Reflections on Operationalising Value Based Assessment

Professor Adrian Towse

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Agenda

• VBP context
• Some issues
  • VBP versus VBA
  • What do we value?
  • Societal perspective
  • Eliciting social preferences
  • Aggregating elements of value
• Decision making in the rest of the NHS
VBP context

VBP as initially proposed by the government was intended to:

1. Introduce a broader definition of value
2. Replace NICE appraisal with an algorithm
3. Impose/negotiate prices with the industry
4. End the 5-year negotiated PPRS agreements
5. Get rid of “no” or “restricted/optimised” decisions from NICE (and so get rid of anti-NICE, anti-DH newspaper headlines)
6. Enable the Cancer Drugs Fund to be got rid of

Only the first is now being actively pursued
Trends in decisions for cancer medicines before and after establishment of Cancer Drugs Fund (Q4 2010–Q3 2013)

(Source: OHE analysis from data on NICE website)
VBP versus VBA

- Optimal global R&D comes from prices reflecting value at local CE thresholds for patent duration
- Price setting by governments/HTA bodies can lead to:
  - commercial uncertainty
  - opportunistic behaviour

VALUE-BASED DIFFERENTIAL PRICING: EFFICIENT PRICES FOR DRUGS IN A GLOBAL CONTEXT

PATRICIA DANZON1, ADRIAN TOWSE2 and JORGE MESTRE-FERRANDIZ2
1The Wharton School, University of Pennsylvania, Philadelphia, PA, USA
2Office of Health Economics, London, UK

ABSTRACT
This paper analyzes pharmaceutical pricing between and within countries to achieve second-best static and dynamic efficiency. We distinguish countries with and without universal insurance, because insurance undermines patients’ price sensitivity, potentially leading to prices above second-best efficient levels. In countries with universal insurance, if each payer unilaterally sets an incremental cost-effectiveness ratio (ICER) threshold based on its citizens’ willingness-to-pay for health, manufactures price to that ICER threshold; and payers limit reimbursement to patients for whom a drug is cost-effective at that price and ICER, then the resulting price levels and use within each country and price differentials across countries are generally consistent with second-best static and dynamic efficiency. These value-based prices are expected to differ cross-nationally with per capita income and be broadly consistent with Ramsey optimal prices. Countries without comprehensive insurance avoid its distorting effects on prices but also lack financial protection and affordability for the poor. Improving pricing efficiency in these self-pay countries includes improving regulation and consumer information about product quality and enabling firms to price discriminate within and between countries. © 2013 The Authors. Health Economics published by John Wiley & Sons Ltd.

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KEY WORDS: differential pricing; ICER thresholds; value-based pricing

1. INTRODUCTION

Achieving efficient pricing of pharmaceuticals between and within countries is a complex conceptual and policy problem. In any industry, pricing to maximize social welfare must consider both static efficiency (optimal use of existing products) and dynamic efficiency (optimal investment in research and development (R&D)).

Danzon, Towse & Mestre-Ferrandiz (2013)
Impact of Patient Access Schemes

If all positive decisions since 2009 where a PAS was implemented were assumed to be a “not recommended” decision in the absence of a PAS (bar labelled “without PAS”), the share of not-recommended decisions increases to 47%.

Source: OHE analysis from data on NICE website

Chart: share of decision outcome for all medicines decisions from 2009 to Q3 2013, with and “without” PAS
Need for flexible pricing and more outcomes-based PAS

Garrison et al (2013)
What do we value?

• What is valued by payers/HTA bodies varies greatly
• Core is (a) health gain (life extending, improved health status) (b) reducing system cost
• How far beyond the core?
• Is this decided by:
  1. The (extra-welfarist) decision maker
  2. The (welfarist) search for social / individual preferences
  3. Or 1. informed by 2.? 

Towe and Barnsley (2013)
Societal perspective

• DH conceptual model is a good one except:
  • “Impacts beyond QALYs” and “defining WSBs as the impact on net resource contribution” assumes QALYs capture all welfare benefits
  • But does the QALY includes all welfare benefits from improved quantity or quality of life? This is an empirical issue. But I suspect the answer is “no”.

• Challenges with data sources
  • There are issues, but data will improve if it is used
  • Allow companies to make bespoke data submissions

• Optionality over submission?
  • Move from automatic calculation towards a trigger option in the scoping phase
Eliciting social preferences: End-of-life findings highlight the challenges

Linley and Hughes (2012)

Shah, Tsuchiya and Wailoo (2013)
A reordering of process?

Criteria: broader definition of value (risks, benefits)

Safety

Efficacy, effectiveness

Other factors of value to D-M (ethical issues, social values, feasibility of implementation, unmet needs, innovation value, legal issues …)

Affordability (BIA)

Value for money (CE)

Overall D-M Framework: Opportunity costs (value-for-money)

Source: Professor Ron Goeree, Director PATH Research Institute, McMaster University
Types of judgement

**Scientific judgement** is usually about an effect (positive or negative), its size, the ways in which it can be achieved, for whom, for how long . . . .

**Value judgements** tend to be in a different territory but they might be about, for example, how worthwhile a technology is, how defensible the tough bits of the decision are, how tolerant of uncertainty the committee ought to be . . . . inter-personal comparisons . . . whether the [outcome measure] was a good tracker of the relative health benefits of the interventions that were compared.

Source: Culyer (2009)
Aggregating elements of value

- Weighting multiple criteria relevant to the decision (MCDA)
- A pure deliberative process does not use any formal structure and so is a “black box” to outsiders and potentially to itself over time (may lead to a lack of consistency and a lack of clear signals as to what matters)
- A pure algorithmic approach does not need a committee
- Is there something workable (theoretically robust and practical) in between?
Decision making in the rest of the NHS

Methods for the Estimation of the NICE Cost Effectiveness Threshold

Final Report

Karl Claxton,1 Steve Martin,1 Maria Soares,1 Nigel Rice,1 Edson Spockman,1 Sebastian Hinde,1 Nancy Devlin,2 Peter C. Smith,2 Mark Sculpher2

1. Centre for Health Economics, University of York
2. Department of Economics and Related Studies, University of York
3. Office of Health Economics
4. Imperial College, London

Claxton et al (2013)

Critique of CHE Research Paper 81

"Methods for the Estimation of the NICE Cost Effectiveness Threshold"

December 2013

Paul Barnsley, Adrian Towse, Sarah Karlsberg Schaffer and Jon Sussex

Barnsley et al (2013)

Searching for Cost-effectiveness Thresholds in NHS Scotland

December 2013

Sarah Karlsberg Schaffer, Jon Sussex, Nancy Devlin and Andrew Walker

Schaffer et al (2013)

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HESG Plenary, 8 January 2014
Marginal services: Costs-per-QALY ranges

Source: Schaffer et al (2013)
Conclusions

1. Work on the broader definition of value is the key outcome of the current VBP/VBA dialogue
2. It requires better understanding of the preferences of the public and of patients. We need to invest in preference elicitation
3. Price flexibility by indication/subgroup and outcomes-based CED/PBRSA schemes are important for getting dynamic and static efficiency from the use of drugs
4. A deliberative process is necessary in value assessment. Introducing structure to this process (MCDA) is a challenge
5. We need to take this thinking into decision making about the other 95% of NHS spending.
References


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Office of Health Economics
Southside, 7th Floor
105 Victoria Street
London SW1E 6QT
United Kingdom
+44 20 7747 8850
www.ohe.org
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