Risko de idadismo no uso de limiares de custo-efetividade nas recomendações da comissão nacional de incorporações de tecnologias no Sistema Único de Saúde no Brasil

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VIEWPOINT

Risk of ageism in the use of cost-effectiveness thresholds in the recommendations of the national commission for incorporation of technologies in the Brazilian Unified Health System

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Government agencies perform health technology assessment when evaluating requests to incorporate technologies in public health systems. To promote participation in this decision-making process, the National Commission for the Incorporation of Technologies in the Unified Health System (CONITEC) makes its recommendations available for public consultation for 20 days, which may occasionally be reduced or extended. Recently, CONITEC published its recommendations about the use of cost-effectiveness thresholds in health care decision-making. When reviewing the criteria for alternative cost-effectiveness thresholds, given that they promote innovation and equity in the Brazilian Unified Health System, we realized that the criterion “diseases affecting individuals at the end of life” was excluded from the list. This viewpoint article is a request for CONITEC to reconsider this position. The report disregards technical aspects related to the use of quality-adjusted life years as a metric in patients with low life expectancy, indicating the potential to discriminate against older adults and ignore the practical considerations of international organizations on this topic.

Keywords: health technology assessment; ageism; older adults.

Resumo

A avaliação de tecnologias em saúde (ATS) subsidia as agências governamentais voltadas à avaliação dos pedidos de incorporação de tecnologias junto aos seus respectivos sistemas públicos de saúde. Para promover a participação da sociedade no processo de tomada de decisão para a incorporação de novas tecnologias, a Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde (CONITEC) disponibiliza suas recomendações em consulta pública por um prazo de 20 dias, que pode ser excepcionalmente reduzido ou estendido. Recentemente, a CONITEC disponibilizou para consulta pública suas recomendações sobre o uso de Limiar de Custo-Efetividade (LCE) nas decisões em saúde. Ao revisar os critérios previamente considerados no início das discussões sobre contextos passíveis de LCE alternativos, percebemos que o critério “doenças acometendo indivíduos no final da expectativa de vida” foi excluído da lista de critérios de flexibilização. Este artigo de ponto de vista discute o pedido de reconsideração enviado à CONITEC para que a posição seja revista. O entendimento expresso no relatório desconsidera aspectos técnicos relacionados ao uso do QALY como métrica em pacientes com baixa expectativa de vida, além disso, tem potencial discriminatório em relação à população geriátrica e ignora considerações práticas de órgãos internacionais em relação ao tema.

Palavras-chave: avaliação das tecnologias de saúde; idade; idade; adultos.

On behalf of: Núcleo de Avaliação de Tecnologias em Saúde, Faculdade de Medicina de Botucatu, Universidade Estadual Paulista, Brazil.
Although the development of new health technologies is desirable, concerns over their cost and the pressure for rapid incorporation add to the phenomenon of health judicialization. In addition to considering people's needs and preferences, universal public health systems, which administer finite public resources, are constantly pressured to choose which technologies should be incorporated into the population's health care.

Health technologies range from organizational, educational, informational, and support strategies and systems to therapeutic interventions such as drugs, chemotherapy, vaccines, and health products and procedures.

Government agencies assess health technologies after requests for their incorporation into public health systems. In Brazil, the National Commission for Incorporating Technologies in the Unified Health System (CONITEC), assisted by the Department of Management and Incorporation of Technologies and Innovation in Health (DGITIS), aim to “advise the Ministry of Health about factors related to the incorporation of, exclusion, or alteration of health technologies in the Unified Health System, as well as about the development or alteration of clinical protocols or therapeutic guidelines.” Figure 1 is a flowchart of how technology is incorporated into the Brazilian public health system.

Considering the principles of universality, equity, and integrality, as well as the guidelines for decentralization and public participation in the Unified Health System, CONITEC
includes mechanisms for public involvement in decisions to incorporate technologies, including consultations and public hearings. Thus, CONITEC makes its recommendations available for public consultation for a period of 20 days, which may occasionally be reduced or extended.

Determining the value of a technology requires assessment of the short- and long-term financial impact of incorporating it, as well as assurance that it offers greater health benefits than other treatments and interventions, which will result in the reallocation, exclusion, or reduction of current technologies to cover the additional cost of incorporating the new one.

To support such decisions, the analysis must be based on scientific evidence, considering aspects such as the technology’s efficacy, accuracy, effectiveness, and safety, in addition to comparative economic evaluations of its costs and benefits in relation to current technologies. Health economic evaluations provide information on cost-effectiveness, expressed as an incremental cost-effectiveness ratio (ICER), which is the relationship between the difference in costs and the difference in effects. To maximize the system’s social gain, discarding less cost-effective alternatives and incorporating those with better cost-effectiveness, the ICER can be compared to a cost-effectiveness threshold.

Ideally, the cost-effectiveness threshold should be based on studies of value in health care and global comparisons on the subject. However, in Brazil, not only are these studies scarce, but the development of health economics is also incipient. Recently, CONITEC published its recommendations on the use of cost-effectiveness thresholds in health care decision making:

1. Health technology assessments should adopt a cost-effectiveness benchmark that must not be isolated from other factors in the discussion.
2. In the cost-effectiveness assessment of a health technology, it is important to consider quality-adjusted life-years (QALY), a measure of the expected quality and quantity of life, as the main outcome. Nevertheless, decision-makers should not limit their discussions to QALY.
3. Cost-effectiveness threshold values should be determined according to the health system’s methodological approach for efficiency (opportunity cost), as well as its approach to the efficiency frontier, when applicable.
4. At CONITEC’s discretion, the following contexts would be subject to alternative cost-effectiveness thresholds (for promoting health innovation and equity for the Unified Health System): diseases affecting children and implying significant reductions in quality-adjusted survival; severe diseases with significant reductions in quality-adjusted survival; rare diseases with significant reductions in quality-adjusted survival; endemic diseases in low-income populations with few available therapeutic alternatives.
5. In situations consistent with the alternative threshold assumption, it is acceptable to raise the threshold (from the reference value of 1) to 3 times the gross domestic product per capita.
6. Discussion about advanced technologies (gene therapies or curative gene therapies) or ultra-rare diseases (≤ 1 case in 50 000 people) will be based on specific criteria.

When reviewing the criteria for contexts prone to alternative cost-effectiveness thresholds, we noticed that the criterion “diseases affecting individuals at the end of life” was excluded from the criteria for flexibility of the threshold (item 4). Through the public consultation mechanism, the Botucatu School of Medicine Health Technology Assessment Center (NATS) suggested that this should be reconsidered. Excluding this criterion disregards technical aspects of QALY as a metric in patients with low life expectancy, has the potential to discriminate against the older adult population, and ignores the practical considerations of international bodies regarding this topic.

QALY, a health-related quality of life metric that has been widely used internationally, summarizes (in values between 0 and 1) gains in terms of life expectancy and quality of life. It is based on the premise that gains in quality are equivalent to those in life expectancy (Figure 2). One of its advantages is the possibility of comparing interventions from different areas using a common metric, thus maximizing the health gain in different populations.

An empirical consequence of this premise is that interventions for patients with low life expectancy produce lower gains in QALY. This distortion is especially evident in programs that incur short term costs but have long-lasting quality of life benefits, such as preventive and health promotion strategies. Such distortions in the application of QALY have been described in the literature, such as the ceiling effect, and can lead to bias, especially when evaluating technologies aimed at health care for older adults.

This effect has a simple explanation: young people have a longer life expectancy and thus more time to benefit from quality of life gains, accumulating more QALYs. A second
Ageism in cost-effectiveness thresholds’ use

 aspect is that small gains in life expectancy for patients at the end of life are not adequately recognized in QALY measurements and do not reflect the preferences of this group of patients. Several studies have empirically shown that programs aimed at older adults almost always produce fewer QALY than those aimed at youth, which impacts the ICER. Health care decision-making mechanisms based on QALY are just another potentially discriminatory aspect of the interpretation of scientific evidence. A 2022 report by the World Health Organization reinforces concerns about impact of ageism on the use of artificial intelligence to make prioritization or allocation decisions about scarce resources.

The problem lies in the fact that the datasets used to train artificial intelligence models (including clinical trial data) often exclude older people, who are thus frequently considered a “minority” dataset in these technologies. If an artificial intelligence algorithm is trained with data from predominantly younger populations and then used for an older population (for which it has not been trained, validated, or evaluated), it may be ineffective or provide incorrect diagnostics or predictions.

Due to inherent problems in the application of QALY, the agency responsible for assessing health technology in Germany is reluctant to incorporate studies that use it in health care decision-making. On the other hand, in 2010 the UK’s National Institute for Health and Clinical Excellence, which has extensive experience with QALY metrics, adopted criteria for assessments involving low life expectancy (UK Equality Act 2010).

Flexibility in the cost-effectiveness threshold should be considered according to certain criteria, known as the end-of-life rule. Advisory bodies are more cautious about recommending a technology when they are less certain about the ICER presented in the cost-effectiveness analysis:

1. When there are strong reasons indicating that the change in quality of life assessment is inadequate, which could distort the health gain; or
2. When the intervention is an innovation that adds substantial, demonstrable, and distinct benefits that may not have been adequately captured when measuring the health gain.

The technical distortions described in the literature that arise from the use of QALY are largely related to life expectancy, although they also imply the risk of ageism in health care decision-making. We therefore suggest that the report should include cost-effectiveness threshold flexibility parameters for patients with low life expectancy. Finally, we would also like to stress the importance of the Brazilian medical community’s participation in public consultations about health technology assessment to help guarantee equity in incorporating technologies aimed at patients with low life expectancy and the older adult population.

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REFERENCES


