

National Institute for Health and Care Excellence
Review Guide to Process of Technology Appraisal - 2014
Comments

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Section Number Primarily Related to your Comment (please enter only one) Indicate ' general ' if your comment relates to the whole document	Other Section Numbers Related to your Comment	Comments Please insert each new comment in a new row. Please do not paste other tables into this table, as your comments could get lost – type directly into this table.
Foreword (p.5)	2.1 to 2.4	The Foreword (para 1) states that NICE “carries out appraisals of health technologies at the request of the Department of Health”. Under the PPRS 2014 “Companies may request value-based appraisal of their new medicines, and such requests will not be unreasonably refused.” (see https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/282523/Pharmaceutical_Price_Regulation.pdf (para 4.8). Patient organisations will also be able to encourage companies to request an appraisal citing this freedom to companies where products are not planned to be appraised. Can NICE add in a reference to this in the Foreword and in the Selection of technologies section?

1.10	1.11, 3.6.3,	<p>(a) This para does not explicitly reference changes that are being worked on by NICE under Value Based Assessment (VBA). Our understanding is that, although the overarching process will likely be much the same as now, VBA will include consideration of issues such as the Burden of Illness (BoI) and Wider Societal Benefit (or Impact) (WSB or WSI). Therefore, the NICE process will need to ensure that these issues are given sufficient time and weight as part of Appraisal Committee deliberations, as well as forming part of the evidence ‘package’ received by the Committee.</p> <p>Can NICE clarify and ensure that the process guide reflects consideration of BoI and WSI with cross reference, where appropriate, to future changes made in the Methods Guide?</p> <p>This would include potential provision for revised submission templates and/or new content from patients and their representative organisations.</p> <p>(b) We are pleased that NICE has recognised that EQ 5D, as the preferred measure, or other quantitative approaches (e.g. PROMS) do not fully capture all aspects of health related quality of life (HRQoL). This is seen in changes already made to the 2013 Methods Guide, with evidence from patient organisations described as ‘complementary’ (3.6.3). To be in line with this, patient evidence should be seen as a discrete form of evidence to accompany the clinical and economic evidence. This would also mean that this evidence, actively sought by NICE, is given a correspondingly distinct place in the evidence ‘package’ that is drawn upon by the Appraisal Committee. We also note that the January 2014 proposed amendments to the Methods Guide include consideration being given to ‘the loss of an individual’s social function as a result of living with the condition’ (6.2.11) and to any ‘significant benefits other than health’ (6.2.20) resulting from a treatment. These elements are expected to part populate the Appraisal Committee’s deliberation process (6.2.21).</p> <p>To assist them in that task we suggest that:</p> <p>(i) A suitably qualified social scientist(s) whose speciality is the study of social relationships be recruited to an ERG or AG to assess evidence of loss of societal function and any gain in non health benefits resulting from a treatment.</p> <p>(ii) A representative of this social science speciality should join their social scientists colleagues, whose sole speciality is the contribution of economic evidence, on the lead team.</p> <p>(iii) Committees should actively recruit such specialists to join other Appraisal Committee members amongst whom are those with (other) social science backgrounds.</p>
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Table 1 (p.11)		<p>The table provides an overview of participants in the technology appraisal process.</p> <p>(a) Whilst there are a number of ways for patients and their representative organisations to be involved in a TA, we believe that it is key that the lay representatives on the Appraisal Committees are truly representative of patients & the public and are effective advocates. The table notes that the Appraisal Committee includes those from “lay backgrounds (with an understanding of patient and public perspectives on healthcare issues)”. We believe that this role is vitally important, particularly in ensuring that the Committee allocates sufficient time to discuss the patient perspective and evidence since, in our experience, there can be too much emphasis on, and discussion time allocated to, the health economic components within an appraisal. We are aware that this situation has raised concerns about the effectiveness of lay representatives performance in committee meetings.</p> <p>We suggest that NICE commissions a rapid review style, independent evaluation to explore the representativeness, role and performance of lay representatives under the current process to establish if changes are required that need to be incorporated in the process guide.</p> <p>(b) NICE should also acknowledge, especially with the imminent inclusion of BoI & WSI (WSB) components, that it will be those patients and their representative organisations that will have a more in-depth understanding of living with the disease in question and, possibly, the technology under scrutiny.</p>
Table 1 (p.11)		<p>The table also discusses patient expert(s) that can take part in an appraisal. We believe that NICE needs to continue to build on their support for patient experts, and ensure that they are able to fully contribute. NICE should provide bespoke support and allow a more flexible approach to their submissions at least for those with personal experience of the disease and/or technology since their participation in an appraisal will invariably be one time.</p> <p>We recognise that this may pose consistency challenges but we believe it is worth exploring as the submission could provide more useful information to the Committee. This could be piloted and evaluated before becoming routine practice.</p>
Table 1 (p.11)	<p>Table 1 (p.12) Fig 3 p.36 Table 3 p.43 Fig 4 p.44 Table 4 p.50 3.6.5. Appendix C p.86 p.90</p>	<p>Views expressed by employees or officers of patient organisations should not be seen as ‘personal views’ but rightly as views of the patient organisation that they represent. We are concerned that a consequence of describing their views as ‘personal views’, perhaps unintended, is the inference that such views are therefore subjective and warrant the ascription of secondary status to those that are deemed objective.</p> <p>We are aware NICE assigns the same ‘personal view’ descriptor to the submissions of specialist clinicians and NHS commissioners but would suggest, especially since their professional colleagues sit as committee members, the status ascribed to their inputs is far less open to being described as subjective.</p>

Table 1 (p.14)	1.5	<p>We suggest, given the results from the HSCIC Innovation Scorecard in relation to NICE appraised medicines (reconfirmed for a 4th time in the Innovation Scorecard report in March), that NICE assign the highest priority to the post publication element of the Implementation adviser’s role.</p> <p>A compliance protocol could be developed that would be issued, if there is evidence of non-compliance, with a ‘name & shame’ approach.</p>
2.1	2.2, 2.3	<p>There is no mention of how NICE approaches decisions regarding which products will be subject to the Highly Specialised Technologies (HST) appraisal nor how the approach under HST differs to STA and MTA.</p> <p>Can NICE please clarify the decision making process for which approach (STA or MTA vs HST) is appropriate and provide guidance on process for HST (or cross reference as appropriate to other guidance), and timescales as part of the guide?</p>
2.1.3	2.2.3	<p>The aims of the topic selection process include reference to “make topic selection as rapid as possible” and “help make the best use of NHS resources”. There can be a tension between these: we may not know the true value and costs of new treatments until some time has passed. It would be helpful if NICE could make such tensions clear during the process of an appraisal, as we believe that this is where judgement needs to be applied and where patients may have a particular view that can be different to the collective view of NICE.</p>
2.8.3		<p>We believe that the importance of patient organisation and patient expert input into scoping (and the appraisal more generally) will increase as a result of the development of more personalised medicines. This is because personalised medicines will be tailored to particular patient sub-groups, often very small in number, and these patients will be best placed to consider the impact on patients from the use of these new medicines. The process guide acknowledges the need for sufficient expertise to go into scoping, including expertise from patient organisations.</p>
3.2.12		<p>As we mention in our comments on Table 1 above, we believe that there is merit in exploring a more flexible approach to allow patient experts to contribute.</p>
3.4.9		<p>Cancer52 supports the potential for a stakeholder information meeting. We urge that NICE ensures that such meetings allow sufficient time to discuss evidence, including interpretation of the new provisions in the 2013 Methods Guide (4.3.3) that allow for “narrative summaries” from patient organisations.</p>

3.6.5.		<p>The current patient/carer organisation statement template limits responses to 8 pages. The proposal to reduce this by 50% whilst simultaneously offering patient organisations the opportunity to make a more sophisticated contribution to appraisals (4.3.3. Methods Guide) and presumably advance evidence to assist in VBA evaluation is not only inconsistent but casts doubt on the extent of seriousness of purpose regarding patient & patient organisation involvement.</p> <p>We ask that NICE does not reduce the size of the statement template.</p>
3.6.6.		<p>Where indications are for treatment lines distant from first, the patient population may be so small that it will be impossible for the nominating organisation to locate a patient ‘with direct personal experience of the technology’. We suggest a recognition of that situation and some form of wording that would formulate a next best candidate.</p>
3.7.2		<p>We welcome the involvement of the lay representative to advise the lead team on patient-relevant issues when developing the documentation. We note again that that it will be those patients and their representative organisations that will have a more in-depth understanding of the disease in question and potentially the technology under scrutiny. We therefore believe it is important that the Committee as a whole, with intervention from the lay representative if necessary, should ensure sufficient emphasis is placed on the patient perspective and evidence.</p>
3.7.8		<p>We request that all those having a direct input into the discussions, including those on the Committee, that are members of organisations that make financial contributions to the Commissioning Support Advisory Service (CSAS) acknowledge those contributions when invited to declare their interests.</p>
3.7.9		<p>Just as we note above, the lead team needs to ensure that there is sufficient emphasis on the patient perspective and evidence. This is particularly important in light of the patient experts playing a more limited role: they do not make a formal representation to the Committee as noted in 3.7.10. We ask that, to be taken in conjunction with our comment on lay representatives in Table 1 above, that the lay representative make a presentation of patient evidence at the public session rather than simply assisting and advising the lead team in their introduction.</p> <p>This would provide public assurance that patient evidence forms one of the three evidence sources, the others being clinical and economic evidence, available to the Committee in their deliberation and decision making.</p>

3.7.10		In the interests of consistency with the Methods Guide (4.5.2) we would ask that the last sentence be amended to include the possibility of those named being able to also ask, rather than simply respond to, questions.
General		NICE has produced materials specifically to aid the public and patients to engage with NICE TAs. The NICE document ' Contributing to a Technology Appraisal: A Guide for Patient and Carer Groups (Ref N0516), 2009 ' should be updated reflecting: changes to the process guide, changes to the Methods Guide, and forthcoming changes in light of VBA.

Additional comments:

Cancer52 members are building up their experience with NICE TAs. Given this, we'd like to offer some broader reflections to NICE. Currently we see three key interrelated issues that are important for NICE to truly meet their aspiration of 'Putting patients and the public at the heart of NICE's work'.

1. A process: that supports genuine involvement and engagement with patients and their representative organisations. Changes to the process guide are part of this (for example, the potential for a stakeholder information meeting to include patients and their representative organisations) and we believe that the following would also support an improved process, building on the good work of NICE to date:

- (a) Aligning the process guide with on-going changes to appraisal under VBA and HST
- (b) Adding qualified social scientist(s) whose speciality is the study of social relationships expertise to Committees and ERGs and AGs reflecting the move to VBA
- (c) Piloting a more flexible approach to patient expert submissions (and not reducing the size of submissions) and in particular a recognition that patient experts who are either not officers and/or employees, of patient organisations will almost certainly be one time participants in the appraisal process. For example, we would advocate the provision of a handbook with a fictitious worked example to assist them in the preparation of their written template statement.
- (d) Evaluating the success or otherwise of lay representatives as members of the Committees as advocates for patients and the public during appraisals (e.g. do they step in to ensure sufficient time is devoted during Committee discussions to discuss patient evidence and prevent domination of technical aspects of manufacturer submissions) and have lay representatives present the patient evidence to the Committee at the public session
- (e) Updating guidance specifically for patients to engage with TAs

2. Methods: that allow the full breadth and depth of patient experience with and without new technologies and the value that they bring to patients, to be considered by the Committees. This includes providing support for patients and their representative organisations to help them make the most of opportunities set out in the latest Methods Guide to include narrative summaries and supporting them to provide submissions that include BoI and WSI as part of VBA. This also links back to process – patient organisation and patient expert submissions need to be given appropriate time and weight in Committee deliberations.

3. Implementation: of NICE guidance so that the benefits of technologies are experienced across the country – not just set out in theory in guidance. This is where NICE needs to work with others but where NICE should not duck responsibility: if NICE guidance is not implemented then the full value of NICE's work is not realised and therefore does not constitute an effective use of public resources.

Please email this form to: 2013TApocess@nice.org.uk

Closing date: Friday 28 March 2014 5pm