The basis for a new framework to determine cost-effectiveness thresholds

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Background

Novel health technologies are routinely both cost-increasing and health improving. Researchers and policymakers have used Cost-Effectiveness Thresholds (CET) to determine whether a technology's health benefits are worth the additional cost.

There are many ways in which to conceive a threshold. Research in recent years has sought to identify a CET by observing the relationship between health care expenditure and health outcomes based on the premise that the productivity of the prevailing care represents the opportunity cost of expenditure on new technologies (Claxton et al. 2015; Lomas et al., 2021). This approach seeks to identify the shadow price of the budget in terms of QALYs. Numerous researchers have asserted that the inverse of this shadow price may be adopted as a CET (Thokala et al., 2018).

Research on CETs is beginning to shift towards new theoretical frameworks that consider the consumer and producer surplus that arises from investment in new health technologies. A CET may then be identified according to a rule relating to the economic surplus, such as maximising the total surplus or ensuring a particular distribution between consumers (e.g. healthcare providers) and producers (e.g. the life-sciences industry) (Woods et al., 2022; Berdud et al., 2020)

This area of research is in its infancy. A common feature of the very few works published is that there are several factors characterising the life-cycle of a new health technology that affect surplus creation and distribution (Berdud et al., 2020). These, must be considered when identifying the optimal value of a CET within frameworks considering consumer and producer surplus and value generated by new health technologies.

Aim

The immediate objectives of the project are to:

1. Identify the factors that a new framework could include,

2. Consider the likely impact on the CET of accounting for these factors, and

3. Understand the feasibility of quantifying and incorporating these factors in CET estimation.

In this report, we describe our approach to tackling these objectives and discuss the implications for the future development of a new framework.

Methods

We conducted a literature review to identify different factors that have been discussed by researchers in the context of determining an appropriate CET.

The primary objective of the literature review was to generate a long list of all relevant factors that could affect the optimal level of the CET. We used two electronic bibliographic databases – PubMed and Google Scholar – and performed a snowballing search strategy.

Selected studies were assessed using a set of criteria and a scoring scheme. Factors were then classified, presented, discussed and reviewed by an expert panel. The expert panel review produced a short-list of eight factors.

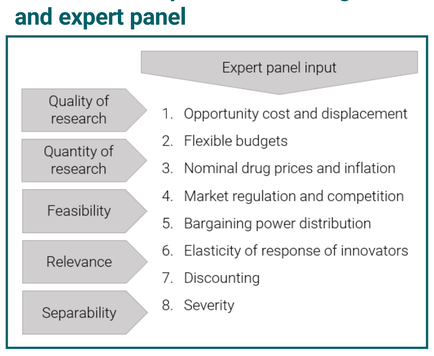
The eight factors short-listed were assessed by their potential to be measured and incorporated into a framework to determine the CET. We developed (basic) theoretical frameworks and case studies to analyse the impact of *budget flexibility*, including manufacturer paybacks as a form of them, and *nominal drug prices and inflation* on the CET.

Results

Literature review

57 factors were identified and rationalised to 40 due to inter-factor overlap. The identified 40 factors were assessed with, (i) a scoring rule based on a set of five criteria, and (ii) expert panel, producing a short-list of eight factors.

FIGURE 1: Output of the scoring rule and expert panel



Two factors were finally selected from the short-list based on their potential for being measured and feasibly incorporated to a new framework to determine CETs in the short-term. These two factors were: ***flexible budgets*** and ***nominal drug prices and inflation***.

Theoretical frameworks

Budget flexibility: impact assessment

Assisted by (basic) theoretical frameworks we illustrate how CETs should change with budget changes in different scenarios using three scenarios:

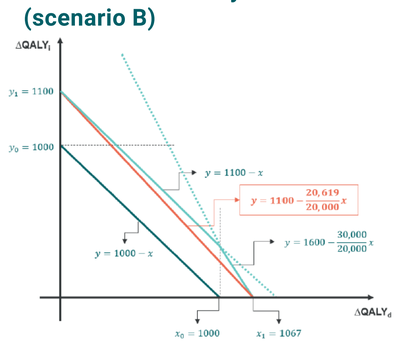
A. Unlimited supply of innovation at Incremental cost-effectiveness ratio (ICER) equal to the opportunity cost (OC) and unlimited possibilities to displace health at the OC

B. Unlimited supply of innovation at ICER equal to OC but limited opportunities to displace QALYs at the OC due to decreasing marginal productivity of the health

C. Budget expansion with limited supply of innovation at ICER equal to OC due to a positively sloped supply at ICER values and with limited opportunities to displace QALYs at the OC

RESULT #1: Although the impact of the budget change on the CET is uncertain in magnitude, we unambiguously show that the OC changes with budget changes. This is driven by the decreasing marginal productivity of health care. Therefore, the CET should be revised to reflect the new OC in the context of a changed budget. In Scenario C, we demonstrate that there may be circumstances in which this adjustment would contribute to the maximisation of population health.

FIGURE 2: Example of additional budget used to expand health services at higher cost per QALY or at same ICER to buy innovation (scenario B)



Manufacturer paybacks. From the budget holder's perspective, the effect of manufacturer paybacks is equivalent to an additional budget equal to the paybacks. Therefore, the result #1 can be conceived in this light.

Inflation: impact assessment

In systems using an explicit CET for adoption decision making, it acts as a price-setting mechanism. As such, it should be adjusted by the level of inflation. Even more, systems where CET reflects the OC require of adjustments by the level of the health production input cost inflation

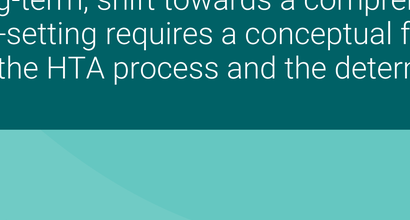
RESULT #2: CET level increase with inflation either by the increase of health production input cost increase when based on OC or by the wide economy inflation level when based on consumption value of health. If CET is not adjusted by inflation, the timing of assessments influence the ICER of technologies resulting in a disadvantage for newer technologies.

Inflation also relates to budget nominal and real changes, and therefore it affects the CET through the budget flexibility mechanism.

RESULT #3: if the budget and inflation increase at rates resulting in a net real expansion of the budget, the CET unambiguously must be increased reflecting both, nominal increase of prices and real budget expansion.

Case studies: a simulation

FIGURE 3: CET impact of four budget change scenarios with 5 years of accumulated inflation



We develop four (numerical) scenarios of real budget expansion including contributions of manufacturer paybacks.

A £20,000 per QALY was considered as a baseline level of the CET.

Inflation effect was incorporated through nominal input cost increase of the NHS for a 5 year period.

In our base case, budget effect ranged from £566 to £724 increase of the CET. Including inflation, the combined impact of both factors ranged from £3,131 to £3,294 accumulated increase for the 5 year period.

Discussion

There are many factors that influence the optimal CET. If all of these factors were considered simultaneously, the overall impact on the threshold would be difficult to accurately quantify, although most of them contradict the idea that the CET should be set below the OC.

To properly represent the determination of CET for decision making policymakers should consider all relevant factors identified.

Some of the identified factors cannot feasibly be incorporated into a framework that could be employed in policy-making in the short term e.g., product specific, issues with data availability

We have specifically explored budget changes and inflation as the two most feasible to be incorporated in the short-term.

For the case of budget mechanisms, those implying a budget increase unambiguously imply a CET increase.

The size of the impact will depend on a variety of assumptions, in particular regarding the availability of new technologies at the prevailing opportunity cost and the elasticity of marginal productivity to changes in the budget (the decreasing marginal productivity of the system).

Conclusion

Efforts to identify an optimal CET should, in the short term, focus on accounting for the effect of budget mechanisms, including expanding budgets, price inflation and indirectly payback mechanisms

Depart from the view that HTA decision-making and the CET used as approval norm need to be based on a fixed budget.

This research shows that there is a case for incorporating budget expansion and inflation as factors that influence CET.

In the long-term, shift towards a comprehensive approach to threshold-setting requires a conceptual framework that identifies the inputs to the HTA process and the determinants of those inputs.

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