

Is the QALY a Necessary Evil?

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Outline of Presentation

- Some background.
- What's good about the QALY?
- What adjustments are required to QALYs?
- Are there suitable alternatives to QALYs?
- What are the issues we have to resolve, QALYs or no QALYs?

Some Background

- The QALY has been the favoured outcome measure for most health economists for 30 years.
- It is recommended in several sets of economic evaluation guidelines (eg Washington Panel, CADTH, NICE).
- Recently, the IQWiG guidelines, and possibly others, reject QALYs.
- NICE has departed from standard QALY methodology in its supplementary guidance for 'end of life' therapies.

NICE's Most Recent Controversy

- In August 2008, NICE published its Appraisal Consultative Document on four new drugs for treating advanced renal carcinoma: *bevacizumab*, *sorafenib*, *sunitinib*, *temsirolimus*.
- It recommended that none of the four drugs should be used in the NHS on the grounds that they were not cost-effective.
- Oncologists and patient organizations were outraged, since these drugs are widely used in many other countries and offer benefit to patients for whom no other effective treatments are available.

Independent Evaluation of Drugs for Advanced Renal Carcinoma (First-line Treatments for Patients Suitable for Immunotherapy)

<i>Drug Comparison</i>	<i>Cost</i>	<i>QALYs</i>	<i>Cost/QALY</i>
Sunitinib <i>versus</i> IFN-alpha	£31,185	0.44	£71,462
Bevacizumab <i>added to</i> IFN-alpha	£45,435	0.27	£171,301
Temsirolimus <i>versus</i> IFN-alpha*	£22,272	0.24	£94,385

(* patients with poor prognosis)

Source: NICE, 2008

Supplementary Guidance for 'End of Life' Therapies

- **If the therapy:**
 - is for a small patient population with life expectancy of less than 24 months;
 - where no equivalent therapy exists;
 - where the therapy adds three months or more to life expectancy.
- **Then:**
 - the QALYs gained should assume full quality of life in the added months;
 - in addition the Committee can consider that the QALYs gained should be weighted sufficiently high for the therapy to be approved given NICE's current threshold.

What are the Desirable Features of the QALY Approach?

- Acknowledges that there are multiple outcomes from interventions, impacting on length and quality of life.
- Explicitly incorporates value judgments from individuals about health outcomes.
- Models benefits and costs of interventions over time.
- Has an explicit decision rule.

Issues Arising from the Use of the QALY Approach

- Methodological issues
- Policy issues

Methodological Issues

- Different measurement approaches (for estimating health state preference values) give different answers.
- Different 'generic' instruments give different estimates of QALYs gained.
- Several key assumptions of the QALY (ie constant proportional trade-off, additive independence) clearly do not hold.

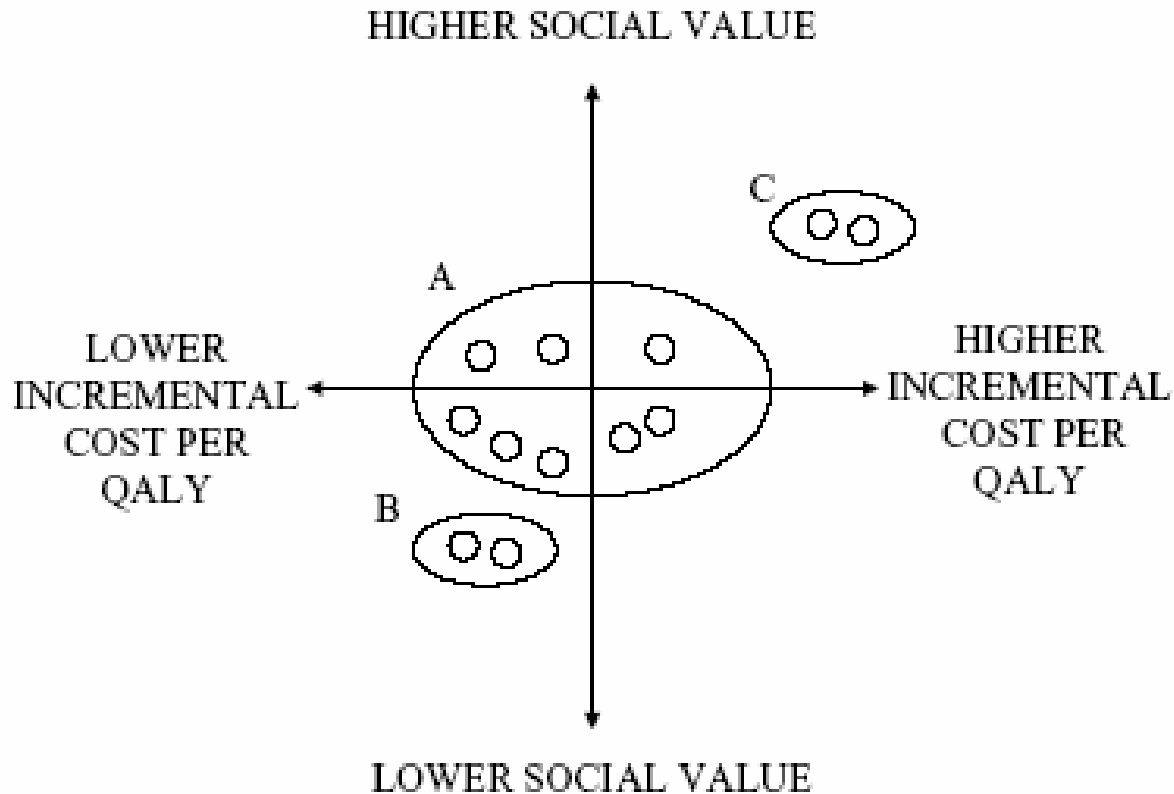
Policy Issues

- If the concern is social value, it is not at all clear that equal weighting of QALYs across individuals is the preferred approach.
- Judgments of value for money are either linked to past funding decisions, or made based on an arbitrary threshold.
- The ICER does not tell us about the opportunity cost of adopting the new technology
(Birch and Gafni; 2006).

Factors Considered Alongside Cost-Effectiveness

- Lack of, or inadequacy of, alternative treatments.
- Seriousness of the condition.
- Affordability from the patient perspective.
- Overall financial implications for government.
- Equity objectives.

The Relationship Between Social Value and Incremental Cost Per Quality-Adjusted Life-Year (QALY)



So What Do We Do?

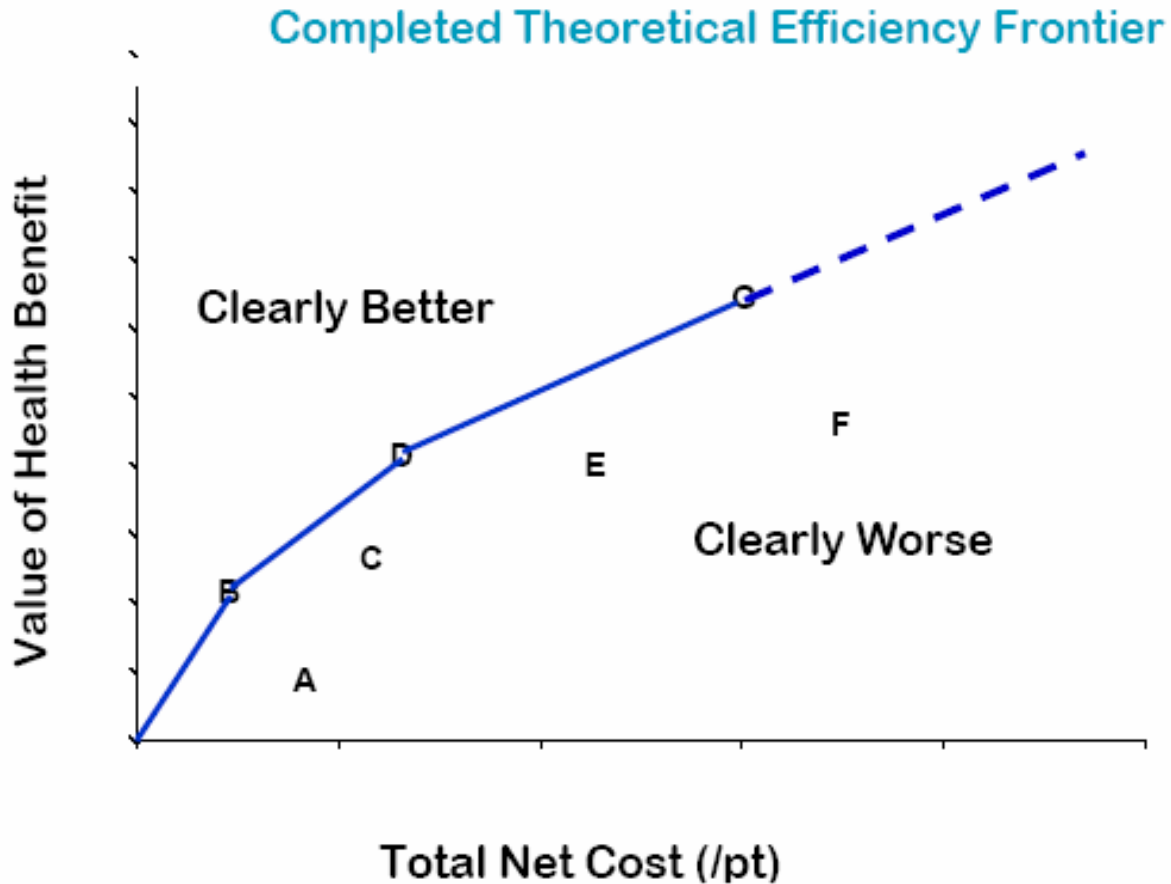
- Develop a series of distributive weights for QALYs?
- Establish a 'deliberative' decision-making process to incorporate other relevant factors (beyond the incremental cost per QALY)?
- Establish a stronger basis for cost-effectiveness threshold(s)?
- Encourage more transparency and public debate about healthcare resource allocation decisions?

Alternatives to QALYs

- Perform a 'cost-consequences analysis' and leave the rest up to the decision-maker.
- Use contingent valuation or discrete choice experiments.

IQWiG's Efficiency Frontier

Source: IQWiG 2008



Issues Apparently 'Avoided' by IQWiG's Approach

- Assumptions about the link between clinical outcomes (as observed in trials) and long term health benefit (as modelling is not necessary required).
- Relative valuations of states of health.
- Specification of a 'threshold' of willingness-to-pay.
- Explicit discrimination between patient groups.

Key Issues Raised by IQWiG's Approach

- Consideration of all relevant alternatives.
- Dealing with multiple health outcomes.
- Reliability of clinical measures for predicting long-term health benefit and value.
- Implicit valuation of health outcomes.
- Relationship between efficiency and equity.

Consideration of all Relevant Alternatives

- Efficiency frontier approach is good for eliminating 'dominated' alternatives.
- Selection of alternatives can change the shape of the frontier.
- Data limitations may inhibit the calculation of the frontier for 'older' interventions.
- The most critical choice appears to be that of the last intervention on the frontier, prior to the new intervention.

Reliability of Clinical Measures for Predicting Long-Term Health Benefit and Value

- A problem for all approaches to economic evaluation.
- Typically a model is used to project long-term outcome, using a mixture of trial-based and observational data.
- Often it is important to recognize non-linearities in the relation between short-term and long-term outcomes.
- In the IQWiG approach will future benefits be sometimes ignored, or 'modelled' implicitly?

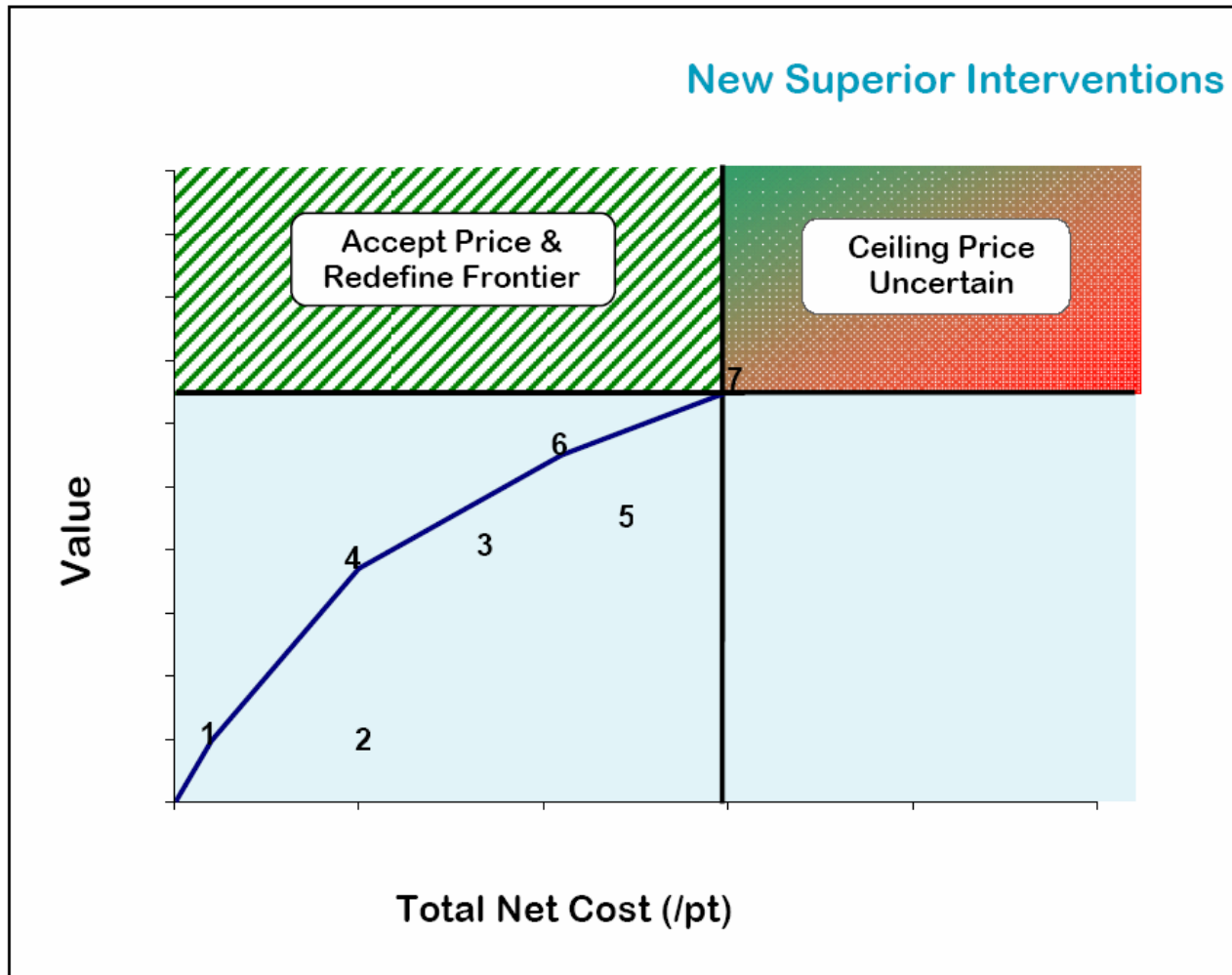
Implicit Valuation of Health Outcomes

- Explicit ‘thresholds’, like that used by NICE, have been criticized.
- Also, it is clear that a threshold range is required.
- In making a decision about a ceiling price for a new drug, IQWiG will implicitly be setting a threshold willingness-to-pay for additional value.

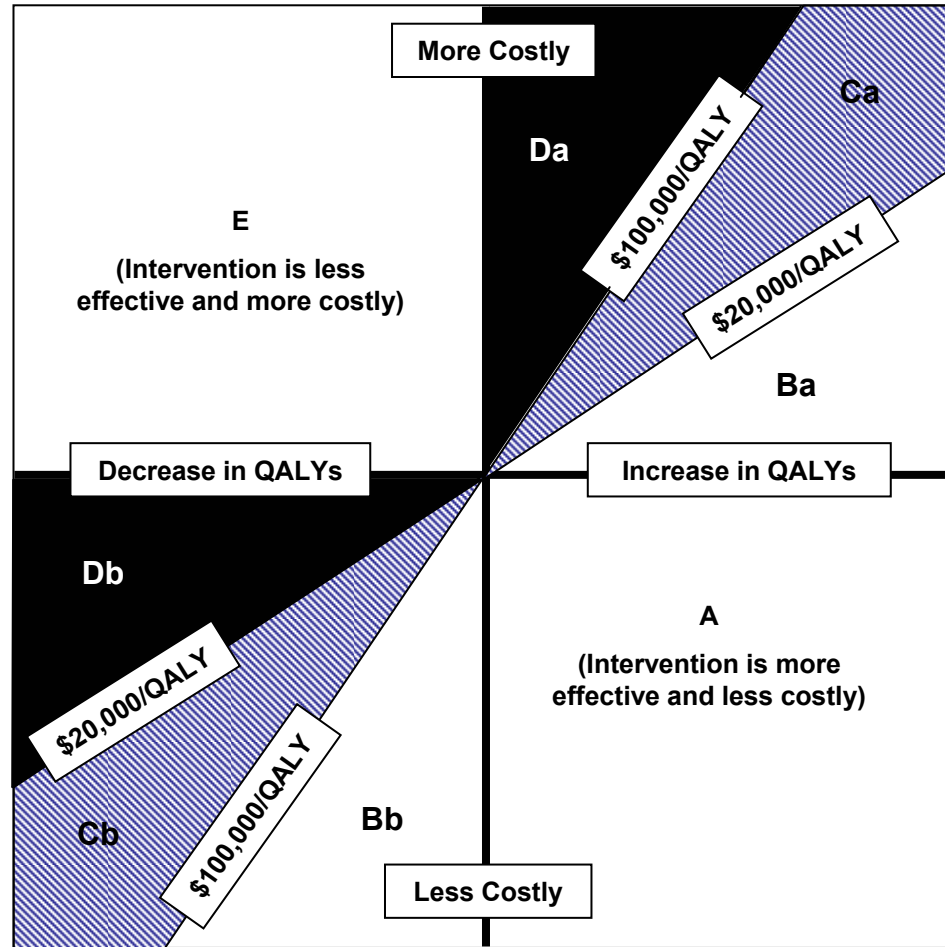
IQWiG's Efficiency Frontier:

Decision zones above the superiority boundary

Source: IQWiG 2008

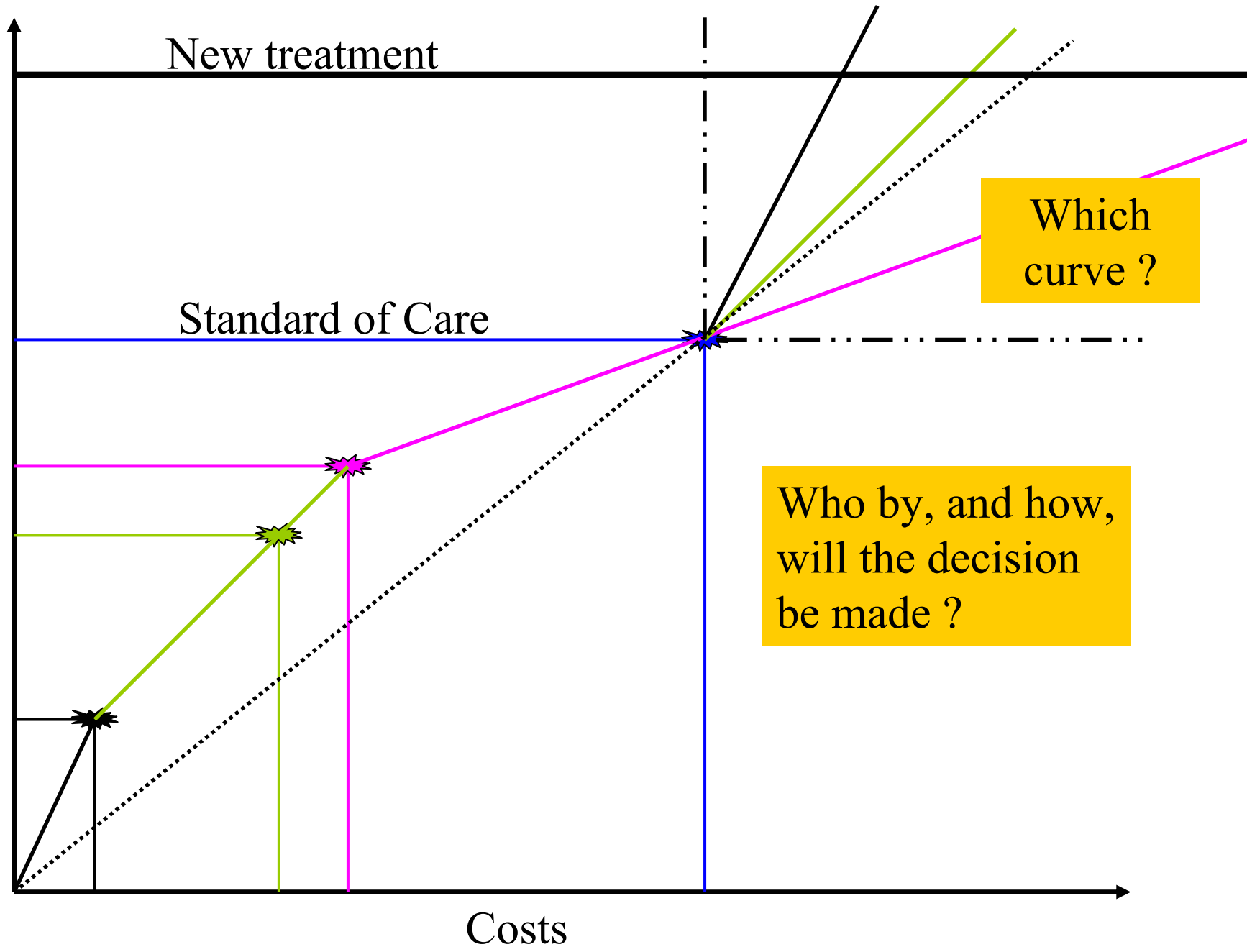


The Cost-effectiveness Plane



Ontario Cost/QALY criteria

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New treatment

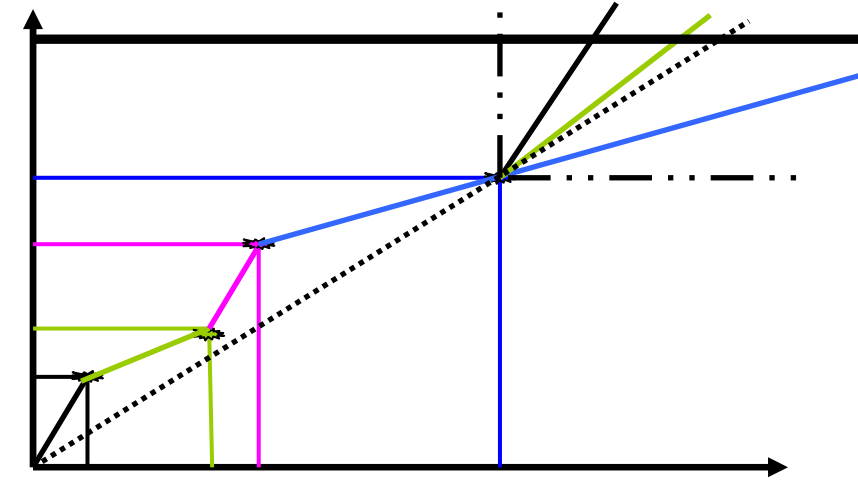
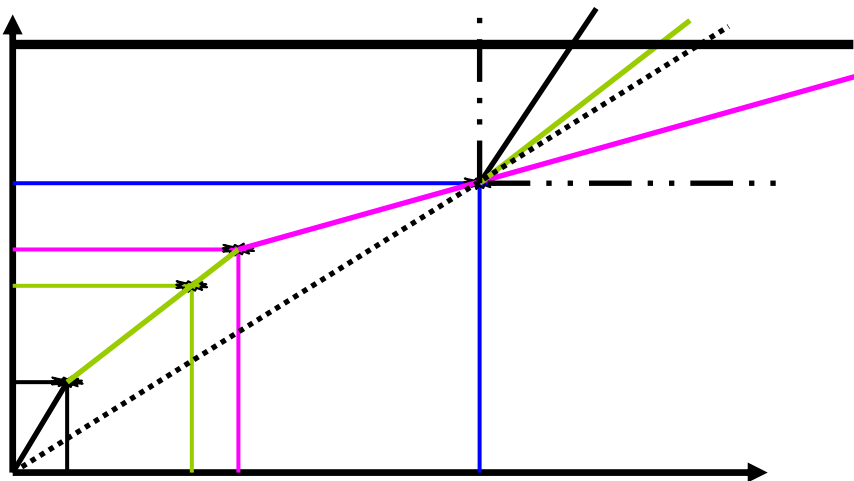
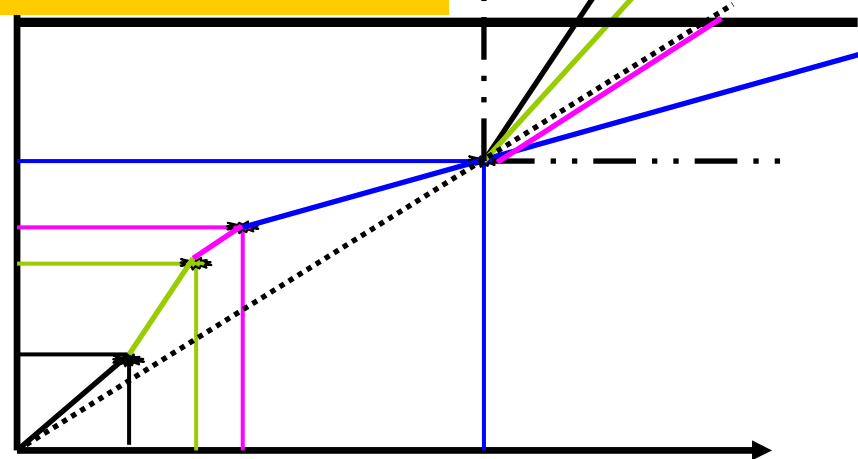
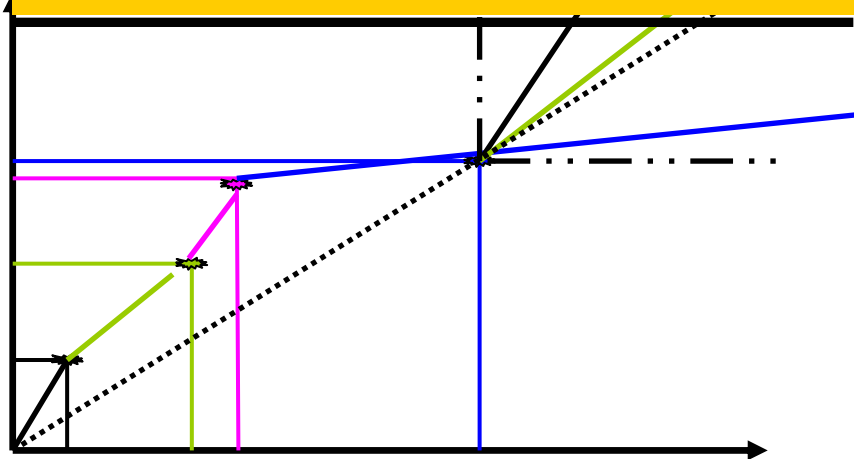
Standard of Care

Which curve ?

Who by, and how, will the decision be made ?

Costs

And what decision, when more than one outcome is relevant ?



Issues We Need to Resolve: QALYs or No QALYs

- Trade-offs among multiple outcomes.
- Projections of long-term benefit.
- Discrimination among different patient groups.

How is IQWiG's Approach Discriminatory?

- As recommendations are made independently in different disease areas, it is likely that the implied amount paid for a unit of health gain (eg a year of life gained) will differ between diseases
- The willingness-to-pay for more health benefit is likely to be determined largely by the slope of the line between the last two drugs on the frontier
- As in the case of NICE, the recommendations from the assessment are accompanied by a deliberative decision-making process

When Are QALYs Useful?

- If you have a 'hard' healthcare budget constraint
- If you feel that the health gain from treatments is a useful starting point for discussing resource allocation
- If you value explicitness in healthcare decision-making

Is There Convergence at Last?

- ***NICE***
 - adjustments to QALYs for end-of-life therapies.

- ***IQWiG***
 - modeling of costs and outcomes over the same time horizon;
 - combination of outcomes (aka QALYs) within therapeutic areas.

The Future for Europe?

NICE  **QWiG**

Conclusions

- The challenges to QALYs posed by the IQWiG guidelines should be taken seriously.
- Advocates of the 'standard' QALY approach suggest that ,while adjustments are required, it is not immediately obvious what these should be.
- Other approaches to resolving resource allocation decisions raise their own challenges and more experience needs to be accumulated.