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Operationalising Value Based Pricing of Medicines: A Taxonomy of Approaches

Jon Sussex, Adrian Towse and Nancy Devlin

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Sussex, J., Towse, A. and Devlin, N.

Office of Health Economics, London

Corresponding author:

Jon Sussex
Deputy Director
Office of Health Economics
7th Floor, Southside, 105 Victoria Street
London SW1E 6QT
Email: jsussex@ohe.org
Phone +44 (0)207 747 1412

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Abstract

The purpose of this paper is to provide an account of the full set of possible means by which value based pricing (VBP) might be operationalised; to describe and categorise them by developing a taxonomy of approaches; to give an initial assessment of the challenges, pros and cons that each of the principal types of approach implies. To achieve this, we review the elements of value that could be taken into account, how they might be measured and valued, how the different elements could be combined into an overall assessment of a medicine's value, and how that then could be linked to the maximum price the health service is willing to reimburse.

The UK Department of Health's consultation document regarding the introduction of VBP (DH, 2010a) outlines one possible approach to these steps – but others are possible.

We begin with a brief discussion of value in economics and theoretical frameworks from economics relevant to the normative question of which attributes of medicines should be taken into account in VBP.

We proceed to outline a taxonomy of approaches to VBP, taking as our starting point that VBP will include a measure of health gain and that this will be built on the QALY. Our principal interest is in the way criteria *other than* QALYs are taken into account. We set out to: (i) identify and describe the full range of alternative means by which "value" might be measured and valued, (ii) identify and describe the options available for aggregating the different components of value to establish a maximum price, and (iii) note the challenges and relative advantages associated with these approaches. Finally, we review the means by which VBP is currently operationalised in a selection of countries and place these, and proposals for the UK, in the context of our taxonomy.

Contents

Introduction

Recent reforms to the National Health Service (NHS) in England include, amongst wider structural changes to the health care system (DH, 2010a; Devlin, 2010), a new approach to the regulation of prices for new medicines. From January 2014, the existing Pharmaceutical Pricing Regulation Scheme (PPRS) will be replaced by "Value Based Pricing" (VBP) for branded medicines sold to the NHS. The UK Government announced this in its July 2010 White Paper (DH, 2010a), in which it defined VBP only rather vaguely, as follows:

> "a mechanism for ensuring patients can get access to the medicines they need by linking the prices the NHS pays drug providers to the value of the treatment" (DH 2010a Glossary)

The meaning of VBP has been made a little clearer, but not much, in the Department of Health's subsequent public consultation document on VBP (DH, 2010b):

> "The purpose of value-based pricing is to improve NHS patients' access to effective and innovative drugs by ensuring they are available at a price that reflects the value they bring. It will give patients and clinicians greater access to medicines, based on an assessment of the outcomes that they can achieve." (paragraph 1.2)

and:

> "Pharmaceutical companies also need a pricing system that …. gives clear signals about priority areas, so that research efforts are directed to maximum effect. We need a system which can recognise and reward innovation, in particular by encouraging a focus towards breakthrough drugs which address areas of significant unmet need." (paragraph 2.16)

and:

> "include a wide assessment, alongside clinical effectiveness, of the range of factors through which medicines deliver benefits for patients and society". (paragraph 3.3)

Thus, the essence of VBP appears to be that the (maximum) price the NHS will pay for a medicine is to be set at the level where the incremental value of using it relative to the next best alternative standard treatment (or palliation) just balances the incremental cost. The incremental "value" will be as judged by the payer (the Department of Health or its chosen agent), based on evidence submitted to it. VBP will apply initially only to *new* medicines, probably 20-30 each year, and may exclude some of these, for example orphan drugs. The prices of branded medicines launched prior to 2014 – which for a number of years will continue to account for the majority of the overall market – will continue to be covered by the existing PPRS arrangements.

The purpose of this paper is to provide an account of the full set of possible means by which VBP might be operationalized; to describe and categorise them by developing a taxonomy of approaches; to give an initial assessment of the challenges, pros and cons that each of the principal types of approach implies. To achieve this we review the elements of value that could be taken into account, how they might be measured and valued, how the different elements could be combined

into an overall assessment of a medicine's value and how that could then be linked to the maximum price the health service is willing to reimburse.

The requirement to regulate pharmaceutical prices arises from the particular set of supply-side characteristics and market failures in this industry. The development of new medicines entails a high research and development (R&D) investment, combined with a high risk. Only a small fraction of new molecular entities that begin development ultimately meet the standards of safety and efficacy required to be brought to the market; and there is a long time lag between initial R&D and eventual market returns. The patent system operates to provide incentives to R&D efforts by offering a period of protection from copying for those products that are launched. This in turn may create a monopoly during some or all of the effective patent life.

Most medicines are purchased for patients via third party payers such as the NHS. This creates the potential for moral hazard, as patients (and possibly their clinicians) want access to drugs irrespective of the price to the third part payer. Regulation is used to restrict the pricing and profits that this combination of monopoly power and moral hazard could produce. Combining patent protection and price regulation can, in principle, strike a balance between dynamic and static efficiency.

The current PPRS regulates prices reimbursed by the NHS by a mix of price and profit control (Towse, 2007). Once set, prices normally cannot be increased later. If companies earn excess profits over the full portfolio of their sales to the NHS they are required to reduce prices and/or make a repayment to the Government to remove the excess profit. However, the major constraint on price is the indirect price control represented by a referral to the National Institute for Health and Clinical Excellence (NICE). Many new products are reviewed by NICE, and the prospect of a NICE review will impact on companies' pricing decisions. NICE does not currently have an explicit role in setting or negotiating prices[1]. NICE is a "price taker": it makes a recommendation, conditional on the price offered to it, as to which, if any, groups of NHS patients should get access to the technology.

NICE has been given by the Government a relatively narrow remit in terms of the benefits and costs to take into account in its assessments. The NICE Appraisal Committees do take account of some additional factors (Rawlins, et al., 2010), but the way these influence decisions and the weight attached to each factor is not explicit, with the exception of the "end of life" weightings (NICE, 2009).

In contrast, VBP would involve a formal process of setting a maximum price that reflects some agreed measure of the health and economic value of new technologies. VBP was first proposed formally in the February 2007 report of the Office of Fair Trading's study of the PPRS (OFT, 2007). Advocates of VBP argue that directly linking maximum prices to the value offered by new technologies will: (a) sharpen incentives for R&D to be directed to areas with the greatest value, aligning industry returns with benefits to patients and the wider economy; (b) promote allocative efficiency, by ensuring that spending on new technologies does not displace other health care services of higher value, given fixed NHS budgets (Claxton, et al., 2008; OFT, 2007); and (c) enable a

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[1] This is in principle the case also in the special *ex post* pricing arrangements for a few medicines, such as risk sharing agreements or "patient access schemes'. See Towse (2010).

process of price setting to be agreed that reduces the likelihood of no use of the product in the NHS, which occurs currently if NICE recommends no use at the price set by the company.

A consultation document, published by the Department of Health in December 2010 (DH, 2010b), set out the UK Government's proposal for VBP in broad terms. Value is suggested in that document to entail a number of key elements. Principal among these are: the improvement in health – both length and quality of life – resulting from treatment, as measured by Quality Adjusted Life Years (QALYs) gained; as well as the burden of illness, encompassing the severity of ill health and the level of "unmet need"; some measure of "innovativeness"; and "wider societal benefits". Thus multiple criteria are to be taken into account in VBP, at least as wide as, or even wider than, in NICE's HTA process, upon which VBP arguably builds.

The assessed value of a new medicine is then to be set against its incremental impact on the costs of the NHS (including those personal social services funded by the NHS) and possibly on the costs of other parts of the public sector or the economy more widely. However, the cost side of the story is not the focus of the current policy discussion prompted by the VBP consultation and we do not discuss it further in this paper.

While improvement in health is at the heart of the assessment of value from new health technologies, other attributes are also relevant (Devlin and Sussex, 2011). As an extension of current HTA processes, VBP highlights normative questions about what these other criteria should be. VBP will also require a more explicit means of establishing their relative contribution to overall value.

The principal means by which the Government's consultation document suggests these criteria are to be taken into account is by estimating QALY gains, and then multiplying them by a series of weights to reflect other aspects of value, noted above[2]. This is intended to allow higher prices to be charged for medicines that have greater health gain; that improve the health of patients with severe poor health for whom there are few current treatment options; that are highly innovative; and that bring other, to-be-specified, benefits; (and lower prices for technologies which do these things to a lesser extent).

However, there are clearly *other* means by which VBP might be operationalised. The objectives of this paper are: (a) to identify and describe the full range of alternative means by which "value" might be measured and valued; (b) to identify and describe the options available for aggregating the different components of value to establish a maximum price; and (c) to note the challenges and relative advantages associated with these approaches. Finally, we review the means by which VBP is currently operationalised in a selection of countries and place these, and proposals for the UK, in the context of our taxonomy.

We take as our starting point the observation that VBP will not be restricted to QALYs alone. Our principal interest is in the way criteria other than QALYs are taken into account and combined with

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[2] Strictly, the DH consultation document suggests a series of different incremental cost per QALY thresholds: with a baseline threshold value being weighted according to the extent of other aspects of benefit present. This is, however, directly equivalent to weighting the QALYs and leaving the threshold constant.

the estimated incremental QALYs a technology produces. We set out the context for expecting other criteria than QALYs to matter.

Understanding the ways in which VBP could work is important. It will create a particular set of incentives that will affect the behaviour of firms with respect (potentially) to R&D, pricing, launch strategies; and to the NHS in terms of commissioning and the uptake of new technologies; and is of great interest to third party payers for medicines in all health care systems, internationally.

Value

2.1 Where might "value" arise from the use of health care services?

The meaning of value is central to economic theory. In the context of consumer choice theory, neoclassical economics defines the value of something as being measured by the maximum a person is willing to give up in terms of other goods and services in order to obtain it. Welfare economics provides the principal theoretical foundations for addressing questions of public policy and resource allocation, and comprises a set of normative theories and empirical methods – cost benefit analysis – for aggregating individual preferences and values.

Evaluating public policy options is, by the conventions of welfare economics, principally an exercise in finding the best way of aggregating the preferences of affected individuals, including their preferences for helping their fellow citizens. Health care raises particular challenges in this respect. It is the improvement in health, or at least the hope that there will be an improvement, that is valued (yields utility), rather than the consumption of health care *per se*. The value of a health improvement is not readily "revealed" by market behaviour and prices, so information on this is usually obtained via stated preference research. Further, market failures may mean that some aspects of health care generate benefits beyond those to treated patients – for example, spill-over effects on other family members or the wider economy, or providing the benefit to others of knowing that those in need of health care are able to access it (a "caring externality"). In these cases, the preferences of treated patients will fail to reflect the value of the positive externalities.

The QALY is a widely used metric for measuring health and changes in health, is the measure used by NICE, and (as noted above) is proposed for use in the new VBP system in the UK. The QALY comprises both length and quality of life. The quality of life weights used to estimate QALYs themselves incorporate an assessment of value (utilities) – based on stated preferences – but arguably the primary importance of the QALY is that it is a convenient and practical way to measure health. The question, from the point of view of public policy, is whether QALYs alone can also be used as a reasonable proxy for the *utility* of a medicine – or whether there are other sources of utility that are also relevant to the assessment of a medicine's value?

The UK NHS, a tax-funded national health care service, has typically based its decisions *not* on assessments of welfare, but instead on a pragmatic decision-maker's approach as to what is valuable and what is to be given up. The framework for supporting decision-making in this context is usually called "extra-welfarist" (Culyer, 1991; Brouwer, et al., 2008)[3,4].

It is helpful, however, to begin with the individual and then think through how the implications differ for decision making through a third party payer such as the UK's NHS.

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[3] Extra-welfarists argue that this pragmatic view of QALYs is all that is necessary to support decision making (Culyer, 2009).

[4] Tsuchiya and Williams (2001) note that the term "extra-welfarism" is problematic and instead use the term "non-welfarist" to describe all competing normative approaches to the question of what the maximand is and what exactly is "extra."

2.2 Value for the individual in utilising health care services

Grossman (1972) provides the seminal framework for thinking about the value of health and health care. In his model each individual is both a producer and a consumer of health. Each individual has a stock of health which depreciates over time; depreciation can be offset by "investments" in health. Health care is both a consumption good that directly yields value, and an investment good that yields satisfaction to consumers indirectly through increased productivity, fewer sick days and higher wages. The demand for health care is derived from the demand for health. Health care is one of many inputs into the production of individual health. Health gain, whether measured using QALYs or otherwise, is valued because of the increase in utility it provides.

Garber and Phelps (1997) and Meltzer (1997) derive cost-per-QALY thresholds for an individual buying health care. We can use this as a building block to help think through an NHS perspective. We assume the individual (in the absence of an NHS) is: (a) taking a lifetime perspective; (b) earning income from working or receiving income from savings; (c) spending money on health care or other goods, paying taxes to "buy" public services; and (d) deriving benefit from a range of sources. This includes getting QALYs from spending on health care; consuming other purchased goods and services; consuming public services; leisure time and other aspects of life (e.g. relationships) which may or may not involve the use of income; and caring externalities associated with helping other people (which may involve donations of income or time) or paying taxes to fund services or transfer payments to others.

As per Grossman (1972), getting a health care intervention involves spending on health care, which can produce gains in terms of QALYs, the ability to earn more income (by getting back to work or improving productivity) and/or to have more time for leisure. The process of care experienced by the patient will also affect the benefit they feel: the pleasantness of the surroundings in which they receive care, the dignity and sensitivity with which they are treated by health care staff, and so on. The intervention may also impact on other people – notably unpaid care givers – affecting their health (as measured by QALYs) as well as their leisure time and income. Let us assume the individual internalises these effects, functioning as a "household." In this context the incremental cost-per-QALY calculation will include all non-QALY effects in the "cost" element. At the margin the individual is spending up until all of the net effects associated with spending money on a health care intervention as opposed to on something else (including "spending" on leisure by working less) are equal to the value of the QALYs gained.

2.3 Value for the third party payer providing health care services

In practice, we have third party payer systems; in the UK the tax-funded NHS. This requires us to depart from the individual case in two stages. Firstly, the individual obtains insurance (in the UK paid from taxes) from a third party payer rather than buying care directly as and when it is desired. The third party payer operates a cost-per-QALY threshold that is determined by the size of its budget combined with the range and quantities of treatments it can provide within that. In a pluralistic competitive market, we can expect this to reflect the *ex ante* preferences of individuals for health care, and therefore their willingness to pay for health insurance.

The second stage is to move to *social* decision making for the third party payer as to: (a) the total budget for the NHS (and for other public services); and (b) the factors to be taken into account in determining access to health care over and above the typical focus of cost effectiveness analysis, i.e. the incremental cost to the NHS and the QALYs gained by the patient. The second element has two sub-elements:

1. The existence of social preferences (weightings) given to a QALY, which may depend on the characteristics of the patient receiving it (e.g. higher priority accorded to low income patients who, as a group, typically have lower life expectancy; or to those with a greater disease severity irrespective of their income level or ability to enjoy improvements in health);

2. The extent to which non-health costs and benefits are taken into account, of the sort we included in our consideration of the individual's utility function, such as the ability to work (and so earn income); the impact on consumption of other public services; and the impact on other family members. There is also clear evidence that things associated with the *process of care* – e.g. dignity, convenience, and speed of access (for example, see De Bekker-Grob, et al., 2010) – other than health gain (but usually complementary to it) matter to people.

The NHS budget at any point in time does not enable all possible care to be available when people need it; nor does it enable all of the non-health aspects of care to be made available. Choices have to be made and, logically, priority is given to the most valuable services (care and non-care related) per £ of NHS budget[5]. What does "valuable" mean in this context? What is the NHS trying to maximise given its resources? What does it value and how does it make choices, i.e. how much does it value one treatment as compared to another, given the trade-offs this will involve?

2.4 What elements of value are likely to matter?

Many possible elements of value can be considered and we identify here those that are most commonly proposed (see Devlin and Sussex, 2011, for more detail). A general problem is that many of these factors may be imprecisely defined and hence overlap, and even if they do not overlap they may not be entirely independent of one another. The independence issue is most stark where "degree of innovation" is considered as an element of value: it appears to mean different things to different people and can be seen as the sum of all the other elements of value a new technology brings, in which case rewarding innovation as well can be seen as double counting (which may be intentional [Kennedy, 2009] or otherwise); or as resulting from the path-dependent nature of the medicines innovation process, in which case it is necessary to avoid double counting the benefits of the ultimate innovation the present medicine may be a step towards (Sussex, 2010).

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[5] The NHS budget is, over time, *endogenous* rather than exogenous to the process of making choices. What can and cannot be provided feeds back (indirectly, via political processes) into NHS budget decisions. Prime Minister Tony Blair pledged in 2000 to increase NHS spend up to European average levels in response to the prevailing view that the NHS had hitherto been squeezed and was not providing enough of the (new) treatments and services that other countries were making available to their citizens and not providing an appropriate standard of non-health elements associated with care.

Health improvement is the single most important benefit from using health care services; the QALY is a practical tool for measuring this. The use of QALYs, however, does rest on some important underlying assumptions (Gandjour and Gafni, 2010) and their use is not without challenges both in measuring and valuing health states. For example, NICE notes the challenges involved in measuring and valuing health related quality of life in children, and indicates this as a reason why children are given special consideration in its health technology assessment process (Rawlins, et al., 2010). The outcomes from some types of health care are simply not appropriate to value using QALYs – for example, infertility treatments (Devlin and Parkin, 2003) – or may not be picked up well by instruments used to measure health related quality of life – e.g. hearing and sight problems and their alleviation. Any system of VBP which relies on QALYs will need to address these sorts of challenges. Where there are concerns about the adequacy of QALYs as measures of health improvement, representing other relevant considerations as weights applied to QALYs would exacerbate that problem.

2.5 We can categorise other elements of value into three distinct types.

First, we have identified the potential importance of the characteristics of the patient who is receiving the health gain. A QALY's "value" (to society) is higher or lower depending on who gets it. These social preferences with respect to QALYs gained might be represented by weights applied to them, as is currently the case with NICE's treatment of QALYs gained at the end of life. Rawlins, et al. (2010) list the following characteristics they say are already taken into account by NICE committees in their deliberations on the merits of health technologies: severity of the patient's condition; whether the patient is near the end of life; stakeholder persuasion that the impact of treatment has aspects not adequately covered by other evidence; significant innovation leading to distinct benefits of a substantive nature; whether the treated population is a socially disadvantaged group, e.g. ethnic minority; children (given methodological challenges in assessing quality of life in children, society would prefer to give them "the benefit of the doubt"). There are other, more controversial, factors that might be taken into account when weighting QALY's: the absence of any previous effective treatment for a disease (particularly a problem for rare diseases) may be a factor to the extent that providing any treatment at all provides hope alongside the QALYs; the extent to which the illness treated is dreaded (cancers being the usual example).

Second, are the "non-health" but health-care-process-related aspects: being treated with dignity, at a convenient time and location, after only a short wait if any; the degree of risk attached to a health care intervention (less risky interventions will usually be preferred to riskier interventions with the same expected outcome). These may have health consequences, but the preference for them (as reflected in patients' stated preferences, or in political targets) goes well beyond any health gain associated with them (see Shah, et al., 2011) and may not vary in relation to the health gain.

Third, there are the other costs and benefits outside of the health gain and process gain to patients and the immediate costs to the NHS. Drawing on the Grossman and Garber and Phelps approaches, these include: patients' ability to go back to work or school, or work more productively; benefits to carers in terms of enjoyment, leisure time or ability to work; cost savings to other publicly-funded services (such as education and criminal justice); cost savings to patients and their carers. Here there are important issues of: (a) what is important; (b) avoiding the problem of double counting

encountered in *any* practical attempt to assess value from a broad perspective (Mishan, 1977); and (c) using the right "exchange rates" for trading gains from one constrained budget into another.

2.6 How are values assigned to these other elements of value – and by whom?

VBP as a mechanism for paying for drugs requires both a statement of *what* is to be counted as being of value, and of *whose preferences* are relevant to the view of value to be reflected in prices. There is no objective way of establishing either. The Department of Health's VBP proposal in its consultation document indicates that burden of disease (which it defines as combining unmet need and severity) and therapeutic innovation are among the criteria of value to be considered alongside QALYs. Various other "lists" of potentially relevant criteria exist – for example: the social value judgements which NICE employs in its current HTA programme (NICE, 2008a; NICE, 2009b; Rawlins, et al., 2009); the various criteria used by different local health authorities in the UK (Devlin and Sussex, 2011) or by similar health care resource allocation bodies internationally (see Golan, et al., 2010); and lists grounded in bioethical arguments (Orr, et al., 2011). The question of which criteria should be taken into account is a normative one.

What has evolved as orthodox NICE practice in its appraisal of health technologies can be seen as pragmatic, but departing from the conventions of welfare economics. For example, the central measure of benefit – the QALY – relies on views of the value of alternative states of quality of life, which are estimated as the average value of members of the general public asked to imagine those states, rather than by seeking preferences of those directly affected (patients). The rationale is that the preferences of the general public are relevant, as they are the taxpayers. Second, the cut-off used by NICE to reflect its willingness to pay to obtain a QALY – the cost effectiveness threshold – is intended to reflect the marginal cost of producing QALYs in the NHS, as a means of reflecting the opportunity cost of new technologies within a fixed budget, rather than reflecting the marginal value attached by patients or the general public to QALY gains. The *perspective* of these evaluations is often described as being "the NHS", although in practice the perspective is a rather odd hybrid of different perspectives: costs include some, but not all, social care (rather than health care) costs, but not changes in other public sector budgets.

Extending the considerations relevant to VBP beyond QALYs invokes complex issues about the perspective from which those are assessed and, because they must be aggregated in some way, about the *consistency* of the perspective from which value is estimated across different criteria.

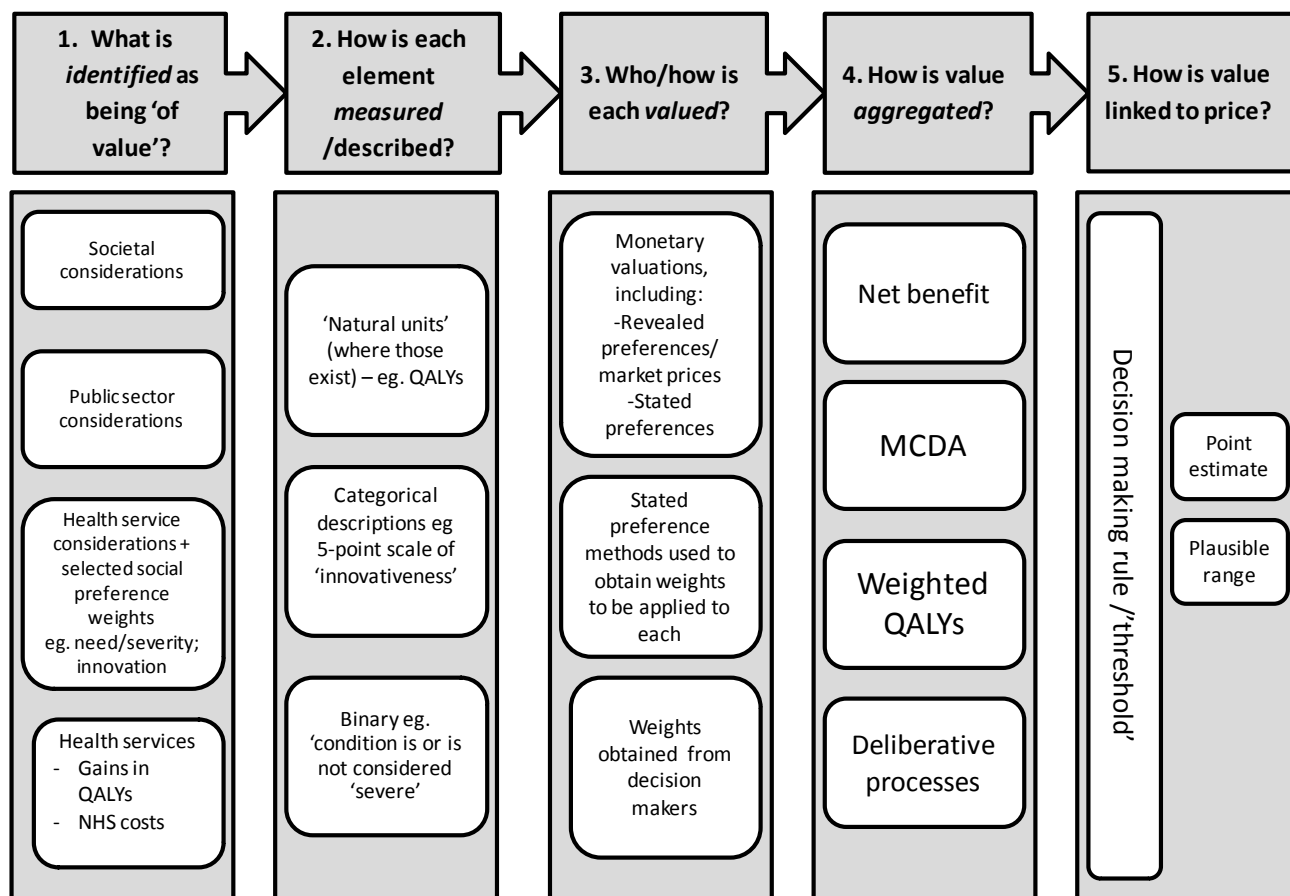The key point is that VBP is unlikely to be restricted to any one "metric" of value, such as QALYs gained. *Other* sorts of considerations and types of benefits will be taken into account. Our focus is on how that might happen. An essential challenge for VBP is how to make the links between disparate types and measures of values and setting the prices for the technologies that generate it in differential amounts.

A taxonomy of approaches to VBP

VBP, as with any approach to economic evaluation, requires an agreed means of *identifying*, *measuring* and *valuing* relevant costs and benefits. VBP further requires an explicit means of *aggregating* these costs and benefits, and a *decision rule* for converting the overall measure of value to the precise maximum price the NHS would pay, given its budget constraint. Figure 1 shows the principal categories of approach to VBP that might be taken.

What is identified as relevant to the assessment of value is closely related to the question of the perspective from which costs and benefits are considered. Options range from the narrow health service perspective to various expanded perspectives including the overarching societal perspective.

Figure 1: A taxonomy of approaches to Value Based Pricing

1. What is *identified* as being 'of value'?	2. How is each element *measured*/described?	3. Who/how is each *valued*?	4. How is value *aggregated*?	5. How is value linked to price?
Societal considerations		Monetary valuations, including: -Revealed preferences/ market prices -Stated preferences	Net benefit	Decision making rule /"threshold"
Public sector considerations	'Natural units' (where those exist) – eg. QALYs		MCDA	Point estimate
Health service considerations + selected social preference weights eg. need/severity; innovation	Categorical descriptions eg 5-point scale of 'innovativeness'	Stated preference methods used to obtain weights to be applied to each	Weighted QALYs	Plausible range
Health services - Gains in QALYs - NHS costs	Binary eg. 'condition is or is not considered 'severe'	Weights obtained from decision makers	Deliberative processes	

Note: The ordering of the text items within each of the columns should not be taken to imply any ranking.

Having identified what is relevant, the next step involves describing and measuring each value component. For some sorts of benefits, there will be some pre-existing scale of measurement – for example, QALYs gained provide a measure of health improvement on a continuous scale. For other sorts of considerations, VBP may require bespoke measures to be developed specifically to capture things not previously explicitly incorporated into HTA decision making – for example, there are no ready-made measures of "innovativeness", burden of disease, or severity. The incorporation of these in VBP requires explicit measurement via either a scale of effect (to describe the magnitude of severity, burden of disease, or innovativeness) or, more crudely, a finite number of discrete categories for each value component (e.g. "major", "medium", "minor"). Whichever approach is used requires clarity over the concepts being measured and agreement over the definitions that underpin each measure.

Having identified the relevant considerations and determined a means of measuring them for a given technology, the next step is to value these. A wide range of revealed and stated preference methods for this purpose exist. The question of *whose* preferences count is closely related to what elements of value are identified as relevant and which perspective is adopted. The question of *how* those preferences are measured is, in turn, closely related to the subsequent question of how value

is to be aggregated: that is, what is the overarching "numeraire" in terms of which each of the elements of value that have been measured will be summed?

VBP requires disparate types of "value" to be taken into account. This requires an aggregation rule; and some means of establishing the maximum (regulated) price given that aggregate measure of value. The principal options for aggregation are:

1. Converting all values into a common currency (e.g. net benefit);

2. Considering each type of benefit in terms of its own "units", and applying a set of weights to each benefit type to represent the rates at which different types of benefit may be traded-off with each other, and scores to indicate how well each benefit type is achieved by the medicine in question. This option is a multiple criteria decision analysis (MCDA) approach;

3. Selecting one principal measure of benefit, the default option being QALYs according to the DH consultation document (DH, 2010b), and then up-rating or down-rating that using a series of explicit weights to reflect the magnitude of other types of benefit that are produced

4. A deliberative process without formal MCDA structuring (Culyer, 2009). However, VBP requires an *explicit* means of linking evidence of value to a specific maximum price if it is to provide the correct signals to medicines manufacturers, in which case deliberative processes where the relative weights remain implicit are probably precluded.

Aggregation of values

The key difference between the alternative approaches to aggregation is what, in each case, is used as the *numeraire* of value and hence how different aspects of value are "traded-off": how much patient convenience (however defined) is deemed to be worth relative to a QALY. The principal approaches shown in the taxonomy in Figure 1 are considered in more detail in Table 1, which highlights some key issues and advantages of each, as well as challenges that are common to all approaches.

Table 1: Approaches to the aggregation of overall value; issues and merits of each; and implications for the identification of the value-based price

	How is value aggregated?	Key issues specific to this approach	Key merits of this approach	Issues common to all approaches
Net benefit	As the sum of the benefits, each assessed in monetary terms	Challenges estimating the value in monetary terms of each type of value	Arguably, a better grounding in economic theory. Facilitates the comparison of value and value for money across health and other sectors	A consensus on the perspective (NHS? Government? societal?) from which value is assessed is required, regardless of which approach is used. The metrics by which aspects of value other than health are *measured* needs to be defined, as a prior step to valuing them
MCDA	As the sum of the points assigned to each aspect of value	The cost effectiveness threshold would need to be re-assessed in terms of the cost per incremental "point"	A pragmatic approach, widely used in the UK public sector. A more transparent (than a weighted QALY, or deliberative process alone) means of addressing multiple criteria. MCDA is used in local NHS commissioning – potential to develop a consistent priority setting framework for both new and existing health care technologies	
Weighted QALYs	By QALYs gained, uprated or downrated by one or multiple weights to represent the magnitudes of other aspects of value	Assumes that all other sources of value are proportional to the number of QALYs gained. Implications for the threshold. If the value of new technologies is assessed in terms of a range of criteria, then opportunity cost has also to be considered in the same terms, not just QALYs foregone. Even if a simple social weighting or QALYs is applied, the opportunity cost will change.		

The net benefit (NB) approach has its foundations in the use of cost benefit analysis in applied welfare economics. The gains and losses of all those affected by the adoption of a new technology would be assessed in terms of the monetary value of compensating or equivalent variations to estimate the utility changes, and these summed to determine whether the sum of the gains outweighs the sum of the losses (thus identifying a potential Pareto improvement). Methods for evaluating these gains and losses would rely on stated preferences (SP) methods to establish, either directly (e.g. using open-ended or payment scale methods) or indirectly (e.g. using discrete choice experiments) willingness to pay or to accept. Such methods are subject to limitations, as are all SP methods (including those that underpin the estimation of quality of life weights used in calculating QALYs). An advantage of this approach is that it facilitates the assessment of allocative efficiency across public sector budgets, rather than being restricted to the NHS. A pragmatic approach to NB[6] involves using QALYs as the measure of health gain and translating QALYs into a monetary value using some agreed "threshold value".

Alternatively, all elements of value could be described in whatever units of measurement are available, and aggregated employing a system of explicit weights. MCDA differs from NB by not requiring the use of money as a means of aggregation. Rather, MCDA reports all sources of value either in whatever "natural units" they are reported in, or by imposing categories on them, and uses a system of weights to aggregate them. The weights might be obtained in a number of ways – differing in terms of whose views count and how those are best reflected. For example, the "decision maker's approach", sometimes associated with extra-welfarism, might suggest that the weights appropriately emerge from the deliberations of the decision maker. The key distinction between this and the current deliberative processes employed by NICE is the *explicit* reporting of the importance attached to each consideration.

An alternative means by which these weights might be obtained is via the use of SP approaches with samples of the general public. That has the merit of being consistent with the way preferences are currently obtained for a key element of value: the quality of life weights used in QALYs. But SP approaches also bring methodological challenges such as those arising from "framing effects", i.e. the way questions are asked influences the preferences stated.

MCDA approaches are already widely used in other areas of the public sector (e.g. transport and local government services). There are also many examples of its use within the NHS, by local NHS bodies making resource allocation decisions (see Devlin and Sussex, 2011). The use of MCDA arguably presents an opportunity to align resource allocation decision making between new and existing uses of NHS resources.

The DH consultation document proposals concerning VBP (DH, 2010b) entail the estimation of QALYs gained as the central measure of value, with some additional considerations then taken into account by multiplying the QALYs gained by weights. The source of these weights is not specified but, as with MCDA, options would include the use of stated preferences methods with the general public; or weights that emerge from decision makers' deliberations.

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[6] This approach to Net Benefit has been widely used in decision analytic frameworks within an implicit "extra-welfarist" approach.

Weighting incremental QALYs makes sense when the additional factors being taken into account are restricted to social concerns/preferences that directly relate to the magnitude of QALY gains (e.g. preferences regarding the importance attached to certain sorts of patients; the severity of their condition; their proximity to death). However, weighting QALYs relies on the principal unit of benefit (the QALY) being a descriptively valid measure of benefit in all cases. Where it is inadequate (for example, where there are challenges in measuring or valuing certain aspects of quality of life) that also means other criteria would be under-represented. Where it is a good measure of health improvement, it will still be the case that weighting QALYs to reflect total value would only be a valid approach if those other sources of value are strictly proportional to the QALYs gained. Wider societal benefits from innovation, or benefits to patients experienced as improvements in process-of-care, are not likely to be directly linked to the QALYs gained by individual patients. A simple multiplier would then over- or under-rate these factors. In the extreme, a technology that generates positive improvements in these aspects of value, but no improvements in QALYs (e.g. replacement of an intravenous treatment with a simple oral treatment), would be mistakenly assumed to have zero value.

Decision rules used to establish maximum prices

All of the three approaches to aggregation in Table 1 pose challenges for identifying the threshold to use in linking value to maximum price.

The cost effectiveness threshold "range" currently employed by NICE is argued to allow NICE the flexibility to exercise judgement regarding factors other than incremental cost per QALY gained. There is an implicit valuation of these other factors by the NICE Appraisal Committees to reflect: (a) these other factors' values in terms of QALYs displaced; and (b) the extent to which these other factors may also arise from the use of the services displaced. But VBP introduces a requirement to be precise about both the appropriate threshold that applies to QALYs and the weights attached to other considerations.

The empirical basis for the threshold, even if defined *only* in terms of QALYs, remains a considerable challenge. For example, in the case of the NB approach, while all technologies with NB > 0 are socially desirable, in practice their cumulative cost may be in excess of NHS budgets. In the presence of such budget constraints, a "rule of thumb" would be needed to establish a cut-off "threshold" benefit cost ratio. If health gain was valued using QALYs multiplied by a cost per QALY threshold, then there would still be a question as to the threshold relevant to the non-QALY elements of value.

In the case of the MCDA approach, the weightings applied reflect *relative* willingness to pay for value, but an "anchor" is needed to understand the opportunity cost, i.e. what in *absolute* terms is the hurdle for adoption.

In the case of a weighted QALY approach, attaching any social or other weighting to a QALY alters the value of the threshold because those social weights need to be applied to potential NHS interventions foregone. Thus, weighting affects the QALY's "value" in two ways: it adjusts the number of QALYs and it alters the threshold value to be applied to those QALYs.

The key point to note is that VBP entails the explicit consideration of factors other than, and additional to, QALY gains and therefore, however total value is defined, value *forgone* needs to be defined in those same terms. It does not make sense to define value in terms of a broad set of considerations, including QALYs plus other things, and then to define opportunity cost only in terms of QALYs forgone. Whatever maxim any VBP is designed to reflect needs to be applied consistently.

It is important to recognise that we will never know the value of an opportunity cost threshold with precision, whether it is expressed in QALYs, weighted QALYs or MCDA benefit points. Evidence is likely at best to establish a threshold "range", not a point estimate. This in turn provides the basis for establishing a plausible range for a maximum price.

In practice, there may be considerable uncertainty regarding the nature of the evidence on the incremental changes in resource use; QALYs gained; the magnitude and value of other sorts of benefits; as well as of the appropriate value of the threshold itself. The means by which uncertainty will be handled in VBP is a key issue. For most decision makers, this implies a range of possible maximum prices. A price within this range is potentially acceptable. Some decision makers will expect to "trade" price for uncertainty. Willingness to "trade" depends on the attitude to risk of

decision makers as well as the opportunity cost of making the wrong decision about using the technology. It is likely that additional studies can reduce uncertainty around cost and health effects, and possibly around some other potential benefits. There will be a cost attached to conducting those studies. Where this cost is less than the value, then there needs to be a mechanism for ensuring the research goes ahead, e.g. by making the price provisional and linked to coverage with evidence development[7].

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[7] In the extreme, if some evidence can only be collected by *not* allowing use of the product in routine NHS treatment then the company may have to choose a lower price with unresolved uncertainty or a delay in access to the market while the evidence is collected to support the expected price.

Examples of approaches to VBP internationally

In this section, we provide a summary of the ways that value is linked to medicines' prices in a range of countries whose third party payers do so more or less explicitly. In some cases the payers categorise medicines according to how favourably they will be looked upon for pricing purposes (e.g. France, Italy, Japan), and in others payers use health technology assessment (HTA) processes either directly for that same purpose or to determine whether at the price sought by the manufacturer the medicine is deemed cost-effective or not (Australia, Canada, England, Sweden). We look at:

- Australia, Canada and Sweden. These countries were highlighted by the Office of Fair Trading 2007 report noted earlier
- France, Italy and Japan – which we have additionally selected because their approach includes allocation of new medicines into a number of pricing categories defined by some notion of the (incremental) value of the medicine
- England – both in the current situation where NICE determines whether the NHS will reimburse or not, given the manufacturer's chosen price, and the VBP approach outlined by the Department of Health (DH, 2010b)

There is not the space here to provide a detailed description and analysis of pricing approaches in the seven countries, but Table 2 sets out the key points to note. For example, the Australian approach to medicines pricing is focused around health gain per dollar, i.e. "clinical effectiveness" and "cost effectiveness". Official guidance there notes that cost per QALY is commonly used but does not require it, meaning that a number of approaches may be acceptable. The overall assessment of the value of a new medicine, in the sense of how different aspects of value are weighed up against price, is opaque. For example, there is no specific monetary "threshold" value applied to QALYs where some of a medicine's benefits are expressed in QALY terms. A national committee representing the payer engages in a deliberative process: there is no formulaic derivation of the price ceiling. Repeat manufacturer submissions are normal as both sides "negotiate" towards an acceptable price.

Table 2 highlights how exceptional is the value based approach to pricing branded medicines that is emerging in England. The Department of Health consultation document (DH, 2010b) implies a breadth of potential elements of value that is approached only by Sweden among the countries listed.

Canada and Sweden share with England the preference for QALYs to measure health gain and they also are commonly used in Australia. But in the other countries shown, the third party payers' approaches to measuring value are permissive rather than prescriptive. In Sweden there is a preference for the QALY weightings to be based on the views of people with experience of the condition, whereas in England a general population perspective is taken to valuing health states when estimating QALYs.

None of the countries has gone so far as to define an explicit method for aggregating qualitatively different non-financial elements of a medicine's value, although three of them group medicines into

a small number of categories prior to price determination: five categories in France, three in Italy and six in Japan.

In most of the countries in Table 2, a medicine's price is ultimately the outcome of a negotiation between the manufacturer and the payer – or its nominated agent; and where negotiation is not the rule, the alternative is usually some form of reference pricing, not value-based pricing. In England currently, prices are set at launch by the manufacturer, but under a VBP system this would presumably change where the manufacturer wishes to exceed the maximum value based price. Just how that maximum price is to be determined precisely is not stated in the DH consultation document.

Table 2: Assessing "value" and linking to price: current practice in selected countries

Country	Elements included in "value"	How measured	How valued, whose values	How aggregated	How converted into price
Australia	- Clinical effectiveness - Cost effectiveness	QALY and incremental cost per QALY are commonly used but not obligatory	Not specified	Deliberation – opaque	Negotiation – Approx. 30% margin on costs for the most innovative products; effectively therapeutic reference pricing for others
Canada – Federal level	- "Cost effectiveness" - "Safety" - "Effectiveness"	- Incremental cost per QALY, where possible - ? - QALY where possible	Not specified	Not specified	Price not linked to value: max price of "breakthrough drugs" = median of prices in 7 other countries; effectively therapeutic reference pricing for others
France	- Efficacy - Availability of therapeutic alternatives - Disease severity	- Not specified - Not specified - Not specified	Not specified	Categorisation by expert clinical committee into one of five categories of incremental health benefit (ASMR)	Negotiation (on price and volume, i.e. total revenue). For drugs with major therapeutic improvements, reference is made to overseas prices, in Germany, Italy, Spain, UK
Italy	- Clinical effectiveness - Availability of therapeutic alternatives - Disease severity	- Unspecified clinical end-points leading to one of 3 categories - One of 3 categories - One of 3 categories	Not specified	Categorisation by expert clinical committee into one of three overall categories	Negotiation
Japan	- Efficacy - Safety - New mode of action - Indicated for children	- Not specified - Not specified - Yes/no - Yes/no	Not specified	Categorisation by Ministry of Health and Welfare into one of 6 usefulness and market size categories	Negotiation
Sweden	- Clinical effectiveness - Cost effectiveness - Cost savings in any sector: health care, non-health, public, private,	- QALYs - QALYs - Money	Preference for "QALY weightings based on appraisals of persons in the health condition in	Not specified	Manufacturer selects price and faces coverage decision by TLV

	patients, carers, relatives - Production loss	- Money (human capital method)	question"		
England - NICE	- Health gain - Health service cost savings - Severity / end of life (cancer only)	- QALYs - Money - Within 2 years of expected death: yes/no	- General population perspective *de facto* - Market prices - Appraiser deliberation	As QALYs (weighted if "end of life")	Manufacturer selects price and faces coverage decision by NICE
England – DH VBP?	- Health gain - Health service cost savings - Availability of therapeutic alternatives - Disease severity (all diseases) - "Therapeutic innovation" - *?Social equity* - *?Cost savings beyond health service* - *?Patient/carer experience and convenience* - *?Patient/carer time savings* - *?Productivity*	- QALYs - Money - Lack of alternative treatment: yes/no - Small number of categories? - *?* - *?* - *Money* - *?* - *Hours* - *Money*	- Population perspective - Market prices - *?* - Appraiser deliberation - *?* - *?* - *Market prices* - *?* - *?Labour market and population perspective* - *?Labour market wage rates*	Weighted QALYs	?

Sources: Australia: http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs-pbpa-policies-contents; Harris, et al., 2008; OFT, 2007, Annexe K.

Canada: http://www.cadth.ca/index.php/en/cdr/process ; http://www.pmprb-cepmb.gc.ca/english/ ; OFY, 2007, Annexe K

France: http://www.sante.gouv.fr/comite-economique-des-produits-de-sante-ceps.html ; OFT, 2007, Annexe K.

Italy: http://www.ispor.org/htaroadmaps/Italy.asp#2

Japan: http://www.ita.doc.gov/td/chemicals/drugpricingstudy.pdf

Sweden: LFN 2003 "General guidelines for economic evaluations from the Pharmaceutical Benefits Board (LFNAR 2003:2)"

England: NICE, 2008; DH, 2010b.

Notes: *Italics* indicate implicit possibilities under the heading "wider societal benefits" but not explicitly proposed in the VBP consultation document (DH 2010b).

? = unclear

Conclusions

Determining the maximum price to be paid for a new medicine by referring to its "value" has intuitive appeal. We note in passing that the maximum, "value"-related, price becomes *the* reimbursed price only when competition from other medicines or treatments is insufficient to reduce price below that level.

Our aim in this paper is to provide a taxonomy of the alternative approaches that might be taken to implementing VBP.

The need for clarity in understanding different options for value-based pricing is heightened by the UK government's active consideration of how to implement it to set maximum reimbursement prices for new medicines made available to the NHS from 2014 onwards. The particular form of VBP outlined in the December 2010 consultation document (DH, 2010b) is one of a wider class of possible approaches. Other countries have applied elements of VBP to medicines reimbursement, and many policy makers internationally will be watching developments in the UK with keen interest.

Central to the challenge of implementing VBP is how to incorporate elements of value that extend beyond QALY gains.

Identifying the maximum value of a medicine to a health care system requires: (a) *identifying* the health gain and other attributes of the technology that are deemed to be of value; (b) some means of *measuring and valuing* those attributes for each particular medicine; (c) a way of *aggregating* the relevant benefits and costs; and (d) a *decision rule* to convert the overall measure of value into a maximum price the health care system would be willing to pay. Each stage entails a value judgement about what to do. There are no simple "right or wrong" solutions.

We categorise three main approaches to aggregating explicitly the chosen elements into a single overall assessment of the "value" of a medicine: weighted QALYs; MCDA; and net benefit. There are non-trivial issues involved in each; none of the approaches is obviously superior to the others.

A weighted QALY approach is described in the Department of Health's consultation document (DH, 2010b): the QALY is taken as the main measure of value, and other elements of value are handled by multiplying the incremental QALYs by weights intended to reflect the other benefits generated by that technology (or by flexing the £/QALY threshold, which amounts to the same thing). An important issue with the weighted QALY approach is that while some benefits may be thought of as broadly proportional to the number of incremental QALYs produced by a technology – e.g. severity of illness reflects the relative value society places on QALYs gained by those with relatively poor health – other elements of value are not proportional to the QALYs produced, e.g. process-of-care benefits to patients or their carers. Further, the approach relies on QALYs being an adequate measure of health gain in all cases.

A pragmatic way of aggregating elements of value that are not well represented by weighted QALYs is to assign scores/points to each type of "value" and assess medicines using multiple criteria decision

analysis (MCDA) approaches. Use of these sorts of benefits "points systems" is already evident in the priority setting processes used by some local NHS commissioners (Devlin and Sussex, 2011). Developing a framework for determining the value of new medicines which is at least broadly consistent with the basis for investment/disinvestment decisions being made elsewhere in the NHS could help to achieve allocative efficiency across the health care system.

Some types of benefits are best expressed financially: time and cost savings to patients and carers; cost savings to other parts of public spending (e.g. social care, education, the criminal justice system). These are best combined with the costs of treatment to provide a net cost measure. But there are difficulties with assigning monetary values to all types of benefits. Decision makers and the stakeholders whose views they value are more comfortable discussing benefits in the natural units in which they occur.

All approaches to VBP ultimately require the conversion of value, however assessed, into a money price. All of the possible approaches face technical challenges in terms of the availability of evidence about the cost effectiveness threshold, regardless of whether "benefit" is defined and measured in terms of weighted QALYs, benefit points, or any other numeraire. The key point is that whatever approach is taken to the overall assessment of benefit from new medicines, benefit foregone must be measured and assessed in those same terms. For example, it would not make sense to assess value of new medicines in terms of a broad concept of value, and to assess opportunity costs more restrictively in terms only of QALYs foregone.

In any country at any time, the absence of a precise, agreed basis for establishing the relevant threshold value means that whatever aggregation approach is used will be associated with considerable uncertainty. Further research could reduce uncertainty about the threshold, but would not remove it entirely. The pragmatic response to that inevitability and to the uncertainties about measuring and valuing all types of benefits and costs is to build in a stage of negotiation at the end of any value-based pricing system. We observe that negotiation is the final stage of price setting in other countries that attempt to measure the value of a medicine as a guide to its price. The value measurement and aggregation process can provide bounds to the price negotiation, but will not automatically identify *the* value-based price.

References

Brouwer, W., Culyer, A., Van Exel, N. and Rutten F. (2008) Welfarism vs. extra-welfarism. *Journal of Health Economics.* 27(2), 325-338.

Claxton, K., Briggs, A., Buxton, M.J., Culyer, A.J., McCabe, C., Walker, S. and Sculpher, M.J. (2008) Value based pricing for NHS drugs: An opportunity not to be missed? *British Medical Journal.* 336, 251-254.

Culyer, A.J. (2009) *Deliberative processes in decisions about health care technologies: Combining different types of evidence, values, algorithms and people.* London: Office of Health Economics.

Culyer, A.J. (1991) The normative economics of health care finance and provision. *In*: McGuire, A., Fenn, P. and Mayhew, K. eds. *Providing health care*. Oxford: Oxford University Press.

De Bekker-Grob, E.W., Ryan, M. and Gerard, K. (2010) Discrete choice experiments in health economics: A review of the literature. *Health Economics.* Epub ahead of print. Available at http://www.ncbi.nlm.nih.gov/pubmed/21171050 [Accessed 5 August 2011].

DH (Department of Health, UK). (2010a) *Equity and excellence: Liberating the NHS.* London: Department of Health.

DH (Department of Health, UK). (2010b) *A new value-based approach to the pricing of branded medicines – a consultation.* London: Department of Health.

Devlin, N. (2010) The economics of a "liberated" NHS. *Pharmacoeconomics* 28(12), 1075-1078.

Devlin, N. and Parkin, D. (2003) Funding fertility: Issues in the allocation and distribution of resources to assisted reproductive technologies. *Human Fertility.* 6(Suppl 1), S2-S6

Devlin, N. and Sussex, J. (2011) *Incorporating multiple criteria in HTA: Methods and processes*. London: Office of Health Economics.

Gandjour, A. and Gafni, A. (2010) The additive utility assumption of the QALY model revisited. *Journal of Health Economics.* 29(2), 325-328.

Garber, A.M. and Phelps, C.E. (1997) Economic foundations of cost-effectiveness analysis. *Journal of Health Economics.* 16(1), 1–31.

Golan, O., Hansen, P., Kaplan, G. and Tal, O. (2010) Health technology prioritization: Which criteria for prioritizing new technologies, and what are their relative weights? *Health Policy*. Epub ahead of print. Available at http://www.health.gov.il/Download/pages/health_policy_journal-dr_Orna_Tal.pdf [Accessed 5 August 2011].

Grossman, M. (1972) On the concept of health capital and the demand for health. *Journal of Political Economy.* 80(20), 223-255.

Harris, A.H., Hill, S.R., Chin, G., Li, J.J. and Walkom, E. (2008) The role of value for money in public insurance coverage decisions for drugs in Australia: A retrospective analysis 1994-2004. *Medical Decision Making*. 28(5), 713-722.

Kennedy, I. (2009) *Appraising the value of innovation and other benefits: A short study for NICE.* London: National Institute for Health and Clinical Excellence. Available at http://www.nice.org.uk/media/98F/5C/KennedyStudyFinalReport.pdf [Accessed 5 August 2011].

Meltzer, D.M. (1997) Accounting for future costs in medical cost-effectiveness analysis. *Journal of Health Economics.* 16(1), 33–64.

Mishan, E.J. (1971) *Cost benefit analysis.* London: Allen & Unwin.

NICE (National Institute for Health and Clinical Excellence). (2008) *Guide to the methods of technology appraisal.* London: National Institute for Health and Clinical Excellence. Available at http://www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf [Accessed 5 August 2011].

NICE (National Institute for Health and Clinical Excellence). (2009) *Appraising life extending, end of life treatments.* London: National Institute for Health and Clinical Excellence. Available at http://www.nice.org.uk/media/E4A/79/SupplementaryAdviceTACEoL.pdf [Accessed 5 August 2011].

OFT (Office of Fair Trading, UK). (2007) *The Pharmaceutical Price Regulation Scheme: An OFT market study*. London: Office of Fair Trading.

O'Neill, P. and Devlin, N. (2010) An analysis of NICE's "restricted" (or optimised) decisions. *Pharmacoeconomics.* 28(11), 987-993.

Orr, S., Woolf, J. and Morris. S. (2011) *What values should count in HTA for new medicines under value based pricing in the UK?* Paper presented at the Health Economists Study Group. Bangor University. 29 June. Bangor, Wales.

Rawlins, M., Barnett, D. and Stevens A. (2010) Pharmacoeconomics: NICE's approach to decision-making. *British Journal of Clinical Pharmacology.* 70(3), 346-349.

Shah, K.K., Praet, C., Devlin, N.J., Sussex, J.M., Appleby, J. and Parkin, D. (2011) *Is the aim of the health care system to maximise QALYs? An investigation of 'what else matters' in the NHS.* OHE Research Paper. London: Office of Health Economics.

Sussex, J. (2010) Innovation in medicines: Can we value progress? *OHE Seminar Briefing*. London: Office of Health Economics.

Towse, A. (2007) If it ain't broke, don't price fix it: The OFT and the PPRS. *Health Economics.* 16(7), 653-665.

Towse, A. (2010) Value based pricing, research and development, and patient access schemes. Will the UK get it right or wrong? *British Journal of Clinical Pharmacology*. 70(3), 360-366.

Tsuchiya, A. and Williams, A. (2001) Welfare economics and economic evaluation. *In*: McGuire, A. and Drummond, M. eds. *Economics evaluation: Merging theory with practice*. Oxford: Oxford University Press.