

# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## Briefing paper for methods review workshop on perspective

The briefing paper is written by members of the Institute's Decision Support Unit. It is intended to provide a brief summary of the issues that are proposed for discussion at a workshop to inform an update to the Institute's Guide to Methods of Technology Appraisal. It is not intended to reflect a comprehensive or systematic review of the literature. The views presented in this paper are those of the authors and do not reflect the views of the Institute.

The briefing paper is circulated to people attending that workshop. It will also be 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 Review of the 'Guide to Methods of Technology Appraisal'**

The Institute is reviewing the 'Guide to the methods of technology appraisal', which underpins the technology appraisal programme.

The original Methods Guide was published in February 2001, and a revised version was published in 2007. The Methods Guide provides an overview of the principles and methods used by the Institute in assessing health technologies. It is a guide for all organisations considering submitting evidence to the technology appraisal programme and describes appraisal methodology.

The current 'Guide to methods of technology appraisal' is available from the NICE website at

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

The review of the Methods Guide will take place between October 2011 and April 2012. As part of the process, a number of workshops will be held to help identify those parts of the Guide that require updating. These workshops will involve a range of stakeholders, including methods experts, patient representatives, industry representatives, NHS staff and NICE technology appraisal committee members.

A summary of the discussion at the workshop will be provided to the Methods Review Working Party, the group responsible for preparing the draft update of the Methods Guide. Further details of the process and timelines of the review process are available from the NICE website.

The revised draft of the Methods Guide will be available for a 3-month public consultation, expected to begin in May 2011. We encourage all interested parties to take part in this consultation.

## 2 Background

### 2.1 *The current position in the NICE Methods Guide*

The current Methods Guide states that

*“... the perspective on outcomes should be all direct health effects, whether for patients or, when relevant, other people (principally carers). The perspective adopted on costs should be that of the NHS and PSS. Technologies for which a substantial proportion of the costs (or cost savings) are expected to be incurred outside of the NHS and PSS, or which are associated with significant non-resource effects other than health, should be identified during the scoping stage of an appraisal. In these exceptional circumstances, information on costs to other government bodies, when these are not reflected in HRQL measures, may be reported separately from the reference-case analysis. The intention to include such data will normally be agreed with the Department of Health before finalisation of the remit.”<sup>1</sup>*  
(Section 5.2.7)

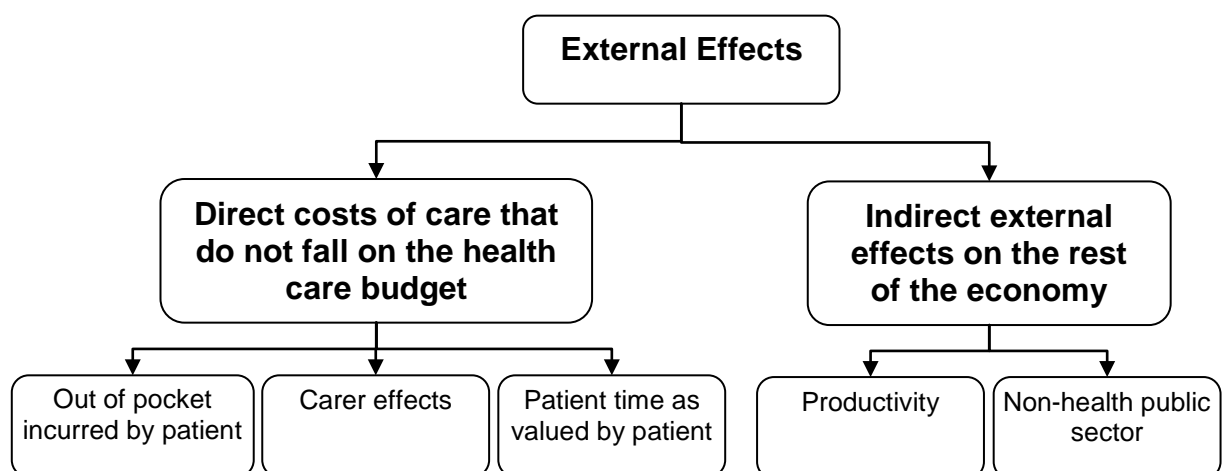
Hence the current Reference Case uses cost effectiveness analysis to compare the health benefits expected to be gained by using a technology with

the health that is likely to be forgone due to additional costs falling on the health care budget and displacing other activities that improve health. Except in the exceptional circumstances referred to above (and then only costs falling on other parts of the public sector), this approach assumes that any effects outside the health sector are small or not socially valuable compared to the effects within the health sector. Effects outside the NHS come in two general forms (see Figure 1).

## **2.2 Direct costs of care that do not fall on the health care budget**

Some of the direct costs of care are borne by patients, such as out of pocket costs as well as their time in accessing care. It may also include the direct financial consequences of ill health (and earlier recovery) for patients and families if these are not fully captured in measures of health related quality of life (HRQoL). It can cover the time and resources devoted to caring for patients outside the health care system. These costs may be direct costs to the patient if formal (marketed) care is purchased. More often informal (non marketed) care is provided but the opportunity cost of this activity (what society loses) still needs to be valued. An effective health technology may reduce these costs (for example, a quicker recovery) or increase them (for example, prolong survival in a chronic disease state).

**Figure 1. Categorising the different types of external effects**



## ***2.3 Indirect external effects on the rest of the economy***

The indirect external effect on the wider economy also needs to be valued. These are effects external to patients, their families or informal carers but are valued by the rest of society. For example, returning a patient to active participation in the labour market may add to production in the economy. This will be a net benefit to society if the value of the additional production exceeds the individual's additional consumption over their remaining life expectancy. An effective health technology may provide external benefits by reducing mortality in economically active groups whose production is likely to exceed their consumption.

Table 1 summarises the approaches used to measure and value the different elements of direct and indirect external effects. It also indicates the choices and issues that exist in this regard. The table also gives examples of the types of appraisal where the different forms of external effect may be relevant.

## ***2.4 Alternative perspectives***

What alternative perspectives could NICE adopt in its decision making? The economic evaluation methods literature describes and often advocates a 'societal' perspective; that is, considering all the costs and benefits of the options being compared. It may also be considered that there are some 'middle ways'; for example, to consider costs falling only on the public sector. The problem for policy is that, in the face of budgets set by a 'higher authority' (that is, government) including the NHS budget, it is not clear how or whether a broader perspective can be implemented and reflected in NICE decisions – particularly if transfers between sectors are not regarded as a feasible option. There is also the fundamental difficulty of specifying how the trade-offs between health, consumption and other social objectives, as well as the valuation of market and non market activities, ought to be done.

**Table 1. Definitions of the different components of external effects and a summary of measurement and valuation methods and issues**

	Definition	Measurement	Valuation	Issues
<b>External care effects</b>				
Out of pocket expenses incurred by the patient or family.	<p>Any out of pocket health care costs not covered by the NHS and falling on the patient or family. These could include: transportation costs, home improvements, additional private health care.</p> <p>An example of where this has been potentially relevant in appraisals: the cost of nursing homes falling on the individual patient (for example, interventions for Alzheimer's).</p>	Monitoring of any costs incurred by the patient or family due to the patient's illness but not covered by the NHS. Can be collected prospectively using questionnaires (for example, in trials).	Based on costs recorded by patients with relevant inflation adjustment as necessary.	<ul style="list-style-type: none"> <li>• A clear definition of what constitutes care costs is required; for example, do home improvements necessary to maintain a suitable quality of life come under the umbrella of care costs borne by the patient?</li> <li>• Possible scope for work to estimate a set of standard mean costs relating to different NHS activities (for example, GP visit, out-patient visit) or health states (for example, cost per period for given EQ5D state).</li> </ul>

	Definition	Measurement	Valuation	Issues
Carer effects	<p>Carer effects include any costs or benefits to the carer (formal or informal) that are not accounted for in the health budget. These are likely to be split into three sections: out of pocket, time and health effects.</p> <p>Example of where this has been potentially relevant in appraisals is drug therapies for Alzheimer's disease.</p>	<p>i) Out of pocket - as for patient/family above but falling on a carer.</p> <p>ii) Time: possible use of structured interviews or detailed diaries to record time inputs to care.</p> <p>iii) Health: possible use of EQ5D which could incorporate influence of care-giving on health. Alternative use of specific instrument for example, CarerQOL but would need to link to QALYs.</p>	<p>i) Out of pocket - as for patient/family above.</p> <p>ii) Time: for example, net market wage as a reflection of opportunity costs, reservation wage, net wage for formal carer.</p> <p>iii) Time can also be valued using preference elicitation methods such a conjoint analysis and contingent valuation.</p> <p>iv) Health can be valued in terms of QALYs which are, in principle, additive to patients' QALYs.</p>	<ul style="list-style-type: none"> <li>Health effects on the carer are already covered in the NICE Reference Case.</li> <li>If carers gain some benefits (for example, reassurance) from providing care themselves rather than employing others, then market rates may over value the true opportunity costs.</li> <li>Similarly, the net wage might not represent the marginal value of a patient's leisure time as choice of working hours is often restricted.</li> <li>Possibility of double counting if QALYs are used to capture health effects and additionally time is valued in monetary terms based on market rates for formal carers as the market price of a carer will include a health premium.</li> <li>Potential problems in measuring the time spent providing care due to possible joint production by the carer. This occurs if the carer can undertake other activities while at the same time caring for the patient.</li> </ul>

	Definition	Measurement	Valuation	Issues
Patient time	<p>Patient time will incorporate all time implications of receiving health care to the patient. This includes the time taken to find or receive care. There may also be benefits to patient time if, for example, surgery reduces the time spent receiving a medical treatment. The time effects can result in forgone work or leisure time. Forgone work time has similar issues to productivity costs (see below).</p> <p>An example of where this may be relevant in appraisals is the development of a new product which reduces the time patient needs to spend in hospital or clinic (for example, an oral rather than intravenous medication).</p>	Time spent identifying and consuming health care could be collected prospectively (for example, in trials).	<p>Valuation will depend on whether leisure or work time is being forgone</p> <ul style="list-style-type: none"> <li>• Forgone leisure time likely to be considered captured in the QALY (reflected in HRQoL though, for example, the EQ5D).</li> <li>• The value of forgone work time due to consuming care is not expected to be captured in the QALY, but may be captured in monetary terms using similar methods as for productivity (see below).</li> </ul>	<ul style="list-style-type: none"> <li>• Cost of forgone work time may not fall on the patient, depending on nature of employment. Hence may be costs falling outside patient (for example, employer, wider economy).</li> <li>• Any lost work time falling on the patient could be valued at net wage.</li> </ul>

	Definition	Measurement	Valuation	Issues
Productivity impacts on patient	<p>Ill-health (morbidity and mortality) impacts on attendance at work and productivity whilst at work. The effect of forgone work time can fall on the patient (through reduced income and consumption) and on the wider economy.</p> <p>An example of where this may be relevant in appraisals is the use of a new procedure which reduces the duration of convalescence and allows patients to get back to usual activities earlier (for example, laparoscopic surgery vs. open surgery). Also, in principle, any intervention which reduces mortality risk.</p>	Various standardised measures exist to measure changes in productivity due to morbidity, and these can be used prospectively in trials or surveys.	<ul style="list-style-type: none"> <li>• The effects of ill-health on leisure time can be assumed to be captured in the QALY.</li> <li>• Effects on patient of lost productivity due to mortality can be assumed to be captured in the QALY (through its life years component).</li> <li>• Effects on patient (in terms of reduced consumption) of reduced productivity due to morbidity may be captured through the QALY. This will depend on whether responses to valuation questions (for example, for EQ5D health states) reflect possible loss of income. If not, then such effects would be captured as part of monetary valuation methods (see below).</li> </ul>	<ul style="list-style-type: none"> <li>• The main issue is whether morbidity effects on consumption can be reflected in the QALY. Recent reviews suggest that this effect is minimal with the EQ5D, in which case monetary valuation as part of the wider productivity effects would be appropriate.</li> </ul>



	Definition	Measurement	Valuation	Issues
<b>Non-care effects imposed on the wider economy</b>				
Productivity impacts on those other than the patient (that is, employer, wider economy).	<p>That proportion of the productivity effects from ill-health (mortality and morbidity) and time away from work affecting the wider economy (that is, other than the effect on the patient's consumption).</p> <p>In principle unpaid production should also be included. This could be a reduction in childcare and voluntary work.</p> <p>As above.</p>	As for the productivity effects on patients.	<p>There are three main alternative means of valuation (covering both morbidity and mortality).</p> <p>i) Human capital method whereby productivity is valued at the gross wage on the assumption that this (marginal cost) equals the value of lost production (marginal revenue product) when markets are in equilibrium.</p> <p>ii) Friction cost method<sup>2</sup> which adjusts the human capital method for various factors. Most importantly, the existence of involuntary unemployment reflects the fact that market equilibrium cannot be assumed, so productivity costs are only incurred during the period it takes to replace an ill or dead or sick worker with someone from the pool of unemployed.</p> <p>iii) US Panel Approach<sup>3</sup> whereby the effect of productivity loss on the patient is (by design) captured through the QALY. Only the productivity effect on the wider economy is reflected in financial terms.</p> <p>These estimates will also include the proportion of value accruing to patients from which they benefit in terms of consumption. If this has been captured separately through the QALY (see above), it needs to be netted off the value of the wider effect. This is essentially the US Panel approach.</p>	<ul style="list-style-type: none"> <li>• Each method for measurement and valuation incurs its own set of issues.</li> <li>• Implicit equity concerns of valuing productivity if it only relates to those in paid employment.</li> <li>• There are similarities in the issues with how patient time costs are valued.</li> <li>• Are the effects of reduced productivity (mortality and morbidity) on the patient's family adequately reflected?</li> </ul>

	Definition	Measurement	Valuation	Issues
Non-health public sector	<p>Covers the effects (resource costs and consequences of value in the sector) on other, non-health care, parts of the public sector. It presents the implications, beyond productivity, on the wider public sector.</p> <p>Examples of where this may be relevant in appraisals include the possible impact on the education and criminal justice systems of parent training programmes in the management of children with conduct disorders, the impact on criminal justice of interventions to reduce opioid dependence and the effect in education costs and outcomes of cochlear implants.</p>	<p>Similar issues of measurement to those relating to NHS resource use. Also need to capture non-resource consequences. Can measure prospectively in trials and other studies.</p>	<p>For costing, it may be possible to use of standardised unit costs, micro-costing exercises etc.; similar issues to costing in health.</p> <p>Also need to reflect the opportunity cost of costs falling on the budget for those other sectors. These are equivalent to the cost effectiveness threshold used by NICE. This also permits any cost or savings in these other sectors to be valued in terms of their valued outcomes.</p>	<ul style="list-style-type: none"> <li>• Few other parts of the public sector have developed a generic measure of effect such as the QALY in health care.</li> <li>• Similar lack of quantified cost effectiveness thresholds in other sectors.</li> <li>• If cost and outcome data and cost effectiveness threshold estimates are available across sectors, compensation tests can be used to assess whether interventions with costs and/or outcomes falling in different sectors are worth undertaking. This assumes some scope to adjust budgets over time.</li> </ul>

A recent review of current UK policy and of policies adopted elsewhere reveals considerable variation in the type of perspective claimed, a lack of clarity on what constitutes a broad societal perspective and little or no consideration of the impact of fixed budgets.<sup>4</sup> The justification for type of policies adopted is also somewhat limited, commonly resting on literature which ignores the implications of fixed budget constraints. This lack of clarity and ambiguous terminology is also reflected in the results of an extensive review of the cost perspective adopted in published cost-effectiveness literature, with many studies claiming to take a societal perspective when in fact their analysis is restricted to the health care system.<sup>5</sup>

A series of challenges, therefore, presents itself to NICE is considering the appropriate perspective to adopt for technology appraisal:

- If a wider perspective is to be incorporated into the Methods Guide, should this include the full range of external effects (both direct and indirect)? Or is it possible to 'pick off' particular elements of non-NHS costs?
- What are the implications of the fact that a wider perspective would not increase the NHS budget but could effectively result in the transfer of some NHS resources to patients, their families, other parts of the public sector or the wider economy?
- There are not only external effects (costs or benefits) from new technologies, this will also be true of services that are displaced by budget re-allocations resulting from recommending new (more costly) technologies. How are these external effects from displacement to be factored in?
- Consideration of the impact of a wider perspective on other social objectives. For example, the implications would need to be assessed of including productivity costs (net of individual consumption) for older retired patients compared with younger patients active in the labour market.
- To implement a wider perspective appropriately would potentially add complexity to the analyses presented to NICE. This would be an added

challenge to critical review by assessment groups/evidence review groups and NICE.

### 3 Proposed issues for discussion

After consideration of the developments in this methodological area, the current Methods Guide and the requirements of the Institute's Technology Appraisal Programme, it is proposed that the following key areas are discussed at the workshop.

#### 3.1 *Reflecting the relative value of external effects*

##### 3.1.1 *Summary of the issue*

Using cost-effectiveness analysis to inform NICE decisions compares the benefits expected to be gained in the health sector using QALYs to the health that is likely to be forgone due to additional costs falling on the health care budget (represented by the cost effectiveness threshold). This is the case when the incremental cost effectiveness ratio (the additional cost falling on the NHS budget,  $\Delta c_h$  divided by the additional health,  $\Delta h$ ) is less than the cost effectiveness threshold,  $k$ :

$$\frac{\Delta c_h}{\Delta h} < k \quad (1)$$

This is entirely equivalent to establishing whether the health gain from the new technology ( $\Delta h$ ) is greater than the health forgone due to the increased cost falling on the budget ( $\Delta c_h$  divided by the cost effectiveness threshold):

$$\Delta h - \frac{\Delta c_h}{k} > 0 \quad (2)$$

It is also equivalent to establishing whether the monetary value of the health gain ( $\Delta h$  multiplied by the cost effectiveness threshold) is greater than the costs falling on the NHS budget:

$$k.\Delta h - \Delta c_h > 0 \quad (3)$$

As described above, this is a reasonable approach when no relevant or important effects (direct or indirect) lie outside the health sector. When external effects are considered relevant and important, it is not clear how these should be factored into the analysis and how they should impact on NICE decisions. NICE has no direct responsibility for setting the NHS budget but is charged with making decisions which use NHS resources efficiently.

When a new technology is considered cost effective in terms of health gain and NHS costs, but also generates benefits outside the health sector (for example, reducing informal care costs), a NICE decision to recommend that technology is consistent with efficiency more widely. However, there may be situations where there are clear trade-offs in the value of a technology in different sectors. For example, a new intervention for Alzheimer's disease may not be considered cost-effective in terms of health gain and NHS costs (that is, its funding would reduce net population health), but may generate net benefits outside the health sector through significant reductions in informal care costs. How should these two effects (within and outside the health sector) be traded-off?

One approach is to ignore effects outside the health sector. This may be difficult to sustain when such effects are relevant and important. Another is effectively to add these two types of effect together. That is, to express the external effects in monetary terms, add these to the costs falling on the NHS budget, relate the total net cost to the additional health gain using an ICER and compare with NICE's cost effectiveness threshold. This is inappropriate as the threshold represents opportunity costs in terms of health forgone when additional costs fall on the NHS budget but, with such an approach, not all the costs fall on the NHS budget. A third approach is to ignore the NHS budget constraint entirely and to compare 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, ' $v$ '). However, when an NHS budget constraint actually exists, the NHS cost-effectiveness threshold (' $k$ ') is always relevant and cannot be ignored as it represents what is forgone in terms of health when additional costs fall on the budget.

A more feasible way of dealing with the challenge of external effects is to reflect *both* the consumption value of health,  $v$ , and the cost effectiveness threshold,  $k$ . We do this 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, in other words a net consumption cost,  $\Delta c_c$ . Now the allocation decision described in (3) can be generalised to comparing the consumption value of the health expected to be gained to the consumption value of health forgone and other net effects on consumption. The social consumption value of health,  $v$ , represents the amount of consumption that is equivalent to 1 unit of health. Within this framework, the technology should be accepted if the net consumption value is positive:

$$v \cdot \left[ \Delta h - \frac{\Delta c_h}{k} \right] - \Delta c_c > 0 \quad (4)$$

The health expected to be gained is valued at  $v$  rather than  $k$ . But since all costs that fall on the health care budget are also health forgone these must also be valued at  $v$  (the first term). Therefore, if there are no external effects ( $\Delta c_c = 0$ ) a decision based on (3) or (4) will be the same irrespective of the value of  $v$ . When there are no external effects, maximising health or maximising the consumption value of health leads to the same decision: the value of  $v$  and whether or not  $v > k$  is irrelevant, what matters for the decision is the value of  $k$ .

When there are external effects ( $\Delta c_c \neq 0$ ) the decision can be described as a comparison of the consumption value of the net health gained in the health sector (the first term) with the net consumption costs falling on the wider

economy (the second term). If the former exceeds the latter then the technology should be adopted. Alternatively and equivalently the allocation decision in (4) can be expressed in terms of health:

$$\left[ \Delta h - \frac{\Delta c_h}{k} \right] - \frac{\Delta c_c}{v} > 0 \quad (5)$$

Now the decision can be described as a comparison of the net health gained in the health sector (1st term) with the health equivalent of the net consumption costs falling on the wider economy (2<sup>nd</sup> term). If the former exceed the latter then the technology should be adopted. If  $k = \text{£}20,000$  but  $v = \text{£}60,000$  then costs which fall outside the health sector get one third of the weight  $\left( \frac{k}{v} \right)$  of costs that fall directly on the NHS budget. This can be clearly seen when (5) is rearranged to express the decision as a comparison of an ICER, which includes both  $\Delta c_h$  and  $\Delta c_c$ , with the threshold:

$$\frac{\Delta c_h + \frac{k}{v} \Delta c_c}{\Delta h} < k \quad (6)$$

Therefore, 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. Although not undertaken analytically, this could be seen as equivalent to NICE's position in the 2004 Methods Guide and, in exceptional costs, in the 2008 Methods Guide. The approach assumes that either budget transfers between sectors are possible or, if not, then  $\Delta c_h$  must be marginal with respect to the budget, that is, incurring these additional costs will not change the cost-effectiveness threshold.

### 3.1.2 Discussion points

- Does the approach of weighting external costs by  $\left( \frac{k}{v} \right)$  seem a practical means of dealing with the challenge of reflecting external costs in the economic analysis informing NICE decisions?

- Where would  $v$  come from? Would it be based on some form of survey of public preferences using, for example, a contingent or conjoint valuation method? Or should it be based on the judgement of the policy makers or members of the Appraisal Committees?
- There are likely to be some implications of reflecting effects outside the health which may be considered inappropriate (in other words,  $v$  is unlikely to capture everything of social value). For example, any indirect effects of new technologies on productivity (for example, through reduced time away from paid labour) are, when considered net of individuals' consumption, likely to be greater in the young than the old and, in the latter case, may well be negative. How should these implications be dealt with?
- Is the assumption that transfers of budget (for example, between the NHS and Education) tenable? If not, is it reasonable to assume that the effects of decisions regarding new technologies will be marginal on the NHS budget? How should any non-marginal effects be dealt with?

## **3.2 Reflecting forgone external benefits**

### *3.2.1 Summary of the issue*

The cost effectiveness threshold ( $k$ ) represents the health forgone when additional costs are imposed on the health care budget as a result of a new technology being recommended. These opportunity costs are incurred because the NHS budget is fixed, so the only way the local NHS can fund a new intervention is by displacing (doing less of or removing) a service entirely. If the types of external effects discussed here are to be factored into cost effectiveness analysis and more formally reflected in NICE decision-making, then the implications of displacement of services for external effects needs to be considered as well as the implications of displacement for health. In other words, when a new technology is recommended, the changes in local services that ensue as a result of the need to free up funding for the new intervention will not only effect patients' health; they may also have an impact on the direct and indirect external effects which are the focus of this briefing paper. In which case two thresholds are effectively required – the standard



one reflecting forgone health and the second relating to forgone external benefits.

It will, therefore, be necessary to provide a value for this second threshold. Providing an empirical estimate of the cost-effectiveness threshold in terms of forgone health is itself challenging but recent<sup>6</sup> and ongoing<sup>7</sup> research has conceptualised this in terms of estimating the average health effect (in terms of quality-adjusted life-years - QALYs) of a small reduction in the overall budget in the NHS. A similar concept would be relevant to external effects: what would be the impact on direct and indirect external effects of a small reduction in the NHS budget as induced by the recommendation of a new technology? The routine data sources being used to quantify the threshold in terms of forgone health (including programme budgeting data and national mortality data) would not provide any empirical estimates of the change in the types of external effect of interest.

One possible approach is to estimate a relationship between a change in health (in terms of mortality and, if possible, HRQoL) and external effects. If such a stable relationship could be estimated then, for any health forgone as a result of additional expenditure on a new technology expressed through the 'standard' cost effectiveness threshold, it would be possible also to derive an estimate of external benefits forgone. There is a literature on the relationship between health and productivity<sup>8</sup> which could be the basis of such estimation, but it is unlikely that the full range of external effects (including patients' costs and informal care costs) would exhibit a stable relationship with health as they are likely to vary across clinical areas.

### *3.2.2 Discussion points*

- Should consideration of external effects be symmetrical with respect to the net external benefits of the new technology and the net external benefits forgone as a result of displaced services due to increased expenditure on the new intervention?
- What are the alternative ways of estimating the opportunity cost of displaced services in terms of external benefits? How can routine data sources be used for this purpose?

- Is there likely to be a stable relationship between health and external benefits which can be estimated and used for this purpose? Is there an existing literature on this? What data sources exist to estimate it? Would it be consistent across clinical areas or would it need to differentiate by, for example, ICD classification.

If the external benefits associated with displaced services can be approximated by a relationship with the health displaced, should this also be used in considering the external effects of new technologies? Does it suggest that external effects can be given less weight because more effective technologies (in terms of health gain) are the ones which are likely to be recommended anyway?

### **3.3 *Measuring and valuing external effects***

#### *3.3.1 Summary of the issue*

Table 1 above summarises the methods available to measure and value different aspects of external effects. It also describes some of the issues and challenges relating to measurement and valuation. If NICE's perspective is broadened then its methods guidance would presumably have to define the measurement and valuation approaches the Institute would prefer to be used. There are three issues in particular which need careful consideration. The first is the valuation of carer time. Here it may be possible to use the market net wage rate since, in undistorted markets, this should reveal an individual's marginal valuation of their time. However, this is likely to overestimate opportunity costs of most carer time. In addition, if carers gain some benefit (for example, reassurance) from providing care themselves rather than employing others, then market rates may over-value the true opportunity costs. Similarly, net wage might not represent the marginal value of a patient's leisure time as choice of working hours is often restricted, and proposed values range from zero to the overtime wage rate. Others suggest it should depend on what time is being sacrificed to reflect the value of the different types of activities that are forgone. There are also methods which elicit carers' valuation of their own time such as conjoint analysis.

A second key methodological challenge relates to the valuation of productivity effects, both to the wider economy and to the patient directly. For example, returning a patient to active participation in the labour market will, in many circumstances, add to production in the economy. This will be a net benefit to the rest of society if the value of the additional production exceeds the individual's additional consumption over their remaining life expectancy. How to value improvements in productivity due to reduced mortality or earlier return to participation in the labour market due to improved HRQoL is a matter of debate. There are two main approaches supported in the literature: the human capital approach and the friction cost method. The human capital approach assumes that any productivity gained or lost will extend over time and should be valued based on the gross earnings of employment. Gross wages are often recommended on the basis that the gross wage in an undistorted competitive market will be equal to the social (market) value of the production (the marginal revenue product). However, some key assumptions are required: that the labour and associated product markets are competitive and undistorted and that there is no involuntary unemployment due to structural problems in sectors of the economy. Therefore, the gross wage will overestimate the value of productivity if there is unemployment in the relevant sector or if there are distortions in labour and product markets.

Others have proposed a friction cost approach to valuing productivity losses from ill health, which is based on the amount of production lost during the time it takes employers to restore the initial production levels.<sup>9</sup> The total friction cost will include the lost production (over a more limited time frame than human capital estimates) as well as the direct costs employers must incur to restore these initial production levels (for example, recruitment costs, training costs etc). The use of the friction cost *approach* results in much lower estimates of the value of production losses from ill health than those from the human capital approach.<sup>2</sup>

With respect to the patient, an important question is whether the consumption enjoyed by an individual as a consequence of improved length or quality of life is captured in estimates of HRQoL. If, when valuing health states,

respondents take account of the impact that the health state would have on their ability to work and consume, then the financial effects on the patient will already be accounted for in estimates of QALYs gained. In these circumstances adding in the additional consumption enjoyed by the patients through a human capital or friction cost approach would double-count these benefits. This is the position taken by the US panel - a multi-disciplinary group who considered best practice for economic evaluation for the US Public Health Service in 1996.<sup>3</sup> As described in Table 1, the US Panel argued that the value of productivity gains *to the individual patient* can and should be captured within the QALY through the values ascribed to health states by (in NICE's Reference Case) a sample of the public.

It should be noted that NICE's preferred measure of HRQL, the EQ5D, includes in its description of health states the ability to perform 'usual social role' which will include participation in the labour market and its financial implications. When valuing this health state, would individuals consider the impact of moderate or major limitations on this role on their ability to generate income in the labour market and hence enjoy consumption? Other measures of HRQL do not include social role specifically in their health state descriptions, so they might be less likely to capture these effects in their health state valuations. The current evidence suggests consumption or income effects are not currently captured within measures of HRQL,<sup>10-11</sup> although this work cannot be described as definitive. In these circumstances the additional consumption enjoyed by the patient would need to be included as a benefit and set against any indirect external costs (consumption net of production). It should be clear that adding consumption as a benefit to the patient and also as a cost to the rest of society will cancel, leaving just the external value of any production as a positive benefit.

The third key issue regarding measurement and valuation relates to costs and consequences of new technologies falling in other parts of the public sector (for example, criminal justice or education). Each of these sectors has some form of budget constraint relating to its activities. As a result, there are opportunity costs (in terms of outcomes of value in those sectors which are

forgone). Therefore, additional costs falling on a non-health sector as a result of a new technology being recommended in the NHS would result in sector-specific outcomes forgone; cost savings in another sector would be of value because it would free-up resources to generate improved outcomes; and any positive or negative non-resource effect of value in these sectors (for example, changes in educational outcomes in the education sector) could be expressed in monetary terms by reflecting the budgetary cost that would need to be incurred to generate those effects.

To formally quantify these effects on other parts of the public sector methods of measurement and valuation would be needed that are comparable to those used in the NHS. These would include estimates of the resource and non-resource consequences of new technologies recommended in the NHS on other parts of the public sector and the use of standardised unit costs to value resource use in monetary terms. More of a challenge would be the need to agree which outcomes are important in each sector and the relative value between them, ideally expressed as some composite measure of outcome such as the QALY in health. More challenging still would be the need to express the opportunity cost in other sectors in terms of these outcomes using a cost effectiveness threshold similar to the one used by NICE. If these metrics were to be available it would be possible to determine whether an intervention was cost effective from a public sector perspective.<sup>12</sup> For example, consider an intervention which reduces opioid dependency but is not considered cost effective from the NHS perspective. Also assume it generates cost savings and improved outcomes in the criminal justice sector. If the latter are sufficient for criminal justice to compensate the NHS sufficiently to make the intervention cost effective in the NHS, whilst still leaving a net benefit in criminal justice sector, and there is some budget flexibility to allow this, then a broader public sector perspective could be implemented.

### 3.3.2 *Discussion points*

- If a broader perspective is to be used by NICE, what are the methods of measurement and valuation which will need to be defined by NICE?

- If carer's time costs are to be included in any broadening of the perspective, would a single method of valuation need to be prescribed? if so, what would it be?
- If productivity costs are considered relevant to NICE decision making, would specific methods of valuation need to be defined? If so, what would they be?
- If the costs and consequences of new medical technologies falling on other parts of the public sector are to be formally considered in a broader perspective, what methods of measurement and valuation can NICE define?

### ***3.4 Making a broader perspective work in decision making***

#### *3.4.1 Summary of the issue*

There are clearly a number of challenges to be faced if a decision is made to broaden the perspective taken by NICE in technology appraisal. Some of these are amenable to resolution through careful judgement - for example, the most appropriate means of valuing productivity effects. Some could be addressed through further research - for example, deriving composite measures of outcomes and estimating cost effectiveness thresholds for other parts of the public sector, and estimating the external effects associated with displaced health services resulting from the funding of new technologies from a finite NHS budget. However, some of the challenges are potentially intractable. The first of these is the implications of non-marginal effects of the cost of new technologies on the NHS budget such that the NHS cost effectiveness threshold and  $\left(\frac{k}{v}\right)$  changes.

The second is the fact that formally defining the trade-offs in the costs and consequences of new technologies between the NHS, other parts of the public sector and the wider economy using, for example, the approach described in Section 3.1, without fully specifying a social welfare function may lead to prescriptions which conflict with other legitimate objectives of social

policy and principles of the NHS. This is particularly the case when wider considerations will inevitably lead some technologies, which would have been accepted as cost-effective from the perspective of the health care system, to be rejected. These will tend to be technologies in older populations or which offer life extension in chronic diseases where a return to productive activity is not possible. Such decisions might be very difficult to sustain if they rest on measurement and valuation of consumption benefits which are not widely accepted or if they conflict with other objectives of social policy or widely held social value judgements.

It is important to recognise that consideration of external effects would only reallocate existing NHS resources, not add to them. It would change the mix and relative priority of particular technologies; at the margin it would prioritise less effective technologies which offer net consumption benefits over more effective technologies which impose net consumption costs. Therefore, in the short run, it would reduce the overall health gains from the NHS budget. This would be more pronounced with value-based pricing as, if price flexibility is achieved, the price would be set to a level which effectively internalises external effects onto the NHS budget for a greater proportion of newly licensed pharmaceuticals. This may be desirable if all the social objectives and arguments that are relevant are encapsulated in the framework used (that is, it reflects a fully defined social welfare function), but this is unlikely to be the case. There may be sense, then, in avoiding a formalised and analytical approach to incorporating wider costs and consequences in NICE decisions. Instead a deliberative approach to handling these issues can provide a means of balancing the complex network of social objectives and constraints which can almost certainly not be defined mathematically. It is possible to characterise the 2004 (and possibly 2008) methods guidance in these terms - a Reference Case made up of NHS costs and health effects, but wider impacts taken into account in a deliberative process. As noted in Section 3.1, this can also be seen as consistent with the analytical approach of including non-NHS costs and benefits, but down-weighting them by  $\left(\frac{k}{v}\right)$ .

The various challenges of formalising a broader perspective - both technical and in terms of social values - may also suggest the current NICE policy of only considering non-NHS effects in circumstances where they are likely to have a major impact, is appropriate. It is quite possible to retain this position and to consider the implications of wider costs and benefits using a deliberative framework. However, there may be a need for NICE to be more specific about when these circumstances exist and the methods to be used when they do. For example, is there a need for more clarity about the fact that the external effects of a new technology can be relevant and important when there are benefits (for example, reduction in carer time) or costs (for example, costs imposed on another sector such as education)? If the existing wider perspective (public sector outside the NHS) is used when these are significant or in general, how will value in other sectors be assessed? Will it be possible to initiate some form of budget transfer if appropriate?

#### 3.4.2 Discussion points

How can an analytical approach to reflecting the external costs and benefits of health technologies avoid decisions conflicting with other social objectives?

When reflecting broader costs and benefits, what needs to be defined terms in the Methods Guide regarding how this process would work?

What further information should be provided in the Methods Guide on the criteria used to define circumstances for incorporating wider perspectives?

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