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Methodology

## Logical Inconsistencies in the Health Years in Total and Equal Value of Life-Years Gained



Mike Paulden, PhD, Chris Sampson, PhD, James F. O'Mahony, PhD, Eldon Spackman, PhD, Christopher McCabe, PhD, Jeff Round, PhD, Tristan Snowsill, PhD

### ABSTRACT

**Objectives:** This study aimed to assess whether recently proposed alternatives to the quality-adjusted life-year (QALY), intended to address concerns about discrimination, are suitable for informing resource allocation decisions.

**Methods:** We consider 2 alternatives to the QALY: the health years in total (HYT), recently proposed by Basu et al, and the equal value of life-years gained (evLYG), currently used by the Institute for Clinical and Economic Review. For completeness we also consider unweighted life-years (LYs). Using a hypothetical example comparing 3 mutually exclusive treatment options, we consider how calculations are performed under each approach and whether the resulting rankings are logically consistent. We also explore some further challenges that arise from the unique properties of the HYT approach.

**Results:** The HYT and evLYG approaches can result in logical inconsistencies that do not arise under the QALY or LY approaches. HYT can violate the independence of irrelevant alternatives axiom, whereas the evLYG can produce an unstable ranking of treatment options. HYT have additional issues, including an implausible assumption that the utilities associated with health-related quality of life and LYs are “separable,” and a consideration of “counterfactual” health-related quality of life for patients who are dead.

**Conclusions:** The HYT and evLYG approaches can result in logically inconsistent decisions. We recommend that decision makers avoid these approaches and that the logical consistency of any approaches proposed in future be thoroughly explored before considering their use in practice.

**Keywords:** decision making, discrimination, economic evaluation, methods, policy, quality-adjusted life-year.

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### Introduction

The quality-adjusted life-year (QALY) is a widely used measure in health economic evaluation, which quantifies health gains from interventions in terms of their effects on both survival and health-related quality of life (HRQoL). The strengths and limitations of the QALY approach have been widely discussed previously.<sup>1–3</sup> A specific characteristic of the QALY approach frequently cited by critics is that a life extension for a person with poor HRQoL (eg, because of a disability) generates fewer QALYs than an equivalent extension of life for a person with good HRQoL.<sup>4,5</sup> This perceived potential for discrimination has resulted in many legislative bodies in the United States putting limits on the use of the QALY for resource allocation purposes.<sup>6,7</sup>

Alternative measures, which aim to capture the desirable aspects of QALYs without these potentially discriminatory features, have been proposed.<sup>8</sup> The “equal value of life-years gained” (evLYG), a recent modification of an approach originally proposed by Nord et al,<sup>9</sup> assigns equal value to life extensions of similar

length, compared with current treatment, regardless of the associated HRQoL.<sup>10</sup> An important limitation of the evLYG approach is that it assigns no additional value to health technologies that also improve HRQoL during the period of life extension; therefore, the use of the evLYG to support pricing or reimbursement decisions would not incentivize manufacturers to develop technologies that both extend the lives and improve the HRQoL of those with poor baseline HRQoL, including disabled patients, relative to technologies that extend life only.<sup>8</sup>

Recently, Basu et al<sup>11</sup> proposed a new approach called “health years in total” (HYT), which modifies the QALY and combines it with life expectancy into a single metric. The authors claim that HYT overcome both of the issues identified earlier, and “may provide a viable alternative to both the QALY and the [evLYG].”

These newer approaches have attracted some attention. In the United States, the Institute for Clinical and Economic Review (ICER) now considers the evLYG in its published reports alongside the QALY.<sup>9,12</sup> In the United Kingdom, the National Institute for Health and Care Excellence has actively considered whether the

evLYG or HYT would be a more suitable approach than the QALY.<sup>13</sup> The article by Basu et al<sup>11</sup> proposing the HYT approach was awarded the 2021 “Paper of the Year” by *Value in Health*.<sup>14</sup>

In this article, we critically appraise these new alternatives to the QALY, with a particular focus on whether they are logically consistent. We consider how the necessary calculations are performed under each approach and whether the resulting rankings of treatments and comparators satisfy some basic tenets of rational choice theory. We also explore some further challenges that arise from the unique properties of the HYT approach.

### Hypothetical Example

Throughout this article, we illustrate our findings using a simple hypothetical example. Table 1 and Figure 1 present the survival (life expectancy) and HRQoL for each of 3 hypothetical, mutually exclusive treatments: X, Y, and Z.

In this example, we assume that there is no uncertainty, variation, or heterogeneity associated with the survival and HRQoL for each treatment. We also assume that HRQoL is constant for the entire survival period. These assumptions simplify the calculation and interpretation of each approach, without materially affecting our findings.

To explore the unique dynamics of the HYT and evLYG approaches, we assume that treatment Z, with the greatest survival, becomes available sometime after treatments X and Y. This will allow us to consider the implications of (1) changes in what is considered “current treatment” and (2) the availability of a new treatment that provides greater survival than existing treatments.

### Calculations

We will begin by calculating the QALYs, life-years (LYs), evLYG, and HYT for each of the treatments in our example, in each of 2 scenarios: (1) before the availability of treatment Z and (2) after treatment Z becomes available. We will use these calculations later to illustrate our findings.

#### QALYs

The QALYs for each of treatments X, Y, and Z are represented by the area of the shaded region for each treatment in Figure 1. The highest ranked option is treatment Y. Note that whether or not treatment Z is available makes no difference to the QALYs for treatments X and Y.

#### LYs

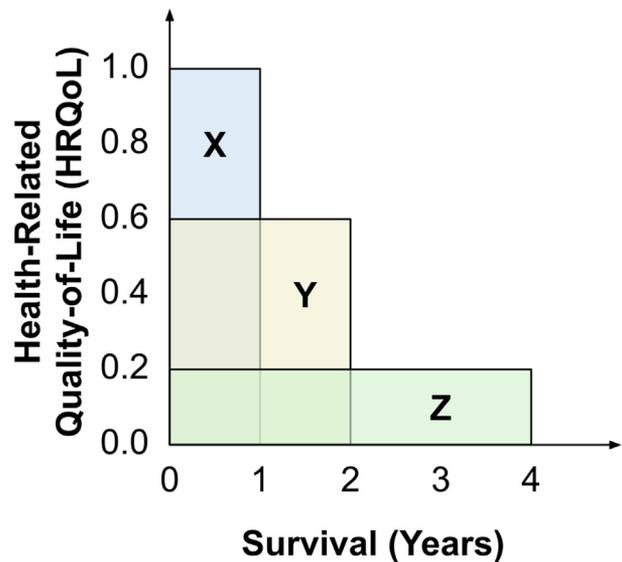
The LYs for each of treatments X, Y, and Z are represented by the width of the shaded region for each treatment in Figure 1. Note that treatment Z, which had the fewest QALYs, is now the highest ranked option. This is because the lower HRQoL with treatment Z is not taken into account under the LYs approach. In common with

**Table 1.** Survival and HRQoL for each of 3 hypothetical treatments: X, Y, and Z.

Treatment	Survival	HRQoL
X	1 year	1.0
Y	2 years	0.6
Z	4 years	0.2

HRQoL indicates health-related quality of life.

**Figure 1.** Survival and HRQoL for each of 3 hypothetical treatments: X, Y, and Z.



QALYs, the availability of treatment Z makes no difference to the LYs associated with X and Y.

#### evLYG

The evLYG is a modification of an approach originally proposed by Nord et al.<sup>9,15</sup> For the evLYG approach, the HRQoL associated with each treatment option is used to value any survival duration up to that associated with current treatment, such that this period of time is valued the same as under the QALY approach. For survival beyond that provided by current treatment (ie, the “life-years gained”), the decision maker applies its own value in place of the HRQoL actually experienced by patients. This value is equal for all treatment options; thus, this period of time is valued using “equal-valued life-years” (evLYs).

The evLYG for each treatment option comprises the sum of (1) the QALYs experienced during the period of survival with current treatment and (2) any evLYs that arise beyond this time period. Unlike the QALY, the evLYG depends upon which treatment option is considered current treatment, its corresponding survival, and the value applied to life-years gained.

Nord et al<sup>9</sup> proposed that “for chronically ill or disabled people a life year gained should count as one and no less than one as long as the year is considered preferable to being dead by the person concerned.” In other words, the value applied to life-years gained should be 1 (equivalent to perfect health), except in cases where the patient would prefer to be dead. ICER’s implementation of the evLYG modifies this approach by instead considering the value applied to life-years gained to be the “value of a healthy life,” which may be lower than 1.<sup>12</sup> For the purposes of our example, we will use a value of 0.85, approximating that used in recent analyses by ICER.<sup>16</sup>

#### Scenario 1: Treatment Z is not available

**X is current treatment.** First, suppose that treatment Z is not available and that treatment X is the current treatment. Given that survival with treatment X is 1 year, the first year of survival for treatments X and Y is valued using QALYs. The additional year of survival provided by treatment Y is then valued using evLYs, based on an equal value of 0.85 for all LYs gained.

The evLYG for each treatment is presented in Table 2. We also plot these on a bar chart in Figure 2A, where the vertical axis represents the evLYG for each treatment. Given that the QALYs and evLYs components are summed, these are stacked. The QALYs in this figure are calculated over the first year only, whereas evLYs are calculated from year 2 onward.

**Y is current treatment.** Next, suppose that treatment Y is current treatment, rather than treatment X. Given that survival with treatment Y is 2 years, the first 2 years of survival for both treatments are now valued using QALYs. No treatment provides survival beyond 2 years, so no evLYs are considered.

The evLYG for each treatment is presented in Table 3 and plotted in Figure 2B. Note that treatment X is unaffected by the change in current treatment from treatment X to Y, given that it has the shortest survival and so is always valued using QALYs only. However, the evLYG for treatment Y falls from 1.45 to 1.2, given that year 2 is now valued using QALYs, rather than evLYs.

### Scenario 2: Treatment Z is available

**X is current treatment.** Now suppose that treatment Z is available and that X is current treatment. Given that survival with X is 1 year, the first year of survival for every treatment is valued using QALYs, and then survival beyond 1 year for every treatment is valued using evLYs.

The evLYG for each treatment is presented in Table 4 and plotted in Figure 2C. Note that the availability of treatment Z has not affected the evLYG for treatments X and Y, which remain the same as in Table 2 and Figure 2A.

**Y is current treatment.** Next, suppose that treatment Y is current treatment. Given that survival with Y is 2 years, the first 2 years of survival for every treatment are now valued using QALYs, and then survival beyond 2 years for every treatment is valued using evLYs.

The evLYG for each treatment is presented in Table 5 and plotted in Figure 2D. Although treatment X (with the shortest survival) remains unaffected by the change in current treatment, the evLYG falls for each of treatments Y and Z because year 2 is now valued using QALYs, rather than evLYs.

Note that the availability of treatment Z has again not affected the evLYG for treatments X and Y, which remain the same as in Table 3 and Figure 2B.

**Z is current treatment.** Finally, suppose that treatment Z is current treatment. Given that survival with treatment Z is 4 years, the first 4 years of survival for every treatment are now valued using QALYs. This is a general result: wherever the treatment with the longest survival is considered current treatment, the QALY and evLYG approaches are equivalent.

The evLYG for each treatment is presented in Table 6 and plotted in Figure 2E.

## HYT

Basu et al<sup>11</sup> state that the HYT approach is "... built on the notion that life-years gained provide distinct utility to individuals from the [HRQoL] gains and that these utilities are separable in nature."

This separability assumption results in QALYs and LYs being considered independently. Furthermore, the QALYs considered are described by Basu et al<sup>11</sup> as "modified" from standard QALYs; they cannot be calculated in the conventional way (ie, by multiplying HRQoL by the corresponding survival) because the value of this survival is assumed to be independent of the HRQoL. Instead, the HRQoL for each treatment option is considered "... over a time period corresponding to the maximum survival under any given alternative."

Given that patients receiving any treatment other than that with maximum survival would die before reaching the end of this time period, Basu et al<sup>11</sup> introduce what they refer to as a "counterfactual" HRQoL, which is considered during the postdeath period, for all treatments with shorter than the maximum survival, up to the point in time where patients would otherwise have died when receiving the treatment offering maximum survival.

For ease of comparison with the other approaches considered in this article, we disaggregate these modified QALYs into 2 components:

1. "QALYs," which are the standard QALYs calculated earlier, based on the HRQoL and survival that are experienced by patients when provided with the treatment option in question
2. "Counterfactual QALYs," which is the term we assign to the remaining component of the modified QALYs considered only under the HYT approach. Counterfactual QALYs are based on the counterfactual HRQoL for the treatment in question after a patient's death and the additional survival provided by whichever other treatment option offers maximum survival. Neither the counterfactual HRQoL nor the additional survival is actually experienced by patients when provided with the treatment option in question, given that the patients are dead during this time period.

The sum of these 2 components corresponds to the modified QALYs referred to by Basu et al.<sup>11</sup> Calculating the HYT for each treatment requires that these, in turn, be added to the (actual) survival (in LYs) associated with the treatment in question.

### Scenario 1: Treatment Z is not available

If only treatments X and Y are available, the maximum survival is 2 years with treatment Y. To calculate the HYT for each treatment, we must therefore consider QALYs and counterfactual QALYs over a total of 2 years and then combine these with the LYs for each treatment:

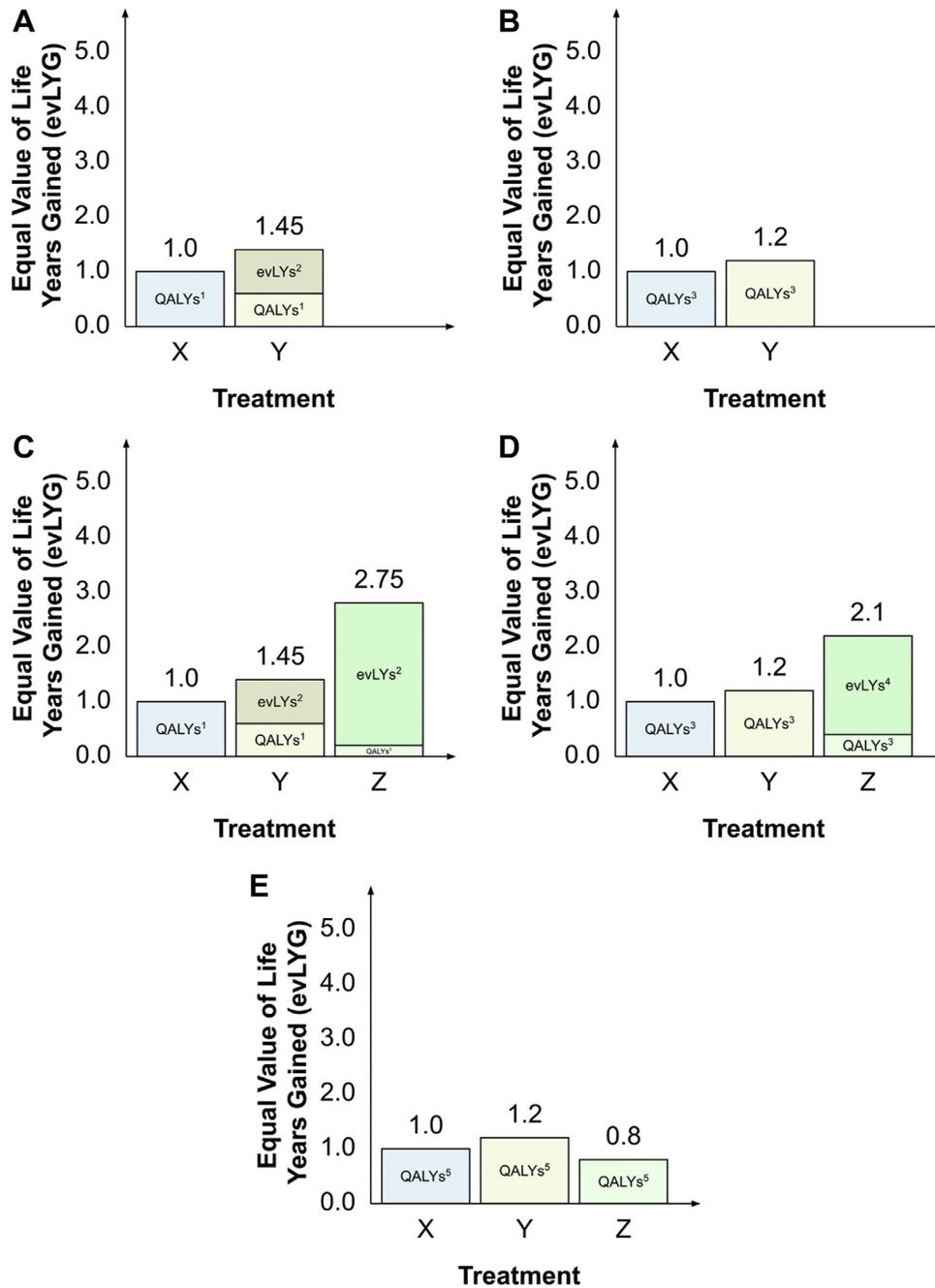
- Treatment X has a survival of 1 year, so we must consider QALYs over this first year only (1.0 QALY, given an HRQoL of 1.0) and counterfactual QALYs over the remaining year

**Table 2.** evLYG for treatments X and Y, assuming treatment Z is not available and treatment X is current treatment.

Treatment	Survival	HRQoL	Value of year 1 (QALYs)	Value of year 2 (evLYs)	evLYG
X	1 year	1.0	1.0	N/A	1.0
Y	2 years	0.6	0.6	0.85	1.45

evLY indicates equal-valued life-year; evLYG, equal value of life-years gained; HRQoL, health-related quality of life; N/A, not available; QALY, quality-adjusted life-year.

**Figure 2.** evLYG for each treatment, assuming (A) treatment Z is not available and treatment X is current treatment; (B) treatment Z is not available and treatment Y is current treatment; (C) treatment Z is available and treatment X is current treatment; (D) treatment Z is available and treatment Y is current treatment; or (E) treatment Z is available and treatment Z is current treatment. Notes: <sup>1</sup>Quality-adjusted life years (QALYs) calculated over year 1 only. <sup>2</sup>Equally-valued life years (evLYs) calculated from year 2 onwards. <sup>3</sup>QALYs calculated over years 1-2 only. <sup>4</sup>evLYs calculated from year 3 onwards. <sup>5</sup>QALYs calculated over all 4 years.



**Table 3.** evLYG for treatments X and Y, assuming treatment Z is not available and treatment Y is current treatment.

Treatment	Survival	HRQoL	Value of year 1 (QALYs)	Value of year 2 (QALYs)	evLYG
X	1 year	1.0	1.0	N/A	1.0
Y	2 years	0.6	0.6	0.6	1.2

evLYG indicates equal value of life-years gained; HRQoL, health-related quality of life; N/A, not available; QALY, quality-adjusted life-year.

**Table 4.** evLYG for each treatment, assuming treatment Z is available and treatment X is current treatment.

Treatment	Survival	HRQoL	Value of year 1 (QALYs)	Value of year 2 (evLYs)	Value of year 3 (evLYs)	Value of year 4 (evLYs)	evLYG
X	1 year	1.0	1.0	N/A	N/A	N/A	1.0
Y	2 years	0.6	0.6	0.85	N/A	N/A	1.45
Z	4 years	0.2	0.2	0.85	0.85	0.85	2.75

evLY indicates equal-valued life-year; evLYG, equal value of life-years gained; HRQoL, health-related quality of life; N/A, not available; QALY, quality-adjusted life-year.

(1.0 counterfactual QALY, given the same HRQoL). Therefore, treatment X is valued at 3.0 HYT, comprising 1.0 LY, 1.0 QALY, and 1.0 counterfactual QALY.

- Treatment Y has a survival of 2 years, so we must consider QALYs over the first 2 years (1.2 QALYs, given an HRQoL of 0.6). Counterfactual QALYs do not need to be considered, given that treatment Y has the maximum survival in this scenario. Therefore, treatment Y is valued at 3.2 HYT, comprising 2.0 LYs and 1.2 QALYs.

These are summarized in Table 7 and plotted in Figure 3A. In this scenario, more HYT are assigned to treatment Y (3.2 HYT) than treatment X (3.0 HYT).

### Scenario 2: Treatment Z is available

After the availability of treatment Z, the maximum survival is now 4 years with treatment Z. Therefore, we must recalculate the HYT for treatments X and Y, considering QALYs and counterfactual QALYs over a total of 4 years, along with the HYT for treatment Z.

These are summarized in Table 8 and plotted in Figure 3B. Note that the ranking of treatments X and Y has changed from that in the first scenario, with more HYT now assigned to treatment X (5.0 HYT) than to treatment Y (4.4 HYT). This change in the ranking of treatments X and Y, after the availability of treatment Z, has important implications that will be considered in the next section.

## Logical Consistency

The treatment option assigned the highest ranking under each approach in our example has been summarized in Table 9 (note that, although in this example the QALY, HYT, and evLYG have the same highest ranked treatment option in Scenario 1, this will not be the case in every example). Two important properties of the QALY and LY approaches are illustrated by this table. First, for any given set of treatment options, the highest ranked treatment is not determined by which is considered current treatment. Second, after the introduction of a new mutually exclusive treatment option (Z), the highest ranked treatment may switch to this new treatment (as it does for the LY in our example), or it may remain

the same as before (as it does for the QALY in our example), but it cannot change to any other treatment option.

As illustrated by Table 9, neither the HYT nor evLYG approach shares both of these properties. We will now consider why this may result in a violation of a fundamental axiom of rational decision making or decision instability.

### Independence of Irrelevant Alternatives (IIA)

#### Background

IIA, often referred to as the “independence” axiom, is a fundamental axiom of rational choice theory.<sup>17</sup> A popular analogy attributed to philosopher Sidney Morgenbesser provides an example of a violation of IIA by an individual<sup>18</sup>:

*After finishing dinner, an individual decides to order dessert. The server offers 2 choices: apple pie and blueberry pie. The individual orders the apple pie. After a few minutes the server returns and says that they also have cherry pie, at which point the individual says, “In that case I’ll have the blueberry pie.”*

More formally, if an individual prefers option A to another option B, then the IIA axiom requires that the introduction of a new mutually exclusive option C does not change the individual’s ranking of options A and B, such that B is now preferred to A.

#### Relevance to social decision making

It is reasonable to expect social decision makers to respect the IIA axiom. Consider the following example, which illustrates a violation of IIA in practice:

*A health technology assessment (HTA) agency considers 2 mutually exclusive treatment options (A and B) for a specific patient population. After reviewing the evidence, the agency recommends that patients receive treatment B. Sometime later, a new mutually exclusive treatment option (C) becomes available. The agency repeats its assessment, this time with all 3 treatments included. The evidence around treatments A and B remains unchanged. The agency rejects treatment C, and switches its recommendation from treatment B to treatment A.*

It is not apparent how an HTA agency (or any other social decision maker) could justify such a change in its recommendation. It would be difficult to specify any rationale, so this would not satisfy the principle of “accountability for reasonableness.”<sup>19</sup>

**Table 5.** evLYG for each treatment, assuming treatment Z is available and treatment Y is current treatment.

Treatment	Survival	HRQoL	Value of year 1 (QALYs)	Value of year 2 (QALYs)	Value of year 3 (evLYs)	Value of year 4 (evLYs)	evLYG
X	1 year	1.0	1.0	N/A	N/A	N/A	1.0
Y	2 years	0.6	0.6	0.6	N/A	N/A	1.2
Z	4 years	0.2	0.2	0.2	0.85	0.85	2.1

evLY indicates equal-valued life-year; evLYG, equal value of life-years gained; HRQoL, health-related quality of life; N/A, not available; QALY, quality-adjusted life-year.

**Table 6.** evLYG for each treatment, assuming treatment Z is available and treatment Z is current treatment.

Treatment	Survival	HRQoL	Value of year 1 (QALYs)	Value of year 2 (QALYs)	Value of year 3 (QALYs)	Value of year 4 (QALYs)	evLYG
X	1 year	1.0	1.0	N/A	N/A	N/A	1.0
Y	2 years	0.6	0.6	0.6	N/A	N/A	1.2
Z	4 years	0.2	0.2	0.2	0.2	0.2	0.8

evLYG indicates equal value of life-years gained; HRQoL, health-related quality of life; N/A, not available; QALY, quality-adjusted life-year.

In practice, manufacturers and other stakeholders would also likely challenge any such change in an agency's recommendations if they were to be used in pricing negotiations. This is an especially important consideration with a growing interest in HTA reassessments, life-cycle HTA, and health technology management.<sup>20-22</sup>

#### Approaches that satisfy IIA

Decision making using either QALYs or LYs satisfies the IIA axiom. This is because, as noted earlier, the QALYs or LYs associated with each treatment are unaffected by the availability of a new mutually exclusive treatment.

The evLYG approach also satisfies the IIA axiom. This is because the evLYG for each treatment requires recalculation only after a change in the survival associated with current treatment; the availability of a new mutually exclusive treatment cannot, *in and of itself*, affect the evLYG for other treatments and result in a violation of IIA. In our example, for any given current treatment, the evLYG for treatments X and Y did not change after the availability of treatment Z.

#### The HYT approach can violate IIA

Decision making using the HYT approach can violate the IIA axiom. This is due to a novel property of this approach, whereby the HYT assigned to a treatment depends upon the survival provided by other mutually exclusive treatment options, even though this has no impact on the health outcomes experienced by patients provided with the treatment in question.

In our first scenario, where only treatments X and Y are available, treatment Y (3.2 HYT) is ranked more highly than treatment X (3.0 HYT) (Table 7 and Fig. 3A). However, after treatment Z becomes available, treatment X (5.0 HYT) is now ranked more highly than treatment Y (4.4 HYT) (Table 8 and Fig. 3B).

An HTA agency that bases its recommendations on the HYT approach would violate IIA when faced with our example, given that it would change its ranking of treatments X and Y solely on the basis that treatment Z is now available, even though this has no impact on the health outcomes provided by treatments X or Y. For the reasons given earlier, this would be very difficult for any HTA agency to justify in practice.

A further consequence is that an HTA agency that bases its recommendations on the HYT approach would be unable to exclude

previously rejected technologies from future reassessments, even if the evidence of their cost and effectiveness remains unchanged. This is because these technologies may have different HYT in future if the maximum survival achievable through *any* technology changes. This would be undesirable for the HTA agency because assessments with more comparators require more resources and in some cases create more opportunities for appeals and legal challenges.

#### Decision Instability

##### Background

Another requirement for an approach to be logically consistent is that its findings must not result in decision instability, whereby any attempt to implement the highest ranked treatment would result in a change in this ranking, implying that a different decision should have been made.

##### Relevance to social decision making

It is reasonable to expect social decision makers to avoid decision instability. Consider the following example:

*An HTA agency considers 3 mutually exclusive treatment options (A, B, and C) for a specific patient population, where B is current treatment. After considering the relevant evidence, the agency recommends that patients receive treatment C. Sometime later, the agency repeats its comparison using the same approach. The evidence remains unchanged; however, because treatment C has become established as current treatment, the agency switches its recommendation to treatment B. Sometime later, after treatment B has become reestablished as current treatment, the agency repeats its comparison, again using the same approach. Even though the evidence still remains unchanged, the agency switches its recommendation back to treatment C.*

As with violations of IIA, it is not apparent how an HTA agency could justify decision instability of this sort. Again, this would seem to violate "accountability for reasonableness."<sup>19</sup> In practice, a scenario in which such instability may arise is in the context of biosimilars or where there is on-patent competition among similar products; reassessments may result in changes in decisions despite no substantive difference in the available technologies.

##### Approaches that avoid decision instability

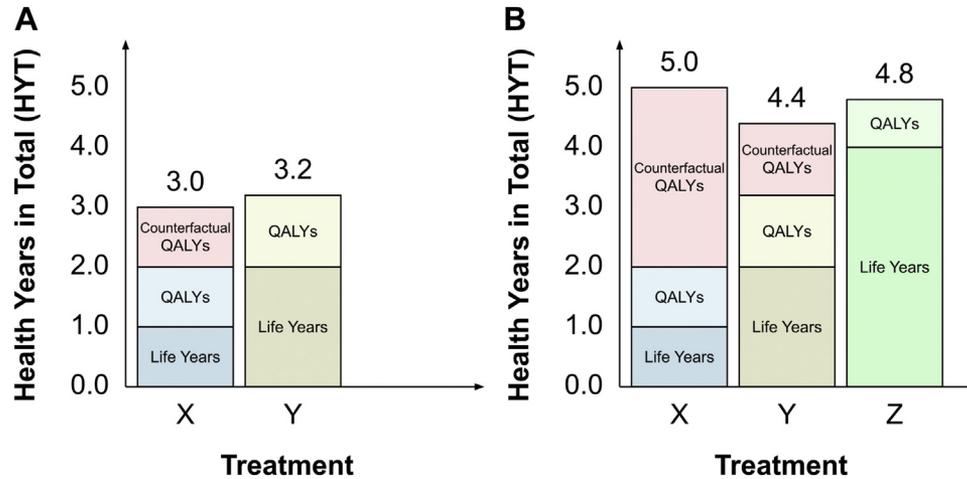
Decision making using either QALYs or LYs avoids the possibility of decision instability. This is because the QALYs or LYs

**Table 7.** HYT for treatments X and Y, assuming treatment Z is not available. The maximum survival is 2 years with treatment Y.

Treatment	Survival	HRQoL	QALYs	Counterfactual QALYs	Life-years	HYT
X	1 year	1.0	1.0	1.0	1.0	3.0
Y	2 years	0.6	1.2	N/A	2.0	3.2

HRQoL indicates health-related quality of life; HYT, health years in total; N/A, not available; QALY, quality-adjusted life-year.

**Figure 3.** HYT for each treatment, assuming (A) treatment Z is not available; or (B) treatment Z is available.



associated with each treatment are unaffected by the survival provided by other treatment options, including whatever is considered current treatment.

Although the HYT approach can violate the IIA axiom when new treatments become available, it does not result in decision instability if comparisons are repeated among existing treatment options after a change in current treatment. This is because the HYT assigned to each treatment option depends upon the maximum survival with *any* treatment comparator, regardless of whether this is considered current treatment. Therefore, a change in current treatment does not affect the HYT for each treatment.

**The evLYG approach can result in decision instability**

The evLYG approach can result in decision instability if comparisons are repeated after a change in current treatment. This is due to a novel property of the evLYG approach, whereby the ranking of each treatment option depends upon the survival provided by whatever treatment option is considered current treatment, even though this has no impact on the health outcomes experienced by patients provided with each treatment option.

In our second scenario, if treatment Y is current treatment, then treatment Z is the highest ranked (Table 5 and Fig. 2D). However, if treatment Z is subsequently established as current treatment because of this finding, then a repeated comparison would find that treatment Y is now the highest ranked (Table 6 and Fig. 2E). If treatment Y is then reestablished as current treatment on this basis, another repeat comparison would find that treatment Z is the highest ranked once again, with this vicious cycle endlessly repeating.

**Further Concerns With the HYT Approach**

The HYT approach raises several additional concerns, which we consider below.

**Counterfactual HRQoL After Death**

The consideration of counterfactual HRQoL under the HYT approach violates logic on several fronts. First, it assumes that a counterfactual HRQoL may be considered postdeath, based on the HRQoL experienced while patients were still alive, yet a prerequisite for considering a patient’s HRQoL is that the patient is alive; if a patient is dead, the patient *by definition* has no quality of life, whether health related or otherwise.

Second, the HYT approach assumes that counterfactual HRQoL may be applied to the additional period of time that a patient would have survived if they had been provided with the treatment option with maximum survival, yet, in reality, the patient has not survived for this additional period of time; they are dead, because they received another treatment option instead. This characteristic of the HYT framework attributes additional value to the treatment actually provided, derived from another treatment option that was not chosen.

Third, the HYT approach does not recognize that, if a patient *had* received the treatment option that provides for maximum survival, they would not be experiencing the counterfactual HRQoL associated with the first treatment option during the period of additional survival, but rather the *actual* HRQoL associated with the treatment option with maximum survival. In practice these may be substantially different; treatments that extend survival to the maximum extent possible might be associated with

**Table 8.** HYT for each treatment, assuming treatment Z is available. The maximum survival is 4 years with treatment Z.

Treatment	Survival	HRQoL	QALYs	Counterfactual QALYs	Life-years	HYT
X	1 year	1.0	1.0	3.0	1.0	5.0
Y	2 years	0.6	1.2	1.2	2.0	4.4
Z	4 years	0.2	0.8	N/A	4.0	4.8

HRQoL indicates health-related quality of life; HYT, health years in total; N/A, not available; QALY, quality-adjusted life-year.

**Table 9.** Highest ranked treatment option under each approach, for each scenario and current treatment possibility.

Scenario	Current treatment	Highest ranked treatment option			
		QALY	LY	evLYG	HYT
1 Treatment Z is not available.	X	Y	Y	Y	Y
	Y	Y	Y	Y	Y
2 Treatment Z is available.	X	Y	Z	Z	X
	Y	Y	Z	Z	X
	Z	Y	Z	Y	X

evLYG indicates equal value of life-years gained; HYT, health years in total; LY, life-year; QALY, quality-adjusted life-year.

poorer HRQoL than less aggressive treatments with shorter survival.<sup>23</sup>

### Axiomatic Foundations

Basu et al<sup>11</sup> state that “the axiomatic foundations of HYT are the same as those for QALY,” citing 2 specific “axioms”: utility independence and constant proportional trade-off (CPTO). They also state that HYT are a special case of the utility function formulated by Pliskin et al (1980),<sup>24</sup> which is one form of utility function supported by utility independence and CPTO.

We consider this to be incorrect. The CPTO assumption ensures that values elicited using a method such as time trade-off (TTO) can be applied to health states of any duration. The CPTO assumption specifies how the value of changes in LYs is *inseparable* from health status; all trade-offs are interpreted as a proportion of remaining LYs. Indeed, this *inseparability* is, arguably, a higher-order axiom for the QALY. In current practice, the TTO method specifies health state values as fractions of healthy years; the assumption that this fraction is independent of LYs remaining (ie, CPTO) provides no support for the assumption that quality and quantity of life are separable in their value. Furthermore, HYT do not demonstrate CPTO, and a simple example shows this (see [Appendix A in Supplemental Materials](https://doi.org/10.1016/j.jval.2023.11.009) found at <https://doi.org/10.1016/j.jval.2023.11.009>).

Therefore, HYT are not built on the same axiomatic foundations as the QALY. HYT rely on a counterfactual outcome (the maximum survival provided by any treatment option), rather than being specified solely on factual outcomes. Although we agree that HYT may assume utility independence, HYT do not exhibit CPTO of LYs.

It should be noted that the axiomatic foundations of the QALY have been criticized, and the fact that HYT have different axiomatic foundations is not a problem per se. However, it is important that these differences be understood and the implications for the internal coherence and defensibility of decision making taken into account.

### The “Separability” Assumption

As noted earlier, the HYT framework is “... built on the notion that life-years gained provide distinct utility to individuals from the [HRQoL] gains and that these utilities are separable in nature.”<sup>11</sup> Separating utilities in this way requires that the following conditions hold:

1. Utility from LYs gained is independent of that from improvements in HRQoL.
2. Utility from improvements in HRQoL is independent of that from LYs gained.

There are 2 interrelated problems with this assumption. First, it seems implausible that condition (1) could hold in practice, and Basu et al<sup>11</sup> do not provide evidence in support of this. It would require that each individual's preferences regarding a potential life extension can be expressed in isolation of any considerations regarding the quality of those additional years, yet it is entirely plausible that an individual could prefer to receive a life extension only if it would be lived in sufficiently good HRQoL and prefer to not have a life extension if it would be lived in sufficiently poor HRQoL. Indeed, there is a growing body of research on the importance to patients of considering HRQoL when making decisions regarding potential life extensions.<sup>25–27</sup>

Second, contrary to the statement made by Basu et al<sup>11</sup> that “no new information is needed to calculate HYT than what is already available in a traditional CEA model,” the HYT framework cannot meaningfully rely on the same HRQoL inputs as QALYs. The value of HRQoL used in conventional approaches is inseparable from the value of time, not least because valuation methods are designed specifically to value trade-offs between longevity and health status and assume that individuals are indifferent between health states when time is zero.<sup>24,28,29</sup> Where HRQoL values for the estimation of QALYs are based on TTO exercises, standard gamble, or discrete choice experiments, they are always measured relative to time in health states. If the HYT approach were to adopt the HRQoL values currently used in QALY estimation, there would be a misalignment between the values and preferences expressed by respondents in those studies and their use in calculating the HYT. To satisfy the separability assumption, the HYT framework would instead require health state valuation methods that can specify HRQoL entirely independently of time spent in health states.

### Patients Can Be Assigned Different HRQoL Values Simultaneously

The algebra used to conceptualize the HYT approach assigns 2 different HRQoL values to some patients simultaneously.<sup>11</sup> This issue is described in more detail in [Appendix B in Supplemental Materials](https://doi.org/10.1016/j.jval.2023.11.009) found at <https://doi.org/10.1016/j.jval.2023.11.009>.

### The evLYG as the “Rationale” for the Separability Assumption

In their conceptualization of the evLYG and HYT approaches (described in [Appendix B in Supplemental Materials](https://doi.org/10.1016/j.jval.2023.11.009) found at <https://doi.org/10.1016/j.jval.2023.11.009>), Basu et al<sup>11</sup> express the evLYG approach in a specific form which “... implies that [the evLYG] separates the calculation of incremental life-years (the first part) from the incremental (slightly modified) QALYs (the second part),” noting that “this rationale will serve us well in the development of the health years in total (HYT) framework.”

We consider this rationale to be flawed. The evLYG approach does not invoke or support the separability assumption

underpinning the HYT approach, under which it is assumed that “life-years gained provide distinct utility to individuals from the [HRQoL] gains and that these utilities are separable in nature.”<sup>11</sup> Rather, the evLYG approach assumes that, beyond a specific moment in time (survival with current treatment), the social decision maker applies its own value for any years of additional survival, in place of the actual HRQoL experienced by patients. Under Nord et al’s<sup>9</sup> original proposal, this value was 1, such that survival beyond this time point was effectively valued in LYs, but this in no way required or implied that LYs gained provide “distinct utility” from HRQoL gains or that these utilities are “separable in nature.” Furthermore, where the value applied to life extensions under the evLYG approach is not 1 (as in ICER’s implementation, which uses a value of 0.851), survival beyond this time point is not valued in LYs, such that this conceptualization of the evLYG approach is incorrect.

### Handling Heterogeneity

The example we have considered in this article is simplistic and does not allow for a consideration of heterogeneity. In [Appendix C in Supplemental Materials](https://doi.org/10.1016/j.jval.2023.11.009) found at <https://doi.org/10.1016/j.jval.2023.11.009>, we consider a second example of 2 mutually exclusive treatments (A and B), each of which provides for a different survival and HRQoL in one-half of the population (subgroup 1) than in the other half of the population (subgroup 2).

If treatment A is superior to B in both subgroups, then logically it should be considered superior at the level of the whole population, yet we find that this is not necessarily the case under the HYT approach. In the example considered in [Appendix C in Supplemental Materials](https://doi.org/10.1016/j.jval.2023.11.009) found at <https://doi.org/10.1016/j.jval.2023.11.009>, treatment B provides greater HYT in each subgroup, yet treatment A provides greater HYT when the population is considered as a whole. No such inconsistency arises when using the other approaches considered in this article.

## Discussion

We have demonstrated that the HYT and evLYG approaches can result in logically inconsistent decisions. The evLYG can result in an unstable ranking of treatments over time, whereas the HYT can violate the IIA axiom, is based upon an implausible assumption that the utilities associated with HRQoL and LYs are separable, and potentially considers a counterfactual HRQoL for patients who are dead, among other problems. The conceptualization provided to support the HYT approach seems flawed, requiring the assignment of more than one HRQoL value to the same patients simultaneously and providing a faulty rationale for the separability assumption. The HYT approach also results in logical inconsistencies when handling heterogeneity.

These problems are inherent to the underlying foundations of the HYT and evLYG approaches. For this reason, we regard neither approach as providing a satisfactory alternative to the QALY for use in resource allocation decision making.

It is important to note that our critique of HYT and evLYG should not be interpreted as an endorsement of QALYs. There is merit in considering alternatives to the QALY, and Nord et al<sup>9</sup> and Basu et al<sup>11</sup> deserve credit for proposing novel approaches. Nevertheless, we recommend that decision makers thoroughly explore the logical consistency of these and any other approaches proposed in future before considering their use in practice.

### How Common Are These Problems?

It is reasonable to consider how often, and under what circumstances, the logical inconsistencies and other problems identified in this article would be expected to arise in practice.

Logically, the evLYG approach will suffer from decision instability in all cases where the top-ranked treatment option differs from that under the QALY approach, provided this top-ranked treatment under the evLYG approach is subsequently adopted as current treatment; in any future comparisons, this treatment would be valued using QALYs only, resulting in decision instability given that another treatment option provides greater QALYs. In all other cases, the evLYG will not result in decision instability, but it also will not result in different implications for decision making than the QALY approach.

The problems with the HYT approach identified in the previous section would arise every time the HYT approach is used in practice. The HYT approach would violate IIA in some, but not all, cases; an empirical investigation of how often such cases would occur in practice, and under what circumstances, would be a worthwhile topic for future research.

### What About Costs?

In practice, decision makers do not consider health benefit in isolation, but also consider the costs associated with each treatment option, with decisions often informed by the cost per incremental unit of health benefit (eg, cost per incremental QALY or cost per incremental evLYG). It is on this basis that interventions are routinely ranked.

Logically, if an approach to measuring health benefit is inconsistent, then any composite measure of the cost per incremental unit of that health benefit will also be inconsistent. Furthermore, the consideration of costs broadens the circumstances under which logical inconsistencies can arise.

For example, earlier in this article we identified that a violation of IIA can arise under the HYT approach. When considering HYT alone (without costs), such a violation occurs when the launch of a new treatment Z causes the ranking of the HYT for treatments X and Y to change, yet if decisions are made by considering “cost per incremental HYT” and if the costs of treatments X and Y differ, then a violation of IIA could occur even if the ranking of the HYT for treatments X and Y does not change, provided that the change in HYT is sufficient to reverse the ranking of treatments X and Y in terms of “cost per incremental HYT.”

### The US Policy Debate

Although the focus of this article is on the logical inconsistencies associated with the HYT and evLYG approaches, we recognize that these approaches have been proposed in the context of a heated US policy debate under which the US Congress and some state legislatures have passed laws limiting the use of the QALY for informing drug price negotiations and resource allocation decisions in health.<sup>1,30,31</sup> For example, the Patient Protection and Affordable Care Act states that the Patient-Centered Outcomes Research Institute “shall not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual’s disability) as a threshold to establish what type of health care is cost effective or recommended.”<sup>32</sup> Similarly, the Inflation Reduction Act of 2022 states that “... the [Secretary of Health and Human Services] shall not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an

individual who is younger, nondisabled, or not terminally ill.”<sup>33</sup> In June 2023, the Centers for Medicare and Medicaid Services confirmed that QALYs will not be considered in negotiations conducted under the new Medicare Drug Price Negotiation Program.<sup>34</sup>

In this context, it is understandable that US decision makers would be interested in alternatives to the QALY. However, although a full consideration of the US policy context is beyond the scope of this article, we would caution against the adoption of any approaches that violate fundamental principles of rational decision making or that rely upon assumptions that lack credibility. This is particularly the case when other potential solutions exist that avoid these problems; we propose one such potential solution in the following section, in which equity weights are used to assign additional value to the lives of elderly, disabled, or terminally ill people.

### Equity-Weighted QALYs

One potential means for addressing the perceived discrimination of the conventional QALY approach, while avoiding the logical inconsistencies of the evLYG and HYT approaches, would be to apply direct equity weights (or “modifiers”) to QALYs. This is an approach that has been used by numerous HTA agencies worldwide.<sup>35-37</sup>

In principle, equity weighting could be applied on the basis of age, severity of illness, disability, or other criteria, in a way that aligns with prevailing laws and other restrictions. Notably, this could be implemented in such a way that the equity-weighted QALYs for people with disabilities over a given duration of life extension are assigned the same average value as an equivalent duration of life extension for individuals without a disability. This approach would reflect a similar normative foundation as the evLYG; however, unlike the evLYG, such an approach could assign a relatively greater value to new technologies that both extend the life of disabled patients and improve their HRQoL, thus incentivizing their development and potentially reducing health inequities between people with and without disabilities. Although no solution is perfect, this proposal would address the primary issue with QALYs raised by disability advocates and would avoid the logical inconsistencies inherent to the HYT and evLYG approaches.

The practical challenges associated with such an approach have been well documented.<sup>38,39</sup> Care would need to be taken when identifying the relevant characteristics for equity weighting, determining the magnitude of preference for each characteristic, and calculating the corresponding weight to apply to the QALYs for each patient subgroup.<sup>40</sup> These weights would need to be acceptable to the public, evidence based, and periodically revised to reflect evolving societal values. Policy makers would need to recognize that opportunity costs arise when health technologies are funded by public or private insurers, resulting in health losses for other patients, and that some of these health losses are experienced by patients with disabilities.<sup>41</sup> A consistent and ethically defensible approach to equity weighting would therefore require that policy makers assign equity weights to both health gains and health losses experienced by disabled patients.<sup>42</sup> The use of equity weights allows for a transparent and considered assessment of the appropriate relationship between HRQoL and life years.

### Recommendations

The logical inconsistencies in the HYT and evLYG approaches can be traced back to the absence of a specific property of other approaches. Although the QALYs and LYs for each treatment are independent of the characteristics of other mutually exclusive treatment options (including the survival associated with each

and the status of which is considered current treatment), this is not the case for the evLYG and HYT. Instead, the value assigned to mutually exclusive treatment options is affected by a change in the survival associated with current treatment (under the evLYG approach) or by a change in the maximum survival provided by any treatment (under the HYT approach). This is despite such changes having no impact on the health outcomes experienced by patients under other mutually exclusive treatment options.

Therefore, we recommend that the developers of any future approaches ensure that the value assigned to each treatment option is independent of the characteristics of other mutually exclusive treatment options.

We also recommend that policy makers exercise caution and avoid adopting any approaches that violate fundamental principles of rational decision making or that rely upon assumptions that lack credibility. As one possible solution, policy makers may wish to consider assigning equity weights to QALYs, which may overcome the perceived discriminatory aspects of the standard approach to maximizing QALYs, while avoiding the logical inconsistencies inherent to the evLYG and HYT.

### Conclusion

The HYT and evLYG approaches can lead to illogical and untenable decision making that does not occur when using QALYs or LYs. The adoption of HYT or evLYG could result in challenging situations for policy makers, who would need to defend their irrational implications and potentially renege on previous decisions. Policy makers should consider alternative solutions that facilitate trade-offs between quality of life and longevity, while recognizing the complexity of attributing value to health gains across different patient groups.

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### Article and Author Information

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**Author Affiliations:** School of Public Health, University of Alberta, Edmonton, AB, Canada (Paulden); Office of Health Economics, London, England, UK (Sampson); School of Economics, University College Dublin, Dublin, Ireland (O'Mahony); Community Health Sciences, University of Calgary, Calgary, AB, Canada (Spackman); Centre for Public Health and Queens Management School, Queen's University Belfast, Belfast, Northern Ireland, UK (McCabe); Institute of Health Economics, Edmonton, AB, Canada (Round); Department of Pediatrics, Faculty of Medicine and Dentistry, University of Alberta, Edmonton, AB, Canada (Round); Health Economics Group, University of Exeter, Exeter, England, UK (Snowsill).

**Correspondence:** Mike Paulden, PhD, School of Public Health, University of Alberta, 3-264 Edmonton Clinic Health Academy, 11405 87 Ave NW, Edmonton, AB T6G 1C9, Canada. Email: [paulden@ualberta.ca](mailto:paulden@ualberta.ca)

**Author Contributions:** *Concept and design:* Paulden, Sampson, O'Mahony, Spackman, McCabe, Round, Snowsill

*Acquisition of data:* Paulden, Snowsill

*Analysis and interpretation of data:* Paulden, Snowsill

*Drafting of the manuscript:* Paulden, Sampson, O'Mahony, Spackman, McCabe, Round, Snowsill

*Critical revision of the paper for important intellectual content:* Paulden, Sampson, O'Mahony, Spackman, McCabe, Round, Snowsill

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