information on two components to be elicited from the respondents, that is, the health gain in terms of QALYs and the WTP corresponding to these health gains. Therefore, the second part of the interview will focus on eliciting health gains from the respondents. To assess the health gain, first, the participant will be presented with two alternative lives, life A in the best of health and life B in his/her current health. Second, the respondent will be presented with life A being the current health state and life B in a predefined health condition. Using time-trade off (TTO) method, an assessment of the difference between these two lives will then be done in terms of the number of years a person is willing to trade-off to be in current health. For this purpose, six health conditions have been chosen, which will represent life B. The selection of health conditions was done keeping in view that (1) these conditions can be easily imagined by the respondents, (2) represent health gains from different severity levels and (3) the severity levels can be easily differentiated by the respondents. As a result, six health conditions, each differentiated in two severity levels, were chosen. These include allergy (mild and severe), joint pain (backache and multiple joint pains), blindness (night blindness and bilateral blindness), paralysis (monoplegia and paraplegia), depression (major depressive disorder and psychotic depression) and respiratory/lung disease (chronic obstructive pulmonary disease and advanced stage lung cancer). Vignettes that describe these health states have been created for each of these conditions and will be used by the interviewers to help the respondents understand each health state. Only four health conditions will be randomly presented to the respondents. Further, only one severity level for each of the health conditions will be allocated randomly to each respondent.

For assessment of health gain using TTO valuation, we aim to interview the respondent to indicate the amount of time he/she will be willing to give up at the end of life to avoid the morbidities associated with a hypothetical health condition. Two lives (life A and life B) will be presented to the respondent on the computer screen, where, life A will be described as their current health and life B will be described as being in one of the hypothetical health conditions as explained above. The respondent is then asked to imagine being in these two alternative health states (life A and B) and express his/her preference using TTO. After the respondent has well imagined himself/herself in both lives, he/she is then asked if they prefer to live for 10 years in current health (life A) or 10 years in the hypothetical health state (life B). The respondents will also be explained that after this duration of 10 years, in the assumed scenario, they will experience immediate painless death in both lives and there is no available treatment for life B. If the respondent chooses life A over B, he/she will be presented with the next question, wherein he/she will have to choose between living for 5 years in life A and living for 10 years in life B. Consequent to this, if the respondent prefers living in an inferior health state (i.e., life B) for 10 years over living for 5 years in perfect health (life A), he/she will then be presented with the next situation, wherein 5.5 years of perfect health will be provided in life A, and 10 years of the hypothetical health state will be provided in life B. Conversely, if the respondent prefers living 5 years in perfect health (life A) over living for 10 years in an inferior health state (ie, life B), he/she will then be presented with the next situation, wherein 4.5 years of perfect health will be provided in life A, and 10 years of the hypothetical health state will be provided in life B.

In the TTO task, the time available in life B will be kept constant at 10 years and only the time available in life A will be changed sequentially. The respondents will be asked to select the better alternative between life A and life B until the point of indifference is achieved, wherein the respondent feels that both life A and life B are of equal value. The time that is traded-off in life A will be recorded at this point of indifference and this value represents the amount of time in current health which the respondent is willing to give up to avoid living in the inferior health state (life B). The degree of severity of the hypothetical health state (life B) is directly proportional to the time the respondent would want to give up to avoid it. To assess the value of health from these responses, we will estimate x/t, where 'x' is the time remaining in life A at the point of indifference and 't' is the time offered in life B, that is, 10 years.[28]

The third part of the interview corresponds to the assessment of WTP for the QALYs gained in the second part, which will be investigated using the contingent valuation technique. In contingent valuation, survey methods are used to investigate the hypothetical WTP to attain good health.[29] In our study, we will use card sorting method wherein a series of payment cards will be shown to the respondents at random and the respondent would be asked to sort them into the amounts he/she would definitely pay, the amounts he/she definitely would not pay and the amounts about which he/she was unsure. For the payment cards in the unsure column, the respondent will once again be asked to finally sort them into the 'definitely would pay' and 'would not pay' columns. The maximum card value that the respondent is definitely willing to pay and the minimum he/she is definitely not willing to pay will then be summarised, and the respondent is asked to state his/her maximum WTP in an open-ended response constrained by the summarised range. The different prices displayed on the payment cards will be created using actual treatment costs for the hypothetical health states and responses of pilot test interviews. However, if the respondent will be willing to pay less than the minimum offered price on the card or higher than the maximum offered price on the card, their WTP amount will be determined using open-ended questions. If the respondent says that he/

she would not pay for treatment, his/her reason for not doing so will be asked.

Each respondent will be administered four health states (one severity level of each hypothetical health state) followed by its WTP (card sort) elicitation. The respondent will be asked if he/she is willing to pay for treatment which will result in restoring the current health for the remaining life. If he/she does not pay for the treatment, they will be suffering from the disease condition for their remaining life. The respondents will be asked to think carefully before making their decision and to be sure that they could pay that amount of money. If they opt to pay too little, they might not get the treatment, as it will not be financially worthwhile for the provider. However, if they opt to pay too much, it would impact their family's finances.

The interview tool has been attached as online supplemental file S1.

Data analysis

The responses elicited from the second and third part of the interview, that is, assessment of health gains and assessment of WTP, will be combined to ascertain the value of WTP per QALY. The second part of the interview will provide us with the utility scores of each health state as rated by the respondents. To convert this into health gain, we will subtract this utility score from the respondent's valuation of his current health done prior to administering the health states. Further, we need to assess the health gain in terms of QALYs for the remaining life of that respondent. Therefore, we will extrapolate this health gain by multiplying it with the respondent's remaining years of life. The remaining years of life will be calculated by subtracting the respondents age from the life expectancy. Separate age and gender-specific estimates for life expectancy in India will be used from the recent census data.[30] At the completion the all the study interviews, we will have the health gains (QALYs gained) and their corresponding WTP for 21 640 observations given the sample size of 5410 (as each respondent will be administered 4 health states).

A relevant aspect to be assessed while handling the data is whether to trim data to remove outliers or not. Though, it is recommended to remove outliers when handling such data, it might result in underestimation of WTP, especially in the Indian scenario.[31] Income is an important determinant of WTP and the inequalities in income distribution in India have been very well documented.[32 33] In 2015, the top 1% income group was earning 21% of the national income, top 10% earning approximately 56%, whereas the bottom 50% held a mere 14% share of the same.[32 34] In addition, the All India Debt & Investment Survey conducted by National Sample Survey in 2019 revealed that the wealthiest 10% Indians possess half of the assets whereas the bottom 50% of the population owns less than 10% assets.[35] As a result, if we remove the outliers, the WTP elicited by topmost earning groups in India will get filtered out and may not give a true picture of average WTP of the country.

Finally, these estimates will be combined to generate an average WTP/QALY. This can be done using either of the two approaches, aggregated approach and disaggregated approach. In aggregated approach, the mean WTP and the mean utility value across the sample are computed separately and combined into a ratio (ratio of means), whereas disaggregated approach implies calculating this ratio for each individual and computing the mean across the sample (mean of ratios). If we use this individual calculation method, that is, disaggregated approach, then we will have to exclude those who did not trade for TTO (non-traders) as their responses would imply an infinite WTP. Alternative to this, we can use an aggregated approach (ratio of means) wherein we can include all the non-traders as well.[36] Further, even in context of cost-effectiveness analyses, it has been argued that the ratio of means approach should be preferred keeping in view the internal consistency properties or the problem of zeros.[37] Consequent to this, we will use the aggregate approach to assess the mean WTP per QALY for India. However, in our sensitivity analysis, we will also analyse the data with disaggregated approach to compare and comment on how the estimates differ from each other given the two analytical approaches and its implications for decision-making.

The WTP/QALY value will be calculated with the following formula:

For aggregated approach:

$$\text{WTP per QALY} = \frac{\sum_{i=1}^{21640} \text{WTP}_i}{\sum_{i=1}^{21640} \text{Health gain}_i}$$

Descriptive analyses will be conducted to describe the sample characteristics which will be obtained from the information collected in the background section. Bivariate analysis will be performed using F test and Student's t-test to assess the impact of sociodemographic and socioeconomic characteristics on the respondent's WTP. The variables that will be included are age, sex, education level, marital status, occupation, status of health insurance, consumption expenditure, total number of family members and earning members in the family. This will be followed by multiple linear regression models using ordinary least square method for estimation of parameters and checking for the assumptions of linearity, normality, presence of homoscedasticity and absence of autocorrelation and multicollinearity. The WTP per QALY being the dependent variable, the factors that are significantly associated with WTP per QALY in bivariate analysis will be used as predictors to understand their influence on the response variable.

Quality control

To ensure standardisation of the interviews and data collection process at all the sites, strict quality control (QC) measures will be undertaken. There are two important aspects for QC viz protocol compliance and

interviewers' effect. Different respondents may provide different trade-off values as an interpretation of each health condition and is subjective to one's assessment. Further, the WTP for treatment depends on each respondent's capacity to pay, the severity of the condition in eyes of the respondent, their financial condition and other factors. Thus, the differences in each observation should only be a result of respondent-related characteristics and not due to differences in mode of interview administration. To ensure this, the interviewers at each study site will be rigorously trained by competent trainers using a uniform agenda. Given the linguistic diversity among the Indian states, each state will be assigned its own set of bilingual interviewers and separate training sessions will be held at all the sites. After the hands-on training, all the interviewers will be put through a process of pilot interviews.

To assess the interviewers' effect, the data will be analysed in terms of distribution of TTO and WTP responses concerning different health states for each interviewer, presence of clustering in the TTO and WTP responses, and proportion of non-traders (individuals who refuse to give up any amount of time in the TTO, thus giving all health states the value of 1 among the respondents). The distribution of TTO responses will be interpreted by comparing the data of a specific interviewer with the pooled data from all interviewers. Second, to ensure protocol compliance, three criteria have been set which are to be achieved in every interview. The interviews are flagged as non-compliant if the time taken for assessment of utility of current health last for less than 120 seconds, if the total time taken for all four TTO tasks is less than 240 seconds, and if the total time taken for card sorting tasks is less than 180 seconds.

Three rounds of ten pilot interview each will be conducted for every interviewer. The pilot interviews will be conducted until each interviewer approaches the point where protocol compliance has been achieved and the interviewers' effects have disappeared. If there is any interview where protocol compliance is not attained or interviewers' effect is reflected, the interviewer will be assisted by the team of investigators via phone and video calls during the conduct of next round of pilot interviews and observations will be made to assess if tasks are properly explained to the respondent and if there is any task shortcutting. The interviewers will be assisted personally to overcome any difficulties. However, if there is no sign of improvement, such interviewers will be removed from the team. Once all the interviewers have achieved a consistent performance and adhere well to protocol compliance, then they will be allowed to proceed beyond the pilot and start data collection. To ensure that quality data is collected, the QC reports will be generated at regular intervals to monitor the performance of each interviewer and inform them on any deviation from the set standards. Further, personalised feedback process will be followed at all times throughout the data collection period to address any problems faced in the process.

We have filled out the relevant sections of the Standards for Reporting Qualitative Research checklist attached as online supplemental file S2.

Patient and public involvement

No patient or public involvement was there in the designing of this research protocol. Public involvement during the conduct and dissemination of the study will strictly be as per the established standards of ethics in research.

DISCUSSION

The present study aims to develop a CET for HTAIn. The evidence generated from HTA needs to be interpreted in view of this benchmark, which informs on the maximum value that should be spent to generate one unit of health, that is, one QALY. The threshold, that is, value of WTP per QALY generated as a part of this study will be used by HTAIn and researchers in India who conduct economic evaluations to aid the process of policy-making in health.

The estimation of CET from the demand-side approach is based on the assessment of the society's WTP for healthcare, which would guide the allocation of resources to health. Methods pertaining to the estimation of marginal WTP vary across the literature, that is, using revealed/stated preference methods, contingent valuation methods by using value of health employed in other areas of resource allocation or both together.[38] Further, some studies allow for eliciting social preferences via an aggregated method or disaggregated method of combining the WTP values and QALY gains for all individuals. An international survey on general health conducted by Shiroiwa *et al* reported average WTP for an additional QALY at a disaggregated level, which varied significantly from country to country, from £23 000 in the UK to US$ 62 000 in the USA and NT$ 2.1 million in Taiwan.[39] Bobinac *et al* revealed a threshold ranging from €80 800 to €113 000 in the Netherlands by aggregation of individual preferences.[40] In Thai settings, a ceiling of 160 000 Baht per QALY was reported, which is 1.2 times gross national income per capita.[41] Similar to Thailand, a cross-sectional contingent valuation study was conducted in four states of Malaysia to estimate the CET ranging from US$4000 to US$8900.[42] Both these studies acknowledge that a single threshold may not be applicable to guide resource allocation for all types of interventions.[41 42] When comparing the estimates of WTP from different country setting to the GDP per capita, a recent systematic review for 20 publications from 17 countries reveals that most of the mean WTP/QALY values were in the range of 0.5–1.5 times GDP per capita.[43] Given the variation in conduct and reporting of WTP studies implies that the estimates are largely dependent on methodological and contextual factors, as well as the characteristics of the population in a country setting.[33] Therefore, it becomes all the more important that a threshold is well contextualised in the country context where it is to guide decision-making.

HTA plays a pivotal role when it comes to decision-making in health. For any country aiming to provide an all-inclusive coverage for health to its people without causing any financial hardship, it is essential to efficiently use the existing resources in addition to increasing allocation to health. HTA, as a tool to guide resource allocation decision, caters to this dual purpose of sustainable utilisation of resources as well as advocacy for increasing allocation to health. The evidence generated from HTA is helpful in deciding where to expend the existing resources so as to get best value from the resources spent. More importantly, as India thrives to achieve UHC implying more allocation to health, HTA is a useful resource to guide where and how much to spend in order to maximise health for every rupee spent. Consequent to this, HTAIn has been committed to build capacity for the conduct of HTA and deliver high-quality HTA evidence to support decision-making at the central as well as state level.[44] A working example of these efforts is the use of HTA evidence to devise the benefits package for Ayushman Bharat-Pradhan Mantri Jan Arogya Yojana (AB-PMJAY).[45] AB-PMJAY is the largest ever publicly sponsored health insurance scheme in India that aims to cover around 1949 secondary and tertiary care procedures for approximately half a billion beneficiaries.[46]

The threshold generated by this study will be based on 21 640 observations of WTP per QALY, which will be the largest study to be conducted so far. Our interview tool has been built with 12 health states that will be randomly administered to the respondents. These conditions have been chosen such that a spectrum of mild, moderate and severe conditions is presented to respondents so as to estimate how WTP changes with severity of conditions. More importantly, there is a huge variation in the choice of time horizon considered for estimating the WTP based threshold in the published literature.[39 41 47–49] If a time horizon too low for experiencing the health condition is chosen, which is followed by reversal to current health, it might result in underestimation of the true WTP. Conversely, a time horizon too long might result in overestimation of the same. Both of the situations will result in a WTP per QALY not being marginal enough so as to guide policy decisions. This implies that the choice of time horizon is an important predictor of WTP estimation. To dispense with this issue, in our study we will extrapolate the health gains for the remaining life of an individual based on the age and life expectancy followed by eliciting the corresponding WTP so as to get realistic estimates on the value of one additional QALY.

Another notable methodological aspect is whether to use the generic EQ-5D health states or specific health conditions for TTO exercise to assess the utility of the health condition followed by estimation of health gain. Different studies report using either EQ-5D health states or different disease descriptions depending on what is best suited contextually.[41 47 50–52] In context to the Indian population where approximately 70% of the population resides in the rural areas, it becomes perplexing for the population to visualise the EQ-5D health states and then elicit their WTP for treatment. Conversely, if a health condition is described to them, it becomes comparatively easy to imagine living in the condition and further to visualise how treatment will help them restore their current health. Therefore, we chose to use different health conditions ranging from mild to severe, which can be described to the sampled population to elicit their WTP.

Finally, there are some limitations to our study. Given the huge cultural and geographical variation in India, there exists a risk of the interviews being susceptible to interviewer's effect. Second, respondent fatigue may set in due to the exhaustive interview process leading to hastening of the interview which makes it further prone to interviewer's effect and thus the latter responses may be less valid. To minimise the interviewer's effect, the same set of master trainers will train the field investigators in all the regions. Further, strict quality check measures will be employed at all times during the data collection period to ensure data quality. One-to-one telephonic communication with each field investigator will further help to overcome any challenges experienced in the field.

This threshold is exigent to interpret the findings of an economic evaluation, in absence of which, it is not possible to make decisions regarding the potential cost-effectiveness of interventions. This threshold will be contextualised in view of the characteristics of Indian population and will serve as a useful guide to the resource allocation decisions taken for health. This will not only ensure sustainable use of limited resources, but will also act as a tool to increase public spending in health.

ETHICS AND DISSEMINATION

The interviews to be conducted as a part of this study will be administered by well-trained interviewers who will ensure that all participants have a pleasant experience and extreme care is taken regarding their ethnicity, religion, language, sexual orientation, literacy level and socioeconomic status. All the participants will be presented with informed consent forms (ICF) and participant information sheets (PIS) in the local language. A written signed informed consent will be sought and the participant has full authority to withdraw at any time during the interview. The PIS will contain all the information related to the study and enough time will be allocated so that the participants can read and seek any clarifications related to the study. The privacy and confidentiality of the study participants will be maintained at all times.

The necessary ethical approval for the conduct of the present study has been obtained from the Institutional Ethics Committee of Postgraduate Institute of Medical Education and Research, Chandigarh, India vide letter number PGI/IEC/2021/001452. The findings of this project will be disseminated in the form of scientific publications and presentations at related conferences/meetings. Publication/authorship guidelines will be according to the international guidelines for authorship

about their specific contribution as per the International Committee of Medical Journal Editors guidelines.

The outcome of this project will provide a benchmark that will be used to make resource allocation decisions for various health interventions. This threshold will be made available for general use via a website hosted by the Department of Community Medicine and School of Public Health, Postgraduate Institute of Medical Education and Research; and HTAIn, Department of Health Research, Ministry of Health and Family Welfare, Government of India.

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Funding The study is funded by the department of health research, Ministry of Health and Family Welfare, Government of India vide grant number F.NO.T.11011/02/2017-HR (Part-1)/3176774.

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 Not commissioned; externally peer reviewed.

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