

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Report to the Methods Review Working Party

Key issues arising from workshop on Perspective

This report is written by members of the Institute's team of analysts. It is intended to highlight key issues arising from discussions at the workshop on structured decision making. It is not intended to provide a detailed account of all comments expressed at the workshop. The report has been written independently of the people who attended the workshop.

The report is circulated to the members of the Method's Review Working Party, the group responsible for updating the guide. For further details regarding the update of the Guide to the Methods of Technology Appraisal please visit the NICE website at

<http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/GuideToMethodsTA201112.jsp>.

1 Introduction

Participants at the workshop addressed seven of questions raised by the briefing paper in five groups facilitated by representatives of the NICE Decision Support Unit.

This report describes the key responses to these questions under a number of broad headings to assist consideration at the Working Party. Key issues for consideration by the Working Party are proposed at the end of the report.

2 Definition and inclusion of external effects

Q1: What are the relevant external effects of a new technology which could, in principle, be considered in an appraisal? Under what circumstances would these constitute costs versus benefits?

Q2: Are there any circumstances where it would be permissible for population health to be forgone (through greater costs falling on the NHS) in order to realise external benefits?

Q3: If external effects should be considered in appraisals, is it necessary for all effects identified in 1. above to be assessed? If not, which elements of external effects should be selected for consideration? Does this depend on the characteristics of the technology or patient population? What ethical principles are relevant to these considerations?

Groups generally agreed that the categories described in section 2.2, figure 1 of the briefing paper are reflective of the relevant external effects which could potentially be considered in an appraisal. Other external effects not specifically included in the briefing paper and that might be appropriate for consideration were patient experience, patient choice and care in the community (that is, current NHS objectives). However, it was noted that these external effects may already be captured in the HRQoL measures such as the EQ-5D, or could be considered within the overall decision framework.

Participants broadly agreed that, in principle, it would be reasonable for population health to be forgone in order to realise external benefits but that this should only be considered in exceptional circumstances. One representative suggested incorporating decision rules such those used for the supplementary advice on appraising life extending treatments at the end of life criteria for each of the external effects in the Methods Guide to describe the exceptional circumstances in which they each could be considered.

Groups recognised that the Guide to Methods will need to list the external effects that can be considered for inclusion in a technology appraisal, as it

does now for costs incurred outside of the NHS and PSS. This would promote the transparency, standardisation and comparability of the appraisal process across topics. Even if, overall a deliberative approach is taken when considering the impact of external effects, it was felt that a description of the preferred external effects to be considered and the evidence required should be specified as clearly as possible in the methods guide. Some described this as a 'sub-reference case'.

Participants generally considered that selection of specific external effects will need to depend on the topic under appraisal, and that the scoping phase of an appraisal would be the best time and place to explore and, perhaps, agree them. It was suggested that consultation with a broad panel of stakeholders including ministries of education, transport, defence, justice etc. would be necessary for inclusion of costs to the public sector not directly related to health.

The majority of the participants felt that out-of-pocket expenses should be considered only in exceptional circumstances and should not be part of the routine technology appraisal process. Those who agreed for inclusion of 'carer effects' acknowledged that not much research have been done in this area and suggested that a conservative approach of minimum wages for working age people could be a starting point. They suggested that reassurance benefit could be assumed to be levelled out by the loss of leisure time (if not estimated at a higher wage).

Productivity was one of the components that participants found most challenging to consider for inclusion in the broadening of the perspective. The likely ethical consequences of inclusion of the impact of a new technology on the productivity of patients, and possibly their carers, was explored and participants disagreed about the appropriateness of inclusion. Participants did agree that including 'productivity' benefits is likely to disadvantage older cohorts of people compared with a younger cohort. It was suggested that possible equality issues should be highlighted with estimation of loss or gain of productivity rather than not doing it at all. A pragmatic approach was also suggested to consider productivity only in the appraisals where there is very

significant potential of getting working people back to work early (for example laparoscopic surgery versus laparotomy). However, participants also cautioned that only including these effects when it is likely to provide positive effects for the technology will invite criticism of being too selective.

Many of the participants felt that health related quality of life measurement already captures patients' time during illness and treatment phase and additional consideration would lead to double counting; more so if loss of productivity is also considered.

Most participants agreed that effect on non-health public sector should be considered only if there is a general willingness and formal agreement/understanding across Government sectors about budget reallocation. Some participants were sceptical about the feasibility of such arrangements. Those who favoured its inclusion suggested that it should be considered in all appraisals with simultaneous negotiations with the government about budget reallocations.

3 Opportunity cost and displacement

Q4: If external effects are considered, how should any trade-off with health be quantified? (that is, what should the 'exchange rate' be between health and external effects?) If the consumption value of health is relevant to this, how should it be estimated?

Q5: Should the external effects of displaced activities (as a result of a technology imposing additional costs on the NHS budget) be formally considered? If so, how should this be quantified?

The briefing paper discussed three methods for determining the 'exchange rate' between health and external effects; each of which was discussed at the workshop by participants.

- The first method involved expressing the external effects in monetary terms, adding these to the costs falling on the NHS budget, relating the total net cost to the additional health gain using an ICER and comparing

with NICE's cost effectiveness threshold ('k'). In general, participants were not in favour of this 'lumping' approach as they acknowledged that these external costs would not fall under the NHS budget. However, some participants supported this approach stating that: 'In NICE Committee experience so far, external effects have not had a large impact on appraisals, therefore this simple lumping approach may be practical, assuming that external effects are marginal', and that 'PCT's have been considering carer costs as a proxy for external costs within NHS budgets and the lumping approach would be in line with this'.

- The second method involved comparing an ICER made up of NHS and external costs with some sort of 'societal willingness to pay' (that is, a value society puts on health gain expressed in terms of forgone consumption, 'v'). Participants indicated this was not a good decision rule as the NHS faces a budget constraint and therefore 'k' cannot be ignored. Moreover, issues around the estimation of 'v' would apply to this method as well.
- The third method involved reflecting both the consumption value of health, v, and the cost effectiveness threshold, k and comparing the net health gained in the health sector with the health equivalent of the net consumption costs falling on the wider economy. This amounts to weighting external costs by k/v and, assuming that $v > k$, this decision rule could be interpreted as taking external effects into account but not giving it the same weight as NHS costs. Most participants agreed that while the k/v weighting approach was reasonable, v was a difficult concept and open communication around it was very important. Some participants were concerned that quantification would result in a lack of flexibility and judgement that Appraisal Committee's are established for. On the other hand, it was considered that a deliberative approach could potentially result in a lack of transparency and that it was very important to set out everything clearly. Participants suggested that by way of a scenario analyses, a range of k/v values could be presented to the Committee for a deliberative discussion. Most participants agreed that while the

measure of evaluation should be formalised, the decision should be deliberative. However, some participants felt that before any question on quantifying the trade-off could be addressed it would have to be assumed that all external effects can be measured in monetary terms (for example, crime) and this made them cautious about commenting.

One participant said that the Department of Health is already using a value for 'v' for cost-benefit analyses; set at £60,000 per QALY gained, and based on evidence adapted from the Department of Transport's 'value of a life' work. Alternatively, participants stated that values can be informed by trade-offs of individual preferences expressed in hypothetical choices using contingent valuation or discrete choice experiments; the work by Donaldson on the social value of a QALY was specifically referred to.

It was generally felt that if external effects are to be considered for a technology which is being appraised then the external effects of displaced activities should also be considered in order to ensure a consistent approach. Some expressed the view that even if aspects of a broader perspective will be only considered on a case by case basis for individual technology appraisals, as proposed above, all aspects of an agreed broader perspective should be taken into account in quantification of the threshold of cost effectiveness. A number of attendees rejected the notion that external effects for displaced activities should be considered, on the grounds that it is impossible to know what they are and so to accurately measure them.

Attendees raised a number of issues around the feasibility of considering external effects of displaced activities. For example, there is currently a lack of data about what is disinvested following the introduction of a new technology, which would present challenges to researchers who were attempting to establish the external effects of these disinvestments.

One participant suggested that the 2004 Guide to the Methods of Technology Appraisal appeared to have provided for consideration of a broader perspective in establishing the range of cost-effectiveness ratios that reflect the opportunity cost of accepting a new technology as an effective use of NHS

resources. In the 2004 Guide, 'wider societal costs and benefits' is included in the shortlist of factors likely to inform a judgement about the acceptability of the technology as an effective use of NHS resources; noting though that the 2004 Guide also indicates that this is only expected 'where appropriate'.

It was generally felt that the methodology for assessing the external effects of displaced activities is not yet in place. It was considered by some that only if and when NICE stipulates that external effects for displaced activities should be formally considered, would more research be conducted in this area, and so would relevant methodology be developed. The following suggestions around how the external effects of displaced activities might be quantified were made:

- It was noted that in effect, at present, NICE values external effects with a value of zero for both the new technology and for any displaced technologies. It was felt by some that the external effect could as well be positive as negative and that, in fact a value of zero may well be reasonable. Other attendees expressed this same issue using different language: it was felt by a substantial number of attendees that the external costs and benefits of adopting a new technology may cancel out the external cost and benefits of any displaced activities. In this regard, there was a leaning towards the status quo.
- Some attendees thought that if the cost and/or effects of the displaced activities are substantial enough, then they will be accounted for using NICE's existing methodology.
- There was a suggestion that data could be gathered on actual displacement seen. A study looking at displaced NHS activities has already been conducted which adopts this type of approach, although one of the authors conceded that this was a challenging study in itself and raised questions over the feasibility of such a study in a wider context, looking at displaced activities both within and outside the NHS.

- It was noted that currently PCTs are specifically asked about the likely activities that might be displaced if a technology is adopted, during the process of an appraisal. Such an approach could be an option to explore in order to obtain data on displaced activities, albeit within and not outside of the NHS. Nonetheless, such an approach in itself could be far from reliable or consistent due to regional variations and uncertainties around what is being displaced.
- A suggestion was proposed that a study could be commissioned which sets out to investigate the external effects of displaced activities, possibly by disease area. The results from this study could then be applied to any technology being appraised in the specific disease area.
- Another approach which was suggested was to develop a regression equation which predicts the costs and effects of displaced activities. In such a study, some people thought that it would be necessary to use a wide range of possible variables, so as to ensure that all possible effects were captured. Other people thought that it might be possible to identify key effects to include, so to limit the number of variables in the equation.

4 Measurement and valuation

Q6: How should the various elements of external effect be measured and valued? To what extent should the NICE Methods Guide be prescriptive about these methods?

There was consensus among the participants that the measurement and valuation of external effects is a significant challenge. Many participants suggested that a conservative approach needs to be adopted. It was suggested that in practice it is inconceivable that the full integration of external effects could be included in one step, so it will be necessary to proceed in stages, perhaps based on crude assumptions at the beginning. These methods for measurement and valuation could be improved as research established more robust methodology.

Some participants felt out-of-pocket patient expenses are hard to quantify consistently and should not be considered. If they are to be considered, the methods guide should be prescriptive about what expenses could be included.

The question of whether the financial effects of ill-health on the patient is included in the QALY and the problem of double counting was discussed. It was generally felt that EQ-5D does not measure productivity or consumption of an individual very well and a more accurate picture could be obtained by use of a well-being measure which could capture broader dimensions in more detail. The difficulty of converting this type of well-being measure into QALYs or monetary terms was mentioned. Some participants felt that an additional problem with well-being was the potential number of attributes and there was some discussion regarding the use of a multi-criteria approach to deal with this.

There was some discussion about the best method of valuing carers' time based on for example net market wage or the minimum wage. One group agreed that the minimum wage was probably the most practical approach as although it is conservative in value it also balanced the positive effects associated with caring but that this should be reviewed as methodology develops.

If productivity gain or loss is to be considered most felt that the "frictional cost" method of measuring it was the preferred (pragmatic but not perfect) method. Frictional cost method was suggested to be challenging from ethical point of view as it values people from their earning power. One group suggested relating the method of productivity evaluation to the indication: human capital method might be suited to long-term chronic illness and a friction-based approach to short term illness.

Many participants felt that measuring and valuing external effects on the non-health public sector was important for some technologies. It was recognised that it would be very difficult to work out parameters such as k and v for different departments. However some participants felt that using information

from the Green Book (H.M. Treasury), current methodology from the Dept. Of Health and other national health evaluation agencies, the external effects on non-health public sectors could be quantified and this could be improved as methodology develops in the future.

5 Decision making

Q7: If external effects should be considered in appraisals, should this be undertaken formally as part of the economic analysis? Or should they be considered as part of the Appraisal Committee's more general deliberation? What should the Methods Guide specify regarding any deliberative approach?

When considering the question of the extent to which external effects should form part of the formal analysis, delegates expressed a range of views encompassing both ends of the spectrum of opinion.

Those in favour of incorporating external effects into the formal analysis as part of the NICE reference case gave the following reasons:

- If an expanded perspective is to be considered then it should be done to the same standard of evidence as analyses according to the current reference case.
- Even though it accepted that methods are not fully developed and high quality evidence may not be available for all the additional components of an expanded analysis, at least all the assumptions would be explicit.
- It would be difficult for committees to be consistent in their decisions without a formal analysis. In order to have such consistency, the preferred methods of analysis incorporating external effects should be specified in the reference case.
- External effects are unlikely to be significant for every technology appraisal, but one would need to undertake a formal analysis to know that for certain.

- The deliberative process does not work – the outcome depends too much on who is at the table.

Those thought that external effects should be considered only as part of the deliberative process gave the following reasons:

- The status quo already allows for the Appraisal Committee to depart from the reference case and it has occurred very infrequently. There is nothing to stop manufacturers presenting external effects in their submissions if these are thought to be significant.
- Formal analysis adds in more complexity with much more uncertainty. Cost effectiveness analysis is as complex as necessary now.
- The mathematical approach may not produce better decisions. Formal analysis makes the decision more transparent but does not necessarily make it right.
- For a lot of technologies external effects will not impact on the analysis and the extra effort (and cost) put into the analysis would be wasted.
- Evidence for quantifying external effects for the purposes of inclusion in the analysis will be weaker than the evidence used for current reference-case analyses.
- Formal analysis may introduce opportunities for gaming by manufacturers.

Some delegates suggested a compromise between the two extremes of a formal analysis including external effects becoming the new reference case and consideration of the additional factors only in a deliberative approach.

1. Only consider inclusion of external effects in the formal analysis in cases where it is appropriate. The need for an expanded-perspective analysis could be identified at the scoping stage. A 'sub-reference case' could be specified for these analyses which could allow a quantification of external effects to be made, but not include them in

the baseline ICER. The main advantage of this approach was thought to be its efficiency in that the more resource-intensive approach was only used where necessary. Disadvantages included a lack of consistency between appraisals, and the lack of good information on which to make the decision at the scoping stage (it would be a 'guess' as to whether an expanded-perspective analysis was needed).

2. Those who thought that a deliberative approach was preferred nevertheless thought that deliberation should be informed and systematic. Therefore information should be sought on the external effects that are likely to impact on the decision. It was suggested that it might be useful to develop some standard ways of quantifying external effects while not necessarily including them in the analysis. This could possibly take the form of a tariff including predefined valuations for things like carer time, absence from work, travel time and costs borne by patients.
3. Some thought that limited expansion of the formal analysis was warranted, perhaps taking a 'government' perspective rather than the current reference case which is limited to NHS and personal social services. Remaining external effects would continue to be considered as part of the deliberative process.

6 Rapporteurs

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On the basis of feedback from Anju Keetharuth, Anwar Jilani, Bernice Dillon, Claire McKenna, Clara Mukuria, Helen Starkie, Janet Robertson, Jon Tosh, Raisa Sidhu, Richard Diaz, Sarah Willis and Tess Peasgood; whose contribution is gratefully acknowledged.

7 Key issues for consideration by the Working Party

Assuming that the Directions to NICE allow for consideration of a broader perspective than only the NHS and PPS in appraising the cost effectiveness of technologies, the following key issues are to be considered:

1. Is it right to include effects outside of the health sector? That is, is it desirable to sacrifice health for non health savings and outcomes?
2. If so, does the wording used in 5.2.7 of the Guide to the Methods for Technology Appraisals allow for appropriate consideration of a broader perspective than that of the NHS in economic evaluations?
3. And if so,
 - a) should the exceptional circumstances be described in more detail and/or expanded upon? And how?
 - b) should the requirement for agreement with the Department of Health before inclusion be removed?
 - c) should a description of all possible external effects be included? And how?
 - d) should some be excluded from consideration? And why?
 - e) should consideration be given to the external effects of services likely to be displaced? And how?
 - f) should a wider range of stakeholders be consulted? And who should it include?
4. Once measured, and in the context of decision-making, should the external effects form part of deliberation or part of formal analyses?
5. If part of formal analyses, should;

- a) the net addition of effects outside of the health sector (expressed in monetary terms) to the costs falling on the NHS and subsequently related to the additional health gain, be compared with the current threshold range used by NICE? Or,
- b) the net addition of effects outside of the health sector (expressed in monetary terms) to the costs falling on the NHS and subsequently related to the additional health gain, be compared with the some sort of 'societal willingness to pay'?
- c) consideration be given to reflecting both the consumption value of health ('v') and the cost effectiveness threshold ('k') by expressing all the costs and benefits falling outside the health sector in terms of their positive or negative effects on society's ability to consume goods and services generally?

How should the Guide to Methods reflect on issues of measurement of (each of) the external effects? What could be the role of technical support documents and/or evidence submission template(s).