

# Is the QALY a Necessary Evil?

Michael Drummond  
Centre for Health Economics,  
University of York

# 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)

| <b><i>Drug Comparison</i></b>         | <b><i>Cost</i></b> | <b><i>QALYs</i></b> | <b><i>Cost/QALY</i></b> |
|---------------------------------------|--------------------|---------------------|-------------------------|
| 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.

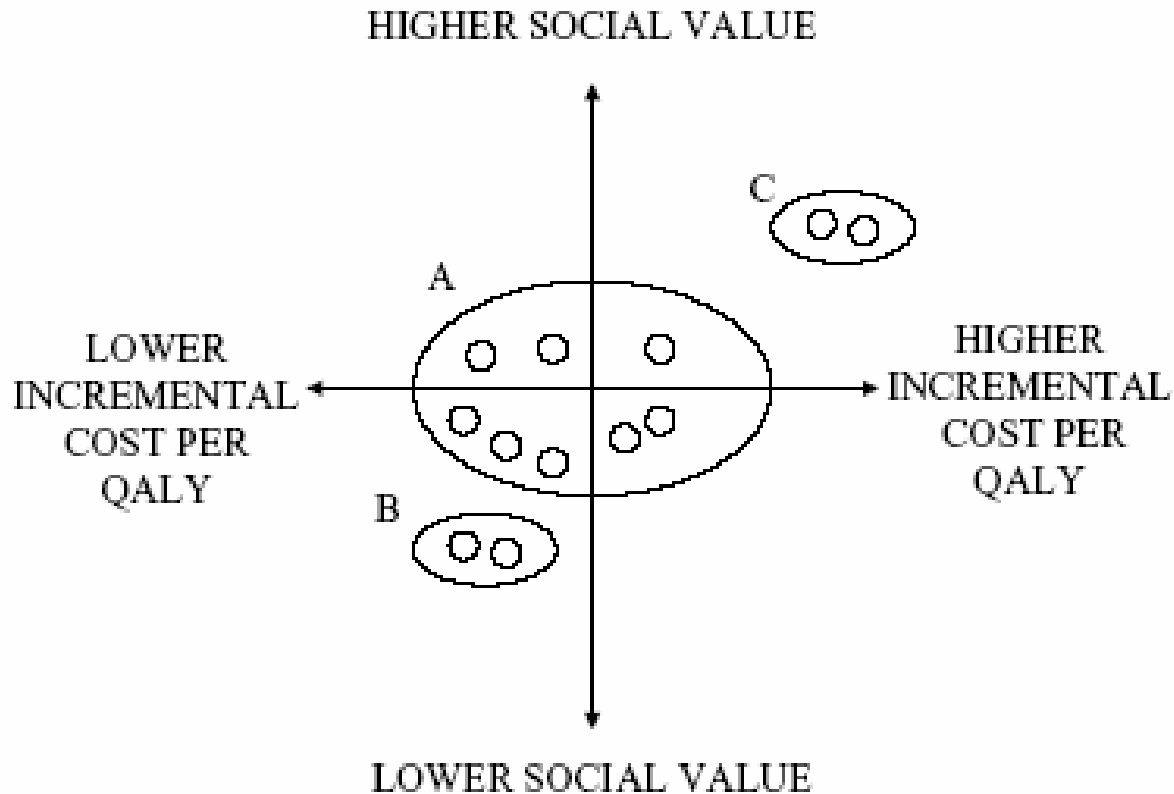
# Policy Issues

- 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?

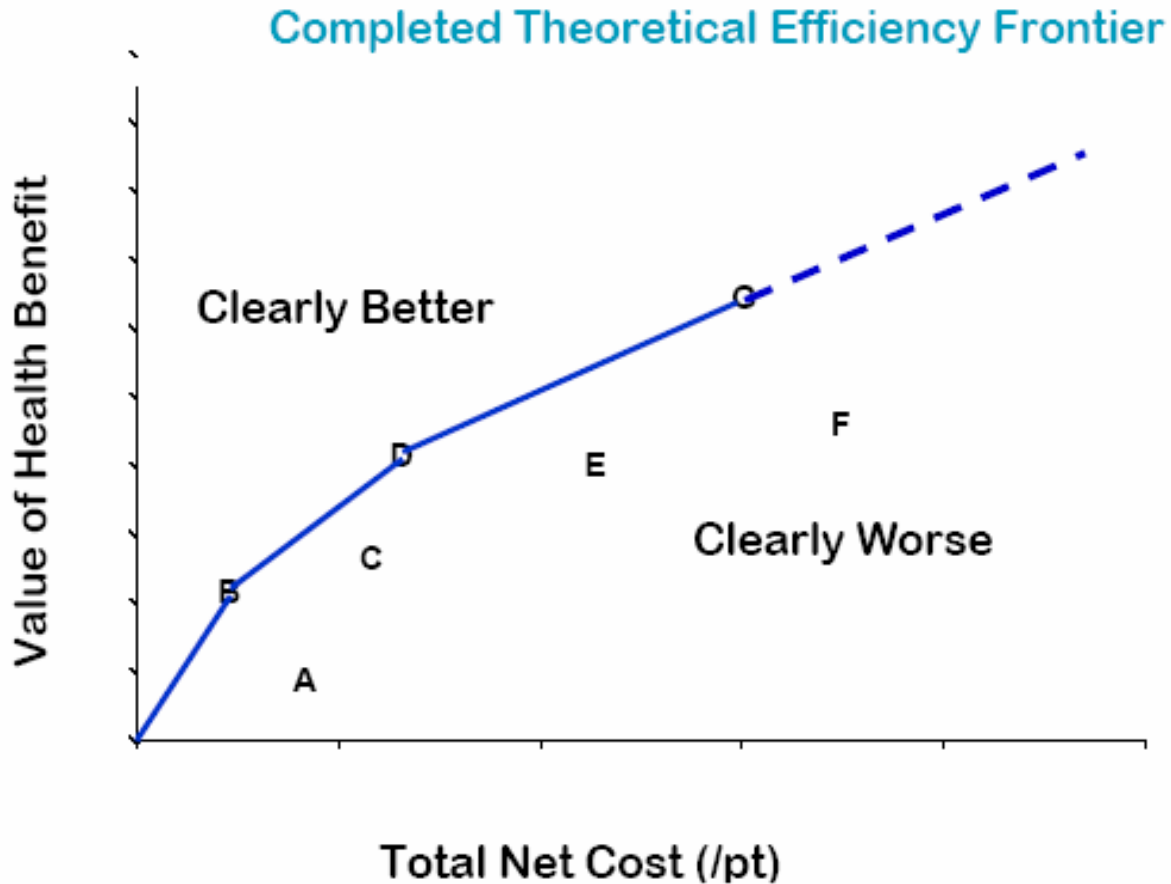
- Develop a series of distributive weights for QALYs?
- Establish a 'deliberative' decision-making process to incorporate other relevant factors (beyond the incremental cost per QALY)?
- Establish a stronger basis for cost-effectiveness threshold(s)?
- Encourage more transparency and public debate about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

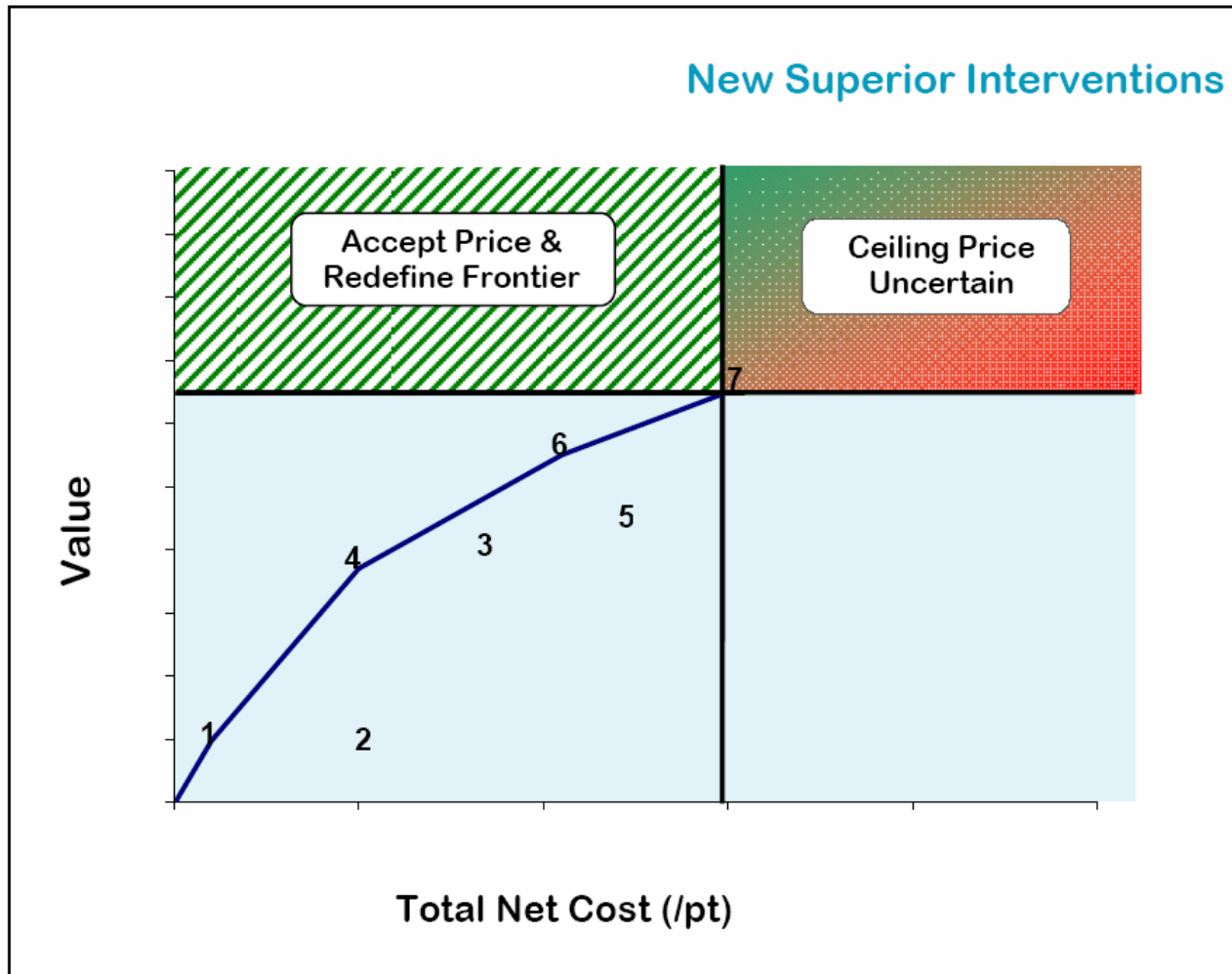
# Implicit Valuation of Health Outcomes

- 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.

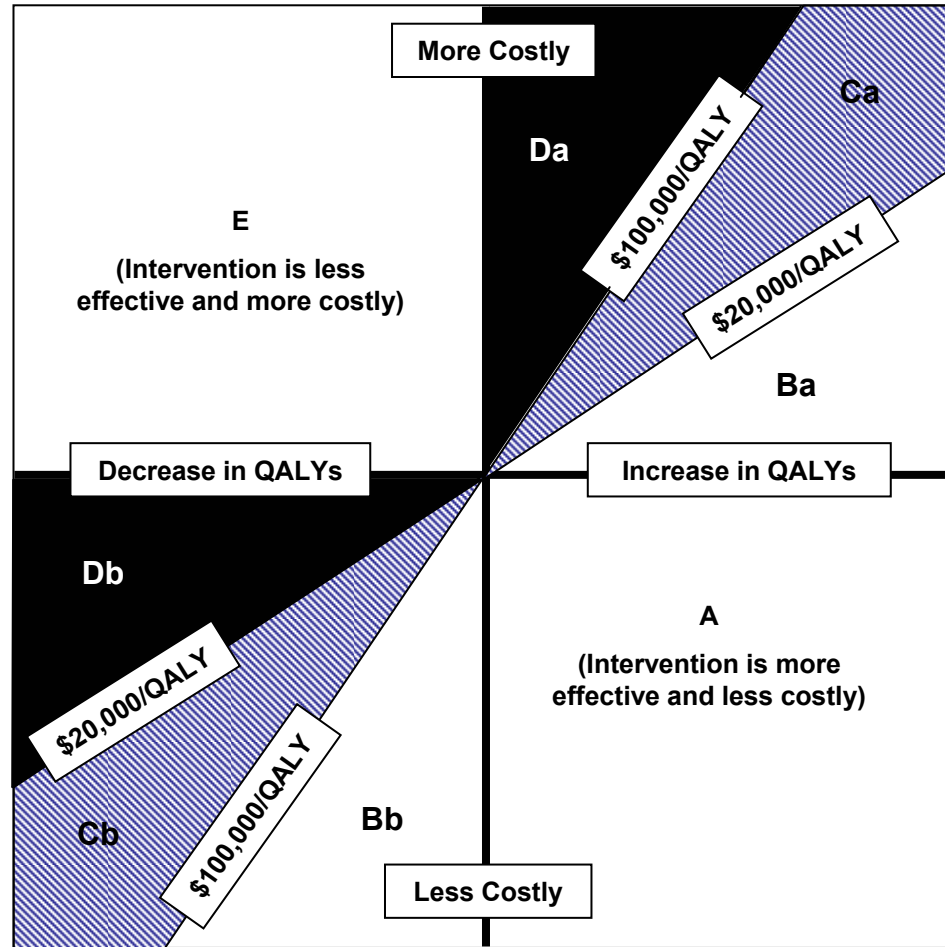
# IQWiG's Efficiency Frontier:

Decision zones above the superiority boundary

Source: IQWiG 2008

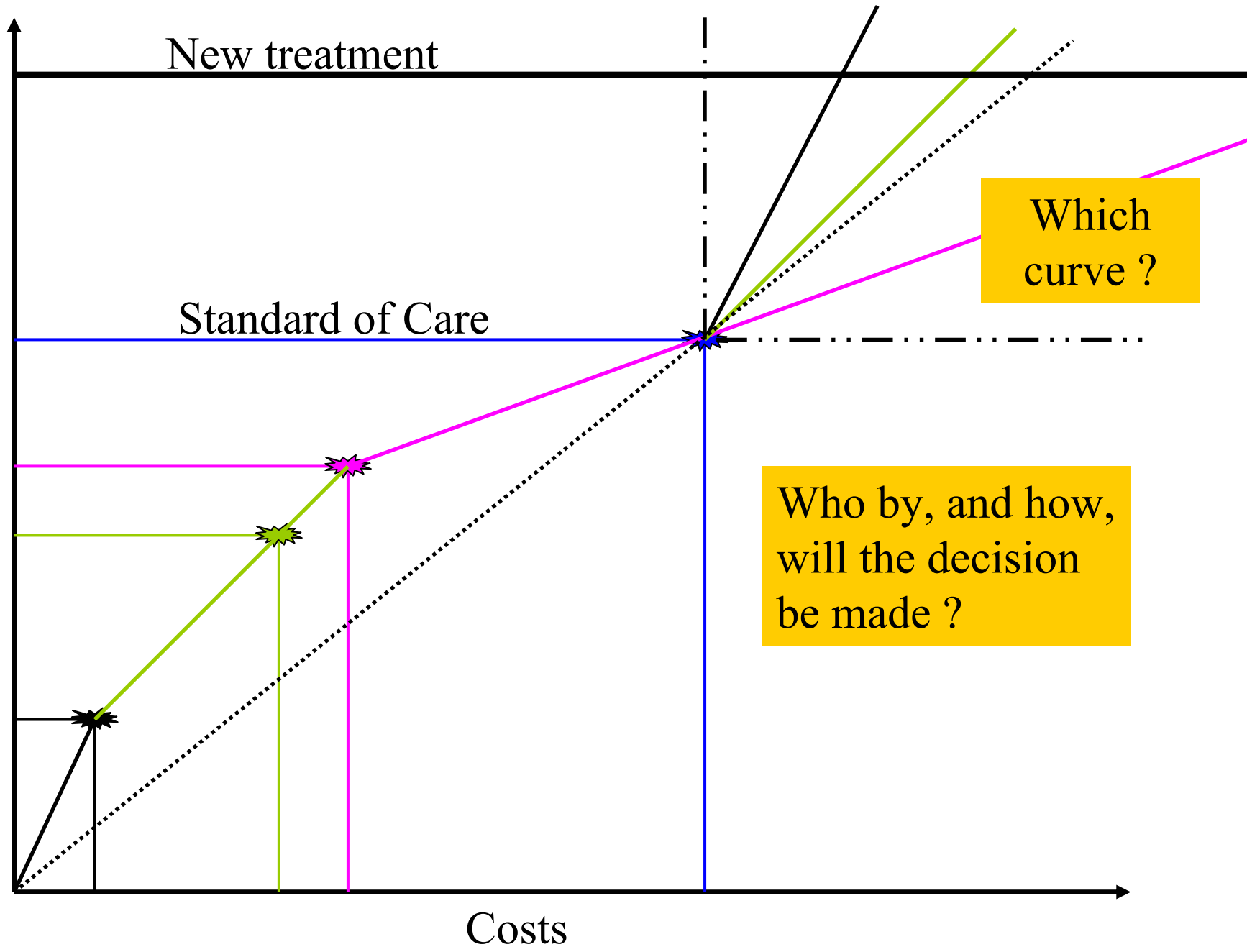


# The Cost-effectiveness Plane



Ontario Cost/QALY criteria

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New treatment

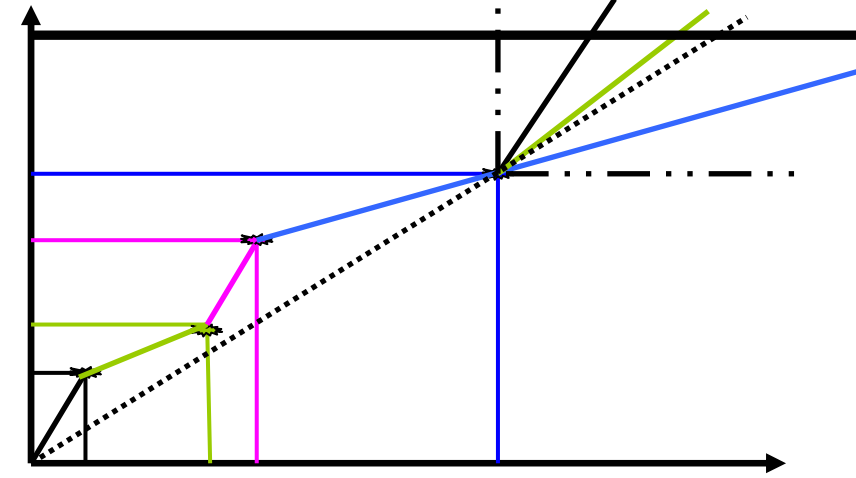
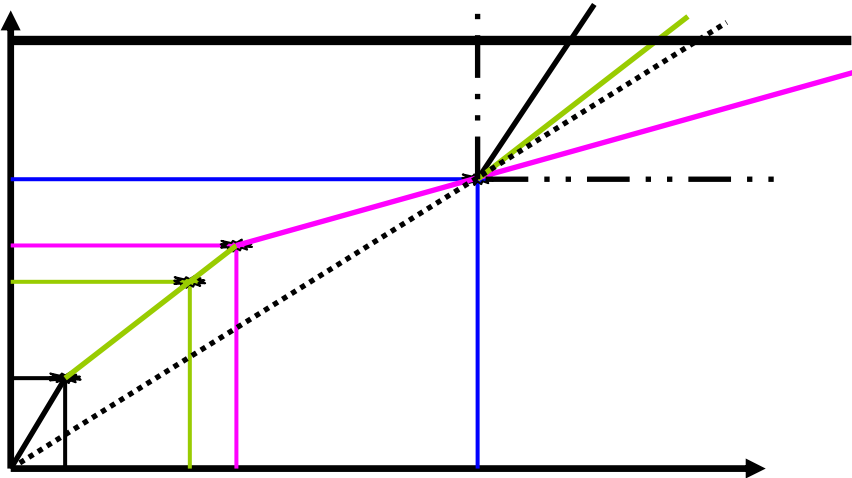
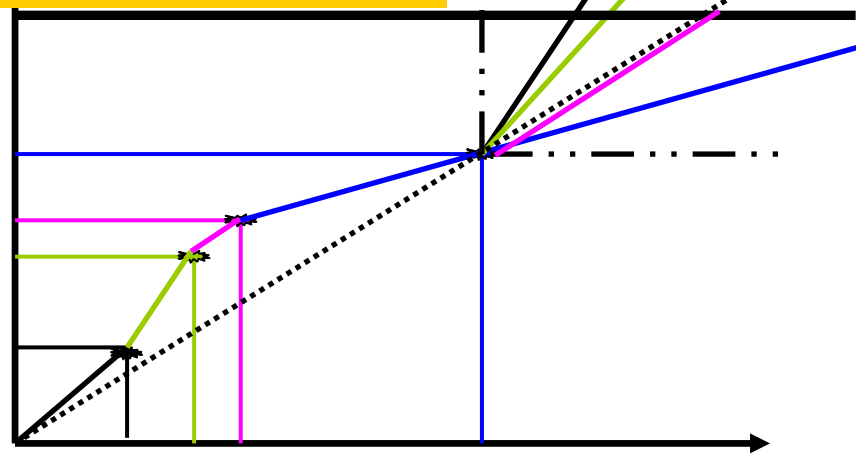
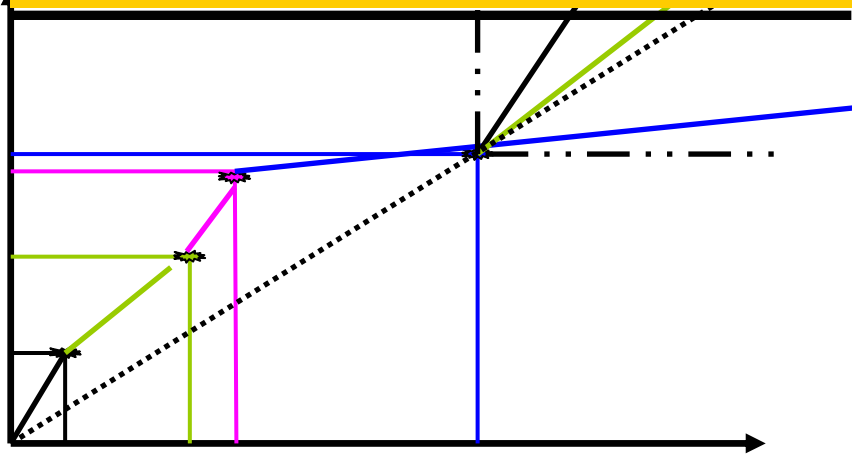
Standard of Care

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.