Questions on Quality-Adjusted Life Years (QALY)

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Issue

This report answers questions on the use of quality-adjusted life years (QALY) in health care. Questions and answers follow. See also OLR Report 2020-R-0001.

What are QALYs?

QALY is generally 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.

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

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, the 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., 0.8 QALY).
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, usually seeking to allocate resources away from low value treatments and toward high value ones.

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 by comparing treatment options across diseases or conditions assuming limited resources. Proponents argue that the QALY methodology is “an objective and generalizable metric that provides important information about the balance between fiscal realities and public health needs.”

Opponents of the QALY methodology argue, among other things, that the dollar amount used to value a year of good health may be arbitrary or subjective. They also argue that QALYs are disadvantageous for people with disabilities because treatments that extend or improve their lives may “result in fewer QALYs than a treatment developed for a non-disabled or younger population where the treatment is able to return the patient to so-called perfect health.”

Others argue that methodologies that put a monetary value on human life have informed policy decisions for decades in the United States and elsewhere and that “all ways of deciding how to use collective resources are discriminatory to someone…the best we can hope for is to make those decisions in a transparent process.”

Summarize findings and recommendations from the National Council on Disability’s recent report on QALYs.

The National Council on Disability (NCD) is an independent federal agency created to advise the president, Congress, and other federal agencies on issues affecting people with disabilities. NCD submitted its report, “Quality-Adjusted Life Years and the Devaluation of Life with Disability,” in November 2019, as part of a five-report series on the intersection of disability and bioethics, for the stated purposes of (1) “examin[ing] how use of QALYs may impact people with disabilities in the United States,” and (2) “inform[ing] Congress and the executive branch on the ways in which QALYs impact people with chronic illnesses and disabilities’ access to treatment and health care.”

Findings

NCD lists the following findings in their report:

1. There is sufficient evidence that QALYs are discriminatory, or at least potentially discriminatory, warranting the concern of stakeholders and bioethicists.
2. The federal government does not have a single, comprehensive policy on the use of QALYs. Some agencies are banned from using QALYs, while others use them frequently.

3. The federal government has an increasing interest in reducing the cost of health care by modeling parts of its national health insurance programs after the healthcare systems of other countries, some of which use QALYs in benefits and coverage decisions. The experiences of people with disabilities in countries that use QALYs (i.e., coverage denials and loss of access) illustrate the potential negative results of using QALYs in the United States.

4. While insurers consider many different types of evidence when making decisions, they likely use QALYs and the analyses that rely on them in internal decision-making processes, about which there is limited public knowledge.

5. Alternatives to QALYs are available, including cost-benefit analysis, value frameworks, and multi-criteria decision analysis. While many alternatives can themselves be discriminatory, some can be used in a nondiscriminatory manner. No single alternative serves all the functions of QALYs.

**Recommendations**

The report makes recommendations to Congress, federal agencies, and public and private insurers directed at rejecting QALYs as a method of measuring cost-effectiveness for medical care. NDA provides the following recommendations:

1. Congress should avoid enacting healthcare provisions that require the agency with management and oversight responsibilities to either (a) cover only the most cost-effective drugs and treatments or (b) impose restrictions on less cost-effective treatments.

2. Congress should pass legislation to (a) prohibit the use of QALYs by Medicaid and Medicare and (b) provide funding to the Department of Health and Human Services (HHS) for best practices on using cost-effectiveness to inform benefits and coverage decisions for national health insurance programs.

3. The Department of Justice (DOJ) and HHS Office for Civil Rights should issue guidance clarifying how and to which health insurance programs Title II of the Americans with Disabilities Act, Sections 504 and 1557, apply.

4. HHS should consider including people with disabilities and chronic illnesses as members of committees and working groups formed to develop effective healthcare reform and strategies for lowering the cost of prescription drugs.

5. HHS should issue guidance to healthcare providers about what to do if their patient’s health insurer refuses to cover recommended treatment based on that treatment’s cost-effectiveness.
6. The Centers for Medicare and Medicaid Services (CMS) should use well-established alternatives to QALYs (e.g., multi-criteria decision analysis and cost-benefit analysis) when the exact benefits and costs of a drug or treatment are known.

**Summarize a recent law passed in Oklahoma limiting the use of QALYs.**

Effective November 1, 2020, Oklahoma’s Nondiscrimination in Health Care Coverage Act (HB 2587) prohibits state agencies from developing or using a dollars-per-QALY measure to establish what type of health care is cost-effective or recommended. It further prohibits state agencies from using QALYs to determine coverage, reimbursement, incentive programs, or utilization management decisions, whether it comes from within the agency or a third party (63 Okl. Stat. Ann. tit. 63, § 2560 et seq.).

When proposing a new utilization management measure, state agencies must post it for public comment and provide the rationale for its use. A state agency must include (1) the availability of alternatives, (2) an analysis of the potential impact on atypical patient populations and subgroups, (3) an estimate of the population likely to be impacted by the measure, and (4) a description of both internal and third-party value assessments used in internal deliberations on the measure.

Additionally, state agencies making decisions on utilization management measures, coverage, reimbursement, or incentive programs must consult with advocacy groups and follow specified procedures designed “to ensure robust stakeholder engagement and full transparency surrounding the provision of any research and analysis relied upon for decision-making.” Under the law, the process must include:

1. notice and comment processes for (a) vendors providing research and analysis and (b) any research and analysis an agency uses;
2. deliberation on health care coverage and reimbursement in open meetings after publicly releasing any research and analysis relied on by the agency;
3. third-party disclosure of conflicts of interest and funding sources;
4. prohibiting sole-source contracts for research and analysis; and
5. an annual report assessing beneficiary access to health care treatments and services that is submitted to the legislature and posted on the state Medicaid website.

State agencies may only rely upon research that both considers meaningful differences in the characteristics, needs, and preferences of patients and people with disabilities, and measures outcomes prioritized by them.
Have other New England states considered legislation limiting use of QALYs in Medicaid or private insurance?

In 2021, the Massachusetts state legislature considered S. 753. The Senate referred the bill to the Health Care Financing Committee, which held a hearing on it on November 9, 2021, but has taken no further action.

The bill’s provisions apply to both the Division of Medical Assistance (the state’s Medicaid agency) and the Massachusetts Health Policy Commission, which generally monitors health care spending, establishes annual benchmarks for health care cost growth, reports to the legislature on medical cost trends, and recommends policies to increase the health care system’s efficiency.

The bill prohibits the division and commission from developing or using a dollars-per-QALY or similar measure when determining a treatment’s value. It also requires them to (1) ensure that research they rely upon to determine a treatment’s value meets “patients-centeredness” standards and (2) publish a summary of the standards. Under the bill, these standards include evaluating a range of research and analysis that (1) includes outcomes prioritized by patients and people with disabilities within a specific disease area and (2) looks at relevant patient subgroups to consider differences in preferences and clinical characteristics within patient subpopulations. Both the division and commission must require research and analysis to consider the full range of relevant, peer-reviewed evidence and refrain from over-interpretating inconclusive findings, instead allowing time to conduct more research.

The bill also prohibits the division from placing a limit on patient access to health care treatments unless there is also a mechanism for appeals or a provision allowing physicians to override the limit.

What is Medicare’s policy on using QALYs?

Federal law generally prohibits HHS from using a dollars-per-QALY or similar measure to determine coverage, reimbursement, or incentive programs under Medicare (42. U.S.C. § 1320e-1(e)).

Federal law established the Patient-Centered Outcomes Research Institute (PCORI) as a nonprofit, nongovernmental organization to conduct research and disseminate findings to assist patients, clinicians, and other stakeholders in making informed health decisions (42 U.S.C. § 1320e(b) & (c)). In practice, PCORI funds clinical effectiveness research, among other things. The law prohibits PCORI from using QALYs to establish what type of health care is cost effective or recommended (42. U.S.C. § 1320e-1(e)).
More broadly, the law prohibits HHS from using clinical effectiveness research conducted by PCORI to determine coverage, reimbursement, or incentive programs under Medicare in a way that (1) treats extending the life of an elderly, disabled, or terminally ill person as less valuable than extending the lives of others or (2) precludes or discourages someone from choosing a health care treatment based on his or her values concerning the tradeoff between extending life and risking disability (42. U.S.C. § 1320e-1).

HHS may only use evidence from PCORI’s research and findings if it does so through an iterative and transparent process that includes public comment and considers the effect on subpopulations (42. U.S.C. § 1320e-1(a)).

However, the law does not prohibit HHS, when making decisions in Medicare, from using research findings that compare efficacy of alternative treatments in extending someone’s life due to his or her age, disability, or terminal illness. HHS may also apply differential copayments for Medicare based on cost or type of service (42 U.S.C. § 1320e-1(d)).