



2013 Policy Forum

**HTA and Value:
Assessing value, making value-based decisions,
and sustaining innovation**

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Hotel Miramar Barcelona
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HTAi Policy Forum Meeting 2013

HTA and Value: Assessing value, making value-based decisions, and sustaining innovation

Background Paper

1. Introduction

Purpose of this paper

This paper is intended to provide background information to assist in framing the discussion at the HTAi Policy Forum meeting entitled **HTA and Value: Assessing value, making value-based decisions, and sustaining innovation**, in Barcelona, February 3-5, 2013.

Background

Most health systems base coverage/reimbursement decisions on some kind of formal or informal determination of the value of a health technology. International discussion is ongoing about the need to ensure the definition and interpretation of value reflect aspects important to patients, caregivers, other stakeholders and society more broadly, and to devise methods identifying and measuring these, and factor them in to evidence-based decision-making.

There is growing debate regarding ways to determine value, including how to effectively capture patient and caregiver preferences, how to determine and take account of the different weight given to similar gains in health in different circumstances (such as severe or life-threatening conditions, or conditions with no current effective treatment), and how to capture and take account of benefits accruing to those beyond the patient (such as caregivers, the health system, the social security system, and the economy and society more widely). There is also debate about how these various aspects of value can best be factored in to evidence-informed decisions about the use of technology, and about the relationship between the definition, interpretation and measurement of value and technology innovation. This includes whether innovation has value in itself over and beyond the benefits the technology will itself deliver to patients, caregivers and other beneficiaries, and how HTA-based decisions, methods or payment processes that draw on measures of value can impact technology innovation.

Health systems around the world use various approaches to define and measure value and to factoring these assessments into decisions about technology adoption and use. While there are differences in methods for assessing value, there are similarities in general approaches across health care systems, and there is growing interest in examining and refining these. It is therefore timely to promote international discussion of HTA and value.

2. Scope and framing of HTAi Policy Forum discussion

At the June 2012 HTAi Annual Meeting in Bilbao, the Policy Forum held a scoping meeting where the topic of “HTA and Value” was discussed by Forum and HTAi members to gather ideas about the scope, key issues and general approach to the February 2013 Policy Forum meeting. A detailed summary of the scoping meeting proceedings is available on the HTAi website¹ and this has been used by the Policy Forum Committee to develop the proposed meeting scope and framing presented in this background paper.

It is proposed that the format of the February Policy Forum meeting follow a structure to examine issues in three main areas around the value of health technologies: defining and measuring value, approaches to decision-making informed by value assessments, and value and innovation. This paper is based on previous discussion in the Policy Forum Committee, at the June 2012 scoping meeting, and from key literature sources, and sets out some of the main issues in preparation for the February 2013 Policy Forum meeting discussion.

Defining and measuring value in the assessment of health technologies

Defining value

Value can be generally defined as²:

- **A fair return or equivalent in goods, services, or money for something exchanged.**
- **The monetary worth of something (e.g., market price).**
- **The relative worth, utility, or importance (e.g., a good value at the price, the value of base stealing in baseball, had something of value to say).**

There is no consensus definition of *value* used in health care, and there are divergent views about whether or not value is proportional to cost, i.e., where value is measured by relevant benefits per unit of cost. Definitions of value related to health technologies can be grouped into two broad categories: those based on value-for-money such as the “health outcomes per dollar achieved”³ and those that take account of broader values such as the importance or desirability that patients (or society) place on a health state⁴, or the social/psychological aspects of living with an illness or of using a technology, and/or the ethical implications of technology use⁵.

Ideas of “value” at times may be confused with “values” such as freedom of choice, provider autonomy, equity, or solidarity. Social values can vary across and within countries⁶, and they can be important drivers in the shaping of stakeholder perspectives and public perceptions on what counts as value. How value is defined can play a role in determining who gets a say in choosing the kinds of criteria that will be looked at, and what weightings these criteria receive in decision-making. This diversity

¹ See the HTAi Policy Forum blog available at: <http://www.htai.org/index.php?id=714> Available online until February 2013.

² Merriam-Webster Dictionary, online version: <http://www.merriam-webster.com/dictionary/value>

³ Porter M. (2010). What is value in health care? *NEJM*; 363(26):2477-2481.

⁴ Owens D, et al. (2011). High-value, cost-conscious health care: concepts for clinicians to evaluate the benefits, harms, and costs of medical interventions. *Ann Intern Med*; 154:174-180.

⁵ Facey K, Boivin A, Gracia J, et al. (2010). Patients’ perspectives in health technology assessment: a route to robust evidence and fair deliberation. *Int J Technol Assess Health Care*; 26(3):334-40.

⁶ See Journal of Health Organization and Management Vol. 26, 2012. Special issue: Social values & healthcare priority-setting.

of approaches to conceptualizing value can present challenges in communication, particularly when translating value propositions into different languages or communicating them across developed and developing country contexts.

Table 1 presents an overview of the stakeholders whose views might be brought to bear on the selection of criteria and measures used in a particular setting or for a particular technology.

Table 1. Overview of stakeholders and examples of criteria for assessing technology value

Stakeholders	Examples of Value Measures
<ul style="list-style-type: none"> • Patient and/or group of patients • Caregivers/families • At-risk/vulnerable populations • Clinicians • Professional associations • Health delivery organizations • Health system • HTA bodies/systems • Academia/Researchers • Payers (national/regional health authority, health plan, insurance company) • Government • Regulators • Technology developers (device and pharmaceutical industry) • Generic manufacturers • Public/society • Non-health sector stakeholders & programs (employers, workforce, EI, pensions, taxes, penal system, education system, etc.) 	<p style="text-align: center; font-weight: bold;">Whose perspective counts? Which criteria count?</p> <p>Health outcomes (population and individual health outcomes)</p> <ul style="list-style-type: none"> • Increased effectiveness, including level of certainty of outcome or heterogeneity of treatment effect. • Increased safety <p>Other patient, caregiver and/or population health benefits</p> <ul style="list-style-type: none"> • Reduction of uncertainty (e.g. following diagnosis) • Reduced caregiver burden/early return to normal activities and work (productivity) • Technology meets unmet need • Greater treatment choice • Improved access to service • Greater equity <p>Health system benefits</p> <ul style="list-style-type: none"> • Decreased net cost of delivery per patient • Lesser budget impact • Fewer sunk and other costs (e.g., operating costs) • Greater economies of scale or scope • Greater ease of incorporating technology into current system (and ease of future disinvestment) • Improved administration/delivery <p>Benefits beyond the health system</p> <ul style="list-style-type: none"> • Decreased costs to other areas of government (e.g., education, penal system) • Greater political acceptability • Positive social impact (e.g., increased societal productivity, more environmentally friendly “greener”)

Measuring value

Health technology value may be determined by deliberation based on expert opinion alone, but in most health systems based on transparency and accountability, some form of methods and metrics are used to measure value to provide evidence for decision-making. How value is defined informs the types of measures that are prioritized for assessment. The value offered by a technology can vary across disease segments or indications where some patient groups receive great benefit while others receive little or no benefit from the same treatment, and careful analysis of patient sub-groups is necessary.

The value criterion most often looked at in assessments of technology is health outcomes, i.e., does the technology provide better or more health for individuals. In social welfare systems, decision makers also consider equity and affordability, amongst other aspects, to ensure limited public resources are utilized in ways that are important to society.

Quantitative approaches

Current quantitative methods to measure technology value for use in coverage/reimbursement decision-making can be grouped into the following general categories:

- **Measures of clinical/therapeutic effect**, e.g., morbidity/mortality rates, functional status such as spinal flexibility, and other clinical endpoints or validated surrogate endpoints.
- **Measures of disease-specific health, functioning and quality of life**, e.g., years of disease/pain-free survival, pain levels measured by VAS, functional status measured using an instrument such as the Oswestry Disability Index for back pain.
- **Measures of generic health, functioning and quality of life**, e.g., level of mobility, level of pain/discomfort, capacity for self-care, levels of anxiety/depression, etc., captured using questionnaire instruments such as the SF-36, 15D, or scales of the Quality of Well-being and the Assessment of Quality of Life⁷, and typically expressed on a scale from 0 (death) to 1 (perfect health).
- **Patient utilities derived from quality of life measures**, e.g., quality-adjusted life years (QALY) most often captured using the EQ-5D survey tool (EuroQOL 5-item scale) where level of mobility, capacity for self-care, and other dimensions are ranked by the respondent according three levels: *no problems*, *some problems*, or *extreme problems*, and an index value is produced to represent health status. QALYs allow for health gains in one condition (at an individual or population level) to be compared directly with health gains offered in other unrelated conditions, however, QALYs can be less sensitive to small changes in health and value that disease-specific measures can capture. Further debate on the QALY is summarized in the section on decision-making, below.
- **Measures of economic value**. An economic evaluation is a comparative analysis of two or more competing alternatives in terms of both cost and outcomes. In value-for-money approaches, value is assessed as health outcomes per dollar achieved⁸. Health systems vary in the degree to which they seek to consider costs and value-for-money in coverage/reimbursement decisions. Two methods most often used to measure the value-for-money offered by a technology are:
 - Cost-effectiveness analysis (CEA) compares technologies according to the net cost required to achieve a unit improvement in benefit, usually life-years gained or illness avoided. CEA is typically expressed as an incremental cost-effectiveness ratio (ICER) (e.g., cost/death averted), where the net costs and net health outcomes of two or more competing alternatives are compared to each other (e.g., intervention versus the next best alternative, standard practice, or no intervention).
 - Cost-utility analysis (CUA) is the same as CEA, described above, however the outcomes in CUA are explicitly measured in quality-adjusted life years (QALYs). One key advantage that CUA offers over general CEA is that it allows the benefits offered by a technology (i.e. QALYs gained) in one disease area to be directly compared to others.

⁷ Weinstein MC, Torrance G, McGuire A. (2009). QALYs: the basics. *Value in Health*; 12(S1):S5-S9.

⁸ Porter M. (2010). What is value in health care? *NEJM*; 363(26):2477-2481.

Qualitative approaches

Qualitative approaches can be used in two distinct ways. First, qualitative methods can be used to measure technology value in areas not suited for measurement by quantitative methods. For instance, a technology's ease of administration in current delivery systems, political acceptability, or the broader social impacts or bioethical considerations might best be captured through observation, interviews, focus groups, or telephone surveys where the specific instruments used will vary depending on contextual factors and the nature of the technology being assessed. For example, Delphi panels are being used in some settings where experts compare the unmet need and the severity of symptoms across different sub-populations within a disease space and across disease spaces, e.g., oncology, that have heterogeneous patient populations.

The second way qualitative methods can be used is to define priorities, preferences or weightings amongst different dimensions of value, to more deeply explore areas where the evidence is equivocal, or to provide supplementary data where decision makers feel certain aspects of value are inadequately represented by the evidence, for instance, by applying expert opinion. Such applications of qualitative methods are distinguished from actual measures of technology value, as these are most often used as part of decision-making processes rather than the assessment process.

Measures of incremental value

To make sense of the evidence of value for coverage/reimbursement decision-making, it is important to make comparisons amongst relevant treatment alternatives to determine the incremental value offered by different options. Regardless of the dimension of value looked at (effectiveness, health outcomes, safety, patient preferences, or others) comparing one treatment to another to determine the benefits provided reveals the incremental benefit offered by alternatives. For new technologies, this means comparison with technologies that are commonly accepted as standards of practice. Incremental benefits can be combined into an aggregate measure, such as the incremental cost-effectiveness ratio (ICER) that creates a ratio of cost per incremental benefit offered by an intervention, or the components of incremental costs and benefit can be laid out separately, as is done in cost consequence analysis.

Value-based decision-making on health technologies

Around the globe, health system decision makers are faced with the difficult task of identifying, prioritizing and reimbursing worthwhile technologies to provide effective, equitable, and affordable care in ways that provide the greatest value to patients, caregivers and society more broadly. Different decision contexts can influence how technology value is viewed and measured, with decision-making occurring at different levels of the health system (i.e., clinical, hospital, population, and system levels) and the choice of what aspects of value to look at, and the extent to which some or all of these are objectively measured and transparently accounted for in decisions varies across health systems.

The perspective that decision makers are required/instructed/decide to take determines how widely value is defined and assessed (e.g., focusing on economic factors, whether budget impacts are considered, and/or wider societal benefits such as increases in the workforce). Furthermore, whether an individual or population-level view is taken can play a significant role in the assessment of value and in the conclusions drawn about the advantages offered by different technology alternatives.

Different system perspectives of value

Some systems focus on assessing technology value using outcomes and measures that are disease or condition-specific (e.g., French and German systems). These approaches determine the incremental benefits offered by one technology over alternatives and select those that provide greatest benefit to patients living with these conditions. These approaches can encounter challenges with comparing technologies across different disease areas to understand the trade-offs between them, although some comparison is possible where “generic” outcome measures are used, e.g., length of life or cost of delivery, which are not disease-specific. Comparison is also possible where new technologies are assigned to categories based on comparative effectiveness. For instance, France uses Service médical rendu (SMR) to assess the therapeutic value of new drugs on five levels from *major* to *insufficient*, and Amélioration du service médical rendu (ASMR) to assess the relative medical benefit for new drugs, or “level of innovativeness” according to a scale from *major* to *no improvement*. In Germany, comparative clinical evidence is assessed and coverage decisions made based on the added benefit offered by a drug relative to a comparator in current use. Based on this assessment, new drugs can be classified into three levels: those offering *major additional benefit*, *important additional benefit*, or *slight additional benefit*. Where such categories are assigned some comparison across disease areas is possible.

Other systems have adopted approaches based on utility measures (e.g., QALY-based systems used frequently in the UK, Canada, Sweden and others). These systems aim to address some of the difficulties encountered with other system approaches, as QALY-based systems enable comparisons to be made across different conditions and diseases categories, which are useful in considering opportunity costs in resource allocation decisions. Cost-utility analysis based on QALYs can include broader aspects of value such as weightings for condition severity or areas of unmet need, however there is ongoing debate^{9,10,11} about the appropriate use of QALYs, with key themes summarized in the note below¹².

Systems vary in the extent that they seek to consider cost and value-for-money either explicitly or implicitly in determining technology value. Decision makers can be assigned or choose to use cost thresholds to guide decisions. Systems that use QALYs or similar measures can assess value-for-money in a way that aims to be transparently and consistently expressed across conditions and patient groups, as *cost-per-QALY*.

Both QALY and non-QALY based systems face challenges when choices must be made across disease areas that prioritize different outcomes and utilize different measures to assess technology value. Grouping outcomes related to therapeutic effect along a continuum (proxy measures, disability, pain and death) may provide some ways to compare between different diseases and outcomes. However, patient demographics, service delivery environment and other contextual factors can complicate these kinds of comparisons.

⁹ Goldman D, Lakdawalla D, Philipson TJ, Yin W. (2010). Valuing health technologies at NICE: Recommendations for improved incorporation of treatment value in HTA. *Health Econ*; 19:1109-1116.

¹⁰ Claxton K, Sculpher M, Carroll S. (2011). *Value-based pricing for pharmaceuticals: Its role, specification and prospects in a newly devolved NHS*. CHE Research Paper 60, University of York.

¹¹ McGuire A. (2001). Theoretical concepts in the evaluation of healthcare. In: Drummond M, McGuire A, editors. *Economic evaluation of in health care: Merging theory with practice*. New York: Oxford University Press.

¹² Key themes in QALY debate: Being collective measure of utility, the QALY may lack sensitivity in reflecting individual utilities and they may not be equally valued by all patients. Processes to formulate QALYs can lack transparency viz. the selection and incorporation of value criteria and they may fail to capture the full spectrum of benefits important to patients and society and/or the “spillover” benefits accruing from new uses of the same technology. Equal QALY weights must be applied to QALYs forgone elsewhere to determine opportunity costs.

Different system-level decision-making processes on technology value

Systems configure decision-making in different ways. There may be a single central body that is responsible for both assessment and decision-making, or there may be a separate advisory body assigned to provide recommendations rather than – or as well as – providing constituent information for the decision. Public or patient representation may occur at different points in the technology appraisal and/or decision-making processes through direct representation on appraisal or board committees, in separate lay committees or citizen advisory councils, or through ad hoc public consultations.

Most health systems use a mix of both deliberation and more structured/quantitative methods to arrive at decisions. Deliberative decision-making processes may be more or less formal, in some cases drawing upon methods to improve the transparency and accountability of decisions, such as the Delphi method or analytical hierarchy process. As decisions are becoming more complex, multi-criteria methods such as multi-criteria decision analysis (MCDA) or conjoint analysis enable the trade-offs, preferences and/or weightings amongst different value criteria to be made explicit, which can be particularly helpful where there are many types of dissimilar information to consider together, and/or where multiple stakeholders are involved. Further description of MCDA and conjoint analysis methods is provided in Appendix A.

Overview of selected approaches to value-based decision-making

Table 2 (next page) contains an overview of approaches in selected jurisdictions to assess technology value.

Table 2.

Partial summary of approaches in selected jurisdictions to assess technology value¹³

	Australia	Canada	France	Germany	Netherlands	Sweden	UK
	PBAC	CADTH	HAS	IOWiG	Health Care Insur. Bd., CHF	TLV	NICE
Types of technologies/interventions assessed							
• Drugs	✓	✓	✓	✓	✓	✓	✓
• Devices		✓	✓				✓
• Procedures, diagnostics, tests, surgeries			✓				✓
• Public health interventions			✓				✓
• Systems/services/delivery		✓					
Information requirements		Clinical benefit; health economic information required to establish value for money. Other evidence on equity, public health, and budget impacts may be submitted.	Clinical benefit; health economic information recommended, but not required, to establish value for money. Other evidence on public health impact; innovative characteristics, and budget impact may be submitted.	Clinical benefit; health economic information only considered when a manufacturer and the GKV-SV cannot reach agreement regarding price, at which time IOWiG may conduct an economic assessment. Other information includes additional benefit in relation to appropriate comparator therapy and budget impact.	Clinical benefit; health economic information required to establish value for money. Other evidence on innovative characteristics and budget impact may be submitted.	Clinical benefit; health economic information required to establish value for money. Other evidence on disease burden/severity and equity impacts may be submitted.	Clinical benefit; health economic information required to establish value for money. Other evidence on societal preferences, equity impacts; innovative characteristics, and budget impact may be submitted.
Assessment of therapeutic value (preferred/required approach)							
• QALY	✓	✓			✓	✓	✓
• SMR/ASMR			✓				
• Benefit assessment categorization				✓			
Assessment of economic value (preferred/required approach)							
• CUA	✓	✓			✓	✓	✓
• CEA	In some cases	✓	✓		In some cases	In some cases	In some cases

¹³ Adapted from Fleurence RL, Sorenson C, Naci H, et al. (2012). *The Rise of Value Based Health Care: A Report of the ISPOR Health Policy Special Interest Group, Value Based Health Care Working Group.* Draft Manuscript Version 3.0.

Table 2. (continued)

	Australia	Canada	France	Germany	Netherlands	Sweden	UK
	PBAC	CADTH	HAS	IOWIG	Health Care Insur. Bd., CHF	TLV	NICE
Assessment of economic value (preferred/required approach)							
• CMA		✓	✓				
• CBA				✓			
Patient subgroup analysis required or considered	✓	✓	✓	✓	✓	✓	✓
Aspects of value assessed							
• Size of therapeutic effect	✓	✓	✓	✓	✓	✓	✓
• Quality of clinical evidence				✓			
• Burden/prevalence of disease					✓	✓	
• Relevant clinical endpoints	✓	✓					
• Clinical uncertainty		✓	✓				✓
• Cost-effectiveness (and degree of uncertainty in economic analyses)	✓	✓			✓	✓	✓
• Quality of clinical and economic modelling evidence		✓					
• Budget impact	✓	✓	✓	✓	✓		
• Severity of disease	✓				✓	✓	
• Availability of treatment alternatives	✓				✓	✓	✓
• Public health impact			✓				
• Innovative characteristics			✓		✓		
• Legal/ethical/equity considerations					✓	✓	
• Patient affordability	✓						
• Social values/preference							✓
Decision threshold	None fixed. High would be AUS\$50,000 (USD\$49,000)	None explicit	No	No	None fixed. Examples around €20,000	None fixed. Examples around 500,000 SEK (USD\$74,000)	Yes, approx. £20-30,000

Recent international developments to achieve improved value

Recent initiatives aiming to achieve improved value by aligning stakeholder interests around the creation of greater value include: *Value-based pricing*, which aims to align pricing and innovation processes with the needs important to patients and society more broadly; and, *value-based insurance design*, which uses patient co-payments to direct technology utilization towards higher value treatments. An overview of these approaches is provided below with more detail available in Appendix B.

Value-based pricing (VBP)

United Kingdom – In 2014, the UK will introduce value-based pricing (VBP) that will change how brand-name drugs are priced. VBP is intended to promote innovation and improve access to medications in areas deemed important to UK society (e.g., areas of high burden of illness, therapeutic innovation in areas of unmet need, reduction of time spent with caregivers), and to establish closer links between the price paid for a drug and the value it provides, particularly for patient subgroups.

Germany – Since early 2011, elements of VBP have been introduced to ensure the benefits provided by new health technologies merit the funding level awarded by statutory health insurance schemes. Drug companies are now required to provide evidence of the added benefit of a new medication compared to other available treatments, with higher reimbursement prices considered only for drugs that demonstrate a clear, unique benefit.

Sweden – Started in 2002, VBP in Sweden draws on a societal perspective to price reimbursed medicines based on criteria of cost-effectiveness, equity, and need, with threshold values based on individual maximums of willingness to pay for a QALY, and the marginal decreasing utility of treatment to account for varied benefit for different indications or severity.

Canada – There has been recent discussion of a pan-provincial VBP program to address inefficiencies from varying drug prices by establishing a bulk purchasing alliance for pharmaceuticals across the Canadian provinces.

Value-based insurance design (V-BID)

V-BID, primarily used in the United States, aims to remove financial barriers to essential, high-value interventions and services by shifting patient utilization towards treatments that offer the greatest value. In V-BID arrangements, high-value interventions are available to patients with low or no co-payment or premium, while interventions offering lower value are available with a co-payment or premium. Different rates of co-payment/premium can be assigned for different patient groups, e.g., providing free or reduced rate eye exams for diabetes patients. Substantial savings can be realized through appropriate utilization leading to prevention of chronic conditions.

Considerations for innovation and technology value

Within the broader debate about how the value of health technologies is to be defined and measured, and how evidence of value is to be utilized in decision-making, there is increasing debate about how innovation is to be conceptualized and considered in pricing, reimbursement and coverage decisions.

Defining technology innovation

A technology is generally considered to be innovative where it offers something new that improves results, outcomes or processes in comparison to current practice. Examples of definitions of “innovation” in the scientific literature include¹⁴:

- Different ways of doing things which bring improved outcomes.
- The adoption of new-to-the-organisation [...] technology products and/or service delivery processes, comprising incremental or disruptive change, and resulting in a significant improvement in patient outcomes, experiences, safety and potentially cost effectiveness.
- When new drugs provide medical breakthroughs or significantly improve on standards of care delivered by existing treatments.
- A product represents an important innovation when it is new; constitutes an improvement on existing products; and offers something more: a step-change in terms of outcomes for patients.

Innovation is best thought of as a gradient measure, rather than a binary concept where something *is* or *is not* innovative. This gradient ranges from incremental improvements, such as a reduction in mild side effects or dosing schedules, to more substantial improvements that can change the current standard of care, or to radical changes from so-called “disruptive” innovations that have major implications for the design and function of health systems.

The main themes of the debate about technology innovation cluster around three areas: if and how innovation might be considered as an aspect of technology value to be measured separately from improvements in clinical outcomes or other areas of benefit already captured; how the process of innovation – as conceived as both a process of ongoing incremental improvement but also as producing step-wise innovation – might be valued; and, the ways that technology assessments can impact the innovation process itself.

Should innovation be considered a distinct aspect of value?

There are arguments for and against the proposition that innovation be considered a distinct value criterion separate from other measures of benefit. Some argue that innovation is already adequately accounted for in other measures of value, such as improvement in clinical effectiveness, cost effectiveness, quality of life and other areas of benefit. Even if it was desired that innovation be considered separately, it is difficult to define and is not easily isolated amongst other dimensions of value and problems may arise with double-counting. In practice, some mechanisms exist to account for technologies offering innovative value, for instance, QALY thresholds can be raised or lowered for products offering improved treatment alternatives in areas of societal preference, such as meeting the needs of vulnerable groups or those with specific conditions¹⁵, and value-based pricing is an example of an approach to make these types of social value judgments more explicit.

Others argue that innovation should be a criterion unto itself, and indeed, some systems already measure a technology’s level of innovativeness, usually assessed on a scale such as *major innovation*, *minor improvement* or *no improvement*. However, there are recognized challenges to measuring innovation. Comparative assessment with current standards of practice is essential, and for new technologies it can be difficult to determine an appropriate comparator, particularly for new branded drugs

¹⁴ Sample definitions taken from Kennedy, I. (2009). *Appraising the Value of Innovation and other benefits: A short study for NICE*, p 37-8. Retrieved August 3, 2012 from: <http://www.nice.org.uk/media/98F/5C/KennedyStudyFinalReport.pdf>

¹⁵ Towse A & Raftery J. (2009) Should NICE’s threshold range for cost per QALY be raised? *BMJ*; 338:268-9.

where results can be biased in cases where a generic drug is the comparator.^{16,17} In comparative assessments the full scope of innovation may not be immediately apparent, as clinician familiarity with the technology and/or system adaptation may be required before a technology's full innovative potential is realized.¹⁸ Innovation may also accrue through "spillover" or dynamic benefit¹⁹ where new uses of an existing technology are discovered beyond what was expected at the time of initial assessment, which may not be captured in the original assessment of technology value.

How might innovation – and processes of innovation – be valued?

Most people would agree that the process of technology innovation is valuable as it is the means by which new products are developed or existing ones improved to bring greater wellbeing to patients and families and to improve efficiency in health systems more broadly. If, however, innovation is to be conceived of as a separate criterion in the assessment of technology value then the next question is how this value is to be recognized, and if technologies deemed to be innovative should be reimbursed and, if so, if they should receive premium pricing.

Some argue that health systems already pay a premium for innovation by allowing higher prices for technologies offering a greater therapeutic benefit or gain in QALYs,²⁰ and that innovation is already adequately supported by health system support for research and industrial policy providing patent support and tax incentives.^{21,22}

If innovative technologies are to receive pricing premiums, some argue that it should be paid out only when the innovation realized,²³ in areas meaningful to patients,²⁴ with steps taken to avoid reward the same innovation both today and in the future.²⁵

There are also implications for technology development processes should price premiums be paid for innovation as they may incentivize industry in different ways. Paying a premium for innovation will incentivize long-term innovation processes by ensuring technology developers receive a fair share of the social surplus (profits).²⁶ But it might be argued that all consumer surplus is already allocated to the developer in most cases. Paying a premium for or choosing to cover only innovations offering step-change improvements creates disincentives for developers to generate incremental improvements which are both valuable in themselves and an essential part of the continuum to produce step-change innovations.²⁷ Paying a premium

¹⁶ Healy P & Pugatch M. (2012). Capturing Value: Why dynamic efficiency should be considered in the pricing and reimbursement of medicines. Stockholm Network.

¹⁷ Claxton K, Sculpher M, Carroll S. (2011). *Value-based pricing for pharmaceuticals: Its role, specification and prospects in a newly devolved NHS*. CHE Research Paper 60, University of York.

¹⁸ Ibid.

¹⁹ Goldman D, Lakdawalla D, Philipson TJ, Yin W. (2010). Valuing health technologies at NICE: Recommendations for improved incorporation of treatment value in HTA. *Health Econ*; 19:1109-1116.

²⁰ National Institute for Clinical Excellence. (2011) NICE's response to the Department of Health Consultation on Value Based Pricing. Retrieved July 4, 2012 from : <http://www.nice.org.uk/media/D7E/05/NICEVBPConsultation.pdf>

²¹ Claxton K, Sculpher M, Carroll S. (2011). *Value-based pricing for pharmaceuticals: Its role, specification and prospects in a newly devolved NHS*. CHE Research Paper 60, University of York.

²² Stiglitz J & Jayadev A. (2010). Medicine for tomorrow: Some alternative proposals to promote socially beneficial research and development in pharmaceuticals. *J of Generic Medicines*;7(3):217-226.

²³ Kennedy, I. (2009). *Appraising the Value of Innovation and other benefits: A short study for NICE*, p.39. Retrieved August 3, 2012 from: <http://www.nice.org.uk/media/98F/5C/KennedyStudyFinalReport.pdf>

²⁴ UK Department of Health. (2010) A new value-based approach to the pricing of branded medicines: A consultation. Prepared by Medicines, Pharmacy & Industry Group, Department of Health. Retrieved August 1, 2012 from: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_122793.pdf

²⁵ National Institute for Clinical Excellence. (2011) NICE's response to the Department of Health Consultation on Value Based Pricing. Retrieved July 4, 2012 from : <http://www.nice.org.uk/media/D7E/05/NICEVBPConsultation.pdf>

²⁶ Husereau D & Cameron C. (2011). *Value-Based Pricing of Pharmaceuticals in Canada: Opportunities to Expand the Role of Health Technology Assessment?* CHSRF Series of Reports on Cost Drivers and Health System Efficiency: Paper 5.

²⁷ Claxton K, Sculpher M, Carroll S. (2011). *Value-based pricing for pharmaceuticals: Its role, specification and prospects in a newly devolved NHS*. CHE Research Paper 60, University of York.

for innovation today to one developer may weaken the marketplace by reducing incentives for competitors to provide alternatives or improvements.²⁸ Technology developers may also be de-motivated to collect evidence of technology benefit in the future should price be based on the initial assessment only.

There are additional arguments that innovation processes are to be valued because they are a “public good” bring broader social benefits, such as how a strong biotechnology sector creates jobs and contributes to GDP.²⁹ However, this may fall more appropriately under the remit of industrial policy, and if health policy makers are to reward innovation processes for these broader social reasons, they may require convincing arguments as to why innovation is singled out for support at the expense of other areas public good such as equity, access, or universality.

What is the impact of value assessments on innovation processes?

Innovation processes can be impacted by how value assessments are constructed and executed. Where clear value criteria are established, innovation processes can proceed with greater confidence as developers receive clear signals about the areas of value important to decision makers and what kinds of products are likely to be reimbursed. Conversely, where value criteria are not clear or are frequently changed, this creates uncertainty for product development.³⁰ The type of value criteria or measures chosen can also have an effect, as they can incentivize industry towards certain kinds of innovation, for instance, incremental cost-effectiveness approaches may incentivize industry to focus on incremental innovation rather than products offering step-change innovation.³¹ In these ways assessments can impact on innovation processes, but the line of causality between these processes can be challenging to identify as there are many other factors at play, e.g., the structure of the patent system³²; configuration of clinician reimbursement³³; established physician prescribing practices³⁴; or slow health system adaptation to innovation.³⁵

How HTA processes are organized can also impact the adoption of innovative technologies. For instance, in a linear step-wise process where therapeutic benefit, cost-effectiveness and budget impact are assessed sequentially, failure on any one point may lead to the premature rejection of a technology of value which might not have occurred if all of these criteria were assessed conjointly. Replacing a linear assessment with a collective assessment (perhaps through a MCDA-type of arrangement) provides an opportunity for the trade-offs between these criteria to be made apparent by allowing the benefits offered by the innovation to be viewed holistically.³⁶

²⁸ UK Department of Health (2010). Value-based pricing: impact assessment. Retrieved on July 13, 2012 from: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_122823.pdf

²⁹ UK Department of Health. (2010) A new value-based approach to the pricing of branded medicines: A consultation. Prepared by Medicines, Pharmacy & Industry Group, Department of Health. Retrieved August 1, 2012 from: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_122793.pdf

³⁰ UK Department of Health. (2010) A new value-based approach to the pricing of branded medicines: A consultation. Prepared by Medicines, Pharmacy & Industry Group, Department of Health. Retrieved August 1, 2012 from: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_122793.pdf

³¹ Ibid.

³² Stiglitz J & Jayadev A. (2010). Medicine for tomorrow: Some alternative proposals to promote socially beneficial research and development in pharmaceuticals. *J of Generic Medicines*;7(3):217-226.

³³ Porter M. (2010). What is value in health care? *NEJM*; 363(26):2477-2481.

³⁴ UK BioIndustry Association. (2008). *Review & Refresh Bioscience 2015: A report to Government by the Bioscience Innovation and Growth Team.*

³⁵ Sorenson C, Drummond D & Kanavos P. (2008). *Ensuring value for money in health care: The role of health technology assessment in the European Union.* European Observatory on Health Systems and Policies, Observatory Study Series No.11.

³⁶ Lee EK. (2012). *How to harmonize HTA and value for innovation?* Issue Panels – Session I, Sept. 3, 2012. ISPOR 5th Asia-Pacific Conference. Slide presentation.

In the future, methods to assess innovation may need to evolve to properly evaluate new technologies that are more precise, personalized, and targeted or “niche” therapies.³⁷ The evolving nature of health systems such as the rise of personalized medicine is changing the way health care technologies, particularly pharmaceuticals, are being developed and HTA bodies and decision makers may wish to consider the potential impacts of assessment methods and processes on the evolving nature of technology innovation processes.

3. Key questions to be considered

The Policy Forum discussion in February will focus on several key aspects surrounding *HTA and Value*. Discussions will seek to address the following major areas, with the understanding that viewpoints will differ across jurisdictions:

Understanding the different approaches and trade-offs to assessing value and making decisions based on this evidence:

- In what ways are various systems similar or different from each other?
- What are the trade-offs, or pros and cons, of different systems in regards to the:
 - Account taken of different stakeholder interests?
 - Techniques used, e.g., qualitative approaches, quantitative measures such as CUA, disease specific measures, deliberative decision-making, MCDA, etc.
 - Level of ease and acceptability of operation?
- What are the policy implications of different approaches? For instance: impacts on incentives in different systems; or unintended consequences, e.g., between assessment of drugs and devices?
- Is it feasible to create or promote a harmonized/standardized approach? For instance: to address therapeutic effects among different disease areas and/ or an approach that takes account of all stakeholder perspectives and weighs them simultaneously?

The impacts of recent developments to measuring and using value in decision-making

- To what extent are major developments such as value-based pricing, MCDA and value-based insurance design addressing key issues in assessing and using value measurements in decision-making?
- What aspects of value or other considerations are not being adequately addressed by these initiatives, i.e., what gaps exist?
- Are new problems arising related to these initiatives and approaches in the measurement and use of value in decision-making?
- Is there common understanding emerging across initiatives of which therapeutic areas in severe diseases or those with high burden of illness additional benefit might matter most to patients and decision makers?
- Are these approaches integrated into the local health care system as a necessary hurdle, or are they applied ad hoc to only a selection of technologies? What impacts might these different configurations have on decision implementation and integration of the new technology in the health system?

³⁷ Lee EK. (2012). *How to harmonize HTA and value for innovation?* Issue Panels – Session I, Sept. 3, 2012. ISPOR 5th Asia-Pacific Conference. Slide presentation.

Key implications and debate about value and innovation

- How should innovation be defined?
- How should the value of innovation be defined?
- What are the ways that innovation can be “rewarded”? What are the pros and cons of these different approaches? Are there approaches or techniques that can identify those innovations that positively impact patients, providers, and other healthcare stakeholders?
- How do systems which use assessments of value in decision-making impact the innovation processes? Are some approaches to assessment or decision-making more impactful on innovation processes than others?

4. Outputs

Anticipated outputs of the February 2013 HTAi Policy Forum discussion include a paper that explores a summary of key themes discussed at the meeting. This may include different stakeholder perspectives of the objectives, conceptual issues, and challenges to defining and measuring value, using value in decision-making, and implications for and debate around value and innovation. A PowerPoint slide deck will be prepared of the main themes of the discussion that Policy Forum members can use to disseminate within their organizations and at other venues.

Reference List

- Baltussen R & Niessen L. (2006). Priority setting of health interventions: the need for multi-criteria decision analysis. *Cost Effectiveness and Resource Allocation*; 4(14).
- Claxton K, Sculpher M, Carroll S. (2011). *Value-based pricing for pharmaceuticals: Its role, specification and prospects in a newly devolved NHS*. CHE Research Paper 60, University of York.
- Dolan JG. (2010). Multi-criteria clinical decision support : A primer on the use of multiple criteria decision-making methods to promote evidence-based patient-centered healthcare. *Patient*; 3(4):229-248.
- Facey K, Boivin A, Gracia J, et al. (2010). Patients' perspectives in health technology assessment: a route to robust evidence and fair deliberation. *Int J Technol Assess Health Care*;26(3):334-40.
- Fleurence RL, Sorenson C, Naci H, et al. (2012). *The Rise of Value Based Health Care: A Report of the ISPOR Health Policy Special Interest Group, Value Based Health Care Working Group*. Draft Manuscript Version 3.0.
- Fuhrmans, V (2004). A Radical Prescription: While most companies look to slash health costs by shifting more expenses to employees, Pitney Bowes took a different tack. The results were surprising. *The Wall Street Journal*, May 10, 2004:R3.
- Goetghebuer MM, Wagner M, Houry H, et al. (2008). Evidence and value: Impact on decision-making – the EVIDEM framework and potential applications. *BMC Health Services Research*; 8:270.
- Goldman D, Lakdawalla D, Philipson TJ, Yin W. (2010). Valuing health technologies at NICE: Recommendations for improved incorporation of treatment value in HTA. *Health Econ*; 19:1109-1116.
- Healy P & Pugatch M. (2012). *Capturing Value: Why dynamic efficiency should be considered in the pricing and reimbursement of medicines*. Stockholm Network.
- Husereau D & Cameron C. (2011). *Value-Based Pricing of Pharmaceuticals in Canada: Opportunities to Expand the Role of Health Technology Assessment?* CHSRF Series of Reports on Cost Drivers and Health System Efficiency: Paper 5.
- Kennedy, I. (2009). *Appraising the Value of Innovation and other benefits: A short study for NICE*, p.39. Retrieved August 3, 2012 from: <http://www.nice.org.uk/media/98F/5C/KennedyStudyFinalReport.pdf>
- Lee EK. (2012). *How to harmonize HTA and value for innovation?* Issue Panels – Session I, Sept. 3, 2012. ISPOR 5th Asia-Pacific Conference. Slide presentation.
- McGuire A. (2001). Theoretical concepts in the evaluation of healthcare. In: Drummond M, McGuire A, editors. *Economic evaluation of in health care: Merging theory with practice*. New York: Oxford University Press.
- National Institute for Clinical Excellence. (2011) NICE's response to the Department of Health Consultation on Value Based Pricing. Retrieved July 4, 2012 from : <http://www.nice.org.uk/media/D7E/05/NICEVBPConsultation.pdf>
- Owens D, et al. (2011). High-value, cost-conscious health care: concepts for clinicians to evaluate the benefits, harms, and costs of medical interventions. *Ann Intern Med*;154:174-180.
- Persson U. (2011). *Value Based Pricing (VBP) in Swedish Health Care*. Slide presentation at Value Based Pricing, London 17-18 February 2011. Retrieved July 15, 2012 from: <http://www2.lse.ac.uk/businessAndConsultancy/LSEConsulting/conferences/persson.pdf>
- Porter M. (2010). What is value in health care? *NEJM*; 363(26):2477-2481.
- Renn O. (1999). A model for an analytic-deliberative process in risk management. *Environ. Sco. Technol.*; 33(18): 3049-3055
- Ryan M & Farrar S. (2000). Using conjoint analysis to elicit preferences for health care. *BMJ*; 320:1530-3.
- Ryan M. (1999). Using conjoint analysis to take account of patient preferences and go beyond health outcomes: an application to in vitro fertilisation. *Social Science & Medicine*; 48:535-546.
- Sorenson C, Drummond D & Kanavos P. (2008). Ensuring value for money in health care: The role of health technology assessment in the European Union. *European Observatory on Health Systems and Policies, Observatory Study Series No.11*.
- Stiglitz J & Jayadev A. (2010). Medicine for tomorrow: Some alternative proposals to promote socially beneficial research and development in pharmaceuticals. *J of Generic Medicines*; 7(3):217-226.
- Towse A & Raferty J. (2009) Should NICE's threshold range for cost per QALY be raised? *BMJ*; 338:268-9.

- UK BioIndustry Association. (2008). Review & Refresh Bioscience 2015: A report to Government by the Bioscience Innovation and Growth Team.
- UK Department of Health (2010). Value-based pricing: impact assessment. Retrieved on July 13, 2012 from: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_122823.pdf
- UK Department of Health. (2010) A new value-based approach to the pricing of branded medicines: A consultation. Prepared by Medicines, Pharmacy & Industry Group, Department of Health. Retrieved August 1, 2012 from: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_122793.pdf
- University of Michigan Center for Value-Based Insurance Design. Accessed on October 11, 2012 from: <http://www.sph.umich.edu/vbidcenter/about/index.html>
- Weinstein MC, Torrance G, McGuire A. (2009). QALYs: the basics. *Value in Health*; 12(S1):S5-S9.
- Youngkong S, Teerawattananon Y, Tantivess S & Baltussen R (2012). Multi-criteria decision analysis for setting priorities on HIV/AIDS interventions in Thailand. *Health Research Systems and Policy*; 10:6.

Appendix A.

Summary of MCDA and Conjoint Analysis

Multi-criteria decision-making (MCDA)

MCDA is a technique to assimilate and analyze multiple types of dissimilar information and to assess the relative importance of each. It is commonly used in other domains (environmental and agriculture sciences, etc.), and is becoming used increasingly in health care³⁸ where evidence synthesis for decision-making may span clinical medicine, public health, finance, social sciences, ethics, patient preferences, societal values and level of innovativeness. An overview of key components of the MCDA process is provided below, with further explanation available elsewhere.³⁹

MCDA is a 'decompositional' approach whereby those components considered to have an important impact on the value of an intervention are identified and considered in decision-making. MCDA can be more or less formal in the way these components are measured and compared to a set of objectives or outcomes. The components may be quantified using a scale with identifiable anchors (an explicit range of values such as 0-1, high-medium-low).⁴⁰ Most MCDA use a *performance matrix*, which is a table containing rows of interventions to be compared and columns of criteria to be assessed. Data can be either qualitative or quantitative and represented in different units (cost-per-QALY, ordinal scales, or nominal scales). An example is provided in Table 3.

Table 3. Sample MCDA performance matrix

	Severity of side effects	Cost-Utility (per QALY)	Level of Innovativeness	Patient compliance (%)	Quality of evidence
Intervention A	**	€200	Medium	0.94	High
Intervention B	***	€400	Low	0.88	Medium
Intervention C	*	€50	Medium	0.79	High
Intervention D	***	€100	High	0.84	Low

Decision makers can use the performance matrix in different ways. Interventions can be more or less intuitively and quickly ranked by experts or committees according to one or more priority areas. However, it is rare that one intervention clearly dominates alternatives and it may be difficult to weight different types of units. To address this, the performance matrix can be quantitatively analyzed through a linear additive model where the criteria units are converted into a consistent numerical value, with weightings assigned to different criteria categories and a final calculation derived by a multiplication of the unit measurement by the weighting assigned to that category.

³⁸ Baltussen R & Niessen L. (2006). Priority setting of health interventions: the need for multi-criteria decision analysis. *Cost Effectiveness and Resource Allocation*; 4(14).

³⁹ See Youngkong S, Teerawattananon Y, Tantivess S & Baltussen R (2012). Multi-criteria decision analysis for setting priorities on HIV/AIDS interventions in Thailand. *Health Research Systems and Policy*; 10:6, Renn O (1999). A model for an analytic-deliberative process in risk management. *Environ. Sco. Technol.*; 33(18): 3049-3055, and Dolan JG. (2010). Multi-criteria clinical decision support : A primer on the use of multiple criteria decision-making methods to promote evidence-based patient-centered healthcare. *Patient*; 3(4):229-248.

⁴⁰ Goetghebeur MM, Wagner M, Khoury H, et al. (2008). Evidence and value: Impact on decision-making – the EVIDEM framework and potential applications. *BMC Health Services Research*; 8:270.

MCDA offers a tool to make explicit the trade-offs and implicit assumptions or preferences inherent in decision-making and allow for broader stakeholder involvement in the selection and weightings of value criteria and the ranking of interventions for prioritisation or reimbursement decisions.⁴¹ Multi-stakeholder involvement might occur at each step of this process, or at key points where key stakeholder groups can review and revise the matrix where necessary.⁴²

An example of an MCDA decision support tool in current use is the EVIDEM framework⁴³ that includes a value matrix to consider both intrinsic and extrinsic value criteria. Fifteen (15) individual intrinsic value criteria are grouped into four clusters: quality of evidence, disease impact, characteristics of the intervention (e.g., improvement of efficacy/effectiveness over alternatives), and economic considerations. The extrinsic value tool addresses the weights and trade-offs between ethical principles and health-system related components in three areas: utility as the goal of healthcare, efficiency and opportunity costs, and fairness in population priorities and access to health care.⁴⁴

Conjoint Analysis

Conjoint analysis is also known as *preference analysis* or *discrete choice analysis* is a statistical technique that can be used to assess one or all of the following: preferences for and trade-offs amongst alternatives; the overall benefit, utility or satisfaction stakeholders derive from alternatives; the relative importance of different characteristics of an intervention or service; and/or, to identify which characteristics are important to whom.

The process of conjoint analysis starts with describing the characteristics or attributes of an intervention or group of interventions that are deemed to be relevant to a particular situation. Depending on the context, the specific characteristics or criteria looked at may be predefined, or they may be identified through literature reviews, focus groups, or individual questionnaires. Once the characteristics or criteria are selected, individuals are then asked to rank, rate or make pairwise choices between one or more sets of characteristics. The trade-offs that individuals weigh in selecting different criteria can be analyzed statistically to determine the importance of each option. These trade-offs are understood as the rate at which they are willing to give up one unit of a specific characteristic for a specific gain in another, also known as marginal rate of substitution. Where one of the characteristics considered is cost then it is considered an assessment of the individual's "willingness-to-pay" for the intervention or service.

Conjoint analysis is increasingly used in several health care applications to elicit patient and community preferences, for priority setting, or to develop outcome measures, and other areas.⁴⁵ Conjoint analysis is seen by some⁴⁶ as an alternative to QALY-based approaches to assess benefit, as it includes patient preferences and criteria beyond health outcomes such as qualitative experiences related to the intervention context.

⁴¹ Baltussen R & Niessen L. (2006). Priority setting of health interventions: the need for multi-criteria decision analysis. *Cost Effectiveness and Resource Allocation*; 4(14).

⁴² Youngkong S, Teerawattananon Y, Tantivess S & Baltussen R (2012). Multi-criteria decision analysis for setting priorities on HIV/AIDS interventions in Thailand. *Health Research Systems and Policy*; 10:6

⁴³ See <https://www.evidem.org/>

⁴⁴ Goetghebeur MM, Wagner M, Khoury H. et al. (2010). Combining multicriteria decision analysis, ethics and health technology assessment: applying the EVIDEM decisionmaking framework to growth hormone for Turner syndrome patients. *Cost Effectiveness and Resource Allocation*; 8(4).

⁴⁵ Ryan M & Farrar S. (2000). Using conjoint analysis to elicit preferences for health care. *BMJ*; 320:1530-3.

⁴⁶ Ryan M. (1999). Using conjoint analysis to take account of patient preferences and go beyond health outcomes: an application to in vitro fertilisation. *Social Science & Medicine*; 48:535-546.

Appendix B.

Additional information on recent international developments to achieve improved value

Value-based pricing (VBP)

United Kingdom

In 2014, the UK will introduce VBP which will change how brand-name drugs are priced. The VBP system is the government's response to opinions expressed by industry⁴⁷ that NICE processes were not promoting innovation as effectively as it could. This new approach will replace the current Pharmaceutical Price Regulation Scheme (PPRS) at the end of 2013. The move to VBP is intended to promote innovation and improve access to medications in areas deemed important to UK society, and to establish closer links between the price paid for a drug and the value it provides, particularly for patient subgroups.⁴⁸

The UK government will use a mix of standard QALY assessments, the specific benefits offered by the technology and the weighting of each benefit to provide a menu of price thresholds up to a maximum price for the medicine. Threshold amounts could be adjusted for drugs delivering additional value in areas of wider societal benefits or which reflect societal preferences, specifically, the:

- Burden of illness (seriousness/severity of a condition),
- Scale of clinical benefit provided by the medicine, beyond current best practice, also called "therapeutic innovation and improvement"; and,
- Non-health benefits that may not be reflected in the QALYs, e.g. impacts on time spent with carers, area of unmet need.

The specific methods for measuring these additional benefits are yet to be determined. The success of VBP may depend on the ability for all stakeholders to agree, define and demonstrate an expanded range of value dimensions, and on the implementation of an agreed-upon aggregation process to deliver robust assessments of value.

The UK VBP system is intended to provide more overall net health benefits to the health system since technologies that are cost-effective in smaller sub-groups would not be rejected. It is expected that VBP will limit the number of "me too" drugs covered by linking price to a metric of additional value to health systems. A key issue, however, is how to share in the social surplus/benefit (i.e. profit for industry or savings for the health system) over the longer term after patent expiry and generics become available. Through VBP, clearer messages are sent to industry for consideration in the early stages of product development, to determine if a technology is likely to satisfy the specified value criteria and proceed with or discontinue the product development accordingly.^{49,50}

Germany

Since January 2011, the Act for the Restructuring of the Drug Market (AMNOG) introduced elements of VBP to ensure the benefits provided by new health technologies merit the funding level awarded by statutory health insurance schemes.

⁴⁷ UK Biotechnology Association. (2008). *Review & Refresh Bioscience 2015: A report to Government by the Bioscience Innovation and Growth Team.*

⁴⁸ Claxton K, Sculpher M, Carroll S. (2011). *Value-based pricing for pharmaceuticals: Its role, specification and prospects in a newly devolved NHS.* CHE Research Paper 60, University of York.

⁴⁹ Husereau D & Cameron C. (2011). *Value-Based Pricing of Pharmaceuticals in Canada: Opportunities to Expand the Role of Health Technology Assessment?* CHSRF Series of Reports on Cost Drivers and Health System Efficiency: Paper 5.

⁵⁰ Stiglitz J & Jayadev A. (2010). *Medicine for tomorrow: Some alternative proposals to promote socially beneficial research and development in pharmaceuticals.* *J of Generic Medicines*; 7(3):217-226.

Under the new approach, drug companies are required to provide to the German government evidence of the added benefit of a new medication compared to other available treatments, with higher reimbursement prices considered only for drugs that demonstrate a clear, unique benefit. Where no incremental benefit is demonstrated, the new drug will be priced the same as the comparator. Recent experience in some assessments have raised considerable issues regarding how to identifying an “appropriate” comparator drug.^{51,52}

Sweden

Sweden’s program of VBP started in 2002 in order to price reimbursed medicines based on criteria of cost-effectiveness, equity, and need, in essence creating a flexible threshold that can respond to criteria of equity and need. VBP in Sweden draws on a societal perspective (which considers cost offsets in non-health sectors), uses a threshold value-based on individual maximums of willingness to pay for a QALY, and the marginal decreasing utility of treatment to account for varied benefit for different indications or severity. Assessments occur prior to widespread distribution (*ex ante*) and continued assessments and reviews of price occur after launch (*ex post*).⁵³

Canada

In Canada, there has been discussion regarding a pan-national VBP program to address duplication and inefficiencies from varying drug prices across the Canadian provinces. Currently, each province independently and confidentially negotiates drug prices and there is the potential for a coordinated value-based price negotiation of pharmaceuticals through a “bulk purchasing alliance” is being considered.⁵⁴

Value-based insurance design (V-BID)

The V-BID approach is primarily used in the United States of America, and it is intended to remove financial barriers to essential, high-value health care interventions and services and thereby shift patient utilization of treatments towards those that offer the greatest value. V-BID places patients in the value proposition by aligning their out-of-pocket costs with the value of health services. Those interventions offering greater value are available to patients with low or no co-payment or premium, while interventions offering lower value are available with a co-payment or premium borne by the patient. In the V-BID approach, the short-term financial impact on revenue resulting from reducing co-payments for high value services can be seen as an investment that is expected to pay off in other areas, e.g., reduced hospitalization rates, emergency room visits, less disability and increased productivity. V-BID includes a variable cost sharing approach where different rates of co-payment or premium can be assigned for different patient groups receiving the same intervention, for instance, providing free or reduced-rate eye, foot or exams for diabetes patients. Value-based insurance can improve health outcomes related to the prevention and management of chronic diseases where appropriate early intervention can mean better health for patients and at the same time generate substantial savings. One large HMO was shown to have saved \$1 million from reduced complications after lowering co-payment rates for asthma and diabetes medications.^{55,56}

⁵¹ Healy P & Pugatch M. (2012). *Capturing Value: Why dynamic efficiency should be considered in the pricing and reimbursement of medicines*. Stockholm Network.

⁵² New York Times (February 23, 2012) *Austerity in Europe Puts Pressure on Drug Companies*.

⁵³ Persson U. (2011). *Value Based Pricing (VBP) in Swedish Health Care*. Slide presentation at Value Based Pricing, London 17-18 February 2011. Retrieved July 15, 2012 from: <http://www2.lse.ac.uk/businessAndConsultancy/LSEConsulting/conferences/persson.pdf>

⁵⁴ Husereau D & Cameron C. (2011). *Value-Based Pricing of Pharmaceuticals in Canada: Opportunities to Expand the Role of Health Technology Assessment?* CHSRF Series of Reports on Cost Drivers and Health System Efficiency: Paper 5.

⁵⁵ Fuhrmans, V (2004). A Radical Prescription: While most companies look to slash health costs by shifting more expenses to employees, Pitney Bowes took a different tack. The results were surprising. *The Wall Street Journal*, May 10, 2004:R3.

⁵⁶ University of Michigan Center for Value-Based Insurance Design. Accessed on October 11, 2012 from: <http://www.sph.umich.edu/vbidcenter/about/index.html>



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