Minimizing Cost
per Quality-Adjusted Life Year Gained?

Contribution to Issue Panel:

"The Controversial Role of Cost Effectiveness Analyses
and Incremental Cost Effectiveness Ratio (ICER) Thresholds
in Value-Based Assessments of Health Technologies:

What are the Future Challenges?"

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ISPOR 20th Annual International Meeting, Philadelphia, PA, May 19, 2015

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Prevalent Unease with Thresholds

for example:

HTA Agencies

¬ NICE (England): end-of-life treatments, ultra-orphans

¬ TLV (Sweden): adjustments for severity

Research-Based Biopharmaceutical Industry

¬ Barrieres to access

¬ Innovation (and dealing with uncertainty)

Payers

¬ NHS England: Cancer Drugs Fund

¬ Thresholds actually too high?

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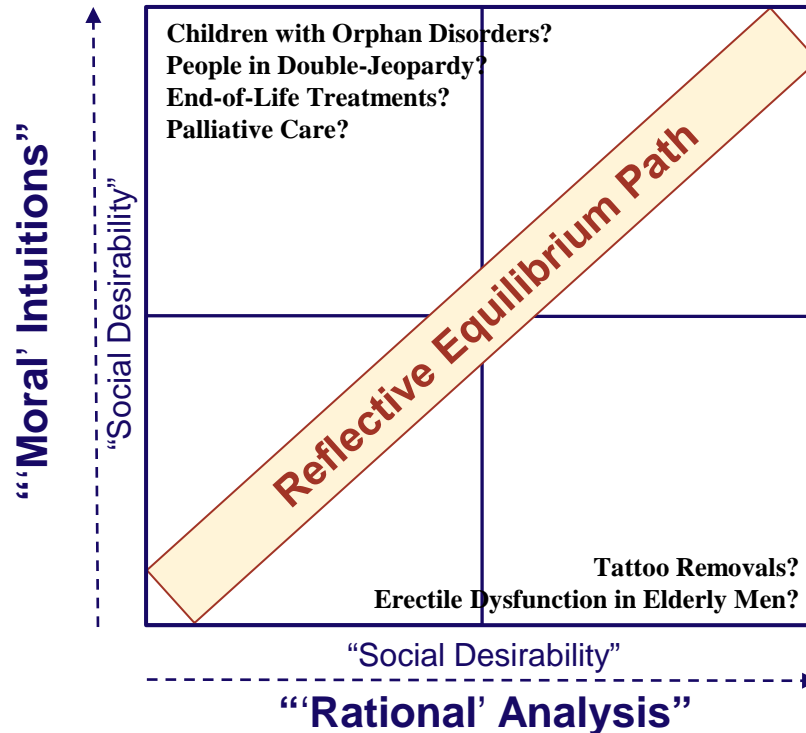
A Fundamental Premise

"Social Desirability of an Intervention is Inversely Related to its Incremental Cost per QALY Gained"

but this assumption may create **Reflective Equilibrium** issues:

¬ Sildenafil for elderly diabetics with erectile dysfunction

¬ Removal of Tattoos

compared to

¬ Palliative Care,

¬ Interventions for people with comorbid conditions
(in "Double Jeopardy", like the chronically disabled)

¬ Orphan Medicinal Products (OMPs) for (very) rare disorders

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Reflective Equilibrium

"Moral' Intuitions"

"Social Desirability"

Children with Orphan Disorders?
People in Double-Jeopardy?
End-of-Life Treatments?
Palliative Care?

Reflective Equilibrium Path

Tattoo Removals?
Erectile Dysfunction in Elderly Men?

"Social Desirability"

"'Rational' Analysis"

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Key Assumptions of the Conventional Logic:

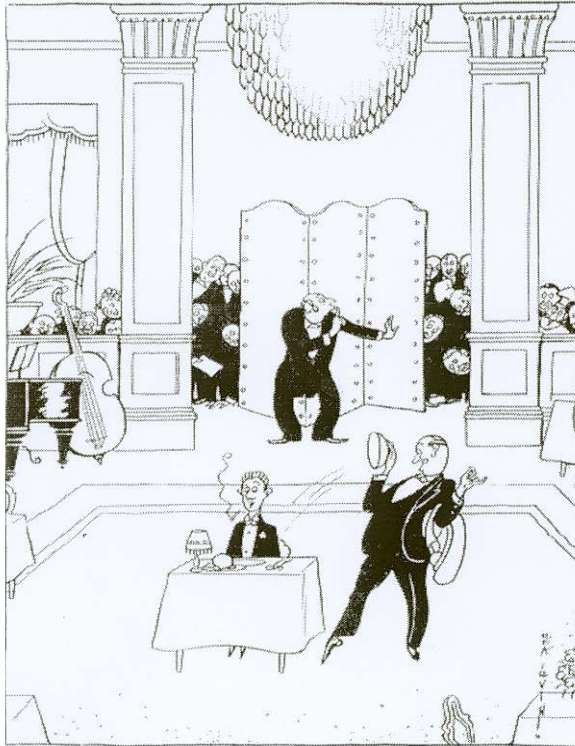## Quality-Adjusted Life Years (QALYs)

¬ (fully) capture the value of health care interventions;

¬ are all created equal ("A QALY is a QALY is a QALY…").

Maximizing the number of QALYs "produced"

¬ ought to be the primary objective
of collectively financed health schemes,

¬ leading to the concept of thresholds (or benchmarks)
for the maximum allowed cost per QALY gained.

Decreasing cost per QALY

¬ implies increasing social desirability of an intervention.

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THE QALY THRESHOLD SURPRISE

Source of cartoon: THE NEW YORKER 1925

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What's Wrong with the Conventional Logic?

Efficiency and effectiveness

¬ by definition, "efficiency" is a secondary or instrumental objective,

¬ whereas the "effectiveness" criterion
invariably represents the **primary objective**.

Static efficiency

Need to distinguish between

¬ technical efficiency,

¬ productive efficiency,

¬ allocative efficiency.

Dynamic efficiency

¬ is more difficult to capture and (therefore?) often ignored.

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Social Norms and Preferences

A Broad Range of Empirical "Non-Selfish" Preferences
indicating objectives apart from simple QALY maximization:

Prioritization criteria supported by empirical evidence include

¬ **severity** of the initial health state,

¬ **urgency** of the initial health problem,

¬ **capacity to benefit** of relatively lower importance,

¬ certain **patient attributes**,

¬ a strong dislike for "**all-or-nothing**" resource allocation decisions,

¬ **rights**-based considerations.

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Three Areas of Concern

Normative Reasons for Concern

¬ (Quasi) Utilitarian "efficiency-first" framework, implying

¬ distinct difficulties to incorporate rights-based reasoning.

Empirical Reasons for Concern

¬ Studies overwhelmingly indicate that the majority of people do not wish QALY maximization, and suggest

¬ a wide range of social preferences (other than QALY maximization).
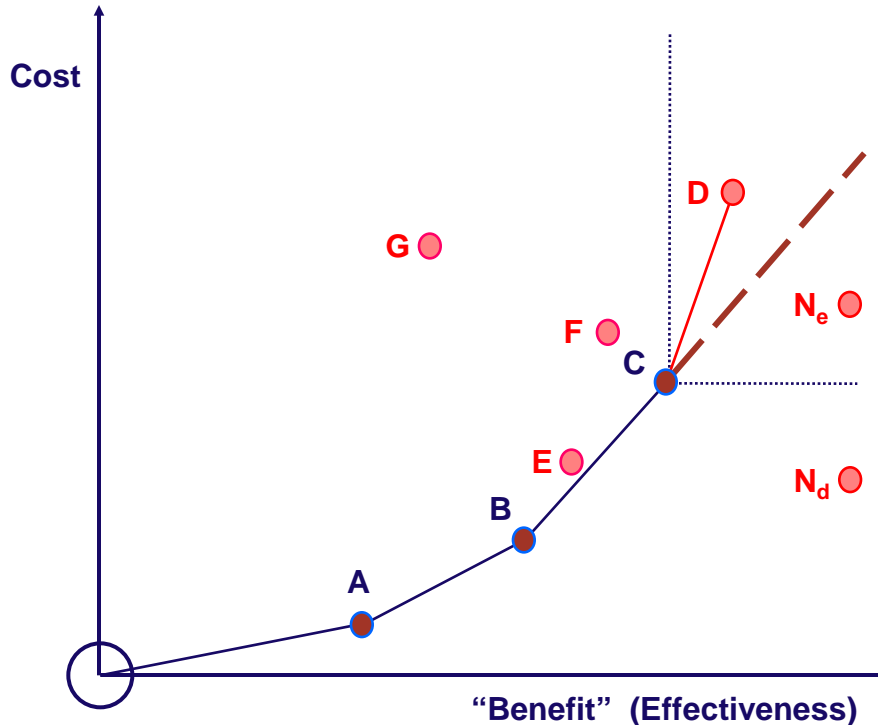
Methodological Reasons for Concern

¬ Valuation results (for VSL / QALYs, and for health state utilities alike) differ greatly as a function of the methodology chosen.

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The German Approach (IQWiG since 2008)

Focus on "Technical Efficiency"

Cost

D

G

F

N_e

C

E

B

N_d

A

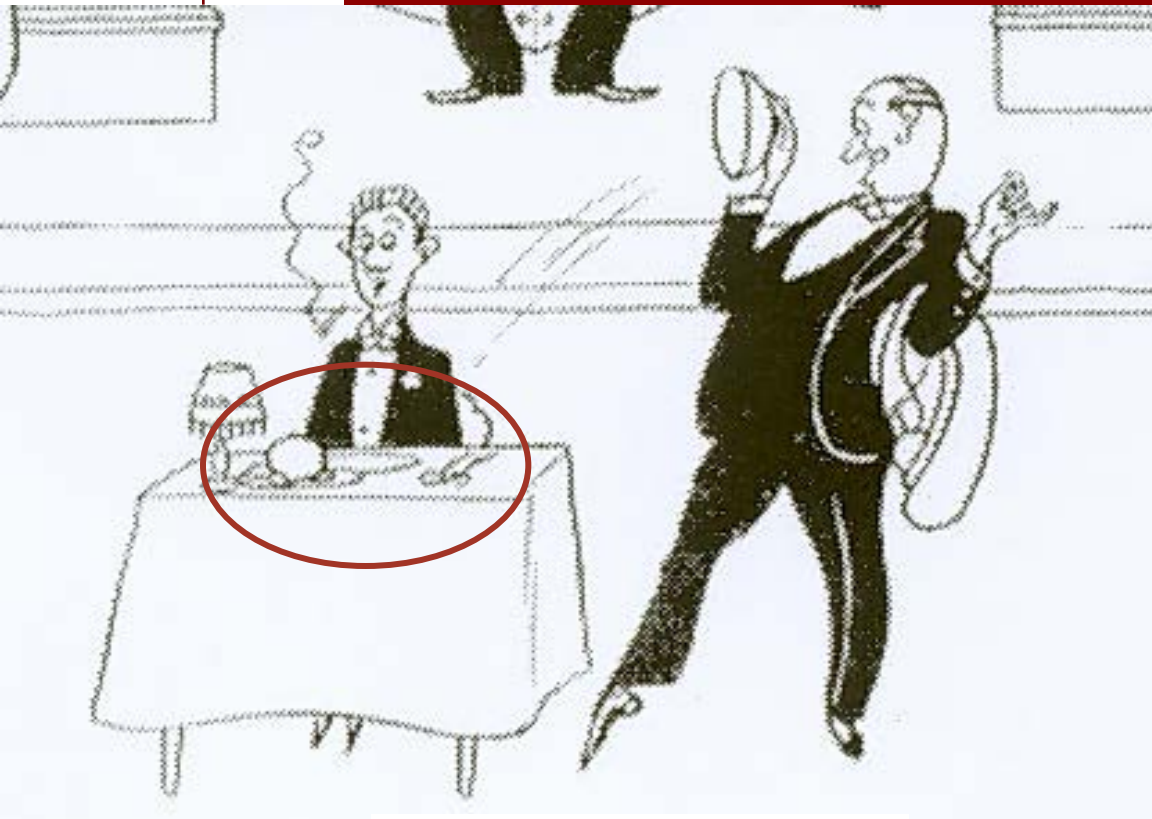"Benefit" (Effectiveness)

'Efficiency Frontier' **Analysis**

¬ **Are There Alternative Treatments**
for the Condition in Question?

¬ Which **Alternatives** Have Been Reimbursed in the Past?

¬ **Dominance**
of New Treatment "N_d"?
=> Reimbursement

¬ **Extended Dominance**
of New Treatment "N_e"?
=> Reimbursement

¬ **Issue**: Were Pricing and Reimbursement Decisions Made in the Past Justified?

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The Swiss Multi-Stakeholder Consensus

SwissHTA (since 2011):

1. **A Prior Normative Commitment**

2. **Objectives** of Collectively Financed Health Scheme
   - ¬ **Social Norms and Preferences**

3. **Efficiency**
   - ¬ **Multi-Criteria Decision Analysis (MCDA)**,
     which, in principle, might incorporate "cost utility" analysis
     with benchmarks adjusted to multiple contextual variables;

   - ¬ **Social Cost Value Analysis (CVA)**,
     a fairness-oriented framework (with far-reaching
     implications for perspectives on both costs and values),
     which, for example, might use the person-trade off
     or the relative social willingness-to-pay method.

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What are the Alternatives?

Alternative 1: "Efficiency-Only" Framework

¬ currently predominant "extrawelfarist" paradigm**?**

Alternative 2: "Efficiency-First" Framework

¬ extended by incorporating "social value judgments"

　　¬ e.g., by multiple adjustments of cost per QALY thresholds
　　　by (disorder- and/or patient-related) contextual variables**?**

Alternative 3: "Fairness-First" Framework

¬ adopting a "sharing perspective" driven by "empirical ethics"

　　¬ (relative) social willingness-to-pay as a proxy for social value**?**

　　¬ budget impact reflecting social opportunity cost**?**

Alternative 4: Rejection of Health Economic Analysis

　　¬ then, what about opportunity costs**?**

　　¬ appropriate role for multi-criteria-decision analysis (MCDA)**?**

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Some Further References

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¬ **SwissHTA**: *www. swisshta.ch*

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Thank You for Your Attention!

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