

Sanofi Short Guide: The QALY Explained

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Introduction

As a health journey partner, Sanofi UK appreciates the important work that patient organisations do to benefit the lives of patients. As outlined in our Patient Charter, we recognise the importance of working collaboratively with patient organisations and strive to adopt an inclusive and supportive approach to everything we do.

This booklet is designed to help those advocating on behalf of patients to understand the use of the Quality Adjusted Life Year (QALY) within Health Technology Appraisal (HTA) processes.



What are QALYs and why are they used?

Governments cannot spend unlimited amounts of money on healthcare. As a result, there is a need to allocate limited resources to meet the needs of the population. This raises difficult questions; for example, how much should the NHS spend on treating heart disease compared, say, to respiratory disease?

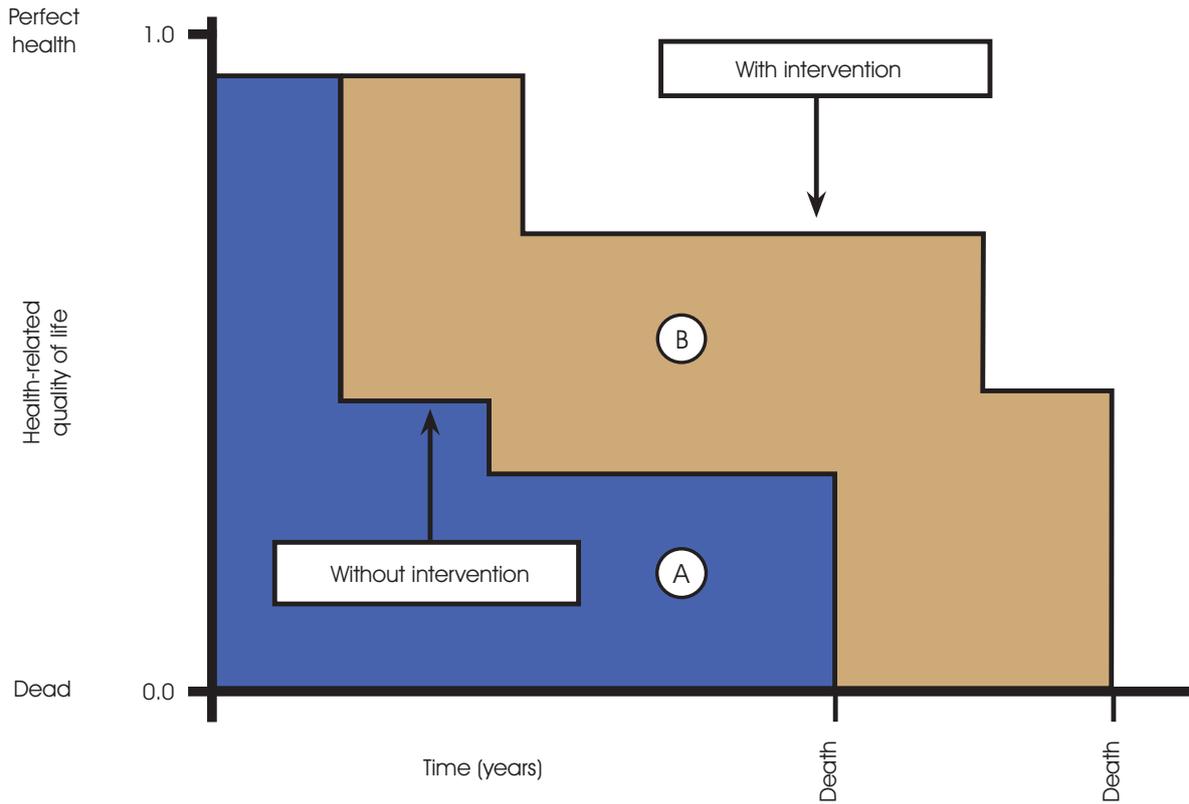
The Quality Adjusted Life Year (QALY) was developed to help allow the comparison of different healthcare interventions which produce different effects. For example, heart disease treatments may reduce blood pressure (measured in mm Hg), whereas an asthma treatment may improve lung function (measured in forced expiratory volume in one second (FEV1)). Converting the effects of each treatment into a common unit allows comparison of these two different treatments in terms of cost per standardised effect.

More formally, the QALY measures the benefit of a health intervention to a patient over their lifetime.¹ It allows decision makers to measure the years a patient might gain by using a treatment as well as the quality of life lived during those years. It combines these two factors into a single index measure so, by definition, one QALY equates to one year of life in perfect health.¹

The graph on the following page gives an example of an assessment of these two factors in two different scenarios. Scenario A looks at the number of years a patient is expected to live without a given treatment and how their quality of life would deteriorate over time. The same factors are then measured in Scenario B, where the patient was given the treatment. By converting the effects of both scenarios into QALYs it allows the comparison between with and without treatment, but also allows comparison with other treatments.

KEY FACT

A QALY quantifies the impact a health intervention will have on a patient's quality and quantity of life.



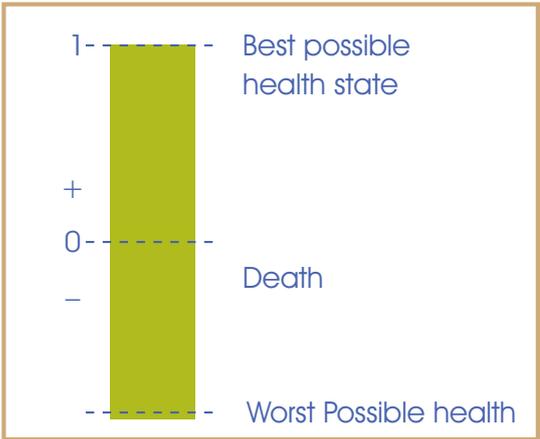
Quality of life scale:

1. MEASURING QUANTITY OF LIFE

To measure the quantity (or length) of life that a patient might gain by using a treatment (usually calculated in years), the Health Technology Agency (HTA), such as the National Institute for Health and Care Excellence (NICE), will look at evidence from clinical trials of the new treatment.

2. MEASURING QUALITY OF LIFE

Quality of life is measured on a simple scale of 0 to 1, where 1 is equivalent to perfect health and zero equals death. Some health states are considered worse than death and so these can be accounted for with negative quality of life scores.²



This diagram was adapted from figure 1 in 'Philips, C., 'What is a QALY?'.²

Quality of life estimates are calculated from clinical trial data, natural history data, expert clinical opinion and patient questionnaires. The values from 0 to 1 are calculated taking the results of patients' descriptions of their health and weighting these against how good or bad members of the public believe various states of health to be. The most common questionnaires that are used to calculate the quality of life for various diseases are called EQ-5D and SF-36. The EQ-5D is preferred by NICE and there are three current examples of the EQ-5D in use and they all focus on five key elements (referred to as dimensions) which include: mobility; self-care; usual activities; pain/discomfort; and anxiety/depression. The questions that are used in the EQ-5D questionnaire are in fact very simple, with patients asked to tick one box that best describes their health on that particular day.³

Sample questions from one dimension of the EQ-5D include:³

MOBILITY

**Please tick
ONE box that
describes your
health TODAY**

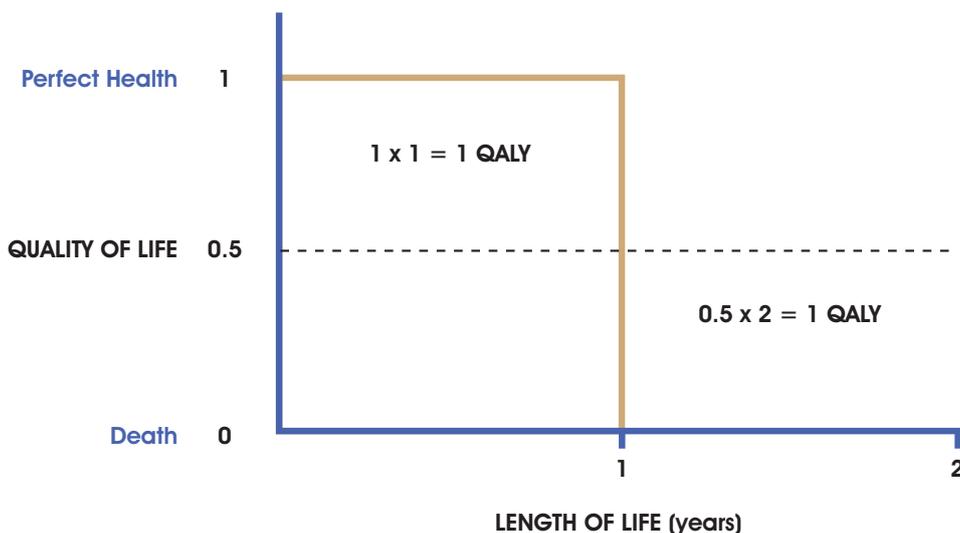
- I have no problems in walking about
- I have slight problems in walking about
- I have moderate problems in walking about
- I have severe problems in walking about
- I am unable to walk about

Calculating the QALY

The QALY is simply calculated by multiplying the quality of life value by the number of years a patient is expected to live.

$$\text{QALY} = (\text{quality of life value}) \times (\text{length of life})$$

Therefore, if a patient is expected to live for one year in perfect health (quality of life value of 1), it would equate to 1 QALY; whereas a different patient living for two years in 50% of perfect health would also equate to 1 QALY.



The QALY allows comparisons between new and existing treatments to understand whether the new treatment brings additional QALYs (a QALY gain).

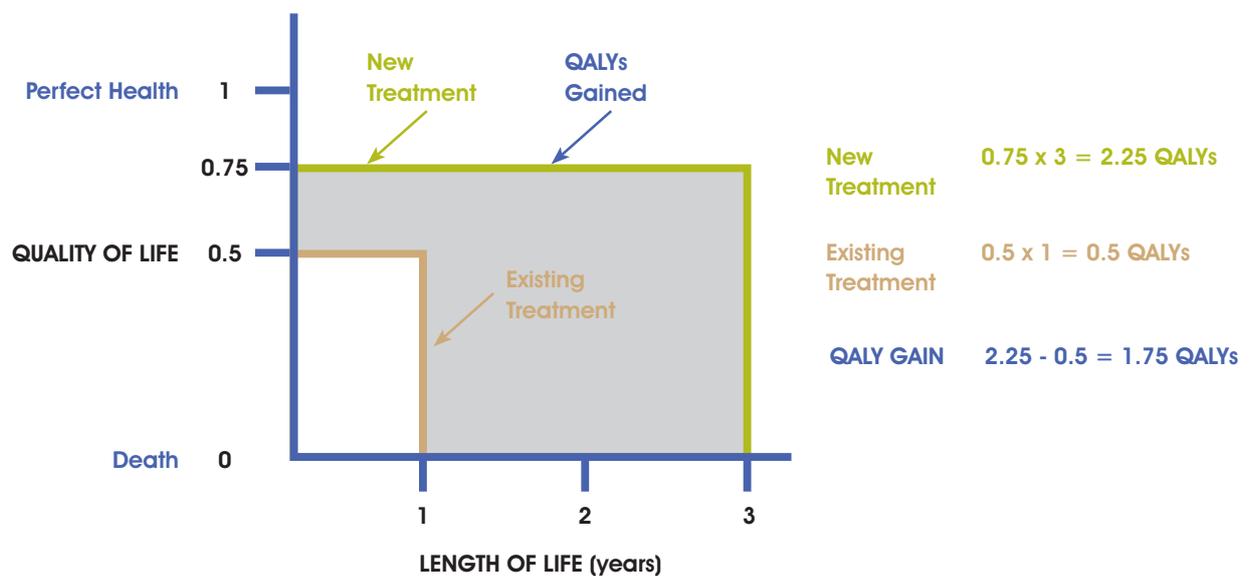
$$\text{QALY GAIN} = (\text{QALY for new treatment}) - (\text{QALY for existing treatment})^4$$

An example of a QALY gain is as follows:

Existing treatment: the patient receives the existing treatment for their condition and is expected to live for one year with a quality of life valued as 0.5.

New treatment: the patient receives the new treatment for their condition and is expected to live for three years (extending their life by two years compared to the existing treatment) with an improved quality of life valued as 0.75.

The new treatment is therefore associated with a QALY gain of 1.75 QALYs, as demonstrated below:

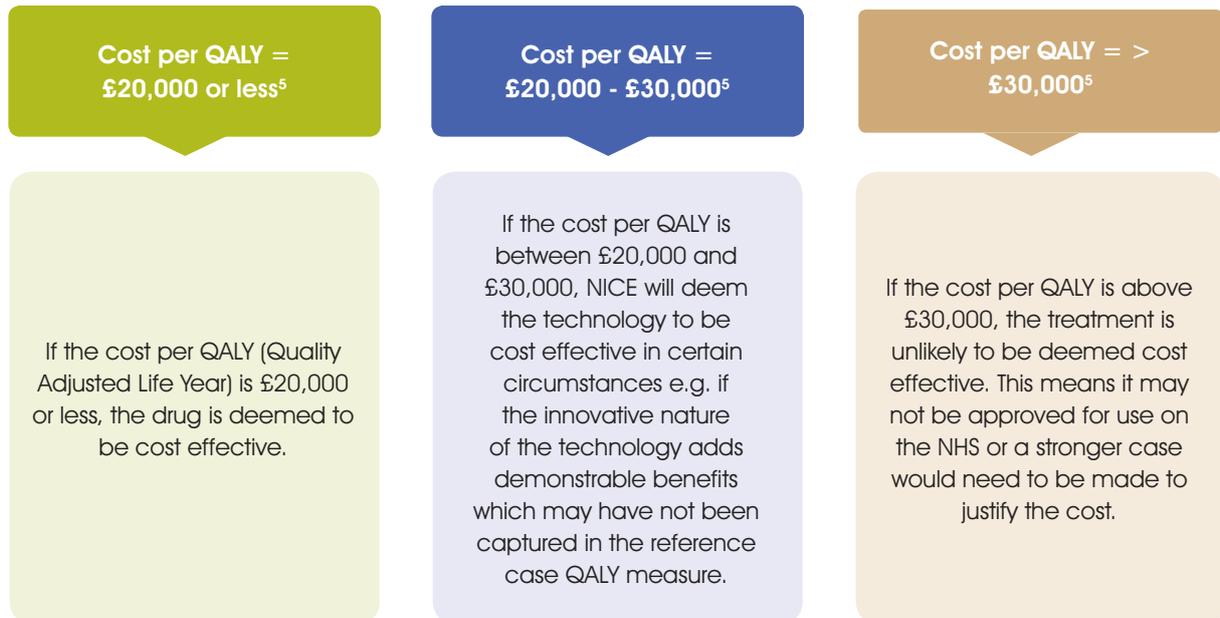


How is the QALY used?

The QALY is used by HTAs to determine the additional value of a particular treatment or intervention. This is done by calculating the cost per QALY.

Treatments are compared taking into account both the total cost per year of the treatment (more correctly the total cost is the costs minus any savings), as well as the outcomes associated with that treatment (the QALY gain). This provides a value of cost per QALY.⁴ Calculating the cost per QALY allows treatments to be compared based on the total cost of their outcome, as opposed to the price of the treatment.

In England, NICE sets thresholds to determine whether a treatment is cost-effective and therefore be made available on the NHS. NICE has a £20,000 cost per QALY threshold, with treatments with a cost per QALY over this amount less likely to be made available on the NHS.⁵

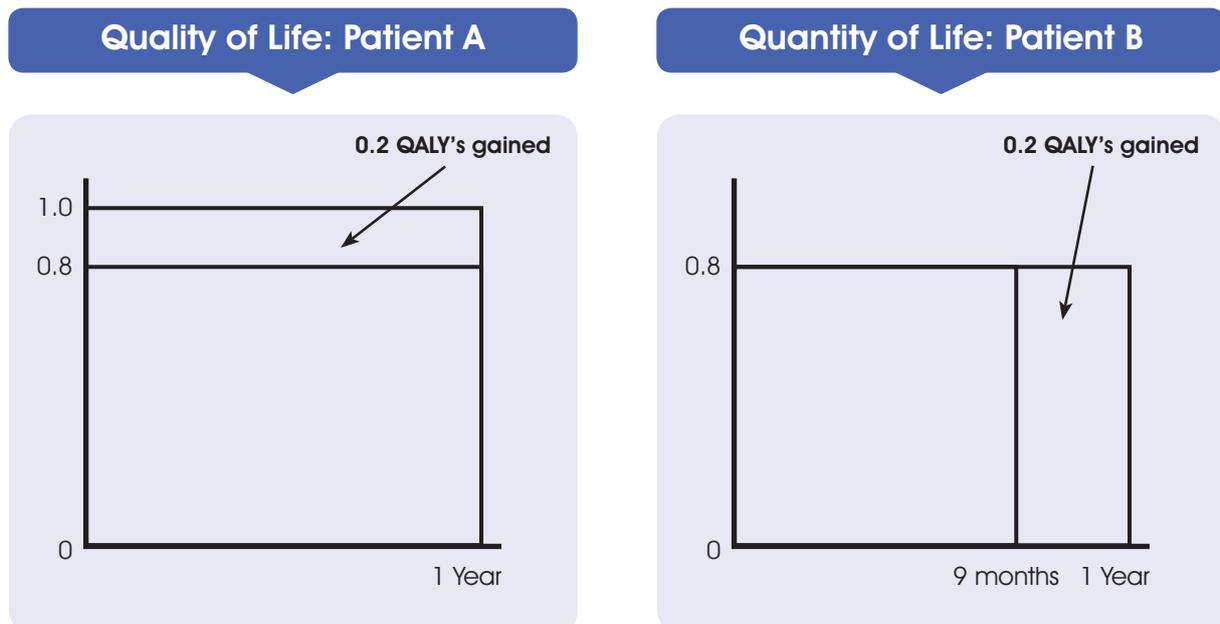


Some problems with QALYs

Despite advantages in using a single measure of effectiveness of health care interventions, there are also some limitations with using QALYs. Some criticisms that have been levelled against the QALY include:

1. Not all QALYs are equal:

Even though QALYs are regarded as having equal weighting, in practice not all QALYs are considered equal. People may subjectively value extra life, over extra quality of life, especially those people or their families with a life limiting illness requiring a new treatment. The example below highlights how different treatment outcomes can be associated with the same QALY value.



For many patients, the three months of life gained by patient B may be deemed more valuable than the improvement from 0.8 to 1 on the quality of life scale for patient A. Yet both outcomes are associated with a value of 0.2 QALYs gained.

For some diseases, the way in which the value of health gains is calculated may also not be appropriate. For example, quality of life measures are valued based on the general population's views on living in a particular state of health. The general population may misunderstand what it is like to live with a condition, such as cancer, which means that the value of health gains deemed important to those cancer patients may not be taken into consideration.⁶

2. Using QALYs for highly specialised technologies:

Doubts have long been expressed about using QALYs to evaluate medicines for rare and very rare diseases, mainly because treating rare and severe diseases attach an additional social value i.e. society has a preference for treating people with these diseases. There are several reasons as to why this is the case, but the most important is considered not of "equity". People with rare and very rare diseases deserve the same chance of being able to access treatments.

However, the economics of developing treatments for very rare diseases (some development costs, but small patient population against which revenue can be generated) mean that the cost per QALY is much higher than for normal diseases. For example, the NICE Highly Specialised Technologies (HST) process has approved medicines where the cost per QALY is typically £500,000.⁷

As a result, many economic commentators believe that QALYs shouldn't be the sole decision making criteria in assessing very rare treatments but rather should be part of the evaluation process.

About Sanofi in the UK

Sanofi is a global life sciences company committed to discover, develop and distribute therapeutic solutions focused on patients' needs. Sanofi in the UK partners with a number of different patient organisations to pursue goals which benefit patients. Our Patient Charter outlines our pledges for working with patients and patient organisations. To view the Patient Charter and learn more about our work with patient organisations, please visit www.sanofi.co.uk

Life is a health journey, with ups and downs, which can be big or small, lifelong or momentary. We, at Sanofi, are there for those challenges, **as a health journey partner**. Many patients are depending on us. We aim to protect, enable and support people facing health challenges, so they can live life to its full potential.

References

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- 6 Office of Health Economics (March 2018) 'Appraising Ultra-Orphan Drugs: Is Cost-per-QALY Appropriate? A Review of the Evidence,' available at: <https://www.ohe.org/system/files/private/publications/468%20-%20Appraising%20ultra-orphan%20drugs.pdf?download=1> (accessed: July 2019)
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