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A Critical Analysis of the History and Impact of Cost Effectiveness Thresholds (CETs)

Emerging Lessons and Insights for Decision-Makers

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Only the spoken word shall attach.



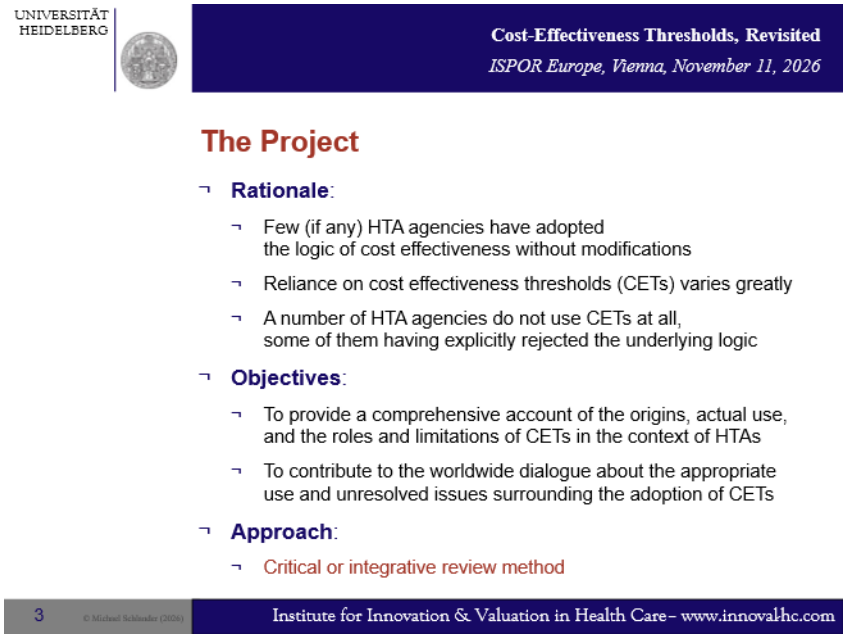
Let me begin with a trigger warning. What follows might be perceived as provocative by some fellow health economists.





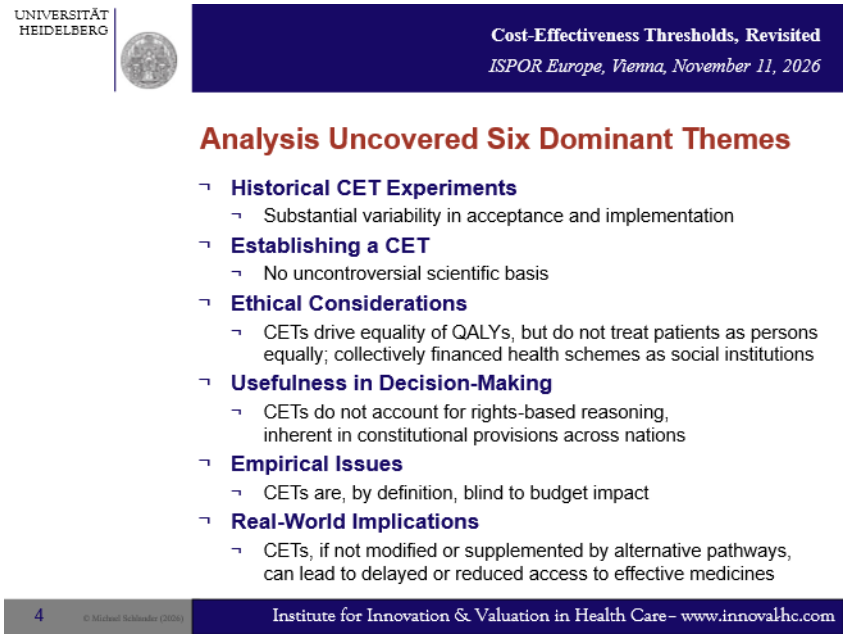
Health Technology Assessments (HTAs) typically rest primarily on one or two pillars. An assessment of comparative clinical effectiveness may be followed by a comparative economic evaluation, which usually takes the form of a cost effectiveness analysis with life years gained or quality-adjusted life years – QALYs – gained as a putatively universal and comprehensive measure of benefit. To be useful across a broad range of therapeutic areas, there is a need for a benchmark or "*cut-off*" level – the «cost effectiveness threshold» (or «CET»). It separates cost effective and not cost effective health care programs.

However, both the use as well as the value of these CETs is controversial and varies across jurisdictions. Few (if any) HTA agencies have adopted the undelying logic of cost effectiveness without modifications – and a number of HTA agencies have explicitly rejected the use of CETs – or even the use of cost effectiveness altogether.

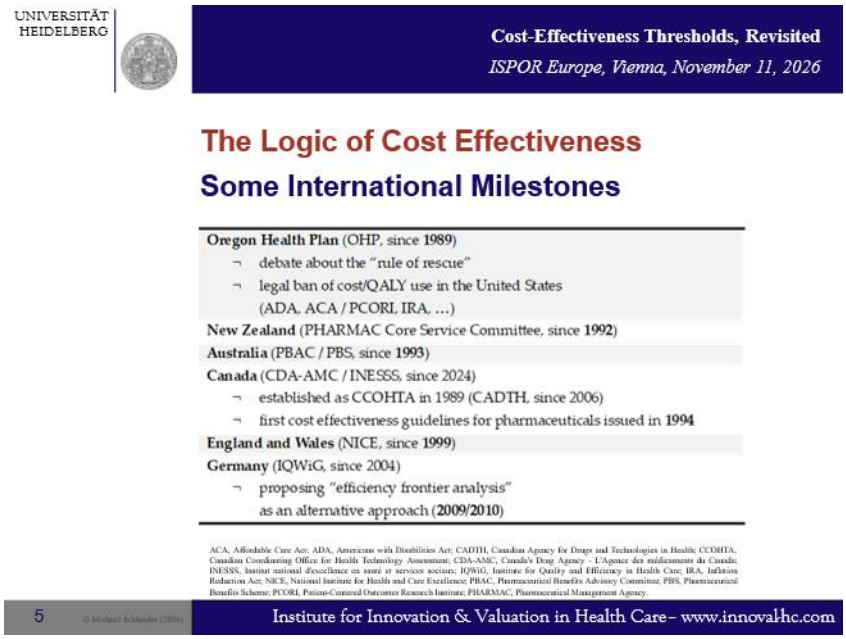


Against this background, we initiated a project with the objective to provide a comprehensive account of the origins, the actual use, and the roles and limitations of CETs in the context of HTAs. Today I will present key insights emerging from the first phase of this project. It is important to emphasize that there will be two subsequent project phases, the first one completing the current review, and the second one following to assess the potential of modifications and alternatives to the application of CETs for priority setting, pricing and reimbursement decisions.

The method chosen has been an integrative review, relying on four complementary search strategies. It has resulted in a first manuscript currently undergoing peer-review and a Working Paper with 500 selected references – clearly exceeding the scope of a 10-12-minute-presentation. I will therefore focus on a top-line summary of our emerging findings. These include – but are not limited to – six dominant themes:



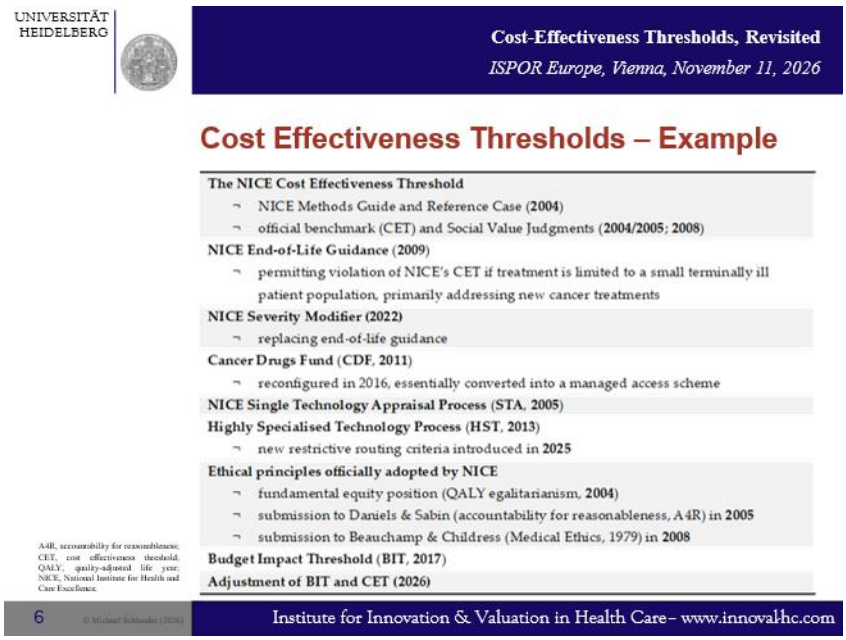
Historic CET experiments, beginning with the informal use of CETs in the Oregon Health Plan (OHP) experiment, show that the use of CETs has been perceived to be of limited utility – at least unless modified. Next, there is no uncontroversial scientific basis to determine the level of CETs. Ethical concerns have been raised that CETs – while driving equality of QALYs – fail to treat patients as persons with equal rights. This way they violate well-documented social preferences and disregard the nature of collectively financed health schemes as social institutions, and they conflict with rights-based reasoning and derived priorities inherent in constitutional provisions across nations. Finally, CETs are by their very definition blind to budget impact, and their use can contribute to delayed and reduced access to effective medicines.



If we take a look at the spread of the underlying logic of cost effectiveness, we can identify a number of international milestones.

The fate of the OHP in the early 1990s foreshadowed some of the issues that are still being debated today. Again and again, official federal agencies (for example, the CMS and PCORI) in the United States have been legally barred from using CETs.

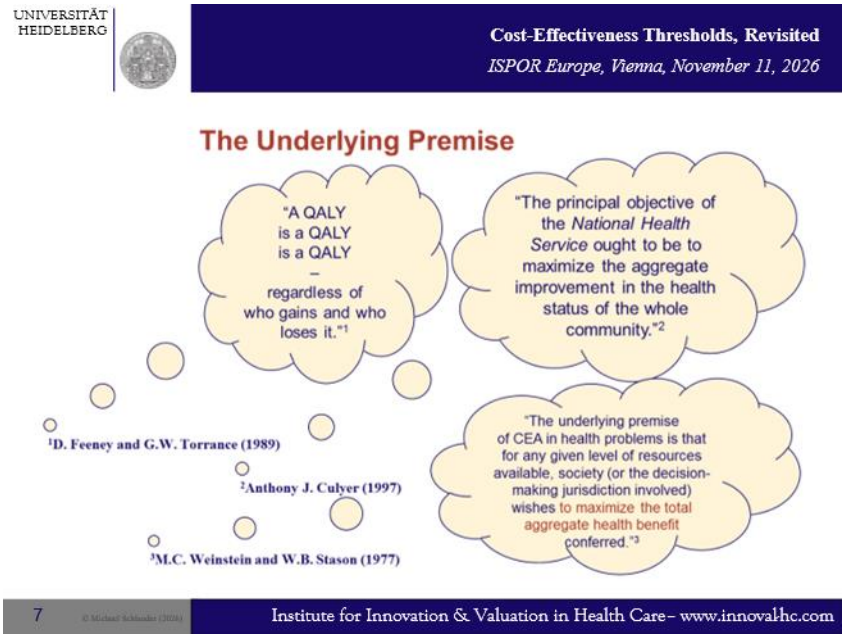
Still, New Zealand, Australia and Canada were forerunners implementing cost effectiveness analysis, despite some variation between the specific approaches chosen by these three jurisdictions. It is impossible to do justice to all European agencies and their respective approaches, just think about ZIN in The Netherlands and TVL in Sweden. You may also wish to consider the reasoning of the official German HTA bodies, the IQWiG and the GBA, who have drawn fire from health economists for rejecting the use CETs and proposing an alternative approach to decision support, so called «efficiency frontier analysis.»



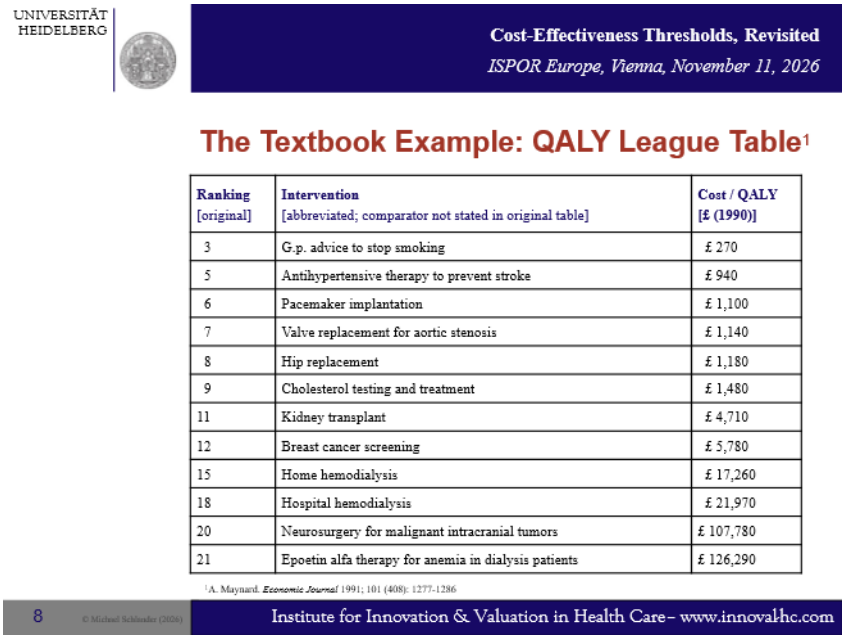
Let's instead take a closer look at NICE. Since its establishment in 1999, the English HTA agency has been broadly considered as an international role model for the implementation and use of cost effectiveness analysis. For instance, it was praised by the late Alan Williams as «*the closest anyone has yet come to fulfilling the economist's dream of how priority-setting in health care should be conducted.*» Remarkably, at the very same time he insisted that «*[affordability] considerations are the only justification there is for having a benchmark!*»

However, even NICE deviated over time in many ways from the pure logic, creating exceptions such as end-of-life guidance in 2009, which was replaced by a severity modifier as of 2022. When NICE assumed responsibility for the evaluation of orphan medicinal products, it realized the need to create another exception – if only for a very small number of «ultra-orphan» products ful-filling the highly restrictive «routing criteria» of its so-called Highly Specialised Technology (HST) process – allow-ing up to 300,000 GBP / QALY gained instead of its standard benchmark of 20,000 to 30,000 GBP /QALY or, more recently since April 2026, up to 35,000 – a decision that was made as part of a trade deal between the UK and the United States – high-lighting the political technocratic nature of NICE's CET. One of the most striking deviations from the logic, however, has been the introduction of a budget impact test by NICE – and perhaps unsurprisingly, the agency has been criticized for the obvious logical inconsistencies created by the combination of CETs and a budget impact test.

If we step back and take a look at the fundamental premise underlying CETs, then it is clear that we find this in the strong normative claims that all QALYs are of equal value and that a collectively financed health scheme ought to maximize their number – regardless of who gains or who loses them.

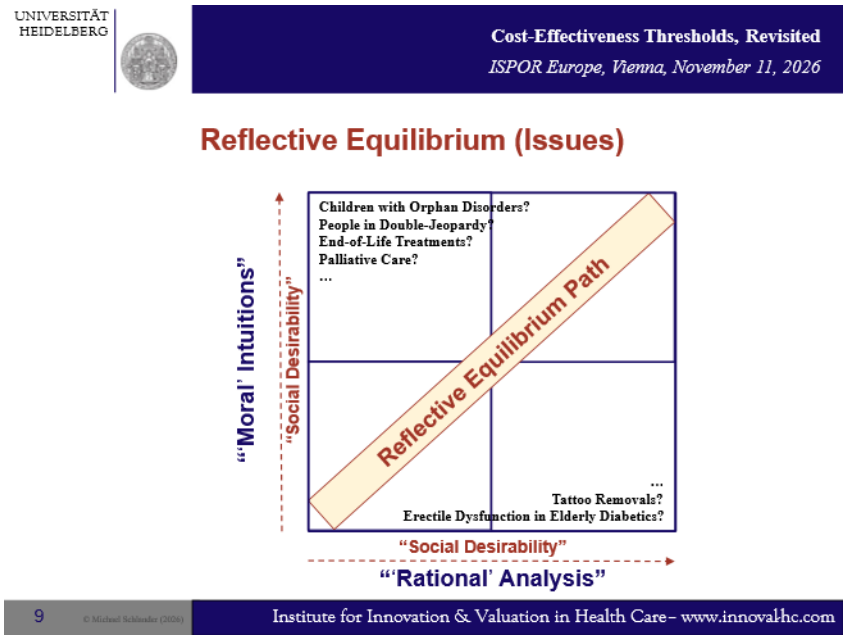


In other words, it is assumed that the social desirability of a health care program is inversely proportional to the incremental cost per QALY associated with its use.

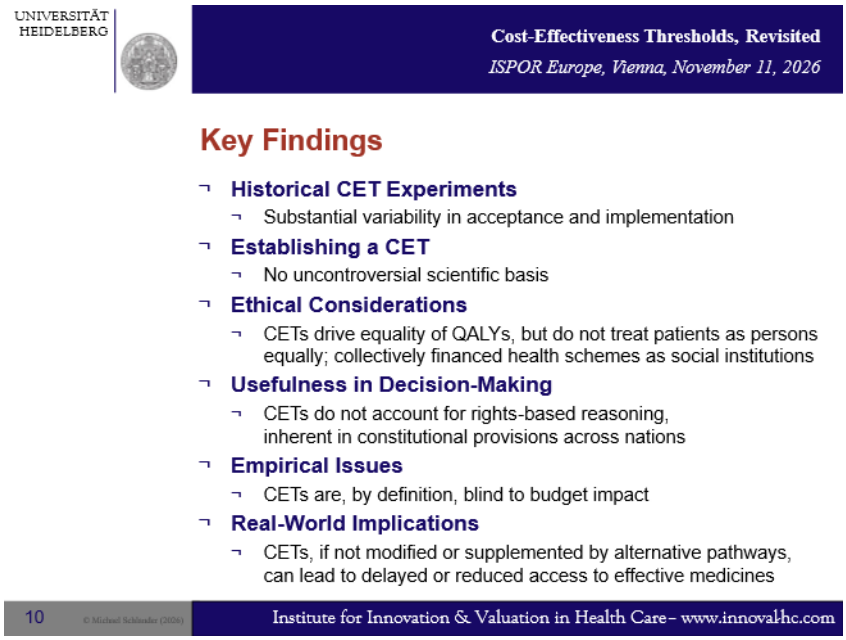


If you accept the logic, then so-called QALY league tables – here is a classical textbook example – will express the ranking of interventions by their desirability, and the role of CETs will merely be to determine where the line between funded and not cost effective has to be drawn.

However, many people get serious headaches looking at some of the implications of such rankings:



There is no doubt that, applying the logic, we would have to give priority to funding drugs for erectile dysfunction or interventions to remove tattoos, whereas we would deprive many patients with orphan diseases from any chance of access to effective medical treatments. In technical language, this phenomenon is indicative a serious «wide reflective equilibrium» issue – applying the logic of cost effectiveness and CETs obviously violates widely shared moral intuitions.



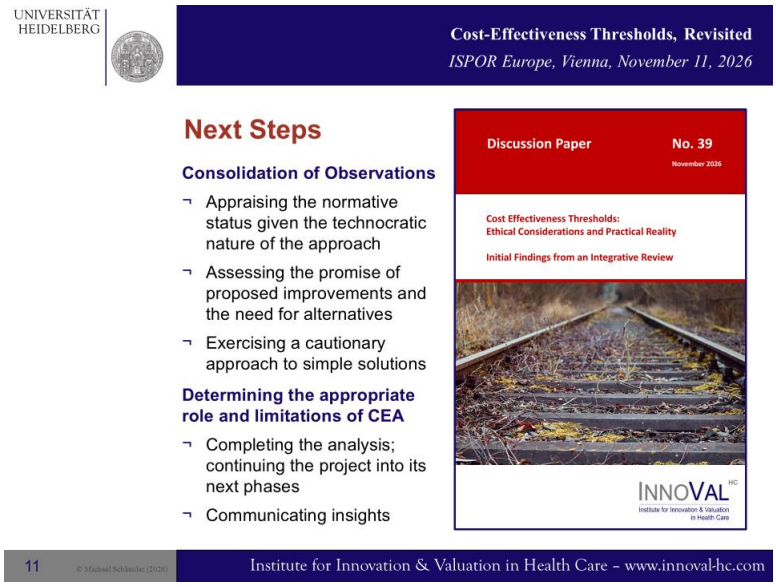
So, summing up this brief overview, we must realize that there are fundamental unresolved issues directly linked to the use of CETs to inform decisions on access to medical treatments in a collectively financed health scheme.

The issues exceed the historic experience with CETs, the lack of an uncontroversial scientific basis to determine their dimension – a topic that I could not address today for time constraints – and a host of ethical and empirical problems. Given the far-reaching consequences for patients and their access to health care, international health care policymakers appear to be well - advised to exercise caution before implementing any approach relying on a simple benchmark for cost effectiveness.

Next project steps will be to double-check and consolide these observations and to assess the potential of modifications to

resolve the most critical issues emerging from the conventional logic of cost effectiveness.

Our analysis suggests at the present stage that, given the multiple and serious dimensions of the problem, it seems unlikely that simple adjustments – such as severity of equity weights – will be sufficient to provide a fix.



For the time being, I can offer a broader and deeper review with the Discussion Paper, which will be made available online at our institute's website.

For realizing the subsequent project phases, we will be open for cooperation with interested partners and sponsors. Many thanks for your attention!

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