HTA137

# Determining Relevant Thresholds for Reimbursement of Healthcare Interventions. Should We Prohibit the Use of the QALY at Last?

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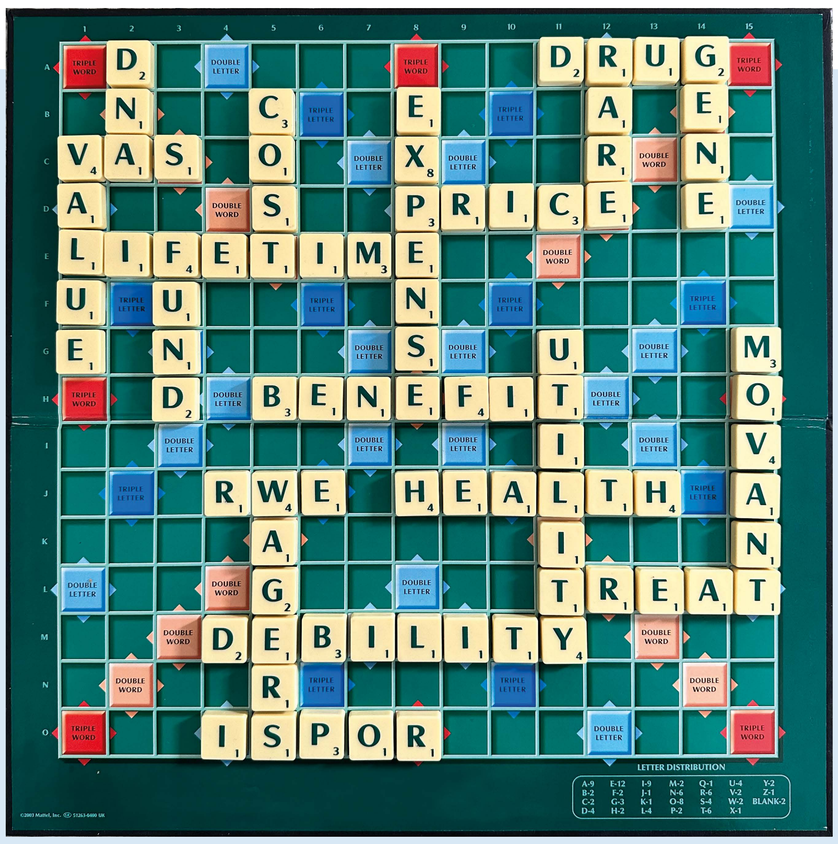
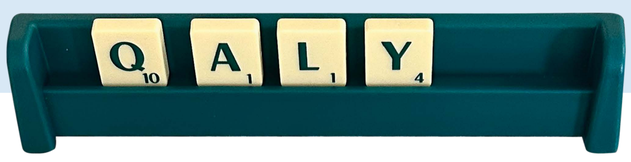
## Introduction

- Despite many years of debate, the quality adjusted life year (QALY) remains the main cost-effectiveness metric used to assess the value of healthcare interventions for patients.[1] However, the use of QALY as a measure of benefit obtained from healthcare expenditure has been increasingly challenged on the grounds that it assigns a lower value to preserving the lives of people with a permanent disability or illness than to preserving the lives of those who are healthy and not disabled.
- The Protecting Health Care for All Patients Act of 2023 (HR485)[2,3] is a landmark legislation that is to be ratified by the 118th United States Congress meeting of the legislative branch of the federal government, that aims to provide equal access to healthcare for all individuals in the United States (US). A significant aspect of this Act is that it would prohibit federal health programs, including Medicare and Medicaid, from using the QALY and similar measures to assess the relative value of medical interventions.
- Additionally, the Act addresses the rising cost of prescription drugs by implementing measures to promote transparency and affordability. It seeks to enhance competition in the pharmaceutical industry to lower drug prices and alleviate the financial burden on patients who rely on essential medications. The significant decision to no longer recognize the QALY as a valid measure for valuing a healthcare intervention reflects a shift in understanding and prioritizing patients' needs and values.




## No place for the QALY?

- The QALY has faced previous criticism for potentially perpetuating discrimination in healthcare: the metric often fails to adequately consider the unique needs and values of different patient populations, leading to disparities in access to treatments.
- This undermines the principle of equitable healthcare for all and may disproportionately disadvantage certain groups, such as elderly people, and those with chronic illnesses or disabilities.
- Further, the QALY does not capture the full spectrum of health outcomes and fails to consider the individual and social dimensions of well-being.
- Health is a complex concept that encompasses physical, mental, and social aspects, and reducing it to a single metric can oversimplify the complex impact of healthcare interventions on patients' lives.
- By abandoning the QALY, the Act emphasizes a more comprehensive and patient-centric approach to healthcare decision-making that should include patient-centric factors such as personal goals, cultural considerations, and treatment burden.
- Thus, by considering a broader range of factors and prioritizing equitable access, this legislation seeks to ensure that healthcare decisions are made in a manner that respects the dignity and autonomy of every individual.

- Nevertheless, to conduct meaningful comparisons across various studies, interventions, or health conditions, it is essential to have a common metric for health outcomes. In health technology assessments (HTA) that are considered by many countries in Europe (e.g. Spain, Italy, Sweden, Switzerland, the Netherlands), and British Commonwealth countries (e.g. Canada, Australia), researchers often present a single utility score that reflects health status for use in cost-effectiveness analysis.
- The EQ-5D is a standardized instrument that is widely used for providing a generic, preference-based measure of health status that can be applied across different health conditions, and commonly used to estimate QALYs for cost-effectiveness assessments.[4] Due to the diversity of patient-reported outcome measures, including quality of life, and the requirement for standardized metrics in economic evaluations, value frameworks often include cross-walking patient-reported outcome measures to the EQ-5D with the aim of comparing and aggregating data across studies and health conditions.[5]
- However, the choice of metric or approach for assessing cost-effectiveness can vary by country, healthcare system, and context, and often depends on the specific goals of healthcare policy, ethical considerations, available data, and the preferences of decision-makers who may opt for the approach that aligns best with their objectives and the values of their healthcare system or population.
- In practice, while QALYs remain a widely used and accepted metric for cost-effectiveness analysis, and for determining reimbursement thresholds (i.e. cost/QALY), other alternatives should be considered in situations where QALYs may not be suitable, or when decision-makers prioritize other factors in their evaluations (e.g. Germany, efficiency frontier; France, ASMR).

Other options might include:

- Multi-criteria decision analysis (MCDA): which involves considering multiple criteria or dimensions, such as clinical efficacy, safety, patient preferences, and budget impact, and allows decision-makers to weigh various factors without necessarily converting them into a single metric
- Return on investment (ROI) analysis: which focuses on the economic return generated by an intervention, including cost savings or revenue generated as a result of improved health outcomes
- Net monetary benefit (NMB): which quantifies the net economic benefit of an intervention by subtracting the total costs from the total benefits (usually measured in monetary terms and not QALYs).

**If adopted, the Protecting Health Care for All Patients Act of 2023 could have a profound effect on the pricing and reimbursement of healthcare interventions in the US. Until researchers and policymakers can agree on an alternative, the future of the QALY outside the US also remains in jeopardy. It is essential that those who design, conduct and report clinical trials and real-world studies address these issues at last, in order to be able to provide equitable healthcare coverage for all citizens.**

## References

1. Rand LZ, Kesselheim AS. Controversy over using quality-adjusted life-years in cost-effectiveness analyses: a systematic literature review. Health Aff (Millwood). 2021;40(9):1402-1410;
2. Rodgers CM, Smith J, Wenstrup B, Burgess B. Protecting Health Care for All Americans Act of 2023, HR 485, 118th Cong (2023);
3. Amendment to committee print of HR 485. Published March 23, 2023;
4. EQ-5D-Y User Guide, 2020. Available from: https://euroqol.org/publications/user-guides;
5. van Hout B, Janssen MF, Feng YS, et al. Interim scoring for the EQ-5D-5L: Mapping the EQ-5D-5L to EQ-5D-3L value sets. Value Health. 2012;15(5):708–15

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