

Cost-effectiveness thresholds and the Brazilian Unified National Health System

Limites de custo-efetividade e o Sistema Único de Saúde

Los umbrales de costo-efectividad y el Sistema Único de Salud brasileño

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The Brazilian Senate is currently reviewing Bill of Law n. 415 of 2015 (PLS 415; <http://www25.senado.leg.br/web/atividade/materias/-/materia/122071>), which requires defining, regulating, and publishing the cost-effectiveness parameter used for analyzing requests for the incorporation of technologies in the Brazilian Unified National Health System (SUS).

According to the bill's author, Senator Cássio Cunha Lima: "*The legal basis is not clear by which CONITEC [the National Commission for the Incorporation of Technologies in the SUS] analyzes a given medical procedure's cost-effectiveness, nor the threshold used to consider a procedure cost-effective. This gap often leads the public administration to apply low-quality technical discretion*".

In his arguments for the bill, Senator Cunha Lima cites the examples of European countries, Canada, and Australia and two internationally accepted parameters: (i) fifty thousand dollars per year of life saved (YLS); and (ii) the World Health Organization (WHO) recommendation of three times the per capita gross domestic product (GDP) per quality-adjusted life year (QALY) or disability-adjusted life year (DALY).

In September 2016, as a technical argument to back the measures recommended by PLS 415, Senator Ana Amélia presented a scientific article that defends the adoption of a threshold ¹.

Before embarking on (or getting carried away by) this wave, which involves setting cost-effectiveness thresholds that are transformed into simple decision-making tools, it is important to discuss the factors that influence how they are calculated and to identify important issues in the adoption of such a threshold, rather than accepting international rules and stubbornly adopting arbitrary numbers that do not apply to the Brazilian context.

Cost-effectiveness thresholds: What are they? What are they for?

The concept of cost-effectiveness threshold was originally proposed in 1973 by health economists ². It is usually represented as the ratio between a monetary cost, generally expressed in domestic currency like the Brazilian real (BRL) in the numerator and a measure of health gain in the denominator. This amount is compared to the result of economic assessment studies (incremental cost-effectiveness ratio – ICER) to back decisions on the incorporation of technologies in health systems. If an ICER falls below the threshold, the recommendation is to incorporate the technology.

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In the United States, the discussion on a threshold (USD 50,000 – USD 100,000) began in 1982, when Kaplan & Bush³ classified ICER in three categories: “cost-effective” (ICER < USD 20,000), “controversial” (ICER from USD 20,000 to USD 100,000), and “questionable” (ICER > USD 100,000). However, the authors failed to present reasonable justifications for the classification proposed in their article. In Canada, in 1992, Laupacis et al.⁴ suggested a similar categorization: “strong evidence” for adoption (ICER < CAD 20,000 per QALY), “moderate evidence” (ICER from CAD 20,000 to CAD 100,000 per QALY), and “weak evidence” (ICER > CAD 100,000 per QALY). Since then, these figures have been used arbitrarily by other countries, without any empirical calculation to justify or back their use.

Thresholds have been calculated with different approaches: (1) based on demand; (2) based on supply; or (3) a combination of the two. When demand-based, they focus on the affected population’s preferences, that is, the willingness to pay for a unit of effect. Supply-based values focus on the intervention’s opportunity cost, i.e., the cost per unit of effect of the most beneficial alternative that would be financed if the intervention were implemented⁵.

For years, the most widely cited cost-effectiveness threshold has been the one published in 2001 by the WHO Commission on Macroeconomics and Health⁶. Based on the country’s per capita GDP and the estimated economic value of a year of healthy life, the threshold suggests that interventions that avoid a DALY for less than 1 per capita GDP for the country are considered highly cost-effective; interventions that cost up to 3 times the per capita GDP are still considered cost-effective; and those that exceed this amount are not considered cost-effective.

These amounts were calculated with a demand-based approach and represent the individuals’ willingness to pay for adding a year to their healthy lives. They were not estimated rigorously and reflect the scientific context of that time⁵.

The WHO recently eliminated the recommendation of using the threshold of 3 times the per capita GDP for averting one DALY, on grounds that it lacked the necessary specificity for countries’ decision-making processes and could lead to mistaken resource allocation decisions⁷.

A research project recently developed at the University of York corroborated this decision when it empirically estimated the cost-effectiveness threshold based on the opportunity cost for the UK and found much lower values than those recommended by the WHO for the UK and other countries^{8,9}.

Use of cost-effectiveness threshold in the international scenario: explicit vs. implicit

The adoption of a threshold for a given health system can be explicit or implicit. Explicit thresholds are defined as values officially acknowledged by the decision-makers in an organization that formally adopts them and makes them public before issuing a decision. Implicit thresholds are unofficial values, not explicitly acknowledged or authorized, which can be inferred by analyzing patterns in previous decisions on coverage in a given health system¹⁰.

Explicit thresholds were identified in the main health technology assessment organizations in Thailand (1.0-1.5 per capita GDP/QALY)¹¹, Ireland (EUR 45,000/QALY)¹², and the UK (GBP 20.00 – GBP 30.00/QALY)¹³.

The previously cited academic study estimated a threshold of GBP 12,936 per QALY for the UK, well below the threshold traditionally used^{9,14,15}.

The threshold’s explicit definition is politically sensitive. Patient groups, healthcare providers, and health technology suppliers have vested interests in monitoring the decision-making process and pointing to inconsistencies in order to favor a technology’s incorporation. Due to scrutiny by the public at large and groups with strong economic and political interests in healthcare resource allocation, policymakers and administrators have been pressured to make the thresholds more explicit¹⁰.

Implicit thresholds were identified in Australia (AUD 50,000), Canada (i.e., Ontario), Sweden, and the United States (USD 50,000/QALY or year of life) and Brazil (1 to 3 times the per capita GDP/year of life)¹³.

Brazil and Thailand appear to use the GDP-based method recommended by the WHO¹³. However, in the denominator they used QALYs or years of life gained rather than DALYs avoided, pro-

posed by the WHO. These denominators have been used indiscriminately in various places without the necessary adjustments.

Use of a cost-effectiveness threshold in Brazil: current situation

No explicit value was set for the cost-effectiveness threshold in the SUS, to be applied by CONITEC¹⁶. A publication drafted by Brazilian Ministry of Health experts suggested a maximum value of BRL 81,675/DALY (three times the per capita GDP/DALY), a threshold from BRL 1,361 to BRL 147,016¹⁷ and three threshold levels: low (< BRL 25,000), medium (BRL 25,000 to BRL 70,000), and high (> BRL 70,000), based on threshold values from CONITEC reports on drug guidelines¹⁸. There were also no explicit thresholds for the incorporation of technologies in Brazil's supplementary (private) healthcare system.

Researchers from the University of York presented a range for Brazil of \$PPP 3,210 – \$PPP 10,122⁸, while the Instituto de Efectividad Clínica y Sanitaria (Argentina) suggested a range of \$PPP 8,885 to \$PPP 11,401/QALY, both lower than the threshold of one per capita GDP.

Due to the small number of CONITEC reports with recommendations that included the ICER calculation (11%), it is not possible to identify an adequate threshold for Brazil based on retrospective analysis of the recommendations¹⁹. In addition to the small number, the economic assessments used heterogeneous ratios (\$/QALY, DALY, or years of life), far short of the expected international standard for methodological quality²⁰.

Controversies in the use of the cost-effectiveness threshold

An international debate is currently under way on the need for countries to adopt explicit thresholds. Critics argue that such thresholds are unable to capture all the important values for society, particularly ethical implications, distributive justice, and other social preferences.

Recent publications from high, medium, and low-income countries emphasize the need for more studies and the interest in developing thresholds that clearly incorporate budget constraints and opportunity costs in these countries^{14, 21}.

There can be a fine line between an explicit threshold's usefulness and its misuse. The danger of misuse is that stakeholders with other interests may manipulate the cost-effectiveness ratios in the studies, making resource allocation even more inefficient. Brazil has limited technical and scientific expertise for producing such studies and assessing their quality²⁰.

All these factors are cause for discomfort, aggravated by the Brazil's current political and economic crisis. How does one set a threshold in a scenario where investments and public spending in health will be frozen for the next 20 years?

The arguments proposed to back PLS 415, namely the internationally adopted threshold (USD 50,000/YLS) or the threshold no longer recommended by the WHO (three times the per capita GDP/DALY) lack a theoretical or empirical basis.

Brazil cannot simply transpose international experiences to its own context. Setting a threshold value is context-specific, i.e., it depends on local wealth, the health system's characteristics, the willingness and capacity to pay, and social preferences. And such a threshold should always be used together with other criteria.

The accumulated research and debate should lead us to reflect on the risk of applying a theory that appears capable of overcoming conflicts of interest, but without acknowledging that the potential to contribute to greater effectiveness, efficiency, and equity in the SUS depends on political conditions that allow the defense of the population's wellbeing and the public good. We can only hope that the explicit cost-effectiveness threshold will longer be a "misplaced idea" at the service of implicit interests!

Contributors

P. C. De Soarez and H. M. D. Novaes planned and elaborated the article.

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