

# THE COST-EFFECTIVENESS THRESHOLD: WHERE SHOULD IT COME FROM AND HOW SHOULD WE GET RELIABLE EMPIRICAL ESTIMATES?

Research

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# Agenda

- What is the problem?
- Deriving an ICER threshold for an individual
- ICER thresholds in a universal coverage system
- A single payer with a global fixed budget: the example of the UK NHS



## What is the problem? Part 1

- We have a social objective of coverage with limited resources to provide:
  - insurance protection and
  - at a higher level of health care provision for low income people than they would be able to obtain with their own income
- We also want to provide a system that is responsive to peoples' preferences
  - About their own health care
  - About other peoples access to health care
- There is inevitably a tension on financing:
  - How much do we pay for the health protection of others?
  - The "ex ante / ex post" tension about paying for insurance



## What is the problem? Part 2

- We have to ration health care
- We value things from the health care system other than health. They are mostly about either the process of health care delivery or benefits or costs that arise from obtaining (or not) a health benefit. But they are not strictly health
- We have social preferences as well as personal ones about the value of a health state, including the characteristics of who gets the health care
- We are struggling to understand what the health system currently does and how efficient it is at using health technologies. We lack information.



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# Deriving an ICER for an individual

- Following Garber and Phelps (1997) a representative individual has income Y which is constant in real terms across time periods
- Expected utility in period 0 can be written:

• 
$$E_0 = U_0 (Y - w_a a - w_b b) + v \Sigma_i [\delta^i k_i \Pi P_j]$$
 (1)

- Where:
  - Period-specific utility of income as viewed from period 0 is v = U<sub>0</sub>(Y), before discounting or quality of life adjustment
  - Income is spent on medical care and other goods.
  - Consumption of medical care in period 0 affects the probability of survival P and the quality of life k in future periods.
  - The expected benefits of medical care can thus be expressed in terms of QALYs
  - Future utility is discounted by a factor  $\delta$ .



# Deriving an ICER threshold for an individual

- Two available medical interventions a and b, with prices  $w_{a, b}$
- The optimal utilization of technology *a* defined by the first order condition can be written:

 $\underline{w}_{\underline{a}} = \underline{v} = \underline{dC} = ICER \quad (2)$   $(dQ/da) U_0' \qquad d(QALYs)$ 

• The ICER, at optimal utilization, (the threshold value of the ICER) is equal to the ratio of future period-specific utility v to marginal utility in the base period, or willingness to pay for medical care



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### ICER thresholds in a universal coverage system

- Garber and Phelps (1997) state that "The optimal CE criterion is equivalent to determining optimal coverage for an actuarially fair insurance policy, under perfect information." (p27)
- Assume, however, that each country operates a universal insurance system for all citizens
- Each system can be represented by a representative individual
- Assume that the system is financed efficiently including the raising of the subsidies to achieve socially equitable access
- We might expect the system ICER threshold to reflect that of the representative consumer



# ICER thresholds in a universal coverage system: accommodating preference heterogeneity

- Commitment to equity and financial support means some sources of heterogeneity are reduced and involves social preferences.
- There are ways in which heterogeneity can be accommodated in universal systems with a single payer or a mandated minimum coverage by competing insurers, to provide "voice" and "exit:
  - In a pluralist health care system, different health plans could choose different ICER thresholds, subject to minimum compulsory coverage
  - National and social insurance systems can vary ICER thresholds by condition to address social and personal preferences e.g. "end of life"
  - Patients deemed ineligible for a given product under the social insurance could be permitted to pay out of pocket



### How to set the budget given the threshold?

- We are interested in willingness to pay (v), i.e. how much of their consumption an individual is willing to give up to improve their own health
  - We want the universal coverage system to mimic a market plus meet equity and efficiency criteria
- We are also interested in understanding willingness to pay taxes /premiums to improve the health of others (v<sub>a</sub>)
- We can use WTP to help understand these values, just as we use individual trade-offs to derive QALY valuations
- A global budget constraint could be raised over time to reflect allocative preferences



Examples of the Values of a QALY via alternative calculations from modelling based on VPF

Basic modelling approach	Value of a QALY (£)
Life-saving	£70,000
Life-extending	£35,000
Quality-of-life-enhancing	£10,000

Sources: Mason H et al (2008); The SVQ Research Team (2008)

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# Three challenges

- We want to achieve allocative and productive efficiency
   (i) What is valued by patients and the public?
  - A QALY is not a QALY, some weighting is needed
  - Other health attributes matter, not captured in the QALY
  - Other non-health attributes linked to health gain also matter
  - (ii) What is the opportunity cost? (maybe we call it *k*)
  - What is given up at the margin if a new technology is introduced?
  - What should be given up at the margin? (iii) Is the system technically efficient?
- We don't have very much information about all three of these. Let us focus on (i) and (ii)



#### What is valued by patients and the public? The inevitability of multiple criteria in HTA decision making

- Cost effectiveness is not NICE's only consideration in the current situation
- NICE's social value judgment documents outline the way in which considerations other than cost effectiveness are taken into account as well as the threshold 'range'.
  - End of Life Guidance (January 2009).
  - Criteria noted by Rawlins et al (2009):Severity of underlying disease; End of life treatments; Stakeholder persuasion; Significant innovation; Disadvantaged populations; Children
- NICE acts as an 'agent' for the NHS
  - NHS decisions seldom based exclusively (or at all) on cost per QALY (Appleby et al 2009).
  - DH decisions admissive of a much wider notion of 'benefit' than NICE decisions (see Shah et al 2010 analysis of DH 'impact assessments').
  - Explicit priority setting frameworks, incorporating multiple criteria, have been used in NHS decision making for a number of years (see Mullen 2004).
- Yet so far non-QALY factors other than severity /end of life have had limited impact on decisions (Shah et al 2011)
- NICE's threshold is above £30,000 per QALY but only affected by costs per QALY except in the case of cancer (Devlin et al. 2011)







What is valued by patients and the public? A continuum of approaches to the existence of multiple criteria in health care decisions

Traditionally, most for resource allocation decisions	NHS NICE; some NHS commissioning	Examples of use in priority setting frameworks; capital appraisal	Points systems for access to elective surgery
Ad hoc, informal decision making; criteria and values unidentified or remain implicit; no systematic or documented process. Not replicable.	Partly explicit, formalised process; widely varying in terms of what criteria are included and how. Often a single criteria may dominate the process. Trade-offs between criteria often not explicitly stated. Partly replicable.	<ul> <li>Predominantly explicit. A range of criteria</li> <li>identified and evidence</li> <li>used to weight each.</li> <li>Decision-aids used to</li> <li>facilitate the deliberative</li> <li>process. Where</li> <li>judgment is exercised, it</li> <li>is clearly justified and</li> <li>documented.</li> <li>Predominantly replicable.</li> </ul>	Fully explicit; formalised decision making approach; systematic and fully replicable. Use of judgement restricted.

Source: Incorporating Multiple Criteria in HTA: Methods and Processes (Devlin and Sussex 2011) http://www.ohe.org/publications/recent-publications/list-by-date-20/detail/date////incorporating-multiple-criteria-in-hta-methods-and-processes.html

# What is the opportunity cost? Martin et al (2008)

- Martin et al (2008) examined variations in NHS local purchaser spending and mortality by disease area for one year
  - concluded the "marginal" cost of a life year gained is £8,000 for circulatory disease and £13,100 for cancer;
  - with rudimentary adjustment for quality of life, this corresponds to a cost per QALY of £11,960 and £19,070.
- The statistical model has wide confidence intervals. For cancer, the 95% upper confidence limit was £23,490 per life year. Applying the authors quality of life adjustments, the upper confidence limit is £34,099 per QALY.
- The variation in local spending observed by Martin et al is considerable, and is suggestive of underlying variations in local efficiency in resource use.



# What is the opportunity cost? NIHR/MRC research

- Make best use of Programme Budget Analysis (PBA) data to inform a judgement about NHS opportunity cost
- PBA data, mortalilty data, adjust spending for 'need', tackle endogeneity using IVs, estimate QoL impact, expenditure elasticities, need to tackle uncertainty around the estimates
- Looking at low spend versus high spend by disease area to generate a production function (what can we get by spending more /lose by spending less in these areas)
- Will come up with estimates of incremental cost effectiveness by disease area
- Will also come up with an "average" effect across programmes using expenditure elasticities (i.e. what has happened to the money, not what should happen to the money)
- Very important input to our understanding of what the NHS is doing



#### What is the opportunity cost? Examples of use of MCDA in the NHS Local commissioning in East Anglia

Decision Making body	Primary Care Trust, East Anglia
	Effectiveness (QALYs)
	<ul> <li>Burden of disease</li> <li>Equity/fairness between social groups</li> </ul>
Criteria	<ul> <li>Deliverability and speed of implementation</li> </ul>
	Engagement of public and professionals in demand management
	<ul> <li>Acceptability to public and professions</li> <li>Containty (quality of avidence)</li> </ul>
	<ul> <li>Fit with national standards/targets</li> </ul>
	Criteria chosen at independently facilitated workshop with PCT managers + GPs
Weights	Effectiveness 23.67%; burden of disease 16.67%; equity 13.67%; deliverability 13.67%; engagement 13.00%; acceptability 7.33%; certainty 7.00%; national standards 5.00%
	Weights selected by workshop participants working in three groups, with one round of challenge and reweighting, and final weight = mean of groups' weights
Use in decision making	Pilot scheme to test applicability to ranking priorities of incremental claims on PCT's budget. Diagrammatic comparison of benefit points and cost per patient to inform decision, but not to make the decision

#### What is the opportunity cost? PCT decision making: Appleby et al (2009)

#### Table 2

Nine NHS services, the nature of decision made in respect of them, and results from an investigation of the cost effectiveness of each.

Service area	Nature of decision	CQG
1. Hysterectomy for heavy menstrual bleeding	Discontinued	No relevant CQG as surgical option dominated by alternative pharmaceutical interventions
2. Surgery for mild/moderate Varicose veins	Discontinued	No relevant CQG as implication that 'mild/moderate' dominated by alternatives of conservative management and sclerotherapy. However, decision
		implies continuation for 'severe' varicose veins, at a reported CQG of £1,936
3. Cochlear implants	Introduced	Reported CQG: £10,341
4. 'Routine' inguinal hernia repair	Discontinued/'managed access'	Detailed nature of restriction unclear. Unable to estimate CPQG.
5. Cataract surgery for patients with good visual acuity	Discontinued	This intervention for 'good visual acuity' (presumed to be 6/12) dominated, therefore no CQG can be calculated
6. Cholecystectomy for	Discontinued	Clinical consensus that intervention confers no clinical
non-symptomatic gallstones		benefit. Intervention dominated and hence no CQG can be calculated
7. Chlamydia screening	Deferred	No clear evidence on CQG, 'widely believed to be very cost effective'
8. Carotid endarterectomy for asymptomatic carotid stenosis	Possible discontinuation/'managed access'	Weak evidence, but CQG could be in the range: £5,000 to £30.000
<ol><li>Cognitive therapy for management of chronic pain.</li></ol>	Possible discontinuation/'managed access'	UK evidence lacking; no reasonable estimate of CQG could be made

# A way forward for the UK as a single payer system

- How should the NHS proceed?
  - With caution.
- (i) At a local level use of MCDA/ PBMA.
- (ii) Nationally NICE needs to look at clinical guidelines, disinvestment, use of MCDA to support TA decision making.
- (iii) Work needs to be done on the non-QALY opportunity cost elements. And on the cost-per-QALY.
- (iv) the threshold NICE uses needs to evolve rather than be revolutionised.
- There is a problem of legitimacy if the public is willing to pay more for a QALY than is NICE
  - an index of strain on NICE  $1 \left(\frac{k}{-1}\right)$



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