Are QALYs a Relevant and Justifiable Outcome Measure for Health Economic Evaluations ?

Panelist

Ariel Beresniak, MD, MPH, PhD
CEO Data Mining International
Echoutcome Project Leader

DATA MINING INTERNATIONAL

NO

Many robust scientific evidences now exist, establishing that the QALY outcome is a flawed indicator

Arthritis & Rheumatism (Arthritis Care & Research)
Vol. 53, No. 1, February 15, 2005, pp 3–4
DOI 10.1002/art.20906

EDITORIAL

Cost-Effectiveness Analysis: Out of Touch With Clinical Reality?

ANDREAS MAETZEL

Arthritis & Rheumatism (Arthritis Care & Research)
Vol. 53, No. 1, February 15, 2005, pp 3–4
DOI 10.1002/art.20906

CONFERENCE PAPER

C
C Information Created to Evade
Reality (ICER)
AN Things We Should Not Look to for Answers

Stephen Birch[1,2] and *Amiram Gafni*[1]

1 McMaster University, Hamilton, Ontario, Canada
2 University of Manchester, Manchester, UK

Arthritis & Rheumatism (Arthritis Care & Research)
Vol. 53, No. 1, February 15, 2005, pp 3–4
DOI 10.1002/art.20906

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CURRENT OPINION

QALYs

Are They Helpful to Decision Makers?

Maurice McGregor[1] and *J. Jaime Caro*[2]

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2 Division of General Internal Medicine and Department of Epidemiology, Biostatistics and Occupational Health, McGill University, Montreal, Canada and Caro Research Institute, Boston, Massachusetts, USA

Arthritis & Rheumatism (Arthritis Care & Research)
Vol. 53, No. 1, February 15, 2005, pp 3–4
DOI 10.1002/art.20906
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CURRENT OPINION

ORIGINAL RESEARCH ARTICLE

Limitations of the Methods Used for Calculating Quality-Adjusted Life-Year Values

Gérard Duru,[1] *Jean Paul Auray*,[1] *Ariel Beresniak*,[2] *Michel Lamure*,[1] *Abby Paine*[3] and *Nicolas Nicoloyannis*[1]

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Vol. 53, No. 1, February 15, 2005, pp 3–4
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CURRENT OPINION

ORIGINAL RESEARCH ARTICLE

PERSPECTIVE

LEGISLATING AGAINST USE OF COST-EFFECTIVENESS INFORMATION

Legislating against Use of Cost-Effectiveness Information

Peter J. Neumann, Sc.D., and Milton C. Weinstein, Ph.D.

> The Patient-Centered Outcomes Research Institute . . . shall not develop or employ a dollars per quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended. The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII.
>
> — The Patient Protection and Affordable Care Act[1]

societies have cited cost-utility studies in support of clinical guidelines.

The ACA specifically forbids the use of cost per QALY "as a threshold." The precise intent and consequences of this language are unclear. One might interpret it to mean that the PCORI, or its contractors or grantees, can still calculate cost-per-QALY ratios as

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Peter J. Neumann, Sc.D., and Milton C. Weinstein, Ph.D.

Is There an International Backlash Against Cost-Utility Analysis?

Scott Ramsey, MD, PhD, 2010-2011 ISPOR President and Full Member and Professor, Fred Hutchinson Cancer Research Center, University of Washington, Seattle, WA, USA

Flawed Multiplicative Model of the QALY

QALY = quality of life (in 'utility') * number of life-years

However…

Grilling a steak for 20 minutes at 100° C

is not the same as

Grilling a steak for 10 minutes at 200°C !

The QALY Outcome Leads to Divergent Results …and Reimbursement Decisions !

QALY = Time x Temp (ºC)

- **OSLO** 2 days x 5 ºC = 10 QALY
- **BARCELONA** 1 day x 25 ºC = 25 QALY

⇒ Go to Barcelona !

QALY = Time x Temp (ºF)

- **OSLO** 2 days x 41 ºF = 82 QALY
- **BARCELONA** 1 day x 77 ºF = 77 QALY

⇒ Go to Oslo !

Use of Multiplicative Formula in Science

- **Ideal Gas Law** **PV = nRT**
  - P: pressure in pascals
  - V: volume in cubic metres
  - n: amount of substance in moles
  - R: ideal gas constant
  - T: Temperature in Kelvin
- **Electricity** **P= U I**
  - P: power in Watt
  - U: voltage in Volts
  - I: intensity in amperes
- **Relativity** **$E = m c^2$**
  - E: Energy in Joules
  - m: mass in Kg
  - c: speed of light in meters/sec
- **QALY** **QALY= Q time**
  - Q: which unit ???

ECHOUTCOME

- **Validation of tests of the QALY underlying assumptions (Pliskin, 1980)**
- **Experimentation on 1361 subjects in 4 countries**

Hypothesis H1

The standard gamble preferences of an agent, whereby lots are respectively elements of T, Z and TxZ, are Neumannian and therefore defined by interval utility functions w, v, and u, respectively

Hypothesis H2

Z and T are mutually independent utilities

Hypothesis H3

The agent is only slightly neutral to risk in probabilities on standard gambles where lots belong to T

Hypothesis H4

The agent's time-trade-off rate g is constant

Mathematical and Experimental confirmation that the QALY multiplicative model is flawed

QALY is <u>scientifically invalid</u> and should no longer be used to assist decisions in health care

ECHOUTCOME
European Commission Research Project

- **Validation of tests of the QALY underlying assumptions (Pliskin, 1980)**
- **Experimentation on 1361 subjects in 4 countries**

The standard gamble pref ts are respectively elements of T, Z and TxZ, defined by interval utility functions w, v, and u, resp

Z and T are mutually inde

The agent is only slightly standard gambles where lots belong to T

The agent's time-trade-off rate g is constant

This European commission project has firmly confirmed that the QALY multiplicative model is flawed and scientifically invalid and that the QALY should no longer be used to assist decisions in health care

ECHOUTCOME Results
European Commission Research Project

PharmacoEconomics
DOI 10.1007/s40273-014-0216-0

ORIGINAL RESEARCH ARTICLE

Validation of the Underlying Assumptions of the Quality-Adjusted Life-Years Outcome: Results from the ECHOUTCOME European Project

Ariel Beresniak · Antonieta Medina-Lara · Jean Paul Auray · Alain De Wever · Jean-Claude Praet · Rosanna Tarricone · Aleksandra Torbica · Danielle Dupont · Michel Lamure · Gerard Durn

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Abstract
Background Quality-adjusted life-years (QALYs) have been used since the 1980s as a standard health outcome measure for conducting cost-utility analyses, which are often inadequately labeled as 'cost-effectiveness analyses'. This synthetic outcome, which combines the quantity of life lived with its quality expressed as a preference score, is currently recommended as reference case by some health technology assessment (HTA) agencies. While critics of the QALY approach have expressed concerns about equity and ethical issues, surprisingly, very few have tested the basic methodological assumptions supporting the QALY equation so as to establish its scientific validity.

Objectives The main objective of the ECHOUTCOME European project was to test the validity of the underlying assumptions of the QALY outcome and its relevance in health decision making.
Methods An experiment has been conducted with 1,361 subjects from Belgium, France, Italy, and the UK. The subjects were asked to express their preferences regarding various hypothetical health states derived from combining different health states with time durations in order to compare observed utility values of the couples (health state, time) and calculated utility values using the QALY formula.
Results Observed and calculated utility values of the couples (health state, time) were significantly different, confirming that preferences expressed by the respondents were not consistent with the QALY theoretical assumptions.
Conclusions This European study contributes to establishing that the QALY multiplicative model is an invalid measure. This explains why cost/QALY estimates may vary greatly, leading to inconsistent recommendations relevant to providing access to innovative medicines and health technologies. HTA agencies should consider other more robust methodological approaches to guide reimbursement decisions.

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Utility Technical Manipulations

And Divergent Results

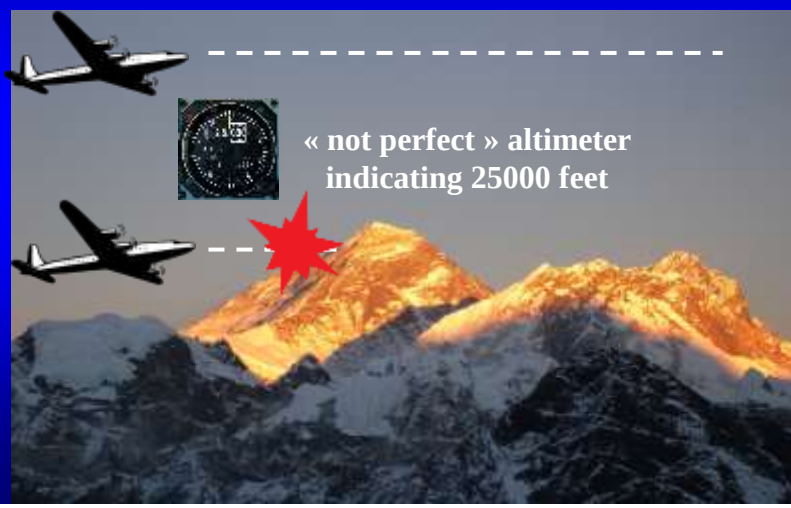
Distorsion of the research process

QALY = scientific misconduct

Serious public health implications
attached to market access decisions
based on dubious and divergent QALY findings

The QALY is « not perfect »

Would <u>YOU</u> fly in an aircraft knowing that the altimeter is « not perfect » ???



The QALY is « not perfect »

Would **YOU** fly in an aircraft knowing that the altimeter is « not perfect » ???

Do you see a better alternative for decision makers, for academia and for other stakeholders ?

Many Scientifically Robust Alternatives to QALY

- **Quantitative outcomes**
  - Cost-effectiveness analyses
  - Cost-benefit analyses
  - Cost-minimization analyses
- **Qualitative outcomes**
  - Quality of Life studies
- **Quantitative and qualitative outcomes**
  - Multi-criteria analyses
  - Logit models
  - Bayesian analyses
  - Etc.

A Lie Told Often Enough Becomes the Truth

Vladimir Lenin

- 11478 QALY references in PubMed to date
- QALY reference case in the UK, Canada & Australia
- Economic dependance of a number of academic & consultancy agencies

Abandoning QALY and adopting scientifically robust alternative methods demand courage and honesty from the health economics community