PharmacoEconomics (2023) 41:1175–1182
https://doi.org/10.1007/s40273-023-01302-6

PRACTICAL APPLICATION

An Alternative Measure of Health for Value Assessment: The Equal Value Life-Year

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Accepted: 29 June 2023 / Published online: 17 July 2023
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Abstract

The quality-adjusted life-year (QALY) is an international standard in cost-effectiveness analysis. A known concern arises from the relatively lower QALY gains attributed to treatments that extend the life of individuals with chronic disability. We analyze here the advantages and disadvantages of the equal value life-year (evLY) as an alternative or a complementary measure to the QALY, and share learned experiences from using this measure in health technology assessments. We present the conceptual rationale for the evLY, describe how it is estimated, and assess the differences in results between analyses based on the evLY and the QALY. We share a how-to guide in estimating the evLY using a downloadable tool and summarize our empirical experience using this measure. Incremental evLYs are feasible and address concerns regarding the risk for a cost-effectiveness analysis to undervalue treatments for people with chronic disabilities. Based on our set of analyses using the evLY, a threshold of $84,000 per evLY gained would be needed to maintain alignment with a threshold of $100,000 per added QALY. The evLY is a measure of health gain that can be used as an alternative or a complement to the QALY to address concerns related to undervaluing treatments that extend the life of individuals with serious illness or chronic disability. We recommend that it be reported within all cost-effectiveness analyses but may have special relevance in the current political environment in the USA, where use of the QALY is often challenged or prohibited.

Key Points for Decision Makers

The equal value life-year is introduced in this article as an alternative or a complementary measure to the quality-adjusted life-year.

In addition to providing readers with a description and tool that demonstrates one approach to estimating the equal value life-year, this article also provides rationale and experiences in using the equal value life-year for health technology assessment.

As a measure of health gained, the equal value life-year may have special relevance for US policy making.

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1 Introduction

The International Society for Pharmacoeconomics and Outcomes Research Task Force and the Second Panel on Cost-Effectiveness in Health and Medicine agree that quality-adjusted life-year (QALY) estimates serve as a preferred measure of health gain to inform medical policy decisions [1, 2]. The QALY is a standard for measuring how well different types of medical treatments lengthen and/or improve patients' lives, and therefore the metric has served as a mainstay of cost-effectiveness analyses in the USA and around the world for more than 30 years. No measure of health gain is without limitations [3], however, and one notable concern regarding the QALY is that it can be viewed as "undervaluing" the health gain of life extension for people with serious illness or chronic disability [4]. Assigning a utility weight to extended life for some people, such as those with disabilities, that is lower than the weight assigned for others raises serious questions of whether cost effectiveness may be discriminatory [5]. This concern has been central in leading to legislative restrictions on use of QALY-based analyses within the Medicare program in the recent opportunity to negotiate drug prices based on the US Inflation Reduction

Act [6], and has negatively colored the active debate on whether a cost-effectiveness analysis should play any role in informing policies on drug pricing and coverage [7].

There is a long history of proposals of alternative measures of utility or health gain that might address concerns over the lower valuation of extended life in lower utility health states [4, 8–11]. Life-years gained is often included in the results of cost-effectiveness analyses. This measure is not open to critique based on weighting life extension differentially, but it usually does not serve as the primary measure of health gain given that it does not reflect differences in quality of life due to improvements or decrements caused by an intervention.

One important effort to designate an alternative measure to address disability discrimination concerns was that of Nord et al., who more than 20 years ago developed the "equal value of life" measure in which any extension of life attributed to an intervention is valued at a quality-of-life weight of 1, or ideal health [12]. This measure did not gain widespread use, perhaps because of the perceived limitation that a valuation of extended life as being in perfect health would skew cost-effectiveness results too far from the consistent utilitarian results based on the QALY. Since Nord et al.'s efforts, most approaches to addressing discrimination concerns regarding the QALY have emphasized the role that deliberative processes should play in integrating important social values into any application of cost effectiveness to public policy. However, in 2019, facing consistent criticisms of the QALY from some patient groups and policymakers, we developed a quantitative variation of Nord et al.'s methodology that we have named the equal value life-year (evLY) [13].

The evLY, like the QALY, captures relative effects of different treatment options on improvements or decrements in quality of life. Like Nord et al.'s earlier approach, the key difference between the evLY and QALY is that the evLY assigns a single uniform utility to any extended life provided by an intervention compared to its comparator. But, as will be described in detail below, unlike Nord et al. we do not assign a utility of perfect health to time during life extension. Instead, we use a population-based utility average that we believe creates a more realistic measure for valuing extended life in health states reflecting chronic disability. Using this average utility also moderates the divergence of the findings on health gain between an evLY-based analysis and one based on the QALY, allowing for evLY-based results to be used as complementary to QALY-based analyses or as a full replacement when desired or required. In either role, the evLY provides cost effectiveness with a measure that can assure patients and other stakeholders that the chance to extend life for patients—whether they are individuals with cancer, multiple sclerosis, diabetes mellitus, epilepsy, or a severe lifelong disability—will be valued equally for all. No individual's treatment, and no individual's life, will be "discounted" or "undervalued." The evLY measure is not without limitations that will be explored in this article, including not reflecting the preferences expressed by society in the assignment of an average utility during periods of life extension.

The goal of this article is to describe the evLY measure, analyze its potential limitations, and present our empirical and policy experience related to its use over the past 3 years. We first share the mathematical definition of incremental QALYs, incremental evLYs, and compare them. We follow with a hypothetical case that visually demonstrates the differences between incremental QALYs and evLYs. Then, we share recommended steps for calculating evLYs, along with a downloadable tool for estimating the evLY, and present empirical case studies using incremental evLYs as compared to QALYs. Finally, we analyze the strengths and limitations of the evLY, including questions related to the impact of using the evLY on appropriate cost-effectiveness thresholds.

2 Mathematical Definitions of Incremental QALYs and evLYs

First, consistent with convention, we define

$$\Delta\text{QALY} = \sum\nolimits_t \left(S_{1t} * Q_{1t}\right) - \sum\nolimits_t \left(S_{0t} * Q_{0t}\right), \tag{1}$$

where S is survival, Q is utility, t is the time periods through death, 0 is the "comparator", and 1 is the "intervention"

Assume that $S_{1t} \geq S_{0t}$ for all t

Then, subtracting and adding the same term in bold:

$\Delta\text{QALY} = \sum_t \left(S_{1t} * Q_{1t}\right) - \sum_t \left(S_{0t} * Q_{1t}\right) + \sum_t \left(S_{0t} * Q_{1t}\right) - \sum_t \left(S_{0t} * Q_{0t}\right)$ reduces to

$$\Delta\text{QALY} = \sum_t Q_{1t}\left(S_{1t} - S_{0t}\right) + \sum_t S_{0t}\left(Q_{1t} - Q_{0t}\right). \tag{2}$$

Further, we define:

$$\Delta evLY = \sum_t Q_t(S_{1t} - S_{0t}) + \sum_t S_{0t}\left(Q_{1t} - Q_{0t}\right). \tag{3}$$

Incremental evLYs (3) assign a treatment's gains in quality of life during S_0 just as incremental QALYs (2) do in that $\sum_t S_{0t}\left(Q_{1t} - Q_{0t}\right)$ remains part of the evLY formula. Incremental evLYs evenly measure each length of life unit gain regardless of the treatment or condition. Therefore, in the above incremental QALYs formula, $\sum_t Q_{1t}\left(S_{1t} - S_{0t}\right)$ changes in the evLY definition by fixing Q_1 to equal one and only one value. In other words, any treatment that adds a year of life has the same incremental evLYs—whether that treatment is for a condition with high underlying health status or for a condition associated with an underlying chronic disability.

In contrast to Nord et al.'s framework in which extended life receives a health-related quality-of-life utility weight of $Q_t = 1.0$ [4], we have opted to assign a utility of 0.851 to Q_t, reflecting the average utility of the general US adult population. The 0.851 utility weight was taken from a sample of 1134 US adults representative of the US general adult population based on age, gender, race, and ethnicity [14]. We recommend a population average rather than an age-specific or sex-specific estimate to promote uniformity across all populations, regardless of disease, age, sex, or other characteristics. We now move to compare the incremental evLY to the incremental QALY by subtraction.

Given cancellations,

$\Delta\text{evLY} - \Delta\text{QALY} = \sum_t \left(0.851 - Q_{1t}\right) * \left(S_{1t} - S_{0t}\right)$,
which is simplified as

$$\Delta\text{evLY} - \Delta\text{QALY} = \left(0.851 - Q_1\right)\Delta S. \quad (4)$$

As we see from the above comparison (4), when there is no difference in life-years between the intervention and comparator, ΔS equals 0 and there is no difference between incremental evLYs and QALYs. When $\Delta S > 0$, then incremental evLYs are larger than incremental QALYs provided $0.851 > Q_1$, where 0.851 represents the mean utility weight for the general adult US population and Q_1 represents the average utility weight for the intervention treated population during the life extension. For most severe conditions, Q_1 is lower than the general adult US population value, suggesting that in most (but not all) cases, incremental evLYs will be greater than incremental QALYs.

3 Visual Example: QALY Gains and evLY Gains

We provide below a hypothetical case study as the basis of a visual representation of the comparison between incremental evLYs and incremental QALYs. We assigned a hypothetical homogenous cohort that all had the same disease where usual care (i.e., comparator) is characterized by the average person in the cohort living an additional 7.0 years at a utility value of 0.5 over this time (Fig. 1). An intervention plus usual care is shown to improve the average person's survival by 2.0 years for a total of 9.0 life-years while also improving the average person's health-related quality of life utility by 0.20 to an estimated utility of 0.70 over this time. The incremental life-years are computed as 9.0 − 7.0 = 2.00 life-years gained. The incremental QALYs are computed as (B + C) – (A) = (7 * 0.7 + 2 * 0.7) – (7 * 0.50) = 2.80 QALYs gained. The incremental evLYs are computed as (D + E) – (A) = (7*0.7 + 2 * 0.851) – (7 * 0.50) = 3.10 evLYs gained. In this hypothetical example, the average person in the cohort achieves higher incremental evLYs versus incremental QALYs given that the intervention's utility during the life extension was less than 0.851, namely 0.70. Using the difference in incremental evLYs and incremental

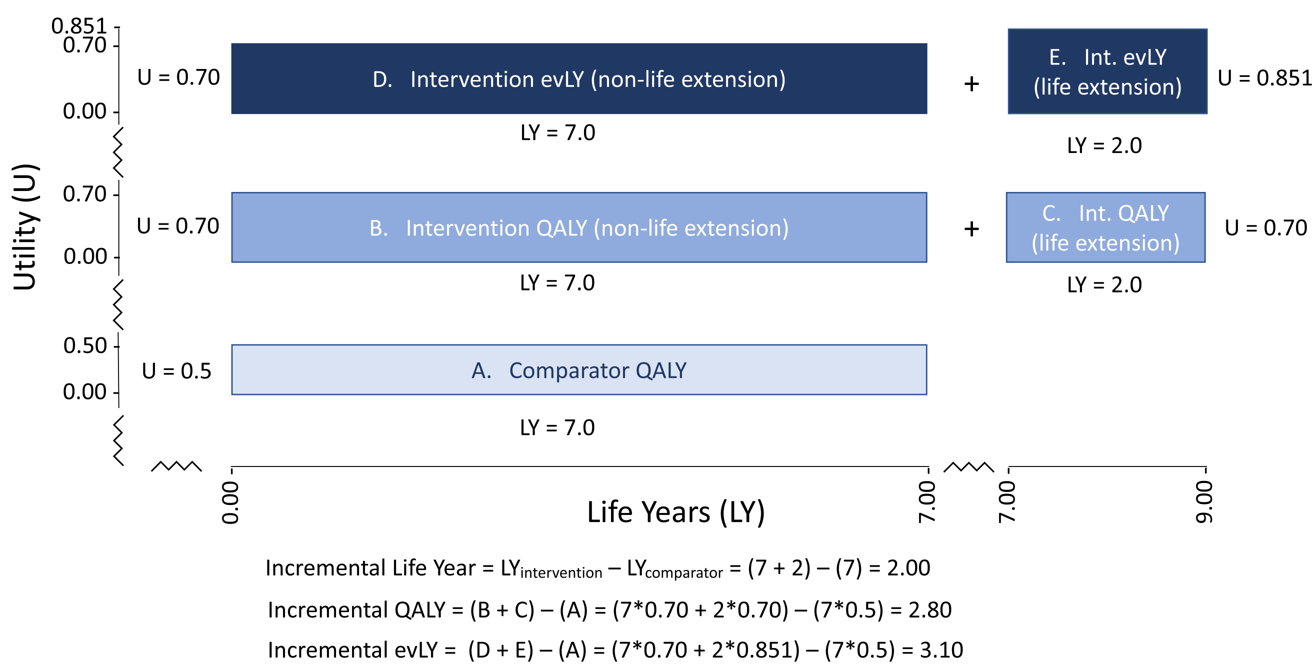

Fig. 1 Case study display of incremental life-years, quality-adjusted life-years (QALYs), and equal value life-years (evLYs) [intervention vs comparator] *Int.* intervention

QALYs equation (4), we see that indeed, (0.851 − 0.70) * 2 years = 0.30 rounded units, which is equal to the area in E–C in Fig. 1 and confirmed by the difference between 3.10 incremental evLYs and 2.80 incremental QALYs.

4 Recommended Steps in Estimating evLYs

4.1 How to Estimate the evLY

Like existing measures of health including life-years and QALYs, evLYs are estimated separately for each treatment strategy (e.g., intervention and comparator), although the measurement of the evLY for the intervention is dependent on the measurement of the evLY for the comparator. When the intervention does not extend life, incremental evLYs and incremental QALYs are identical. Note that if more than one comparator exists, then the one with the fewest life-years (frequently “standard of care”) should be selected as the anchor comparator for all comparisons in order to estimate an intervention’s life extension and corresponding evLYs. As with any assessment, selection of any/all comparators must be justified using clinical and ethical considerations so as to not purposefully game the estimate of incremental evLYs by way of comparator choice.

For the intervention, the evLY is different from the QALY if the intervention is associated with life extensions beyond that of the primary comparator. Because life extension can vary over periods of time (e.g., model cycles), the evLY is estimated for each period of time within the modeled population (e.g., model cycle for the whole population) and then summed across the time horizon. For each model cycle with positive life-years versus the primary comparator, the evLY can be computed by multiplying the life-years shared between the intervention and comparator by the average intervention utility plus the life extension life-years multiplied by the representative utility value (0.851) [14]. If the intervention time period does not have greater life-years than the comparator, then the intervention’s evLY is equivalent to the intervention’s QALY for that time period. The calculation for each time period where the intervention’s life-years > comparator’s life-years is as follows:

$$\begin{aligned}\text{evLY} &= \text{comparator life-years} * \text{intervention average utility} \\ &\quad + (\text{intervention life-years} - \text{comparator life-years}) * 0.851.\end{aligned}$$

The next step is to estimate the intervention’s evLY across the stated time horizon by summing across all time periods. The evLY can be discounted using standard practices. The evLY gained can then be computed by subtracting the comparator’s evLY (equivalent to the QALY for the primary comparator) from the estimated intervention’s evLY.

4.2 Open Access evLY Tool

Readers can refer to a sample decision-analytic model to gain understanding as to how one can measure the evLY within a Markov model framework (Electronic Supplementary Material). Users may follow the “how to calculate the evLY” steps alongside this sample model to enhance their understanding of how they will measure the evLY for their own applications. The sample model includes a hypothetical intervention with a life extension over a hypothetical comparator. Within the spreadsheet, components necessary for the calculation of the evLY and incremental evLYs are highlighted blue. This includes the 0.851 value on the Inputs tab and the columns for undiscounted and discounted evLYs within each modeled trace. Within the Comparator Trace tab and the Intervention Trace tab, the column for undiscounted evLYs (column K) applies the equations presented within this section of the article to calculate the evLY for the intervention and comparator.

4.3 Strengths and Limitations of the evLY

Using an average utility of 0.851 for all time in extended life shares the benefit with Nord et al.’s original approach of eliminating the perceived undervaluation of extended life for patients with chronic disabilities. However, in relation to assuming that extended life should be valued as if it were spent in “perfect health,” using the average population utility has the added benefit that it is a closer approximation to the relative value that community respondents would assign to extended life in relation to quality of life. By remaining closer to the community weighting of these trade-offs, the evLY produces results that are more feasible for use as a true alternative to the QALY and not just as a complementary measure meant to provide additional perspectives on how to value health gain. Therefore, a key strength of the evLY is its ability to measure improvements in quality of life during non-life-extending periods while also applying the same weight to each unit of life extension.

There are notable challenges with the evLY measure. First, as discussed previously, use of the evLY creates a systematic shift that almost always produces improved incremental cost-effectiveness results compared with QALY-based analyses. The implications of this shift and its relationship to cost-effectiveness thresholds are addressed in the subsequent sections. Second, the evLY does not distinguish between two interventions that behave the same during periods prior to life extension, but during life extension, have different quality-of-life profiles. This limitation is a trade-off related to what some consider as a positive aspect of the evLY; namely, the evLY applies the same weight to each unit of life extension. Finally, in extreme cases, the evLY can have circularity challenges if used as the sole measure for treatment adoption recommendations [15].

This circularity problem only occurs when there is a sign difference between incremental QALYs and incremental evLYs. If an intervention is associated with added years of life, most likely it will be associated with added QALYs (i.e., positive incremental QALYs). However, there is a potential that an intervention could extend life but still be associated with negative overall incremental QALYs because of a reduced quality of life before the period of life extension that offsets any QALY gains in the period of life extension. It is therefore highly unlikely but theoretically possible that an intervention would produce positive incremental evLYs but negative incremental QALYs leading to potential circularity if only evLYs were used to recommend treatment strategies. Take standard of care A versus a new intervention B where A is associated with 20 life-years and a utility of 0.9 over all time and where B is associated with 22.4 life-years and a utility of 0.8 over all time. In this simplified example, B > A on life-years (22.4 > 20 life-years), A > B on QALYs (20 * 0.9 > 22.4 * 0.8), but B > A on evLYs (20 * 0.8 + 2.4 * 0.851 > 20 * 0.9). If one were to only use evLYs within an adoption decision rule, one would choose B over A. Assume the same treatments but that A is the new intervention and B is the standard of care. There is no life extension for A versus B so A > B on QALYs and evLYs (20 * 0.9 > 22.4 * 0.8 for both QALYs and evLYs). In this situation, one would choose A over B when using either evLYs or QALYs (i.e., circularity based on what treatment strategy is deemed the comparator versus the intervention of interest).

To resolve this theoretical circularity concern, we continue to recommend that both the evLY and QALY measures be reported in analyses, but we suggest caution interpreting findings in the rare but theoretically possible situations where there are directional differences between incremental QALYs and evLYs. In these situations, we suggest more weight on deliberative processes, contextual considerations, and incremental costs to help support population-level value assessment decisions. When directional differences exist, this caution in interpreting findings will limit the potential circularity concerns of incremental evLYs if this measure were otherwise solely used to support changes to the adoption or reimbursement of the intervention.

5 Experience Across US Assessments with Incremental QALYs and evLYs

From September 2019 to November 2021, we reported evLY results as part of value assessments of 11 US Food and Drug Administration-approved drugs, consisting of 32 unique intervention versus comparator dyads. The majority (66%) of the intervention dyads had incremental evLYs that were greater than incremental QALYs, while 34% had incremental evLYs equal to the incremental QALYs. None of the intervention dyads observed in our dataset had incremental evLYs that were less than incremental QALYs, although this is theoretically possible provided the utility value during life extensions for the intervention is on average, greater than 0.851 (refer to the mathematical formula in the prior section).

The mean percentage change between an intervention dyad's incremental QALYs and incremental evLYs was 16%. The percentage change between incremental evLYs and incremental QALYs for each intervention dyad are reported in Fig. 2. Because of no life extension, there were no differences in incremental evLYs and incremental QALYs for the first 11 treatment pairs presented in the table. In the 21 interventions for which the evLY > QALY, where incremental evLYs were greater than the incremental QALYs, the average percentage change between incremental evLYs and QALYs was 25%, with the greatest percentage difference found for treatments for sickle cell disease.

At the condition level, averaging across treatment dyads within a condition, the average percentage change between incremental evLYs and incremental QALYs was similar at 17%. Figure 3 below displays the percentage change between the incremental evLYs and incremental QALYs at the condition level. For conditions where the treatments evaluated did not generate a life extension, incremental evLYs were equivalent to incremental QALYs.

6 Discussion

Each measure of health comes with its own set of trade-offs. The limitations of the QALY are well established [4, 5], yet its comprehensiveness, its rooting in decades of psychometric and other research, and its clear and consistent ability to capture trade-offs between quality and length of life have sustained its use as the dominant measure of health gain in cost-effectiveness research. We argue that cost-effectiveness practitioners are more willing to entertain alternative measures of health that correlate well with the desirable features of the QALY while addressing specific concerns such as the risk of undervaluing extension of life in certain circumstances. The evLY is one method to address this risk and avoid what can be seen by many as a discriminatory effect on treatments for people living with chronic disabilities. The evLY is able to capture changes in quality of life from treatment, whether it be changes due to improvements in function or differences in relative side effects. It can also distinguish between treatments that have different effects on length of life. While it may obscure some relative differences between treatments in quality of life during any period of life extension, the advantage gained is important: with the evLY there is equal weighting of utilities for extended life, eliminating

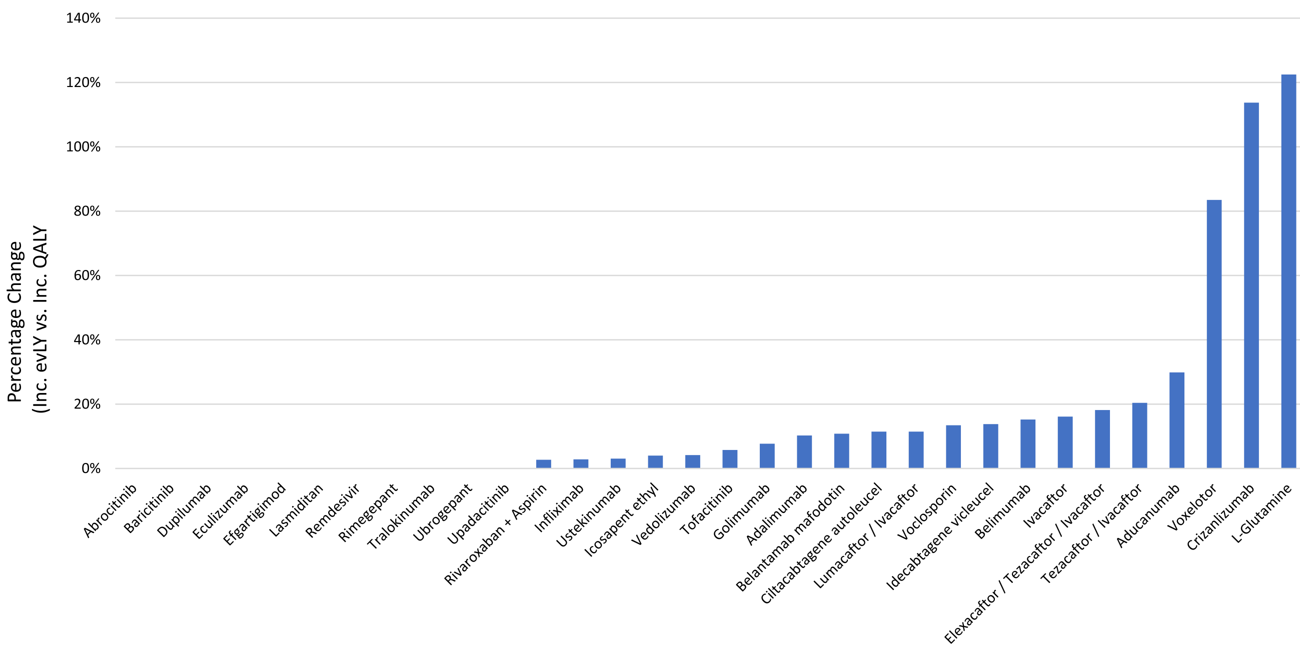

Fig. 2 Percentage change between incremental equal value life-years (evLYs) and incremental quality-adjusted life-years (QALYs), treatment level. *Inc.* incremental

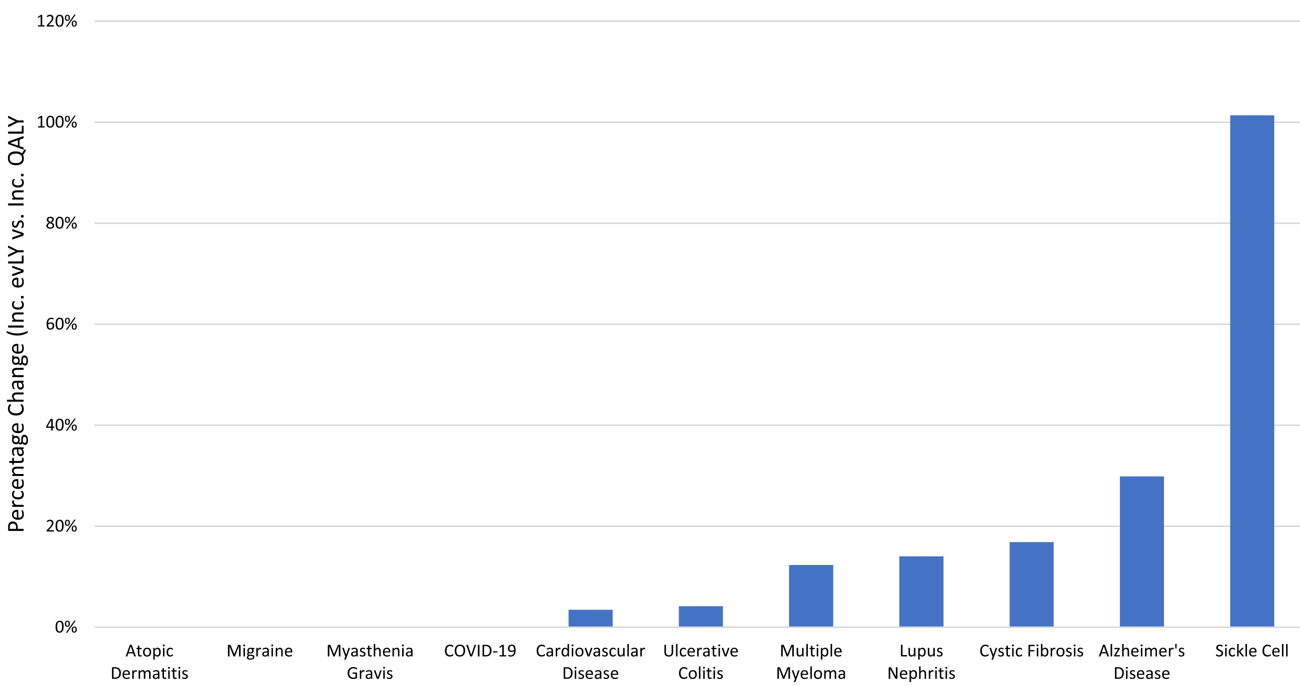

Fig. 3 Percentage change between incremental equal value life-years (evLYs) and incremental quality-adjusted life-years (QALYs), condition level. *COVID-19* coronavirus disease 2019, *Inc.* incremental

the differential weighting by utility that makes it reasonable to view the QALY as a potentially discriminatory measure when evaluating life-extending treatments for people with disabilities or people who will live longer albeit with a lower quality of life [4, 5].

Lessons learned from cost-effectiveness analyses that include both incremental evLYs and QALYs suggest that directional differences between the two measures are not common (none were observed over 32 unique comparisons assessed). As noted, on average, we found that incremental evLYs are 16% higher than incremental QALYs across a wide range of condition scenarios. If a strict opportunity cost paradigm based on previous cost-effectiveness research using the QALY is used to consider appropriate cost-effectiveness thresholds for decision making, the introduction of the evLY would imply the need to shift to approximately 16% lower thresholds.

However, given the uncertainty inherent in most cost-effectiveness analyses, we believe it is not unreasonable to maintain current cost-effectiveness thresholds when reporting and interpreting results based on the evLY. As with all cost-effectiveness analyses, context matters, and in some cases with many additional life-years gained, results based on the evLY may differ so substantially from those using the QALY that decision makers should be actively encouraged to consider the different perspectives on valuing extended life that are reflected by each measure of health gain. The interpretation of differences between evLY and QALY results should also be the subject of further study and debate through theoretical and empirical research.

Another recent effort to address discrimination concerns [4, 5] regarding the QALY was the introduction of the health years in total (HYT) measure by Basu and colleagues [16]. The HYT departs from the evLY in taking an additive approach to life expectancy and quality-of-life impacts. In taking this additive approach, the HYT requires the estimation of a counterfactual quality of life during any life extension to match the maximum life extension across all considered treatment strategies. Although the HYT fully resolves the QALY concern related to valuing treatments differently based on the underlying health functioning of the population during life extensions, barriers may remain to its widespread use in a health technology assessment. Basu and colleagues discuss how this additive measure will require substantial, and currently hypothetical, modifications to thresholds when interpreting the findings of incremental HYTs versus incremental QALYs [16]. More research is needed within the cost-effectiveness threshold domain for all alternative measures of health gained [17].

Ultimately, both our conceptual analysis of the evLY and our experience in using it in multiple health technology assessment reports suggest that it can play a useful role to inform decision making. Unlike the QALY, the evLY has not been rejected by disability community advocates and policymakers [18]. In public deliberative meetings on the results of ICER reports, the evLY results have been accepted and proven helpful in assuring all stakeholders that results obviate the concern about undervaluing the extension of life of patients. We have chosen to frame our “health benefit price benchmark” ranges using the lowest price at $100,000 per QALY or evLY gained (to date always cost/QALY), and the highest of the prices at $150,000 (to date always cost/evLY). Providing a price benchmark between the lowest and highest prices has led to broader ranges, but it has usefully incorporated the idea that decision makers may consider both results when making a broader determination of value.

The answer to the question of whether the evLY should be an additional complementary measure of health gain or should serve as a stand-alone alternative to the QALY must be determined by the context in which cost effectiveness will be integrated into decision making. From a conceptual and academic perspective, it makes good sense to view it as complementary. No known measure of health gain addresses all the QALY criticisms while retaining all the advantageous features of the QALY, thus suggesting measurement trade-offs [19]. The ability to compare results across previous research, combined with the possibility that evLYs could on occasion provide results not consistent with patient or community views on the trade-offs between the length of life and quality of life, suggest that decision makers would do well to view QALY-based and evLY-based results together, exploring any substantial differences to understand why they exist and what they might mean for any priority setting or pricing decisions.

In contrast, in jurisdictions in which the QALY has become “toxic” to stakeholders owing to its differential valuation of life extension for people living with chronic disability versus people living otherwise healthy [16], we believe the evLY is a robust alternative that can suffice to inform decision making. Any measure of health gain, within any formal cost-effectiveness analysis, should be integrated with formal considerations of contextual issues and potential benefits or disadvantages that cannot be captured adequately within any model. However, by design and through experience, we believe that the evLY should gain an important role in cost-effectiveness analyses directed at informing health system decisions.

7 Conclusions

The evLY is a measure of health gain that can be used as an alternative or a complement to the QALY to address concerns related to undervaluing treatments that extend the life of individuals with serious illness or chronic disability. We recommend that it be reported within all cost-effectiveness analyses but may have special relevance in the current political environment in the USA, where use of the QALY is often challenged or prohibited.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s40273-023-01302-6.

Acknowledgements The authors acknowledge Marina Richardson for analytic support included within this article.

Declarations

Funding All authors were employees of The Institute for Clinical and Economic Review (ICER) during the contributions made to this manuscript. The research represented within this article is not grant funded, but is aligned with ICER's work. Please see the ICER's website for information on funding that supports the salaries of all ICER employees.

Conflict of interest Jonathan D. Campbell, Melanie D. Whittington, and Steven D. Pearson have no conflicts of interest that are directly relevant to the content of this article.

Consent to participate Not applicable.

Consent for publication Not applicable.

Availability of data and material This article has data included as Electronic Supplementary Material

Code availability The source code is included as Electronic Supplementary Material.

Author contributions All authors meet the International Committee for Medical Journal Editors authorship criteria. All authors have read and approved the final version of this manuscript.

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