Implementing value-based assessment of medicines

Steve Chaplin BPharm, MSc

Steve Chaplin examines NICE’s proposals to introduce two weighting systems into its technology appraisal process in order to better reflect the value of new treatments.

In 2010, the Government began consultations on implementing value-based pricing for new medicines in the NHS. The idea was first proposed in a 2007 review of the Pharmaceutical Price Regulation Scheme (PPRS) by the Office of Fair Trading and optimistically scheduled for inclusion in the 2014 PPRS.

NICE recommends technologies as value for money for the NHS depending on whether they meet a threshold – the incremental cost effectiveness ratio (ICER). This is currently £20,000–£30,000 per quality-adjusted life-year (QALY) gained compared with a therapeutic standard.

The Government suggested modifying this system by adjusting the ICER threshold according to a medicine’s effect on aspects of life other than the patient’s health and whether it was innovative. In other words, the NHS would pay more for ‘better’ drugs.

Modifying the ICER

Nowadays, NICE takes innovation into account in its technology appraisals. Its guide to the methodology of technology appraisals states that judgments about the acceptability of the technology as an effective use of NHS resources will specifically take account of the innovative nature of the technology, specifically if the innovation adds demonstrable and distinctive benefits of a substantial nature that may not have been adequately captured in the reference case QALY measure.

Medicines judged to be innovative are considered at the top end of the range of acceptable ICERS – that is, they are more likely to be accepted at a higher price.

Deciding whether a medicine is innovative can be as straightforward as clinical opinion. For example, the recent appraisal of rituximab (MabThera; not a new drug) for vasculitis was considered innovative because clinicians and patient experts described it as ‘scene changing’ – it was the first new treatment for this indication since cyclophosphamide was introduced in the 1970s, and the manufacturer showed that, unlike cyclophosphamide, it did not affect fertility (something that was not captured in the QALY calculation).

There is another ‘modifier’ of the ICER threshold that NICE takes into account: medicines that offer life-extending treatment at the end of life (a minimum of...
three months when life expectancy is less than 24 months) may be considered at an ICER that is up to 2.5 times greater than the norm.\textsuperscript{3,5} This notion of weighting has been carried through into the latest proposals.

**Value-based assessment**

Talking about pricing medicines before deciding how to assess their benefits is putting the cart before the horse, so NICE is now consulting on how it should assess value in its technology appraisals.\textsuperscript{5}

It is proposing to continue its reliance on the QALY but wants to obtain a fuller estimate of a medicine’s benefits by introducing new methods of weighting.

Two are outlined: wider societal impact and burden of illness. So complex are these issues that each has a dedicated briefing paper.\textsuperscript{6,7}

NICE is also asking to what degree these measures should be allowed to lower the ICER threshold.

**Wider societal impact**

NICE can already take into account a treatment’s benefits beyond its effect on health but only to a limited extent. It wants to consider a wider range of benefits so as to ‘give preference to technologies developed for conditions that have the potential to restore the ability of individuals to contribute to society’.

The wider societal impact of an illness is defined as the loss (shortfall in the jargon) in a person’s capacity to engage with society compared with their capacity to do so if they did not have the condition. The QALY, as an indicator of the quality and length of life, is a unit that indirectly quantifies shortfall.

Wider societal impact is estimated from the absolute shortfall in QALYs – that is, the difference between the total QALYs expected as a consequence of having the condition and the total QALYs expected for people with the same age and gender distribution without the condition.

This approach means that larger losses in QALYs are more significant than smaller ones. NICE cites the examples of a chronic condition being more significant than a treatable acute illness, and potentially fatal childhood cancer being more significant than chronic heart failure.

**Avoiding disadvantage**

NICE is at pains to distinguish between the concept of wider societal impact, which it prefers, and wider societal benefit. The latter compares the resources a person contributes to society (production) and the amount they consume, with and without the new treatment. This approach ‘cannot comfortably be integrated’ into NICE’s appraisal methodology because it disadvantages elderly people and those with a disability.

NICE has stated that it will not use age, gender or any ‘protected characteristic under equalities legislation’ when deciding whether to recommend a treatment.

However, the Office of Health Economics states that this failing applies to any application of absolute shortfall (and therefore to wider societal impact) because it ‘will automatically treat sufficiently elderly patients as lying at or near the bottom of the burden of illness scale, regardless of their current prognosis and regardless of their previous experience of poor health.’\textsuperscript{8}

It is a complex issue but, in summary, elderly people stand to lose fewer QALYs from ill health than younger people and treatment will seem less cost effective in their age group. If NICE is to introduce wider societal impact, it will have to qualify its application with appropriate safeguards.

**Burden of illness**

This is the total amount of future health lost due to an illness. It is calculated by measuring the relative shortfall in QALYs, defined as the loss in quality and length of life that occurs as a consequence of having a disease or condition as a proportion of the QALYs that people would expect to have over the rest of their lives without the condition.

This concept covers end-of-life considerations, which will no longer be considered separately.

Burden of illness is estimated from a reference data set prepared by the Department of Health, adjusted for the specific patient population. NICE says society places higher values on QALYs gained by individuals with a relatively high burden of illness compared with a lower burden, suggesting that medicines to treat severe disorders will attract higher prices than those for minor conditions.

**Maximum weighting**

There must be a limit to the maximum ICER that is acceptable, NICE says, because ‘valuable care elsewhere in the NHS might be displaced without at least an equally valuable gain being achieved’.

It wants to keep the basic ICER threshold of £20 000 and allow a maximum weighting of 2.5 when all the modifiers are applied, as with end-of-life treatments. NICE does not say why the new limit should be the same as the old one, or why the figure is an appropriate one for the total effect of the new modifiers.

The Association of the British Pharmaceutical Industry does not support the current limit on weighting, stating: ‘We have a particular concern about the potential impact of incorporating NICE’s existing “end-of-life criteria” into the new system. We need to ensure that this does not lead to fewer medicines for patients at the end of their life being approved. There is currently an issue with NICE approving too few new cancer medicines, which the new agreement must address.’

**The consultation**

NICE is inviting comments on whether the relative and absolute shortfalls in QALYs adequately reflect the modifiers of burden of illness and wider societal impact, whether 2.5 is a reasonable maximum for the modifiers, and whether the modifiers should have specific weights that add up to 2.5.

It is also addressing more fundamental principles such as whether the proposal will improve the ‘consistency, predictability and transparency’ of its judgements and defining the risks associated with adopting this approach to value-based assessment.
The consultation is open to patients, carers, patient groups, clinicians, academics, economists, industry and members of the public and closes on 20 June. The changes will be introduced in the autumn.

Conclusion
NICE wants to hear from all stakeholders on its proposals to introduce two weighting systems into its technology appraisal process, the better to reflect the value of new treatments.

The technicalities are probably clearer to health economists than the general public or the GP but the bigger picture is clear enough. If we want a patient-centred NHS, this is one more step towards it.

References

Declaration of interests
None to declare.

Steve Chaplin is a pharmacist who specialises in writing on therapeutics.