Value based pricing: can it work?

From next year the UK will use value based pricing to determine what it pays for new drugs. **James Raftery** explains what this will mean for drug companies, NICE, and the NHS

The idea of paying for "value" in healthcare was boosted by Harvard business strategist Michael Porter, who argued that healthcare should focus on value for patients, defined as "health outcome per dollar of cost expended."[1] Competition in the US healthcare system, he argued, had failed because it did not focus on value. Although aimed at the US system, his terminology was widely adopted. In the United Kingdom, new NHS policies were presented in value terms. Paying hospitals by activity was termed "payment by results," and the system for paying family doctors for specified activities was titled Quality Outcomes Framework. Value based pricing for branded drugs, which will come into force in 2014, is part of this trend. Although the system was intended to improve access to new drugs, the decision to include wider societal costs in the assessment of value could have unintended consequences.

How are drug prices determined?

Drug companies publish prices based on the US market, which accounts for over half of world spending on patent protected drugs. Companies try to have the same prices in all countries, partly to avoid parallel imports, when drugs are bought in countries that have lower prices and exported to countries paying higher prices. However, because all but three countries (Norway, Switzerland, and Luxembourg)[2] have lower income per head than the US, they struggle to pay US prices. Countries have responded with a variety of measures, including price controls, formularies, encouragement of generics, and, more recently, assessment of clinical and cost effectiveness. In those countries that host drug companies, the need for efficiency in healthcare, which implies lower drug prices, also has to be balanced against supporting national industries, which implies higher prices.

Pricing in the UK

Since 1957, drug prices in the United Kingdom have been regulated at company level through the Prescription Pricing Regulation Scheme (PPRS). The scheme applies to branded in-patent drugs, which comprise around 70% of NHS spending on drugs.[3] Although generics make up the bulk of prescriptions, they cost much less.

The scheme aims to secure the provision of safe and effective medicines to the NHS at reasonable prices, promote a strong and profitable pharmaceutical industry in the UK, and encourage the efficient and competitive development and supply of medicines.[4] Prices are usually negotiated for five year periods, and the scheme attempts to balance policies for health and industry through regulating the profits that drug companies can make from UK sales and, in recent years, by imposing general price cuts.

The formation of the National Institute for Clinical Excellence (NICE, now called the National Institute for Health and Care Excellence) by the Labour government in 1999 facilitated examination of the value of individual drugs rather than looking at company profits. NICE was set up to deal with the problem of postcode prescribing—when access to expensive drugs depended on where you lived—by appraising the clinical and cost effectiveness of individual drugs. Although NICE had no power to negotiate price, it could decide whether a drug should be available on the NHS. Initially, there was little interaction between NICE and Prescription Pricing Regulation Scheme (box). However, the 2009 pricing agreement included provisions that enabled price reductions to be negotiated for drugs refused by NICE. The resulting "patient access schemes" have been used by companies to offer price reductions for some drugs unlikely to meet NICE's cost effectiveness criteria. Of the 36

OCEAN/CORBIS

EVOLUTION OF UK BRANDED PHARMACEUTICAL PRICING

1957:	Voluntary Pricing Regulation Scheme established
1978:	Renamed Prescription Pricing Regulation Scheme (PPRS)
1999:	NICE established; PPRS agreement for 1999-2004 contains price cuts of 4.5%
2002:	NICE says no to new multiple sclerosis drugs. Government establishes risk sharing scheme giving patient access to these drugs
2005:	PPRS 2005-10 with price cuts of 7%
2007:	Office of Fair Trading report recommends PPRS is replaced by value based pricing for all branded drugs
2008:	Government withdraws 2005-10 PPRS. Threatening statutory pricing, government negotiates 2009-13 PPRS with 7% price cut for all drugs plus scope for price reductions on particular drugs through patient access schemes. Also includes Association of British Pharmaceutical Industry commitment to reviewing NICE's economic perspective
2009:	NICE's end of life criteria raise cost/QALY threshold for these drugs
2010:	Coalition programme for government includes commitment to value based pricing in next PPRS and establishes cancer drugs fund as "bridge to value based pricing"
2011:	Government response to consultation on value based pricing indicates that it will apply only to new drugs and give greater role to NICE
2013:	Government response to House of Commons Health Committee report confirms NICE to take responsibility for value based pricing (April)
2013:	NICE issued with new framework for value based pricing (June)
2014:	New PPRS 2014-19 to cover most branded drugs plus amended cost/QALY ("value based pricing") for new drugs appraised by NICE

schemes listed on the NICE website,[5] two thirds are simple price discounts. As the discounts are confidential, companies can maintain that listed prices still apply elsewhere.

Reconciling cost effectiveness with patient demand

Thus the UK operates a complex mix of pharmaceutical price regulation, working through the pricing regulation scheme at company level but with NICE appraising individual drugs. Although NICE recommends against less than one third of the drugs it considers,[6] these refusals have been politically difficult. When NICE rejected drugs for multiple sclerosis in 2002, the Labour government established a scheme to enable patients to get them. Costing £50m-£100m (€60m-€120m; $80m-$160m) a year, it was later shown to be a "costly failure."[7] After NICE rejected drugs for renal cancer in 2009 the government required it to apply less stringent criteria for "end of life" drugs, reversing the decision on one of these drugs. The cost to the NHS of this scheme has been put at £549m a year.[8]

Shortly after it came to power in 2010, the coalition government created a £200m cancer drugs fund to enable patients to get treatments refused by NICE. The cost of these three schemes, which has to be met from the NHS budget, has been considerable: just under £1bn, almost 1% of the NHS total spend, or roughly 10% of its drug spend. The coalition also announced that it would "reform NICE and move to a system of value based pricing."[9] Value based pricing, which was strongly supported by the Association of the British Pharmaceutical Industry, was presented as a way of avoiding NICE refusals. How this might happen was left unclear.

Value based pricing of branded drugs in the UK was first advocated by the Office of Fair Trading as a replacement for the Prescription Pricing Regulation Scheme in 2007.[10] It saw profit regulation at company level as providing less incentive for companies to innovate than paying for value at drug level. Value based pricing, as defined by the Office of Fair Trading, was "therapeutic value" and best measured by quality adjusted life years (QALYs): "We believe QALYs are a key tool in securing value for money." It proposed applying this approach to all branded drugs, not just the handful referred by the government to NICE each year.

Government backtracking

It soon became clear that the coalition government's version of value based pricing was different. Gradual retreats were sounded.[11] Value based pricing would apply only to new drugs. The early proposal for new expert panels was dropped. NICE would have a key role. The new system began to be defined in terms of amendments to the cost per QALY framework used by NICE. The focus was on England and Wales because Scotland has devolved powers to assess the value of drugs (but not to set prices).[12]

Scenarios showing how including wider (non-health) costs in calculation of cost per QALY will affect NICE recommendations, assuming £30 000/QALY is borderline

Drug	A	B	C
Drug cost to NHS	£30 000	£30 000	£30 000
QALY gain	1	1	1
Effect on non-NHS care requirements (i)	Reduces	Unchanged	Increases
Effect on employment (ii)	Increases	Unchanged	Unchanged
Total cost/QALY	£30000–(i+ii)	£30 000	£30 000+i
NICE decision:			
Based on health only	Borderline	Borderline	Borderline
Including wider costs	Recommend	Borderline	Reject

Two amendments will be made to NICE's current methods of assessing cost per QALY.[13] Firstly, the relevant costs will be extended beyond those falling on the NHS (and publicly funded personal social services) to include costs to carers and those arising from changes in employment (termed wider social benefits or net resource implications).[14] The Department of Health has provided estimates of these by age, sex, and disease.[15] Secondly, QALYs, instead of being based purely on duration and quality of life, are to be weighted to reflect severity and the end of life. The Department of Health has also attempted to estimate these effects based on population surveys, some specially commissioned, but the results have not been consistent.[14]

The UK operates a complex mix of pharmaceutical price regulation, working through the pricing regulation scheme at company level but with NICE appraising individual drugs

Having struggled to specify value based pricing, the government in June 2013 handed value assessment to NICE. Price negotiation remains with the Department of Health. Although the two proposed changes can be readily dealt with by amending NICE's methodology guide,[16] they raise two big concerns: one to do with the principles of the NHS, the other to do with unintended consequences.

How will the changes affect equity?

Because the new value assessment takes account of the effects of treatment on employment it favours those most likely to be employed and moves beyond clinical need towards ability to pay. The NHS Constitution also states that "Public funds for healthcare will be devoted solely to the benefit of the people the NHS services" (principle 6). However, from 2014, some NHS funds will be devoted to employment. As long the NHS aimed to maximise health from the NHS budget, the cost per QALY threshold for NICE could be based on what would be displaced from health services (the opportunity cost). The cost of what is displaced must in future be cast in terms of wider social benefits. NICE will consult on the detailed implementation of these matters in early 2014, which means that only an interim scheme will be introduced in January 2014.[18]

Unintended consequences seem likely. Extending the cost perspective beyond the NHS will favour some diseases and treatments but disadvantage others. An effective treatment for a disease with high care requirements (such as Alzhemier's disease) or which enabled employment (such as for multiple sclerosis) would involve a lower net cost (widely defined) and hence a more favourable cost per QALY. On the other hand, a drug that extends survival in a highly dependent state, as with many recent cancer drugs appraised by NICE, could incur a higher cost and hence a worse cost per QALY under the new rules (table). Value based pricing will lead to winners and losers.

International experience provides little illumination on how value based pricing will work. The only other country to include wider social costs in cost per QALY estimates is Sweden.[19] However, the Swedish system emphasises a range of factors besides cost effectiveness.[20]

In summary, the inclusion of employment effects in value based pricing challenges the NHS principles of treating all equally and spending NHS funds solely for health. The extent to which this matters in practice remains to be seen. The principle it departs from may be more important.

Although the pharmaceutical industry called for the move to value based pricing, it may not get what it expected. The new arrangements imply higher prices for some drugs but lower prices for others. Some drugs will continue to be refused by NICE and continued controversy is inevitable. Some companies will negotiate confidential price cuts. Special deals will be required for others but may become more difficult within a squeezed NHS budget.

James Raftery professor of health technology assessment, University of Southampton, Chilworth Science Park, Southampton SO16 7NS, UK
raftery@soton.ac.uk

Competing interests: None declared.
Provenance and peer review: Commissioned; externally peer reviewed.
References are in the version on bmj.com.
Cite this as: *BMJ* 2013;347:f5941