Value-Based Pricing Working Party #1: Briefing for DH presentation

This document provides background material for the DH presentation to the first Working Party on the implementation of value assessment under of Value-Based Pricing (VBP).

Rationale for wider value assessment as part of VBP

The current process of assessment of new treatments can be thought of as determining whether the benefit to patients of a new technology, measured in QALY\(^1\) gains, are sufficient to offset the losses to patients elsewhere in the NHS when funds are re-allocated to the new treatment, necessitating the withdrawal of other treatments and services. This decision can be effected by ensuring that the incremental costs per QALY gained from the treatment are no more than the incremental cost of generating QALYs elsewhere in the NHS – which are reflected, in principle, in the cost per QALY threshold.

In principle, this approach will ensure that new treatments do not displace more health gain than they provide, and will lead to decisions which do not diminish the value of benefits gained from the NHS budget, subject to two conditions:

i. That all QALYs provided by treatments, or displaced elsewhere in the NHS, are of equal value to society

ii. That only patients are affected, through the health gains (or losses) from new (or displaced) treatments – and we are not concerned with any impacts on other members of society

The rationale for a wider assessment of value as part of VBP is based on the proposition that these conditions do not hold.

There is evidence that society places greater value on QALYs provided in some circumstances – for example when they are provided to patients in particularly severe health states, or with very high unmet medical need. VBP addresses this prioritisation with a system of weights to reflect the greater societal value of QALYs provided to patients with high “Burden of Illness”.

It is also evident that treatments have impacts beyond their effects on patients. For example, treatments may mean patients are able to return to work or provide care to others, so contributing more to society. They may also need less care, in residential homes or provided by family members, as a result of their treatment. These aspects of treatments have real effects on people which are routinely assessed when considering decisions about other types of public spending. A key objective of VBP is that these “Wider Societal Benefits” will be measured systematically and their contribution to the value of treatments reflected accordingly.

\(^1\) Quality-Adjusted Life Years – a universal unit for measuring health impacts
“Terms of Reference” for development and implementation of wider value assessment by NICE

The methods for value assessment of branded medicines under Value-Based Pricing should:

- be applied to medicines within the scope of the Value-Based Pricing system, and incorporated into the methods for other categories of guidance at NICE’s discretion;
- adopt the same benefit perspective for all technologies falling within the scope of VBP, and for displaced treatments (1);
- be as transparent and predictable as possible;
- be informed by the best available evidence;
- include a simple system of weighting for Burden of Illness that appropriately reflects the differential value of treatments for the most serious conditions (2);
- encompass the differential valuation of ‘End of Life’ treatments in the current approach within the system of Burden of Illness weights;
- include a proportionate system for taking account of Wider Societal Benefits (3);
- not include a further weighting for Therapeutic Innovation and Improvement (4);
- produce guidance for patients and the NHS which describes the clinical and cost effectiveness of the technology and its position in clinical practice.

Notes to Terms of Reference

(1) That is, the value of a new treatment is considered net of the value of what is displaced, and the valuation methodology is applied consistently across treatments, including where the net value impact in respect of an element of VBP may be negative.

(2) For example, using a simple percentage weighting that is proportionate to the QALY loss suffered by patients with the condition.

(3) The perspective adopted for measuring WSBs should, in principle, be as set out in the HMT Green Book for Appraisal and Evaluation in Central Government - which specifies the cross-Government approach for evaluating costs and benefits of spending decisions. However in practice it will be important to reflect uncertainties in the evidence for the magnitude of WSBs, the novelty of the approach, and the degree of consensus among stakeholders. Options may in practice include constraining the weight given to different elements of WSBs in the valuation of treatments, or initially taking a selective approach to the types of benefit included in the assessment framework, in order to support incremental broadening of the value perspective. It will be important to ensure that the approach to incorporating WSB is applied systematically and consistently.

(4) To ensure that innovation is rewarded only when the technology’s use brings extra value.
Burden of Illness
The ToR specify that value assessment in VBP should 

“include a simple system of weighting for Burden of Illness that appropriately reflects the differential value of treatments for the most serious conditions”

Rationale
The QALY calculation methodology ensures, in principle, that QALYs gained by a particular patient are of equal value, regardless of their composition in terms of Quality of Life (QoL) and duration.

But society may still legitimately place greater value on QALYs given to patients in different circumstances – for example when their conditions are particularly serious.

Definition
DH has formulated a definition of Burden of Illness which is designed to capture the seriousness of the condition suffered by patients, as well as the degree of unmet need. In this formulation, Burden of Illness is defined as the number of QALYs lost by the patient because of their condition.

For example, a patient who died of a condition, while they would have been otherwise expected to live for a further 50 years at 90% QoL, would be deemed to have a Burden of Illness (BoI) of 45 QALYs (90% * 50). Similarly, if a patient’s condition did not reduce their life expectancy, but meant their QoL was reduced from 90% to 60% for a period of 5 years, this would correspond with a BoI of 1.5 QALYs (30% * 5).

Evidence of societal preferences in respect of Burden of Illness
A workshop in November 2012 reviewed a wide range of evidence pertaining to society’s preferences in respect of treatments given to patients with different BoI.

The summary of that evidence, as interpreted by DH, was that there was reasonable support for the general notion that society put greater value on QALYs provided to patients with higher BoI, as defined above. However the evidence did not dictate a particular weighting mechanism for expressing this differential valuation. Nor did it specify particular levels of relative weighting for QALYs provided to patients with different BoI.

The workshop also reviewed evidence in respect of society’s prioritisation of treatments on the basis of End of Life – that is, in general terms, the proximity of the patient to death. The interpretation of this evidence was that it did not support a separate weighting for End of Life. However the evidence was consistent with the related notion that society put differential weight on treating patients whose condition reduced their life expectancy. This aspect of conditions is encompassed in the definition of BoI, as it results in a loss of QALYs. One interpretation of the evidence that emerged in feedback from workshop participants
was that society may put a different value on the portion of BoI that results from lost life expectancy, as opposed to loss in QoL.

For example, a patient’s condition might reduce their QoL from 80% to 50% for 10 years, corresponding to a loss of 3 QALYs, and then cause their premature death, with a loss of 5 QALYs. The total QALY loss, and BoI would be 8 QALYs. But the interpretation above would imply that the two components of loss (3 QALYs in QoL, 5 QALYs in Length of Life (LoL)) would be considered separately for the purposes of valuation in VBP, perhaps with differential weightings and contributions to the assessed value of the treatment.

Possible formulation of weighting systems consistent with the evidence and ToR

As explained above, the evidence reviewed was not considered to dictate particular weighting systems, or relative weights. However the DH work describes a simple approach to weighting, which may be considered to be consistent with the evidence and the ToR.

In this system, treatments are awarded a simple percentage premium for every QALY of BoI. For example, if the premium per QALY of loss (to be applied to all treatments) was 5%, then a treatment for a patient with 6 QALYs of loss would attract a 30% weighting.

If the evidence were taken to support a separation of BoI into the QALYs lost through QoL and LoL, then these components might attract different premia. For example, if the premium for QALYs lost in QoL was set at 4%, while that for QALYs lost due through LoL was 6%, then a treatment for a patient losing 2 QALYs in QoL, and 10 QALYs in LoL would be given a weighting of 68% (2*4% + 10*6%).

It might also be considered desirable to use a tapering or capping mechanism to limit the total weighting for any given treatment. The details of possible mechanisms will be explored further in the Working Party meeting considering BoI.

It is important to note that when a new treatment is funded, other treatments elsewhere in the NHS must be displaced – and these treatments will also be associated with BoI. The ToR require that decisions on funding new treatments fully reflect the value of treatments displaced. This implies calculating the BoI weighting for the notional displaced QALYs that are lost when funds are re-allocated to a new treatment. This important aspect of VBP is described in more detail below.
Wider Societal Benefits

The ToR specify that the value assessment mechanism in VBP should

“include a proportionate system for taking account of Wider Societal Benefits”

Perspective for Value Assessment in VBP

The ToR further define the perspective of value assessment to be that set out in the Treasury Green Book\(^2\), which provides a common, cross-Government approach to evaluating the costs and benefits of decision making in respect of public funds. The Green Book states that

“The relevant costs and benefits to government and society of all options should be valued, and the net benefits or costs calculated.”

and

“Relevant costs and benefits are those that can be affected by the decision at hand.”

In respect of funding decisions for health treatments, this perspective implies that, as well as health impacts and NHS costs, value assessment should include other impacts on society. This represents an important change in the perspective adopted in the NICE technology appraisal process.

For the purposes of value assessment in VBP, DH has developed a systematic approach to defining and measuring WSBs that is consistent with this perspective, and is available for NICE to potentially use in implementing VBP.

Definition of Wider Societal Benefits (WSBs)

The approach to reflecting WSBs in value assessment is founded on the principle that any resources a patient contributes or produces, net of resources they utilise or consume, is available for others in society to use and benefit from. Similarly, if a patient utilises or consumes resources in excess of the resources they contribute or produce, then those resources must inevitably be provided by society, and are not available for others to consume and benefit from.

This concept of “net resource contribution” – the patient’s production of resources net of their consumption of resources – provides a definition of the patient’s WSBs. If a treatment changes the production or consumption of resources by a patient, then it will change the amount of resources available for others to benefit from – having an impact on WSBs.

For example, suppose a patient with a particular condition produced £1500 worth of resources per month – through their labour, paid or unpaid. If they consumed £1000 of

resources per month, for instance in the normal goods and services used in everyday life, but possibly also by needing social care, or informal care by family – then, in this perspective, they would be judged to provide a net resource contribution worth £500 per month.

Suppose that a treatment improves the patient’s health, such that they now contribute £1600 worth of resource per month. This increased amount might reflect the fact that they are able to work more. They may also utilise fewer resources, perhaps because they require less care by their family. Suppose they now consume resources worth £900 per month, giving a net resource contribution of £700 per month. This would imply that the effect of the treatment was to increase the patient’s net resource contribution by £200 per month. If the duration of the treatment’s effects was 5 months, the total impact on net resource contribution – and the WSBs ascribed to the treatment – would be £1000.

**Categorisation of WSBs**

For convenience, the production and consumption of resources by the patient are divided into sub-categories.

For production these are

- Paid production – that is, labour provided for a salary or other payment
- Unpaid production – including domestic work, child care and volunteering

For consumption these are

- Formal care – social care paid for by the patient, their family or Government
- Informal care – including care provided by family and friends
- Private paid consumption – including goods and services used in everyday life, such as housing, food, clothes, travel and entertainment
- Private unpaid consumption – utilisation of unpaid production, as above
- Government consumption – using services provided directly by Government, including education and health services (but excluding those directly related to the condition in question)

**Estimating WSBs for patients in different health states**

The DH work to date includes a mechanism by which each element of WSBs – and therefore the total amount of WSBs – can be estimated for a patient, given their

- Age
- Gender
- Type of health condition - defined according to the International Classification of Disease (ICD)
- QoL score (on a scale in which 100% represents full health, and 0% is considered equivalent to death)

So, for example, a **female** patient aged **30** with diabetes (ICD = M) and QoL of **90%** might be estimated to generate £1600 worth of WSBs (net resources contributed) per month (illustrative figures). This sum is composed of the elements of production and consumption set out above.

Each element is calculated using data and modelling from a variety of sources – some existing datasets, as well as analysis that has been specifically carried out or commissioned to support the development of an approach to measuring WSBs as part of VBP. The details of this analysis, and the underlying data, assumptions and modelling, will be presented at a future Working Party.

**Implementation in appraisals**

The mechanism described above allows the WSB rate for a single patient to be calculated, given only the four inputs of age, gender, ICD and QoL. In principle it is straightforward to use this calculation to estimate the WSBs provided by a treatment – by comparing the progression of patients’ diseases over time with the treatment and its comparator, and calculating the net change in WSBs in exactly the same way as QoL profiles over time are used to calculate incremental QALY gains.

However there are practical difficulties associated with integrating WSB calculation in the cost-effectiveness models that are currently used to calculate the incremental QALY gains from treatments. In particular, production of WSBs is highly non-linear with respect to age. It is important, therefore, to use a full representation of the distribution of patients in the expected treatment population to calculate WSBs. This data may not always be available in current submissions to NICE.

To address this issue, a simple “default” calculation mechanism has been developed which provides an estimate of the WSBs associated with a treatment without imposing burdens on companies and appraisal committees. In this approach, a reference dataset is used which includes all the information required to calculate the WSBs (expressed per QALY of health gain) provided by typical treatments in each of 1284 diseases (ICDs). Given knowledge of the indicated ICD, this dataset can therefore be used to calculate (or look up) the estimated WSBs per QALY of health gain.

For example, treatments of rheumatoid arthritis (ICD M06) are provisionally estimated, based on the inputs from the reference dataset, to provide £43,200 worth of WSBs for each QALY of health gain. If a new drug for this condition provides 0.2 QALYs, it would therefore be estimated to provide £8,640 of WSBs.

The accuracy of the above estimate will depend on the degree to which the reference dataset is representative of the actual treatment population. The mechanism has therefore
be designed such that the face-validity of the estimate, and each of its components, can easily be verified by comparing the profile in the reference dataset with any information the company may provide on the actual treatment population. Where evidence shows that the reference dataset is not representative, this data can simply be entered into the calculation to give a more accurate estimate of the WSBs generated.

**Comparing new and displaced treatments in VBP**

When funds are re-allocated to a new treatment they are necessarily unavailable for some other use in the NHS. This means patients elsewhere will have treatments withdrawn, and will suffer health losses as a result. This sacrifice of patient health is reflected in the cost per QALY threshold. However the loss of health elsewhere due to the displacement of treatments implies that WSBs will also be lost elsewhere. The QALYs displaced will also be associated with some level of BoI. The ToR specifically require that value assessment should “adopt the same benefit perspective for all technologies falling within the scope of VBP, and for displaced treatments”

Any WSB gains attributed to new treatments must therefore be calculated net of any WSB losses displaced elsewhere. The BoI associated with displaced QALYs must also be estimated and reflected in value assessment.

For example, suppose a treatment provided 2 QALYs of health gain, and displaced 2 QALYs elsewhere (i.e. its cost per QALY was exactly at the threshold). The new treatment might be associated with £12,000 of WSBs, but the QALYs displaced would also be associated with WSBs. If £8,000 of WSBs were displaced, then the net impact, and the value of the benefit to society, would be £2,000. Note that it is possible the net WSB impact could be negative – and treatments could displace more WSBs than they provide.

The 2 QALYs gained might be associated with a BoI weighting of +50%, meaning they were assigned a value of 3 QALYs (2 QALYs + (2 QALYs*50%)). But this must be compared to the weighting on QALYs displaced. If this was +60%, then the QALYs displaced would be accorded a value of 3.2 weighted QALYs.

Applying the wider value perspective to displaced treatments requires that the notional displaced QALY is characterised in terms of its associated BoI and WSBs. This has been achieved, using empirical data showing how a notional displaced QALY is distributed across the 1284 diseases in the reference dataset described above. The BoI and WSBs for each disease can be calculated, giving a weighted average BoI and WSB estimate for the notional displaced QALY, which can be compared to the BoI and WSBs associated with QALYs gained from new treatments. This calculation will be explained in detail at future working parties.

There are a number of ways in which the BoI and WSBs associated with QALYs gained and displaced can be used to inform NICE decisions. An approach will be described in which the
cost per QALY threshold to be applied to a particular product is adjusted to reflect its BoI and WSBs relative to those of displaced QALYs.

**Equalities**

Widening the scope of value consideration could have impacts on equalities, as treatments for some groups in society may be associated with levels of BoI or WSBs that vary systematically from the average – implying higher or lower value under the new system. These important impacts have been considered in detail in a workshop held by DH. Some important aspect of the potential equalities impact are set out here as context.

First, it is important to note that changes in the valuation of treatments do not necessarily imply changes in access to treatments which would have an impact on equalities. If companies provide access to new products under VBP in the same way they would under the current system, and the same products are made available to patients – albeit at different prices – then the most likely outcome is that there is no impact on equalities.

Second, if there is a change in access, the ultimate impacts on equalities may not be consistent with the most obvious intuition. For example, older patients tend to use more formal care resources, which impose a cost on society. However if treatments improve the health of such patients, this may mean they need less formal care – implying potentially large gains in value, because the patients are now using less of society’s resources, even though they are much less likely to be ‘contributing’ to society through paid employment.

Furthermore, if reflecting attributes such as WSBs results in re-allocation of resources to treatments which provide the greatest additional benefit beyond health, there will be a value “dividend” to society, for example in greater tax revenues. Any such change will always have varied impacts, both positive and negative, on individuals. But overall, groups of people – such as older people – which may receive less health resource would be expected to share in this dividend, for example through increased provision of public services. The share of the “dividend” that benefits these groups could potentially offset, at least in part, any direct reduction in access to treatments.

The equality impact of these measures therefore requires careful consideration, and this will be part of the ultimate evaluation of this aspect of VBP. Finally, it is important to note that while NICE, and all public organisations, have an obligation to understand the possible equality impacts of their actions, and to take any reasonable measures to mitigate such impacts where that is considered appropriate, they are not prevented from taking actions to achieve legitimate goals even if these have differential effects on different groups.

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3 It is worth noting that the effect of these costs would likely be borne, ultimately, by other users of formal care resources, if the budgets for providing this care are limited