

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?	<p>Breast Cancer Care believes that NICE should take steps to ensure that any methodology it uses does not result in under-valuing treatments for terminally ill patients. We are therefore concerned with the proposal to remove the end of life criteria currently used by Appraisal Committees. Although a 'proportional QALY shortfall' approach to measuring burden of illness, rather than an 'absolute QALY shortfall' analysis, would seem to be better at acknowledging the burden of illness for patients near the end of their lives, until we see concrete examples of this in practice we are not confident that this will not lead to an undesirable decrease in access to medicines for patients at the end of their lives. We ask NICE to consider keeping the end of life criteria as an addition to the burden of illness weighting, and evaluate and publish the implications for patients of doing so.</p> <p>We cautiously welcome the use of 'proportional QALY shortfall' instead of 'absolute QALY shortfall' as being more likely to acknowledge the burden of illness in older age, although we remain concerned that older patients are still more likely to receive lower weightings and this may still be an age discriminatory method of analysis. This is a particularly relevant issue for breast cancer as breast cancer risk increases with age.</p> <p>It is important that patients' views are central to any calculation of burden of illness and it is regrettable that this consultation document does not present any details of how patients and patient organisations will be involved in the appraisal of burden of illness (i.e. how NICE's current Patient and Public Involvement Programme will be strengthened to better involve patients in technology appraisals) nor how patients' views on quality of life will be gathered. Patients' views and capturing what they consider to be valuable are central to producing meaningful quality of life data. We ask NICE to specify how patients and patient organisations will be involved and how their views will be incorporated.</p> <p>It is important that methods of value assessment are sensitive to different stages of disease and treatment goals. As a breast cancer charity, we would like to stress the importance of value assessment being inclusive of both the needs of those diagnosed with primary breast cancer (whose treatments aim to be curative) and the needs of those</p>

	<p>diagnosed with secondary (incurable) breast cancer (whose treatments aim to slow the progression of disease). In order to do this, patient-determined quality of life data must be obtained from both of these patient groups and representatives from both groups must be active participants in appraisal deliberations. It is important that the new methodology does not simply view breast cancer as 'one disease' and that the complexities of different types of primary and of secondary breast cancer are taken into account.</p>
<p>2 Does absolute QALY shortfall provide a reasonable proxy for wider societal impact of a condition?</p>	<p>Breast Cancer Care has concerns about the use of 'absolute QALY shortfall' as a proxy for wider societal impact and we are unsure of what results this would produce when put into practice. We also have concerns that this is a very narrow way of measuring the impact on society of a drug technology and it seems unlikely to adequately capture the value cancer drugs provide for patients and carers and their family and friends.</p> <p>As a breast cancer charity, we would particularly highlight how important it is that NICE evaluation methods do not inadvertently result in the under-valuation of treatments for women and for older people. This is a particularly pertinent issue for breast cancer patients as the overwhelming majority are women (around 99%) and breast cancer risk increases with age, with around 80% of breast cancer cases diagnosed in the over 50s, and around a quarter diagnosed in women aged 75 and over [statistics from Cancer Research UK web site, 2014]. Older people are less likely to participate in paid employment and women are more likely to undertake unpaid caring responsibilities outside of the labour market that may not be deemed as valuable in an abstract analysis of societal impact. The consultation document concedes that 'approaches to capture wider societal impact will inevitably take age into account to some degree'. It also clear from supplementary background papers that an analysis on the grounds of 'absolute shortfall' is more likely to be weighted towards younger patients (older patients having less time left to 'contribute to society'). Although the consultation document contains strongly worded reassurances that NICE will not be guided by any results that discriminate on the grounds of age or other 'protected characteristics' under equality legislation, the document does not give any details about how this will be achieved. As a public sector body, the NHS has a duty not only to ensure that discrimination does not take place, but also to actively promote equality and this consultation document does not give sufficient reassurances that this will be the case when it comes to the availability of medicines.</p> <p>We also have concerns that it is likely that the proposed societal impact analysis will not sufficiently value secondary breast cancer drugs that are effective in that they control disease and extend life, but are not curative. We are very concerned that clinically effective treatments for secondary breast cancer patients may be low-scoring in this method of analysing wider societal impact.</p>
<p>3 Does a maximum weight of 2.5 in circumstances when all modifiers apply function as a reasonable maximum?</p>	<p>We do not feel able to comment in detail on this without examples of how this would work in practice. This seems a very inflexible approach, which may mean that particularly innovative drug technologies cannot be favoured in the assessment process.</p> <p>Since 2011, there have been eight negative NICE appraisals (two of these are draft) for breast cancer treatments and we are not confident that this proposed weighting will improve access to breast cancer drugs. The ICERs for the previous seven negative NICE appraisals for breast cancer treatments have, with the exception of fulvestrant in 2011, all shown to be likely to exceed the proposed £50,000 per QALY threshold.</p> <p>ICER per QALY gained - NICE determinations of most likely cost-effectiveness.</p> <ul style="list-style-type: none"> • trastuzumab emtansine (draft 2014): £185,600 per QALY gained

	<ul style="list-style-type: none"> • everolimus plus exemestane (2013): £68,000 per QALY gained • pertuzumab (draft decision in 2013, final decision delayed): manufacturer's base-case ICER showed a 0% probability for pertuzumab plus trastuzumab and docetaxel to be considered cost effective at £30,000 per QALY gained. • lapatinib or trastuzumab in combination with an aromatase inhibitor (2012): lapatinib plus an aromatase inhibitor near to £74,000 per QALY gained; trastuzumab plus an aromatase inhibitor at least £51,000 per QALY gained. • eribulin (2012): £68,600 per QALY gained • bevacizumab in combination with capecitabine (2012): higher than the ICER of £82,000 per QALY gained • bevacizumab in combination with a taxane (2011): between £110,000 and £259,000 per QALY gained and greater than £115,000 per QALY (dependent on which taxane used) • fulvestrant (2011): £35,000 per QALY gained <p>We understand that the NHS has finite resources and therefore there is a need for a rigorous analysis of both the clinical and cost-effectiveness of new drugs. We also acknowledge that the drug manufacturers have a responsibility to price drugs fairly. However, as a patient organisation with contact with thousands of people affected by breast cancer through our services, we are very aware of the distress caused by drugs not being available on the NHS that patients believe would be clinically effective for them.</p>
<p>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 each case?</p>	<p>We do not feel able to comment in detail on this without further information and examples of how this might work in practice. However we do believe that patients with secondary (incurable) breast cancer need assurances that treatments that control disease but are not curative will be valued in this new method of analysis. This may mean giving a higher weighting to the 'burden of illness' for those with secondary breast cancer, but without concrete examples of these methods in action to consider it is difficult to be sure of the best approach.</p>
<p>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?</p>	<p>This consultation is open to patients and patient organisations yet the consultation document and methods described are not accessible for a layperson without any background in health economics. Examples of how these proposed methods would have impacted on previous appraisal decisions would have been helpful.</p> <p>We are concerned that breast cancer patients will not have trust and confidence in such an opaque methodology that cannot be easily communicated in a clear manner. We believe this will amplify distrust of the system already felt by breast cancer patients. We welcome the inclusion of a patient group meeting in NICE's 'Stakeholder engagement' sessions around value based assessment, but it is regrettable that NICE did not include a patient meeting, promoted and accessible to patients not involved in patient organisations.</p> <p>As we described above, we believe that NICE needs to make sure adequate weight is given to and formal processes are put in place for meaningful patient engagement in technology appraisals. It is not clear from the proposals that this will happen. Giving patients a more significant voice (equal to that of health economists, health care professionals and drug manufacturers) could help restore public confidence in NICE decisions. It could also mean that important measures, such as quality of life, are more accurately captured within the decision-making process.</p>
<p>6 Are there any risks which might arise as a</p>	<p>As we described above, we have particular concerns that this approach risks discriminating against older patients and secondary breast patients. It may also discriminate against women whose contributions to society</p>

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Closing date: Friday 20 June 2014 5pm

PLEASE NOTE: NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.