

QALY Methodology

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Issue

Explain quality-adjusted life year (QALY) methodology used to evaluate health treatments and summarize the current debate about its use.

Summary

Generally, QALY is a way to value health outcomes. More specifically, it is a methodology used to evaluate health treatments that considers quality of life by assigning a value to how much a treatment both improves and extends a patient's life. A high value treatment produces good health outcomes compared to its cost; a low-value treatment is one with a relatively high cost for its health outcomes. These cost-effectiveness ratios can be used as a standardized way to compare varying treatment options across different patients with different medical needs.

Organizations use QALY and cost-effectiveness ratios to make healthcare treatment recommendations. Two of the main organizations that make such recommendations are the the Institute for Clinical and Economic Review (ICER) and the National Institute for Health and Care Excellence (NICE). ICER is a U.S.-based organization that evaluates prescription drug and medical treatment effectiveness. NICE is an organization in the United Kingdom that produces evidence-based healthcare guidance. (The National Health Service uses NICE value recommendations as [one factor in determining coverage decisions](#).)

Generally, ICER and NICE recommend allocating resources away from low value treatments and towards high value ones. To establish high or low value, ICER uses a fixed cost-effectiveness ratio: treatments with cost-per-QALY ratios below the limit are high-value and those above the limit are low value. Instead of a fixed threshold, NICE evaluates treatments on a sliding scale. High value

treatments are automatically recommended. Lower value treatments may still be recommended but require evidence that the higher cost-per-QALY ratio is acceptable for the circumstances.

Pharmacy benefit managers, insurers, government health programs, and other organizations can use these recommendations to make health care coverage determinations.

Advocates of the QALY model [argue](#) that, among other things, it helps keep costs down and provides a value-based way to distribute limited health resources. Specifically, it helps compare treatment options across diseases or conditions assuming limited resources (e.g., it produces a standardized way to compare the value of treating blindness in a young child with treating cancer in an elderly patient). Opponents generally [argue](#) that, among other things, it interferes with the physician-patient relationship, unfairly devalues certain cancers and mental health treatments, and fails to account for orphan drugs (i.e., drugs used to treat very rare diseases).

As an example of this debate, CVS [announced in September 2018](#) that it would implement QALY value-based pricing to determine low value drugs to exclude from formularies. However, one year later Reuters [reported](#) that CVS faced “fierce criticism from patient advocacy groups” and delayed marketing plans including these measures.

Quality-Adjust Life Year (QALY)

Generally, the QALY for a new medical treatment or prescription drug measures:

1. how much the new treatment improves the patient’s quality of life compared to either no treatment or the existing standard treatment for the condition, and
2. how long the patient lives with an improved quality of life.

In practice, QALY is standardized to quality over a single year. As a result, one year in perfect health equals one QALY. A year in pain or hospice, or with reduced functionality, is less (e.g., .8 QALY).

Organizations such as ICER and NICE develop QALY measurements and use a range of economic data, including a country’s gross domestic product and willingness to pay for healthcare, to assign a monetary value per QALY. Treatments are assigned a high, intermediate, or low value based on their QALY cost-effectiveness.

ICER and NICE

Generally, ICER assesses a treatment’s long-term value using a specific cost-effectiveness threshold of between \$50,000 and \$175,000 per QALY gained (see ICER’s [2017-2019 framework](#),

pages 16-17). ICER automatically considers treatments with cost-effectiveness per QALY ratios below \$50,000 as high value; treatments with ratios above \$175,000 are automatically considered low value. (These cost-per-QALY ratios are known as incremental cost-effectiveness ratios and are sometimes referred to as 'ICER.')

Treatments between \$50,000 and \$175,000 per QALY are considered on a case-by-case basis, and the cost per QALY is one factor that ICER uses in determining a treatment's total value. According to ICER's [2017-2019 value assessment framework](#), other factors considered include a treatment's short-term affordability, with specific adjustments based on the treatment type (e.g., drug, test, service, medical device, procedure, or an ultra-orphan drug used to treat a very rare disease). (For more information about ICER, see OLR Report [2019-R-0046](#), "Institute for Clinical and Economic Review.")

NICE uses a sliding scale for cost-effectiveness. Treatments that cost less than £20,000 per QALY are considered high value and are automatically recommended. NICE may recommend treatments with higher costs ratios, but requires evidence showing that the existing QALY ratio inadequately captures the patient's improved quality of life and that the treatment produces additional value ([see Developing NICE Guidelines: The Manual, section 7.7](#)).

According to [BHE](#), a health analytics company, the difference in methodologies means that ICER generally does not recommend treatments above the acceptable QALY threshold while NICE may. However, BHE also notes that in practice NICE's range of plausible cost-effectiveness ratios is narrower than those used by ICER because it requires extenuating circumstances and compelling evidence to recommend intermediate treatments.

Debate

There is an ongoing debate in the healthcare community about using QALY measurements to allocate health resources. Advocates argue that resources are limited and considering the return on cost is important to a stable health care system. Opponents argue that doing so monetizes treatment decisions, rations healthcare, and limits health choice by interfering in the physician-patient relationship.

A [2016 article](#) in the Journal of Stem Cell Research and Therapy describes several of these issues in depth. Specifically, it notes that measuring QALYs is more difficult in certain populations, such as the elderly, those seeking mental health treatments, or cancer patients. Because the QALY assigns the highest possible value to perfect health, it can potentially lower treatment values for those with shorter potential lives such as those in palliative or hospice care or elderly cancer patients. (The

National Health Service in the U.K. created the [Cancer Drug Fund](#) in [part because the high price](#) of cancer drugs results in a [lower QALY value](#) compared to using the same money to treat other patients.) These metrics may also assign lower values to extraordinarily high-cost treatments, such as those using orphan or ultra-orphan drugs or gene therapy.

There may also be a bias towards patients with disabilities, who “may not necessarily be able to achieve substantially higher quality of life when directly compared to healthier individuals.” Generally, this is because their “normal state” is not “perfect health” under QALY calculations. Critics argue that this does not make a life more or less valuable.

Generally, QALY advocates argue for refining methodology and calculations with additional data that addresses these concerns. For example, in 2018 ICER began using an additional metric called Equal Value of Life Years Gained (evLYG), which evenly measures any extension of life even if the quality does not improve. In a [December 2018 report](#) describing evLYG, ICER indicates the following about this metric: “if a treatment adds a year of life to a vulnerable patient population – whether treating individuals with cancer, multiple sclerosis, diabetes, epilepsy, or a severe lifelong disability – that treatment will receive the same evLYG as a different treatment that adds a year of life for healthier members of the community.”

Federal and State Action

Federal law generally prohibits Medicare and the Patient-Centered Outcomes Research Institute, which evaluates treatments for coverage by certain federal programs, from using QALY thresholds to determine coverage ([42 U.S.C. § 1320e-1](#)).

Additionally, at least two states, Connecticut and Massachusetts, recently considered proposals to restrict the use of QALY evaluations ([CT 2019 HB 5861](#) and [MA 2019 H.1088](#), respectively). The Connecticut bill would have prohibited health insurers from using QALY or any similar measure to determine coverage. The bill was referred to the Insurance and Real Estate Committee, which took no action. The Massachusetts bill generally prohibited health insurers and MASS Health (i.e., Medicaid) from using QALY to recommend or determine coverage. The bill was publicly heard on September 23, 2019, and no further action was taken.

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