Cost-Effectiveness thresholds for access to medicines.

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Outline

• Introduction: Different use/interpretation of the value of a QALY
• Contradiction?
• Current usage and estimates of value of a QALY in Sweden
• New estimates of the value for health gain
• Discussion and suggestions
Value of a QALY in cost-effectiveness analysis

1. Encourage innovations and speed up the development of new innovative medical products

2. Costs containment, guidelines for treatment decisions

3. Price and Reimbursement decisions in VBP /HTA decisions
1. Value of a QALY, estimates

Signals to Firms and Implications for R&D Investment and Innovation

These signals inform internal project-level go/no-go decisions and the value creation process that is often modeled using traditional finance valuation methods (i.e. NPV analysis).

Source: Vernon et al. Pharmacoeconomics 2009; 27 (10): 797-806
2. Cost containment and treatment guidelines

A) Consumers choose among competing private health plans that offers different coverage (US)

B) Taxpayers choose an annual health budget through a political process (EU)

In either case the payer has a budget that is fixed in the short run and reflects consumers’/taxpayers’ expected marginal utility of spending on health care versus other consumption.

The payer set a threshold (marginal WTP for health, e.g. €30,000/QALY) and reimburses for drugs/indications that meet this threshold.
A threshold value
National Institute for Clinical Excellence (NICE) and its value judgments

A = £5,000-£15,000/QALY
B = £25,000-£35,000/QALY

Probability of rejection

Source: Rawlins & Culyer, BMJ 2004
3. Value Based Pricing (VBP)
Costs per QALY gained

QALY = Quality Adjusted Life Year

**Incremental Cost-Effectiveness Ratio (ICER):**

\[
\text{ICER} = \frac{\text{Costs treatment A} - \text{Costs treatment B}}{\text{QALY treatment A} - \text{QALY treatment B}}
\]

Price and reimbursement can be justified if ICER is below/above the threshold

Maximum VBP of a drug is the sum of cost offsets and the incremental health gain (priced at the threshold)
Do we have a contradiction?

County councils/Regions are responsible for budgets and need thresholds for cost containment

The state, TLV and Socialstyrelsen (NBHW), do not have budget responsibility:
- TLV is responsible for VBP and need to understand individuals valuation of health to make informed decision-making on drug prices
- Socialstyrelsen (NBHW) use information on the value of health for ranking treatment procedures and understand their budget implications
Empirical estimates of the value of a QALY and value of risk reductions in the transport economics
Cost-effectiveness thresholds/value per QALY in health care decision-making?

**Societal perspective**

\[ P_H = \text{Consumption value of health} \]

- **Sweden:** €100,000
- **Netherlands:** €80,000

**Budgetary perspective**

\[ K = \text{Marginal cost-effectiveness of current spending in the health care system} \]

- **England NHS:** £13,000 (€17,700)
- **Netherlands:** €41,000
- **Spain:** €22,000-€25,000

Value of a QALY in Value Based Pricing (VBP) in Sweden, TLV (the Dental and Pharmaceuticals Benefits Agency) 2018

No official threshold value per QALY in Sweden

However there are some reference points:

– About €100,000 from the transport sector
– “Three times Gross Domestic Product (x3 GDP) per capita”, proposed by WHO 2002, appr. €150,000.

Accepted value of a QALY vary by degree of “severity”
Value of a QALY (cont.)
Equity /”need” adjusted reimbursement decisions compared with a constant cost-effectiveness threshold

Cost/QALY

Average degree of severity

High degree of severity

About €100,000

About €50,000

Degree of severity/”need”
WTP for a QALY in Sweden, Value of a statistical life (VSL) in the Transport sector, official value
Trafikverket, National traffic administration

Value of a Statistical Life (VSL)
Value of a QALY = Number of Quality Adjusted life Years Lost

VSL in transport SEK 21.0 million SEK corresponds to a value of SEK 845,000 per QALY (about €100,000 per QALY in 2017 prices).

New research in Sweden increased VSL in transport to 40.5 million SEK (2018 prices)
Should we increase a QALY to SEK 2.4 million (about €240,000).
Results of new research among individuals preferences and value of health gain in Sweden

- VSL SEK 40.5 million, corresponds to SEK 2.4 million per QALY, n=880. ASEK/Trafikverket. Based on Olofsson S et al WTP for reduced risk for fatal and non-fatal casualties in traffic accidents, IHE Report 2016:7


- Dread and risk elimination premium for the value of a statistical life, n=500 age 50-74. Olofsson et al Risk Analysis, Under review.
Discussion

New QALY value?

Equity /“need” adjusted reimbursement decisions compared with a constant average value of a QALY

“Average degree of severity”

Cost/QALY

Degree of severity/“need”

High degree of severity

About SEK 4 million

About SEK 2 million,
Discussion
Paradox: "Cost-effective but unaffordable"

1. **A fixed budget**: Integrate a Cost-Effectiveness threshold in the evaluation so treatments will not be acceptable if budgets are not available. The threshold can be adjusted (reduced) to fit the budget. May results in separate budgets for cancer (England), orphan drugs, new innovative pharmaceuticals, etc?

2. **A Flexible budget** and a value of a QALY based on individuals preferences for health gain.

   Additional funding for new cost-effective treatment:
   - State/Regions made an agreement of extra funding for Hepatitis C
   - Germany “Zusatzengelte” for special expensive treatment in hospitals
   - US, Switzerland, Israel; Private insurances and individualized add on payment to mandatory insurances
Discussion
Paradox: “Cost-effective but unaffordable”

European countries have developed a variety of mechanisms to improve affordability of therapies. Lessons from the introduction of the new effective Hepatitis C treatments.

England:
1. Fast track access to technologies offering exceptional value for money (likely cost per extra year of quality-adjusted life of under £10,000).
2. A budget impact test or ‘affordability criteria’ of twenty million pounds (£20million) per year as an improved way to manage treatments that are cost-effective, but have a very high cost.
3. A sliding, but increased, cost per extra year of quality-adjusted life up to £300,000 per quality-adjusted life year (QALY).

Sweden:
The health care did not have the capacity in the short term to treat all patients who could receive treatment (regardless of severity), TLV weighed into their decision that priority should be given to those with the greatest need.

Source: Flume et al. JOURNAL OF MARKET ACCESS & HEALTH POLICY 2018, VOL. 6, 1478539
Conclusions

• Value of a statistical life (VSL) and value of a health gain (QALY) are important to understand individual preferences (the demand side) and should be used for informed decision-making.

• Threshold values in terms of maximal accepted price for a VSL and QALY gain could be one instrument for cost containment/budget control. However, additional instruments are needed, e.g. ‘affordability thresholds’, price volume agreements or caps on individual product sales, and special budgets for innovative drugs.
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