

# Health outcomes in economic evaluation: the QALY and utilities

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The quality-adjusted life year (QALY) is routinely used as a summary measure of health outcome for economic evaluation, which incorporates the impact on both the quantity and quality of life. Key studies relating to the QALY and utility measurement are the sources of data. Areas of agreement include the need for a standard measure of health outcome to enable comparisons across different disease areas and populations, and the methods used for valuing health states in utility measurement. Areas of controversy include the limitation of the QALY approach in terms of the health benefits it can capture, its blindness towards equity concerns, the underlying theoretical assumptions and the most appropriate generic preference-based measure of utility. There is growing debate relating to whether a QALY is the same regardless of who accrues it, and also the issue as to who should value health states. Research is required to further enhance the QALY approach to deal with challenges relating to equity-weighted utility maximization and testing the validity of underlying assumptions. Issues around choosing between condition-specific measures and generic instruments also merit further investigation.

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## Introduction

Allocation decisions concerning the prioritization of healthcare resources across competing interventions involve evaluating the impact on both costs and health outcomes. Healthcare studies use many different measures of health outcome to demonstrate the effect of a treatment. For example, one study may report survival rates, whereas another may focus on pressure ulcer incidence and pain-free days. When faced with such different types of outcome measures arising from different interventions, it is difficult to determine where healthcare resources should be most efficiently directed. If survival alone is used to differentiate between different healthcare interventions, any impact on the quality of life associated with an intervention is ignored.

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To enable comparisons across different areas of healthcare, a common measure is needed. This measure should ideally encapsulate the impact of a treatment on a patient's length of life and also the impact on their health-related quality of life (HRQoL), which is recognized as a key indicator of treatment outcomes. The quality-adjusted life year (QALY) has been developed in order to capture both of these impacts and is widely used in health economics as a summary measure of health outcome, which can inform healthcare resource allocation decisions.

## Valuing health states: the concept of utilities

When QALYs are used as an outcome, the assessment is known as a cost-utility analysis (CUA). The use of QALYs is required by the National Institute for Health and Clinical Excellence (NICE) in the UK for health technology assessment. In order to generate QALYs, health utilities (or HRQoL weights) are needed. Utilities are preference weights, where preference can be equated with value or desirability.<sup>1</sup> Hence, the utilities for health states should be based on preferences for the different health states, in that the more desirable (i.e. more preferred) health states will receive greater weight and will, therefore, be favoured in the analysis.<sup>2</sup>

Utilities are measured on a cardinal scale of 0–1, where 0 indicates death and 1 indicates full health. Using the 'anchors' of 0 and 1, utility measurement is on an interval scale, where the same change means the same irrespective of the part of the scale being considered (e.g. a change in health from 0.2 to 0.3 is equivalent to a change from 0.8 to 0.9). States worse than death can also be accounted for, with such states taking a negative value.

## Valuing life years: the concept of a QALY

The QALY is able to combine 'the effects of health interventions on mortality and morbidity into a single index',<sup>3</sup> thereby providing a 'common currency' to enable comparisons across different disease areas. Over time, individuals experience different health states, where the health states are weighted according to the utility scores associated with them. The QALY concept, of combining the survival of an individual with their HRQoL, can be seen in Figure 1. This demonstrates the QALYs that can be gained by an individual from receiving treatment as opposed to no treatment. The area under the curve equates to the total QALY value. The lower path shows the health profile if no treatment is received; the HRQoL of the individual reduces over time,

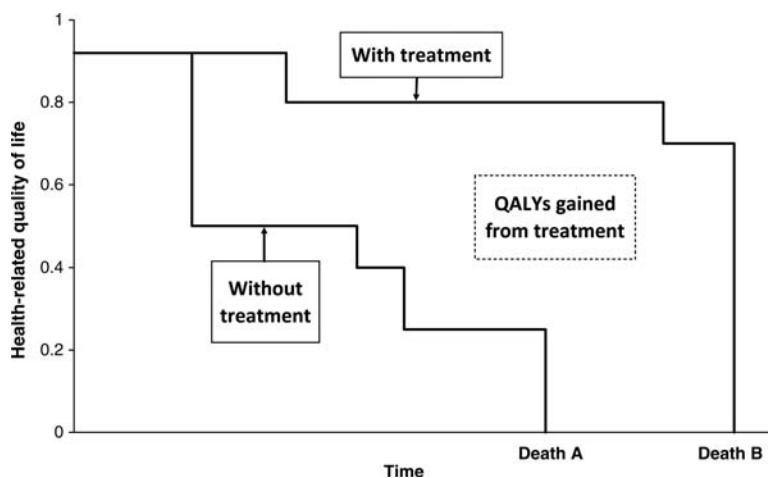


Fig. 1 QALYs gained from treatment.

until they die (Death A). If a treatment is received, however, the individual follows the higher path; their HRQoL remains at a higher level for longer, in addition to living for longer (die at Death B). Hence, the total area between the two curves indicates the number of QALYs gained by the treatment.

QALYs are calculated simply by multiplying the duration of time spent in a health state by the HRQoL weight (i.e. utility score) associated with that health state. Therefore, the two key elements—HRQoL and survival—are incorporated. For instance, if an individual is in a health state for 10 years, where the health state has an associated utility of 0.6, this would generate six undiscounted QALYs (i.e. 0.6 multiplied by 10 years).

Weinstein *et al.*<sup>1</sup> summarize the underlying assumptions of the conventional QALY approach, some of which are listed below and are discussed in later sections.

- Health is defined as value-weighted time (QALYs) over the relevant time horizon.
- Value is measured in terms of preference (desirability).
- Preferences measured across individuals can be aggregated and used for the group.
- QALYs can be aggregated across individuals, i.e., a QALY is a QALY regardless of who gains/loses it.

QALYs that occur in the future are discounted to current values, to incorporate the idea that people prefer to receive health benefits now rather than in the future (i.e. positive time preference). The recommendation by NICE is that QALYs should be discounted at a rate of 3.5%

per year, in line with costs. For instance, in our example above, six QALYs gained over 10 years, when discounted at 3.5%, is equivalent to 4.4 QALYs. However, discounting remains a subject of controversy; for instance, whether QALYs should be discounted at a lower rate than costs continues to be debated.<sup>4</sup> In addition, different people can have different time preferences for health outcomes. For instance, a healthy person may discount the future differently from a patient who actually has a particular health condition.

## Methods for valuing HRQoL weights

The measurement of health utilities, or HRQoL weights, involves first defining health states of interest. The next stage involves valuing these health states, that is, individuals assess different health states and place a value on each of them. In order to generate HRQoL weights, there are either direct or indirect methods (also called generic preference-based measures).

### *Direct elicitation methods*

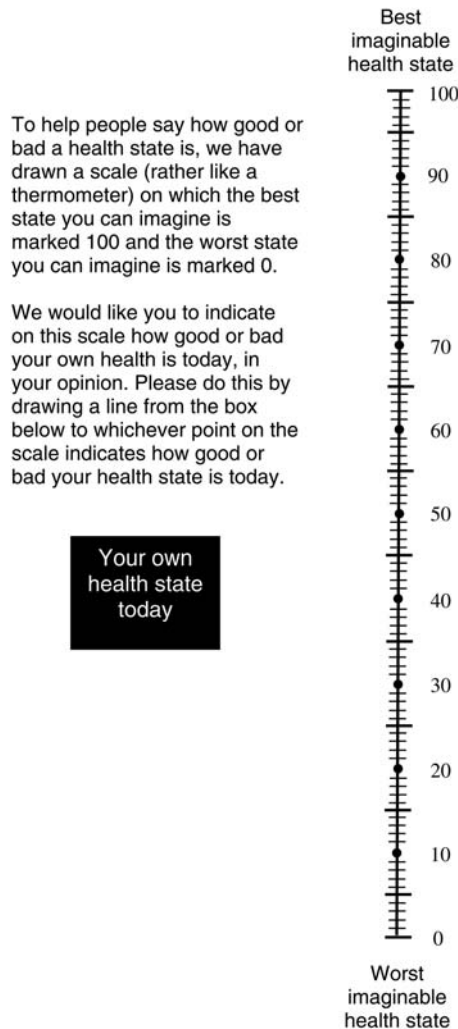
The direct methods that tend to be used most regularly for eliciting preferences include the visual analogue scale (VAS), the time trade-off (TTO) and the standard gamble (SG).

#### **Visual analogue scale**

The VAS (a form of rating scale) is the simplest of the direct methods and involves the use of a scale shown on a single line (Fig. 2). The top of the scale indicates the ‘best imaginable health’, whereas the bottom of the scale indicates the ‘worst imaginable health’. Individuals are asked to indicate where on the scale they consider the health state of interest to be. This method is generally considered to be inferior to the SG and TTO, due to involving a rating task rather than a choice task, and also due to scaling biases<sup>1</sup>. Scaling biases include the end-of-scale bias, where participants are reluctant to place health states at the extreme ends of the scale. However, the simplicity of the VAS means that it is a useful tool often used as a ‘warm up’ exercise before other methods.

#### **Time trade-off**

The TTO method presents individuals with two alternative scenarios and asks which they would prefer. The choice is between living for the rest of their life (for example, 10 years, as in Fig. 3a) in an impaired health state (for instance, type 2 diabetes), or living in full health for a shorter period of time. The time period spent in full health is varied



Source: adapted from the EuroQol Group: [www.euroqol.org](http://www.euroqol.org)

Fig. 2 The VAS.

until the individual is indifferent between the two choices. Hence, participants are asked how much time they would be willing to sacrifice to avoid an impaired health state. In Figure 3a, the ‘point of indifference’ is 8 years with diabetes. At this point, the HRQoL weight can be inferred; 0.8 in this example (8 years divided by 10 years).

### Standard gamble

The SG involves an element of risk in the decisions faced by individuals. This time, the choice is between the certainty of remaining in a particular health state, or taking a gamble of either being in full

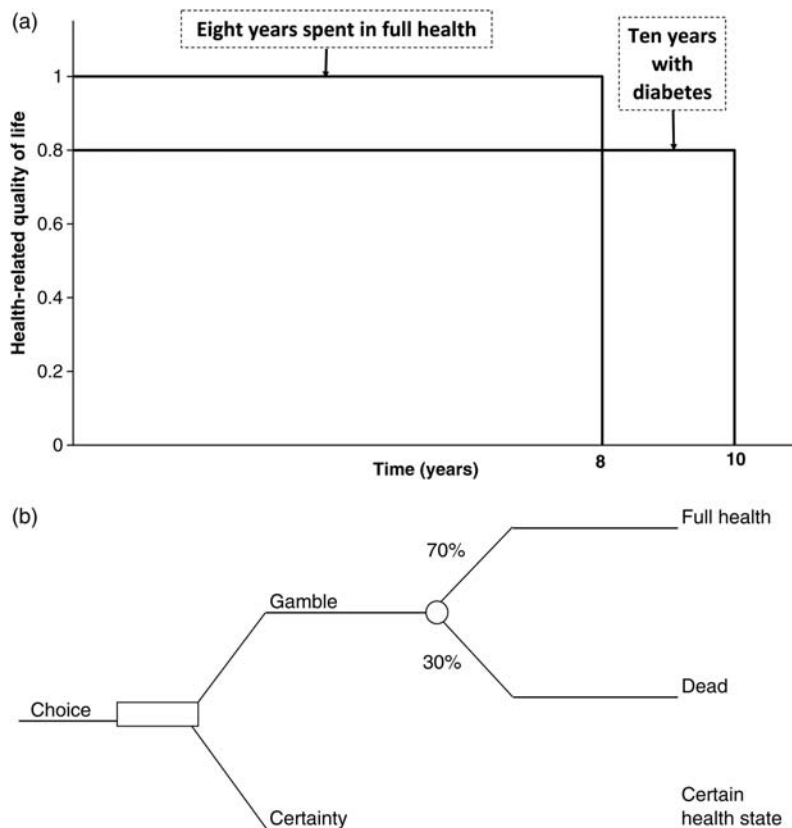


Fig. 3 Direct measures: time trade-off and standard gamble (using numerical examples).

health or risking death (with a 30% probability of death in Fig. 3b). The probability of experiencing death is varied until the individual is indifferent between the certainty and the gamble. The more severe the health state, the greater is the risk of death that the patient would accept to be cured of it. If the individual were indifferent under the scenario illustrated in Figure 3b, the utility generated would be 0.7.

### Generic preference-based measures

It can be difficult, time consuming and unethical to measure patients' preferences for health outcomes using the methods described previously. As a result, indirect elicitation methods, which involve the use of pre-scored generic preference-based measures (also called 'off-the-shelf' questionnaires or generic multi-attribute systems), are

routinely used in healthcare trials. Health states are described using standardized generic utility questionnaires, which cover general aspects of health.

A range of generic preference-based measures have been developed, but commonly used questionnaires include the EuroQol (EQ)-5D,<sup>5</sup> the Short Form 6D (SF-6D)<sup>6</sup> and the Health Utilities Index (HUI).<sup>7</sup> The measures differ in terms of aspects such as the dimensions of health (i.e. attributes) that are included, the number and description of levels defined for each dimension, and the population on which the preferences are based. The instruments also differ in terms of the valuation method: the TTO was used to value the EQ-5D, whereas the SF-6D and HUI involve the SG. Once completed, the questionnaires generate a score using an algorithm based on values that have been obtained from a sample of the general public.

### The different measures: EQ-5D, SF-6D and HUI

The main characteristics of three commonly used generic preference-based measures are summarized in Table 1.

The EQ-5D tends to be the method of choice in most CUA studies; a review of 23 CUAs conducted alongside clinical trials found the EQ-5D was the most commonly used instrument.<sup>8</sup> The EQ-5D questionnaire is completed in relation to five domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. For each domain, there are three levels of response: individuals are asked whether they have no problems, some problems or severe problems, as shown in Figure 4. The answers given for the five areas are then transformed to generate a summary score, which indicates the overall utility. In total there are 245 possible health states<sup>2</sup> (i.e. 3<sup>5</sup> plus unconscious and dead), formed by different combinations of the levels. The EQ-5D is a cognitively simple questionnaire that is well suited for self-completion by participants via postal surveys, at clinics and face-to-face interviews.<sup>9</sup>

**Table 1** Main characteristics of generic preference-based measures.

| Instrument | Domains | Levels of response | Potential health states | Valuation method used | Original population preferences are based on                 |
|------------|---------|--------------------|-------------------------|-----------------------|--|
| EQ-5D      | 5       | 3                  | 245                     | TTO                   | Random sample of approximately 3000 adults in the UK         |
| HUI3       | 8       | 5–6                | 972 000                 | SG and VAS            | Random sample of general population adults in Canada         |
| SF-6D      | 6       | 4–6                | 18 000                  | SG                    | Random sample of 836 members of general population in the UK |

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today

**Mobility**

I have no problems in walking about

I have some problems in walking about

I am confined to bed

**Self-Care**

I have no problems with self-care

I have some problems washing or dressing myself

I am unable to wash or dress myself

**Usual Activities** (e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities

I have some problems with performing my usual activities

I am unable to perform my usual activities

**Pain/Discomfort**

I have no pain or discomfort

I have moderate pain or discomfort

I have extreme pain or discomfort

**Anxiety/Depression**

I am not anxious or depressed

I am moderately anxious or depressed

I am extremely anxious or depressed

Source: adapted from the EuroQol Group: [www.euroqol.org](http://www.euroqol.org)

Fig. 4 The EQ-5D questionnaire.

The SF-6D is a utility instrument that is based on the SF-36, which is a HRQoL questionnaire. It enables any patient who has completed the SF-36 to be uniquely classified, describing 18 000 health states in total. The HUI has three versions, the most recent being the Health Utilities Mark 3 (HUI3). The HUI3 uses eight health attributes, with five or six levels for each. There are 972 000 health states described by the HUI3 altogether.

### NICE recommendations

NICE recommends the use of QALYs as a measure of health benefit for their ‘reference case’, to enable a standardized approach for comparing economic evaluations across different healthcare areas. The EQ-5D is the measure of HRQoL in adults that is preferred by NICE.<sup>10</sup> NICE states that, ‘when EQ-5D data are not available or are



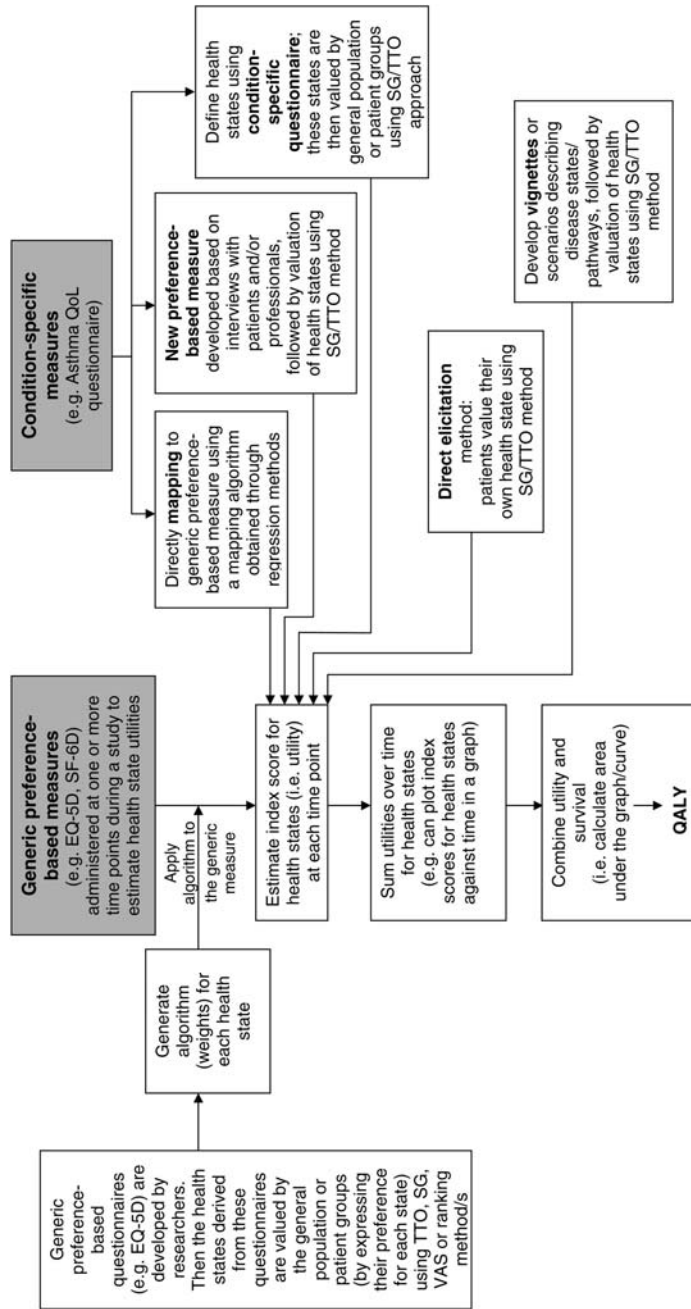


Fig. 5 Summary of common methods used to obtain health state values.

inappropriate for the condition or effects of treatment, the valuation methods should be fully described and comparable to those used for the EQ-5D'.<sup>10</sup> Other health technology assessment agencies differ in terms of the recommendations issued about which approach to take.

### *Condition-specific measures*

Although generic instruments generate utilities that can enable comparisons across different disease areas and programmes, they can sometimes be insensitive to particular aspects of certain conditions. In order to pick up a more specialized representation of HRQoL for a certain disease or condition, condition-specific measures may be used. Such measures work in a similar way to the generic questionnaires, but the questions are more focused towards the disease under investigation. Examples of condition-specific measures are the Asthma Quality of Life Questionnaire,<sup>11</sup> the Inflammatory Bowel Disease Questionnaire<sup>12</sup> and the International Prostate Symptom Score.<sup>13</sup> The values from condition-specific measures cannot be directly used in economic evaluation. Instead, the values must be mapped to a generic measure, such as the EQ-5D.

The different approaches for obtaining health utilities for use in QALY calculation are summarized in Figure 5. It is worthwhile to note that the various approaches can produce different utility values, even where the same individual is valuing the health states. This can partly be due to differences in the health attributes that are evaluated by different valuation methods. Hence, the method used should be considered when interpreting or using such values.

## **A QALY is a QALY is a QALY—or is it?**

The conventional approach to economic analysis evaluates healthcare interventions with the aim to maximize the efficiency of the healthcare system in producing the greatest number of QALYs, given available resources. An implicit assumption that underlies this approach is that all QALYs are of equal social value, irrespective of who accrues them—famously quoted as ‘a QALY is a QALY is a QALY’.<sup>14</sup> In practice, this assumption implies that a QALY gained and lost is blind to health conditions and personal characteristics, including age, sex, severity of disease, level of deprivation, social role of individuals, area of residence (post code) and other individual characteristics—a principle that Culyer termed as ‘QALY egalitarianism’.<sup>15</sup> Anonymity can be argued to be fair because of its impartiality. However, in practice, the principle impedes recognition of differing moral claims of individuals

to healthcare based on their current state of health-related or other personal characteristics.<sup>16</sup> In effect, what matters under this principle is the sum total of the population health and not the distribution of health. When interpreted in conjunction with the efficiency goal, the ‘QALY is a QALY is a QALY’ principle implies that an intervention that results in a small loss of QALYs for some but a greater gain of QALYs for others (i.e. the QALY gainers can theoretically compensate the QALY losers) will result in net efficiency gains and hence social improvement, irrespective of the resulting distribution.

Cookson *et al.*<sup>17</sup> note that systematic reviews conducted between 1987 and 2005 found that distributional effects of healthcare interventions on QALYs have been completely neglected in economic evaluations.<sup>18,19</sup> In the public health sphere, the existing level of inequalities are important, and hence discrimination or ‘targeting’ of resources is frequently advocated. For example, allocating greater resources for contraception services, a smoking cessation programme or infant mortality reduction programme to the socioeconomically disadvantaged areas is generally acceptable, although if this is done at the expense of efficiency, it leads to an implicitly higher valuation of the welfare of certain groups more than others, which in itself has moral and ethical implications.

In the literature, there are two sets of arguments provided in favour of weighting QALYs; those based on efficiency and those based on equity. The efficiency argument points out that if the current distribution of income is ethically defensible, then the QALY gain for those who make the greatest contribution to the society through their higher productivity should be weighted higher than those who contribute less.<sup>20</sup> This will in turn result in greater societal productivity which will trickle down to contribute to a richer society overall. The efficiency argument can also be applied to age. The disability-adjusted life years (DALYs) approach (discussed below) advocates higher weights to be applied to disabilities of young adults who are productive, compared with newborns or the very old.<sup>21</sup>

While some may consider the efficiency argument, based on ‘worthiness’ of individuals in terms of their productivity, to be unfair (for instance, because the highly productive individuals may be born in richer families with more opportunities), there are strong arguments of weighting QALYs due to equity reasons. The literature suggests that a majority of the general population has a preference for putting greater weight to health gains accrued by children, those severely ill and the socioeconomically disadvantaged.<sup>22</sup> To promote equity, an equity–efficiency trade-off may be required, which will result in sacrifice of health gains in order to achieve greater distributional equity of health. For example, it may be more efficient (in terms of lives saved) to implement an intervention in easy-to-reach affluent areas rather than

hard-to-reach poor areas; however, a decision-maker may trade-off equity versus efficiency to promote distributional equity of health outcomes.<sup>17</sup> On the other hand the converse may be true. Thus, targeting healthcare to socially disadvantaged groups may sometimes increase efficiency in the sense that morbidity correlates with social deprivation and therefore more QALYs may be gained by prioritizing the delivery of healthcare towards the less well off. Further research is required in this area before equity-weighted QALY maximization can become the norm in economic evaluation.<sup>20</sup>

## Who should value health?

There are two distinct views on who should value health states. One school of thought argues that patients should value health states, while the other argues that valuation should be based on preferences of the general population.<sup>23</sup> The former view argues on the premise that patients better know their health state compared with someone else trying to imagine it. Also, since it is the patients whose well-being is at stake, they should be the ones valuing their health. The downside of patient valuation is that patients may strategically overemphasize the benefits of the new treatment with the knowledge that they will directly benefit from it.<sup>22</sup> On the contrary, patients may adapt to their health state over a period of time; as a result, they may assign higher values to their own poor health state. In consequence, the quality of life improvement due to the new treatment will be valued less.<sup>24</sup> The advocates of valuation by the general population argue that, since the general public does not have a vested interest in the treatment of a particular health state, they would provide unbiased valuation. Furthermore, since it is the public money that will be used to fund new treatments (at least in publicly financed systems, like the NHS), the public should be the ones valuing health states. The argument against public valuation is that the general population may have little or no experience of the health condition; moreover, they may not want to be asked to value health states.<sup>22</sup> While the debate on who should value health states continues, the current practice in the UK context is to use valuation based upon the preferences of the general population.

## Challenges for the qaly approach

While the QALY approach is probably the most commonly used method in the health economics literature, it does have its challenges. Nord *et al.*<sup>25</sup> point out that when the SG and TTO methods are

applied to patients and individuals with disabilities, many express zero willingness to sacrifice any amount of life expectancy to alleviate their health condition. As a result, it would appear that they have full health even under the condition of illness, which is unreasonable. The authors point out that one possible explanation is that the time units used in the trade-off studies are too long; typically years are used. Hence, patients who may be happy to sacrifice a month or a week, but may refuse to trade-off a whole year, would consequently appear to have full health. Even if shorter trade-off periods are allowed, people may not consider them much of a sacrifice if they are very short periods that are likely to occur in the distant future.

Another challenge is that the QALY measure may be seen to be too reductionist, i.e. it does not capture all the benefits of a healthcare intervention.<sup>26</sup> For instance, an improvement in the health of a woman/man with children may impact on the health of their children and may also help her/him return to work more quickly. While some of these aspects can be captured separately in the analysis, it would not always be possible to capture all benefits of an intervention in a single index. Linked to this is the fact that the generic instruments used to generate utility values are insensitive to some medical conditions, i.e. they may not capture all functional and symptomatic gains from a healthcare intervention. Also, many condition-specific measures are not preference-based, hence not appropriate to derive QALYs.<sup>27</sup>

A further challenge associated with the QALY approach is the validity of underlying assumptions.<sup>28</sup> For instance, the QALY approach assumes that the value of being in a health state, say unstable angina pectoris, for two years is twice that of being in the health state for one year. Another assumption is that the value of a health state is independent of where a health state occurs in a sequence of health events.<sup>29</sup> Some authors have even questioned the very theoretical foundation of the QALY approach.<sup>30,31</sup> Finally, the conventional QALY approach assumes that all QALYs have the same social value; this in turn ignores any equity concerns of the decision-maker (as discussed earlier). While some of these assumptions may at first seem reasonable, further probing is required to ascertain their validity.

## Alternatives to QALYS

There are some alternatives to the QALY approach that are discussed in the literature. Below we discuss three of these alternatives: the DALY, Healthy Years Equivalent (HYE) and the Willingness-to-Pay (WTP) approach.

### *Disability-adjusted life year*

This measure was formed in the early 1990s as a summary measure of population health to estimate the global burden of illness.<sup>32</sup> The DALY is an indicator of the relative impact of illnesses and injuries on losses of healthy life years. The general approach to derive the end product is similar to that used to derive QALYs, i.e. the disability weights are applied to time intervals with the disease. The disability weights were obtained in a valuation exercise with a group of healthcare professionals.<sup>33</sup> The weights were then applied to approximately 500 disabling health conditions. It should be pointed out that while QALY weights reflect relative preferences of an individual for health states (hence their utilities), DALY weights reflect the degree to which health is reduced by a disease condition. An important difference between the DALY and QALY approaches is that the former uses an age-weighting function that values life years differently depending on the age of disease onset.<sup>21</sup> This function gives greater weight to a year lived by a young adult compared with a child or an elderly person. The DALY approach is commonly used for international comparisons of disease burden, and is frequently used by organizations such as the World Bank and World Health Organization.<sup>34</sup>

### *Healthy year equivalent*

Mehrez and Gafni<sup>30</sup> argued that the QALY measure is not consistent with utility theory; hence an alternative measure is required. The authors then propose the HYE as an alternative and claim that this measure truly reflects a person's utility function over their lifetime and health states. In practice, the HYE is a measure of quality of the life that is based on a two-stage procedure using an SG question to elicit preferences.<sup>35</sup> The HYE has been criticized for the difficulty of implementation. For example, to use the HYE in a state-transition model, the respondents would need to evaluate a large number of possible combinations of health states and health-state durations.<sup>29</sup> Therefore, while the HYE has been acknowledged as a better approach in principle compared with QALYs, its practical implementation was considered unworkable.<sup>23</sup>

### *Willingness-to-pay*

An alternative approach used within a cost-benefit framework (instead of the cost-effectiveness/cost-utility framework) is to obtain valuations of health benefits in monetary terms by asking individuals how much they would be willing to pay to obtain or avoid the health effects. The major

criticism of the cost–benefit framework is that it has an individualistic foundation because it relies on elicitation of the individual’s WTP for health gain. Since the WTP is closely associated with the ability to pay (income or wealth), a health-state valuation based on WTP will systematically disadvantage those with lower incomes by directly linking health effects to a person’s economic resources.<sup>16</sup> In contrast, the QALY and the cost-effectiveness/cost-utility approach allow for social judgement to determine the social WTP for an increase in one QALY.

## Discussion

The QALY is considered to be the cornerstone of economic analysis,<sup>3</sup> which combines both morbidity gains and the mortality impact of a treatment. QALYs, through the incorporation of utilities, aid decision-making in healthcare in order to prioritize limited resources. In addition to the use for economic evaluations, HRQoL data can also be useful in monitoring an individual patient’s health status, the measurement of population health or the effect of therapies in clinical studies.<sup>3</sup>

The reference case for healthcare economic evaluation by NICE incorporates QALYs as a key component. However, the QALY approach has been the subject of debate in recent years. The underlying assumptions of the QALY have come into question and methodological issues have been raised. These range from questions about the theoretical foundation of the QALY approach<sup>29</sup> to the fact that QALYs may not take into account all dimensions of health benefits.<sup>26</sup> Also, the implicit assumption underlying economic evaluations that ‘a QALY is a QALY’ has been challenged on the grounds of equity<sup>22</sup> and efficiency.<sup>20</sup> The QALY approach does not explicitly incorporate equity weights, which can be a challenge for public health interventions. While potential approaches to equity-weighted QALY maximization have been widely discussed in the literature,<sup>17</sup> these methods still have some way to go.<sup>36</sup> Finally, the issue of who should value health states is still contentiously debated in the literature. In conclusion, while some health economists have argued for seeking alternatives to the QALY,<sup>30</sup> the general emphasis is on improving the current QALY approach by addressing the challenges posed by it.<sup>28</sup>

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