National Institute for Health and Care Excellence
Review Guide to the Methods of Technology Appraisals Addendum - 2014
Comments

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	Consultation questions
1 Does proportional QALY shortfall appropriately reflect burden of illness?	The ethical principle for taking into consideration the 'burden of illness' is that people suffer a loss when they cannot lead a life that is as long and healthy as chance and choice will allow. Using proportional QALY shortfall as a measure of that loss is one way of capturing this principle. As the Consultation recognises, there is no perfect measure. However, from a practical point of view, a proportional QALY shortfall approach has the advantage compared to a 'fair innings' approach, that it does not require calculation of *previously* experienced QALYs for particular patient groups, when assessing an intervention.
2 Does absolute QALY shortfall provide a reasonable proxy for wider societal impact of a condition?	Absolute QALY shortfall is another measure for 'burden of disease'. As it is more sensitive to age, it can in principle pick up loss of 'productive years' and therefore does give an indication of societal impact on society. However, its disadvantage is that it will not be easy to prevent it having a strong age bias in its application.
3 Does a maximum weight of 2.5 in circumstances when all modifiers apply function as a reasonable maximum?	There is a justifiable rationale for making the maximum QALY weighting for burden of illness, as measured by proportional QALY shortfall, no greater than 2.0. See the next section. Such a weighting would be consistent with, though would not require, additional weighting for wider social impact.
4 Should we allocate specific 'weights' to each of the 'modifiers' so that they add up to a maximum of 2.5? If so, do you have a view on what weight should be added in	The principal challenge in using proportional QALY shortfall as a measure of burden of disease is how to define consistent relative weightings across the whole set of potential patients. Comparisons between *pairs* of patient groups are relatively straightforward and can be undertaken in various ways.

each case

Towse and Barnsley (2013) show how this can be done hypothetically, and Bazier *el al.* (2013) show how equivalent weights can be derived from discrete choice experiments. Shah (2009) surveys other studies. However, it is one thing to derive relative pair-wise weights between two arbitrarily selected groups of beneficiaries. It is another matter to derive a consistent set of weights across all potential beneficiaries. In theory, it is be possible to derive a consistent set of weights through multiple pair-wise comparisons, provided the pair-wise comparisons satisfied certain logical constraints, but in practice this would be very demanding. More importantly, it would not necessarily satisfy the requirements of justification and accountability.

An alternative approach to the challenge is to think of burden of illness as a shortfall from a completely healthy life, say 80 years at full quality.   At present the threshold of acceptability is £20,000 per QALY. This implies that for someone who has reached 79 so far in full health, an intervention would be funded to secure the last year of life at full quality. A person reaching the last year of life, having experienced full quality, can be regarded as falling in the 'most fortunate' category of patients (still requiring an intervention). Consistent weights for all other groups can be defined by comparing each possible group to this 'most fortunate' group.

The approach can be illustrated in the following example. Imagine that maximum life-expectancy is 80, and that the most fortunate individuals, who still nonetheless need treatment, have a condition that enables them to live a full quality of life to 79 (on whatever current treatments there are) and to 80 without the condition. So, at age 78 the members of this have a condition that means they will die at 79, but they would live to 80 without the condition. Call this group Group A, and compare them, in the example given below, with two other hypothetical groups, Group B and Group C.

Table 1: Three Hypothetical Groups, A, B and C

Group	Age Now	With current treatment QoL	With current treatment LoL	With current treatment Total QALYs	LoL without the condition	QoL without the condition	Potential QALYs in absence of the disease	Absolute QALY shortfall
A	78	1	1	1	80	1	2	1
B	18	1	1	1	80	1	62	61
c	1	1	1	1	80	1	79	78

Group A is the most fortunate group, suffering a proportional shortfall of 50% (1/2). B and C suffer a proportional shortfall of 98% and 99% respectively. These shortfalls imply a ratio of 1.96 (98/50) and 1.98 (99/50) compared to A. In indexing both B and C to A, we have also defined relative weightings for B and C compared to one another. Such a procedure could be followed for all other categories of patients with a potential shortfall.

The willingness to pay for the most fortunate group is the standard rate, at present £20,000 per year per QALY. Groups B and C would be weighted more heavily, in accordance with their relative burden of illness, and they would receive a

	weighting of approximately 2:1, implying a willingness to pay of £40,000 per QALY. Since proportional loss can never exceed 100%, the weight relative to the most fortunate group can never be greater than 2:1. Even for those suffering the greatest burden of illness, the collective willingness to pay for treatments would never be greater than twice the standard QALY rate, or £40,000.
	References
	Brazier, John *et al.* (2013) 'Eliciting Societal Preferences for Burden of Illness, Therapeutic Improvement and End of Life for Value-Based Pricings: A Report of the Main Survey', Policy Research Unit in the Economic Evaluation of Health and Social Care Interventions, Universities of Sheffield and York. Available at: http://www.eepru.org.uk/EEPRU%20VBP%20survey%20DP.pdf. (Last accessed 13.6.14.)
	Shah, Koonal K. (2009) 'Severity of illness and priority setting in healthcare: A review of the literature', *Health Policy*, 93, pp. 77-84.
	Towse, Adrian and Barnsley, Paul (2013) 'Clarifying the Meanings of Absolute and Proportional Shortfall with Examples, Office of Health Economics, available at: http://www.nice.org.uk/media/FE2/C7/OHE_Note_on_proportional_versus_absolute_shortfall.pdf. (Last accessed 13.6.2014.
5 Will the approach outlined in this document achieve the proposed objectives of improving consistency, predictability and transparency in the judgements made by our independent Appraisal Committees when they consider the clinical and cost effectiveness of health technologies?	Consistency can only be achieved provided the set of relative weights is defined consistently. Securing such consistency does not require the approach outlined in the previous section, but it would require an approach with equivalent effect. Finding an approach will equivalent effect will be difficult to achieve and there is likely to be controversy over the methods chosen to arrive at the relative weights.
	Moreover, there is an issue of transparency. The discrete choice experiment reported in Brazier *et al.* (2013) showed evidence that participants did not fully understand the task they were being asked to undertake. It is even harder to explain to the public at large why such experiments should be the basis of weighting.
	In this context, the more intuitive idea of comparing each potential group to the most fortunate has advantages. Moving away from the principle that a QALY is a QALY is QALY, which has withstood the test of time, requires some form of moral argument, based on the principle of seeking to give everyone the fullest life possible.
	References
	Brazier, John *et al.* (2013) 'Eliciting Societal Preferences for Burden of Illness, Therapeutic Improvement and End of Life for Value-Based Pricings: A Report of the Main Survey', Policy Research Unit in the Economic Evaluation of Health and Social Care Interventions, Universities of Sheffield and York. Available at: http://www.eepru.org.uk/EEPRU%20VBP%20survey%20DP.pdf. (Last accessed 13.6.14.)
6 Are there any risks which might arise as a	One risk of using any form of proportional shortfall, consistently indexed over different groups, is that the aggregate

| result of adopting the value-based assessment approach as outlined above? If so, how might we try to reduce them? | | effects on spending may be inflationary. Those who suffer a relatively high burden of disease at, say, c.60 diagnosed with only one year of life, will receive a weighting close to 2. This may effectively move the threshold weighting up to £40,000 for a significant group of patients. However, it can be argued that this effect is implicit in the very idea of taking into account the burden of disese.

A second risk implicit in taking over the burden of illness approach is that the approach has intellectual affinity with the WHO definition of health as 'a complete state of physical, mental and social well-being' (WHO, 1948). Huber *et al.* (2011) have contested this concept arguing that, with the growth of chronic diseases, health is better conceived as the ability to adapt and self-manage in the face of social, physical and emotional challenges. On such an approach, proportional QALY shortfall would not be assessed by the degree to which individuals reasonably fell short of perfect health, but by the extent to which they fell short of reasonably expected health, saying living to average life-expectancy but with a set of well-managed 'aches and pains'. In other words, the risk of NICE is that it would find itself having to deal with complex conceptual and ultimately philosophical questions about the good life in the presence of inevitable disease. That would be a demanding expectation on a public body.

References
Huber, Mechtild *et al.* (2011) 'How Should We Define Health?' *British Medical Journal*, 343:d4163 doi: 10.1136/bmj.d4163.
WHO (1948) Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948. |
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