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On the Estimation of the Cost-Effectiveness Threshold: Why, What, How?

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ABSTRACT

Background: Many health care systems claim to incorporate the cost-effectiveness criterion in their investment decisions. Information on the system's willingness to pay per effectiveness unit, normally measured as quality-adjusted life-years (QALYs), however, is not available in most countries. This is partly because of the controversy that remains around the use of a cost-effectiveness threshold, about what the threshold ought to represent, and about the appropriate methodology to arrive at a threshold value. **Objectives:** The aim of this article was to identify and critically appraise the conceptual perspectives and methodologies used to date to estimate the cost-effectiveness threshold. **Methods:** We provided an in-depth discussion of different conceptual views and undertook a systematic review of empirical analyses. Identified studies were categorized into the two main conceptual perspectives that argue that the threshold should reflect 1) the value that society places on a QALY and 2) the opportunity cost of investment to the system given budget constraints. **Results:** These studies showed different underpinning assumptions, strengths, and limitations, which are highlighted and discussed. Furthermore, this review allowed us to compare the cost-effectiveness threshold estimates derived from different types of studies. We found that thresholds based on society's valuation of a QALY are generally larger than thresholds resulting from estimating the opportunity cost to the health care system. **Conclusions:** This implies that some interventions with positive social net benefits, as informed by individuals' preferences, might not be an appropriate use of resources under fixed budget constraints.

Keywords: cost-effectiveness analysis, quality-adjusted life-year, threshold.

Introduction

Among the various countries that claim to incorporate the cost-effectiveness criterion in their investment decisions, only the National Institute for Health and Care Excellence in England and Wales explicitly reports the threshold value used as the system's maximum willingness to pay (WTP) for a quality-adjusted life-year (QALY). The National Institute for Health and Care Excellence uses a range of £20,000 to £30,000 per QALY [1] (~€22,000–€33,000 in 2014 euros). In other countries, specific figures or ranges have been recommended but these have not been formally adopted, such as the range of $20,000 to $100,000 (~€15,000–€75,000) in the United States [2] and Canada [3], or the widely and controversially cited threshold of $50,000 (~€36,000) also in the United States [4,5]. In Sweden and the Netherlands, relevant government authorities and important advisory bodies have recommended thresholds of 500,000 SEK (~€57,000) [6,7] and €80,000 [8], respectively. Furthermore, the World Health Organization recommends that a disability-adjusted life-year be valued at a maximum of 3 times the country's gross domestic product per capita [9].

The lack of theoretical and empirical basis regarding the above figures has contributed to an ongoing debate about the appropriate way of estimating the cost-effectiveness threshold and to an increasing body of empirical research in this area in many countries. However, this growing literature has not necessarily facilitated the adoption of specific thresholds values, partly because of the lack of consensus about relevant issues. There remains much controversy around the use of a threshold, about what the threshold ought to represent,

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and about the appropriate methodology to arrive at a threshold value.

This study aimed to review the different approaches used to date to estimate the cost-effectiveness threshold. We provide an in-depth discussion of the proposed conceptual views, and we systematically review and critically appraise the empirical literature. Furthermore, this comprehensive review allow us to summarize and compare the estimates of the cost-effectiveness threshold available in the literature. The goal of this article was thus to facilitate researchers and decision makers with a comprehensive understanding of the existing evidence and the challenges of estimating a threshold value, and to offer some recommendations about the appropriateness of different alternatives in different contexts.

The Cost-Effectiveness Threshold—Why?

Some authors have argued against the use of a threshold, and more broadly against the use of the cost per QALY approach. These authors consider that this approach is consistent only with the maximization of health gains from available resources under some assumptions, including perfect divisibility of health care programs, and that these conditions do not hold in the settings faced by health care decision makers [10,11]. The use of a threshold has also been related to uncontrolled increases in health care spending [12], and to transferring the full value of new technologies to manufacturers, by encouraging companies to set the price where the cost per QALY equals the cost-effectiveness threshold [13].

However, a number of authors have considered the use of the threshold approach a useful approximation to improve efficiency, and have suggested means to address the above arguments, such as complementing cost-effectiveness analysis with budget impact analyses [14] and regularly adjusting the threshold to account for changes in efficiency and the budget over time [13]. Furthermore, the advantages of setting a threshold have been considered beyond improvements in efficiency, such as allowing for better consistency and transparency of the decision-making process, and enhancing equity and public trust by reducing the room for decision makers' arbitrariness [14].

The Cost-Effectiveness Threshold—What?

Even among those who welcome the use of a threshold there are different views as to what the threshold ought to represent. The two main conceptual perspectives include the view that the threshold should reflect 1) society's monetary valuation of health gains, or 2) the opportunity cost resulting from the disinvestment required to adopt a new technology.

The former perspective is traced to attempts to link cost-effectiveness analysis with cost-benefit analysis and welfare economics [15]. The authors who advocate for this perspective argue this to be in line with the general approach taken in other public sectors in many countries where cost-benefit analyses are used to make investment decisions [16]. The opportunity cost perspective, however, is based on the idea that to adopt a new technology that imposes additional costs on the health care system, displacement of existing services might be required. Disinvesting on existing interventions will most likely result in health losses for individuals elsewhere. The threshold should thus represent the cost per QALY of displaced services, which would allow the assessment of whether the health expected to be gained from the use of a new technology exceeds the health expected to be forgone elsewhere as other services are displaced [17].

The main argument of advocates of the opportunity cost approach is that information on society's valuation of improvements in health is irrelevant for threshold-setting purposes, because it cannot inform on how to allocate a fixed budget within a health care system. The reason is that individuals' monetary valuations for health gains are detached from the budget-setting process [18]. However, those who defend the society-value approach argue that the budget-setting process should, in fact, be informed about preferences of members of the public [16]. In a way of attempting to resolve this "dilemma," Baker et al. [16] suggested a framework that considers both approaches as complementary; in particular, as the demand and supply sides of the "market" for QALYs. Society's valuation provides an estimate of the marginal benefits to consumers of health care services (demand side), whereas the opportunity costs approach relates to the marginal costs of health care spending (supply side). The authors of this article conclude that a framework incorporating these two approaches is to be preferred.

The Cost-Effectiveness Threshold—How?

A systematic review of the literature was undertaken with the aim of identifying empirical research that has focused on estimating a cost-effectiveness threshold. We identified 38 studies that were categorized into demand-side (29 articles) and supply-side (9 articles) studies. A description of search methods and a complete list of references are provided in Supplemental Materials found at http://dx.doi.org/10.1016/j.jval.2016.02.020.

Demand-Side Empirical Research

The underpinning idea of studies focusing on society's value of health gains is that sector-allocative decisions should reflect the strengths of preferences of those members of society affected by their decisions. The study of the maximum WTP has become the norm for the monetary valuation of publicly funded goods in several countries, and especially so in the United Kingdom [19]. Based on our review, there are two ways in which the WTP value for a QALY has been estimated: 1) directly eliciting individuals' WTP using surveys (26 studies) and 2) inferring from information about the value of a statistical life (VSL) the corresponding value of a QALY (4 studies). One of the identified studies used both approaches [20].

WTP surveys

WTP for a QALY survey focuses on eliciting the maximum amount individuals are willing to pay for a, normally, small health gain and then aggregate the WTP needed to gain a QALY. The process normally required three steps: 1) to estimate in terms of utility values a health gain using methods such as time trade-off or standard gamble, 2) to elicit the WTP for that health gain, and 3) to combine the answers of these two estimates to arrive at a WTP for a QALY. The latter step can be applied using an aggregated approach, in which the mean WTP and the mean utility value across the sample are computed separately and combined into a ratio (ratio of means), or a disaggregated approach, which implies calculating this ratio for each individual and computing the mean across the sample (mean of ratios).

Table 1 summarizes the characteristics and results of identified WTP articles, showing separately the values when those were reported using different techniques or when the study provided estimates for different countries. There is a wide variation in results, ranging from just over €1000 to more than 5 million per life-year (LY)/QALY (values reported in €2014). The