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## COMMENTARY

# Why the Coming Debate Over the QALY and Disability Will be Different

*Steven D. Pearson*

**T**he QALY has served for over 30 years as the gold standard within health economics for measuring the impact of treatments on patients' health. Created with the explicit goal of capturing the impact of treatment on both length of life and quality of life, the QALY is a summary measure that can be used in a consistent fashion across all types of conditions, and therefore is uniquely able to help decision-makers compare "apples to apples" as part of cost-effectiveness analyses (CEA) in health and medicine. A staple of health technology assessments in Europe, Canada, Australia, and elsewhere, CEA using the QALY is also at the heart of the methods used by my research group in the United States, the Institute for Clinical and Economic Review (ICER).

Persad<sup>1</sup> contributes valuable new insights and ideas that take their place in debates over the ethical implications of using CEA to help inform decisions about funding, insurance coverage, and appropriate pricing of health interventions. Around many points there is strong consensus. Does the QALY capture all the potential factors of benefit to patients, families, and society that can be gained from successful treatment? No. Does it tell us how to compare equal QALY gains that arise from small health gains for many individuals versus large health gains for a few? No. Does it automatically reflect our individual or social values that might ascribe more weight to health gains for children, for people with more serious conditions, for socially or historically disadvantaged communities? No, no, and no. To address these limitations, ethicists and health economists have always called for deliberative processes to integrate the findings of CEA with

social values and other considerations so that the "cost per QALY" is not used as a single dispositive factor in any decision.

But what about the QALY and its measurement of health gains among disabled populations? Is the QALY inherently discriminatory? If so, is it beyond redemption by deliberative process, requiring some form of quantitative "fix" or even outright rejection as a tool to aid decision-making? Since the early days of CEA experts recognized that any extension of life for patients with a persistent disability would be "weighted" in the QALY by the (lower) quality of life assigned to that health state. For example, a treatment that extends life — but does not improve quality of life — for patients with a condition that requires mechanical ventilation would be assigned a lower QALY gain than a treatment that extends life exactly the same amount for patients with rheumatoid arthritis or cancer. This feature of the QALY raises obvious questions about fairness and equity. In light of these concerns, in this short essay, I seek to accomplish three goals: 1) defend use of the QALY; 2) describe a new quantitative method introduced by my institute that can complement the QALY and address equity concerns; and 3) describe the new environment in which the debate about the QALY and disability will be amplified — and distorted — as it plays out as part of the struggle over the future of drug pricing in the US.

### **Why the QALY is Worth Keeping**

Most clinical studies express health gains in terms of disease-specific measures, such as the number of strokes avoided or the lessening of pain. Although useful for measuring effects and comparing treatments within single conditions, such measures do not permit comparison across diseases. The QALY is the best sin-

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gle measure through which we can make these kinds of comparisons, which are needed if the goal is to have a consistent approach to policy decisions across the entire health system, such as assigning a fair price to new treatments for different conditions. This is one of the chief reasons that the QALY has a long track record of use within national health technology assessment groups around the world, as well as in federal agencies in the United States such as the Centers for Disease Control, the Agency for Healthcare Research and Quality, and the National Institutes of Health.<sup>2</sup> It has also been reaffirmed recently as the best measure of health gain by authoritative groups such as the Second Panel on Cost-Effectiveness in Health and Medicine<sup>3</sup> and the International Society for Pharmacoeconomics Research (ISPOR).<sup>4</sup>

QALYs represent health over time as a series of “preference-weighted” health states, where the quality weights reflect the desirability of living in the state, typically from “perfect” health (weighted 1.0) to death (weighted 0.0). Once the weights are obtained for each

healthy people. Simply put, the QALY does not value people; it examines the value of treatments.

Additionally, because the QALY captures the degree to which a treatment improves patients’ lives, CEA of treatments for people with serious disability or illness have the greatest opportunity to demonstrate more QALYs gained and therefore justify a high price. Patients with less serious conditions have an explicit “ceiling” effect on their ability to benefit from treatment. This is part of the reason why ICER reviews using QALY-based CEA have demonstrated that many innovative new treatments for conditions associated with high severity and/or lifelong disability are highly cost-effective, despite being quite expensive. Examples include CAR-T therapy for childhood leukemia at \$475,000/treatment; emicizumab for hemophilia at \$450,000/year; and personalized lung cancer drugs at \$90,000/year. All proposed alternatives to the QALY introduce new concerns about comprehensiveness or fairness, and this too is why the health economics community has stood by the

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state, they are multiplied by the time spent in the state; these products are summed to obtain the QALYs. Most health care treatments improve quality of life while having little, if any, impact on length of life. But for treatments that do extend life, patients do not care simply about life extension; they care about the impact of side effects and serious harms on the quality of that life, and the QALY represents by far the purest measure — at the population level — by which to combine preferences that strike a balance between potential gains in length of life and gains in quality of life.

It is easy to misunderstand — or misrepresent — how CEA is used in health technology assessment, and some of the philosophical ruminations exploring hypothetical use of CEA to determine which one of two individuals are saved have not helped. CEA is used to compare *treatments within conditions*, not people within treatments. For example, CEA might be used to judge that Drug B is more cost-effective than Drug A in the treatment of a disabling condition; but CEA is not used to determine whether patients with disabilities are less cost-effective to treat with Drug A than are

QALY. Ultimately, the added cost per QALY gained for new treatments remains the best way for policymakers to understand how well the price of a treatment lines up with its relative benefits and risks for patients compared to other treatment options.

### **Another Way to Solve the Disability Question: the Equal Value of a Life Year Gained**

Based on methodological work from multiple sources, some health technology assessment systems have gone beyond qualitative deliberative processes to address social value considerations, including the risk that life extension for conditions associated with disabilities would be underweighted by the QALY. For example, Norway applies a tiered cost-effectiveness threshold to pay more for treatments that provide health gains for conditions that cause substantial lifetime burden of illness, whereas in England a special weighting of QALYs gained is accorded treatment for conditions that are rapidly fatal.<sup>5</sup> Neither of these approaches have gained broad consensus among health econo-

mists, many of whom believe that trying to create a quantitative fix within the QALY itself is less desirable than the integration of consideration of social values through robust deliberative processes.

For ICER the issue of the QALY and disability gained significant new attention when CVS Caremark, a major pharmaceutical benefit manager (PBM), announced in 2018 that it would launch a new health insurance plan for its employees in which coverage could be denied if a new drug did not meet a specific CEA threshold as determined by an ICER report.<sup>6</sup> One organization based in Washington, DC launched a concerted effort to gather patient advocacy groups together to pressure CVS Caremark to abandon its plans.<sup>7</sup> The major criticism was that the QALY was inherently discriminatory against disabled people, with the relatively lower QALY rating for health states associated with disability used as evidence.

The visceral reaction stimulated by this campaign among disability advocates was striking. To address this concern directly, ICER worked with its extended network of health economists to develop a new measure of health gain to complement the QALY. This new measure, dubbed the Equal Value of Life Years Gained (evLYG), evenly measures any *gains* in length of life, regardless of the treatment's ability to improve patients' quality of life. In other words, if a treatment adds a year of life to a 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.<sup>8</sup>

The evLYG is not as flexible as the QALY in capturing benefits to quality of life. In addition, as anticipated, it can “overvalue” life extension in relation to improvements in quality of life. For example, a treatment that extends life for 5 years for patients with a severe disabling condition, without improving their quality of life, might be calculated as producing more evLYGs than a treatment that extends life for 3 years while relieving all symptoms and returning the patient to perfect health during that time. Even if patients would, on average, clearly favor the treatment that provided shorter life extension with relief of all symptoms, the evLYG would force a weight of excellent health onto the extended years provided by the treatment that in fact provided no improvement in quality of life.

The evLYG, then, much like Persad's approach, seeks to reflect one view of how social values should be translated into CEA, and while it does solve one concern about the QALY and disability, it creates the potential for another. This is why ICER has deter-

mined to present CEA results in all reports moving forward based both on the QALY and the evLYG. The QALY remains the best tool to capture the trade-offs that can be inherent in treatments that provide different levels of life extension and quality of life. CEA based on the evLYG represents an approach meant to communicate to all reasonable parties that “discrimination” against the disabled on the basis of underweighting any gains in length of life is no longer a factor: life extension will be rated exactly the same across all conditions, regardless of age, severity of illness, or level of disability.

### Why This Debate About the QALY and Disabilities Will be Different

The debate in the US about the QALY and disability is gaining new momentum due to the advancing use of CEA in drug pricing and coverage negotiations.<sup>9</sup> The debate therefore is occurring in the midst of a major battle between forces seeking to retain the status quo associated with drug pricing policy, and those who seek substantial change. The history of the exploration of the ethical issues associated with the QALY and disability has been notable for its sophistication and nuance as it has progressed across philosophical, legal, and health economics communities. It will be so no longer. What we are starting to witness, and what will very likely continue to play out over coming months, will not be a search for understanding or learning; it will be an attempt to win at all costs through tactics that reflect the larger, brutal political slugfest playing out between all the powerful interests involved or affected by drug pricing and costs in the US.

During the debate ahead the QALY will be reviled in cartoonish versions as akin to eugenics, with the impact of use of QALYs being, as one commentator put it recently, “hospice care could be the default medically necessary treatment for the disabled.”<sup>10</sup> Any effort to defend the QALY, or CEA more broadly, will be depicted as an attempt to save money at the cost of patients' lives. Any suggested methods by which to modify the QALY or its weighting, as suggested by Persad, or to emphasize the importance of public deliberation in applications of CEA, will most likely fall on deaf ears.

But this work must continue, and academics should remember that they have voices that can be heard outside their classrooms and the journals in which they publish. CEA based on the QALY — or a similar measure — is useful for a very important reason: the current drug pricing and insurance system is broken and hurts patients every day. An objective look at how well drugs improve both quality and length of life leads to a more honest discussion about whether the

prices set by drug makers are fair. It sets a clear target for price negotiation; when negotiation leads to fair prices, innovative treatments that make a real difference in patients' lives get their due reward, patients and insurers save money when it could be put to better use elsewhere, and patients reap the ultimate benefits of broader access to more affordable health care.

I believe that by highlighting the evLYG measure of health gain, ICER is responding in good faith to deeply held feelings among some advocates that the QALY could discriminate against vulnerable patient groups. Raising the profile of the evLYG should reassure them and policymakers that when treatments offer the opportunity to extend lives, between the QALY and the evLYG we will make sure that each day, month, or year of extra life will be valued equally. But attacking any form of CEA as a source of information does not serve the interests of patients, be they young, healthy, old, sick, or disabled; it leaves everyone at the mercy of the current system in which manufacturers charge as much as they can and insurers react by restricting care and placing more financial burdens on patients. That should not be our fallback position for today. That cannot be the future we leave our children. They deserve a system that guarantees everyone a fair price and ready access to the care that patients and their doctors determine is best for them. That should be the ultimate goal of academic work and the future debates over the QALY and disability.

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