Critical comments on the use of summary measures of population health (SMPH) in health related Impact Assessment

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My Summary points

• As an epidemiologist:
  • uncertainties in estimating the „life expectancy“
  • application for individuals and for group prediction
  • discounting/tariff of life years in dependence to the Age-QoL-relationship is not a scientific task, it is an economic or political valuation of humans

• As a psychometric scientist:
  • restrictions to formulate a test instruments (questionnaire/ visual scales) resulting in a one-dimensional scale for the „Quality of life“, „Quality of the State of Health“ or „Subjective Wellbeing“ of individuals and populations.
  • weighted aggregation to one dimension is not a scientific based task, it is a valuation.
  • The LE*QoL→QALY scale as a multiplication of two different scales is neither linear, additive, consistent, reliable, neutral nor valid.
Summary points

**Ethical issues:**

- „values/discounts/tariffs“ to „the life of individuals and groups“ like adjusted DALYs are unfair against newborns, elderly and any person with disabilities (UN Convention on the Rights of Persons with Disabilities 2007).
- applying these weights is polically and legally not justifiable.
- survey or panel data (even if they are representative) should not be applied as a basis for adjusting/weighting/assessing of „life years“ against „quality of life“ for population, groups and individuals (equal rights).
Summary points

As a scientific health policy adviser:

Cost-utility-comparison and Cost-QALY–Evaluation can't be done for individuals without taking into account medical and ethical councils, patient-physician interaction and/or individual decisions

.. and in practice:

Using „generic instruments“ for economical Cost-Utility-Evaluation might result in „generic decisions“ for the allocation of resources (money, medical treatment, access to infrastructure, ..)
The 64-year-old Oregon woman, whose lung cancer had been in remission, learned the disease had returned and would likely kill her. Her last hope was a $4,000-a-month drug that her doctor prescribed for her, but the insurance company refused to pay.

What the Oregon Health Plan did agree to cover, written to her in that letter, however, were drugs for a physician-assisted death. Those drugs would cost about $50.
Consensus: Our mission

Policies and programmes to combat diseases and injuries should properly be based on current, timely information about the nature and extent of health problems, their determinants, and how the impact of such diseases and injuries is changing, both with respect to magnitude and distribution in populations.

Available from: [cited 2010-03-02]:
Descriptive Measures in Epidemiology

The Epidemiologist as an observer

- Population data
- Risk factors like age, sex and region, occupation, behaviour, social status, environment, ...
- Morbidity, Mortality, Disabilities, Health Indicators, ...

Epidemiologic measures

Incidence
*New cases per time period*
- Morbidity
- Mortality & Survival
- Remission free time
- Cumulative Incidence

Prevalence
*Number of diseases at a specific time*

State variable
Descriptive measures for the status of physical, behaviour and cognitive development, indicators for burden and function related variables
The Use of Descriptive Summary Measures
- Time, Period, Age: Cohorts and Cross-sectional Views -

Inclination
Age structure of mortality rates: Males ~ Females

Mortality over age groups / Germany 2006-2008
(Cross-sectional-approach)

Data Source for the calculations shown here: © Statistisches Bundesamt, Wiesbaden, 2009
The change of mortality in the first year of life 1871-2004

<table>
<thead>
<tr>
<th></th>
<th>Females</th>
<th>Males</th>
<th>Diff.</th>
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<tr>
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<td>82.7</td>
<td>77.6</td>
<td>5.1</td>
</tr>
</tbody>
</table>

© Statistisches Bundesamt, Wiesbaden 2006
Life expectancy

A conventional algorithm to aggregate age-specific mortality data into a single indicator
Life expectancy as a projection into the future

A Cross sectional data based prognosis

Time/Period [y]

Age [y]

- Death cases
- Healthy

Equal History?

Prognosis
LE at birth seen from cohorts and periods view

A Cohort’s „Age at Death“-Density-Distribution

given an age-sex-specific mortality and a resulting survival table

High variance = High uncertainty in prediction

Variable: Death At Age

Min: 0.00
1st Qu.: 66.00
Median: 76.00
3rd Qu.: 84.00
Max: 100.00

Mean: 73.16
Std Dev.: 15.43

Simulation with 100,000 repetitions / Males: North Germany 1994
M-F- differences in Life Expectancy LE

The result is influenced by economic and social factors

Differences between Male and Female Life Expectancy in 27-EU member states

27-EU members
Period: 2006-2008

EuroStat Data
March 2010

Ranges in LE:
77.0-84.9   Females
66.3-79.8   Males

Contrafactious to 82.5 (M) and 85 (F)
## LE in Europe

### Male and Female Life Expectancy in the 27-EU member states
- **Sorted by F-M-difference**

#### Period: 2006-2008

**EuroStat Data / March 2010**

<table>
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<tr>
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</table>
Survival,
Life expectancy
and QoL adjustment
The Use of Summary Measures of Population Health

- Comparison and evaluation of national/regional economics, economic growth and the impact of political decisions on the public health
- Allocation of restricted resources using decision-analytic approaches for prioritisation and cost-utility-approaches
The DALY is based on years of life lost from premature death and years of life lived in less than full health. There remain substantial data gaps and deficiencies, particularly for regions with limited death registration data. (p. 117)

The disability-adjusted life year (DALY) extends the concept of potential years of life lost due to premature death to include equivalent years of “healthy” life lost by virtue of being in states of poor health or disability.

“A consistent and comparative description of the burden of diseases and injuries, and risk factors that cause them, is an important input to health decision-making and planning processes.“ (The first sentence of the report, p. 2)
WHO (1984): The general model of health transition

The observed mortality and hypothetical morbidity and disability survival curves for females
United States of America, 1980

LE = AUC = LE(0) + LE(1)

$e_0^{**}$ and $e_{60}^{**}$ are the number of years of autonomous life expected at birth and at age 60, respectively.
$M_{50}^{**}$ is the age to which 50% of females could expect to survive without loss of autonomy.

Illustration of the HALY, DALY and QALY concept

Multiplicative Calculation of DALY (no adjustm.)

Life expectancy LE = 85
Death at age = 65 -> LYL = 20
Incidence at age = 20
Quality adjustment Q = 0.8

QoL
0.0 0.2 0.4 0.6 0.8 1.0
0 20 40 60 80 100
Life Years
DALYs = healthy years lost
QALYs = healthy years gained

- DALY (Disease Adjusted Life Years) is a modification of QALY (Quality Adjusted Life Years).
- Both concepts combine information about Length of life and Quality of life.
- A DALY is a negative QALY.
One quality-adjusted life year (DALY) can be thought of as one lost year of “healthy” life, and the burden of disease can be thought of as a measurement of the gap between current health status and an ideal situation where everyone lives into old age, free of disease and disability.

\[ \text{DALY} = \text{YLL} + \text{YLD} \]

where:

\[ \text{YLL} = \text{number of deaths} \times \text{standard life expectancy at the age of death} \]

\[ \text{YLD} = \text{incidence (period)} \times \text{average duration of the illness} \times \text{disability weight} \]

The weight factor reflects the Quality of the disease on a scale from 0 (perfect health) to 1 (death).

World Health Organization (WHO)
Geneva, Switzerland 2008
**Formula for and Effects of Discounting**

\[ QALE_{\text{discounted}} = \sum_{t=a}^{a+L} \frac{Q_t}{(1 + r)^{t-a}} \]

- \( a \) = year of incidence
- \( L \) = LE at incidence
- \( t \) = discounting perspective [years]
- \( Q \) = current value at incidence
- \( t \) = years/time interval past incidence
- \( r \) = discount rate

**The effect of discounts**

![Graph showing the effect of discounts with lines for 1%, 3%, and 5% discount rates.](graph.png)

- Incidence
- Value of a discounted year
Choices behind the DALY concept

In the standard DALYs calculations of YLL and YLD uses an additional 3% time discounting and non-uniform age weights that give less weight to years lived at young and older ages.

*Using discounting* and age weights, a death in infancy corresponds to 33 DALYs, and deaths at ages 5–20 years to around 36 DALYs.

• **Discounting**
  – the value of a life year now is set higher than the value of future life years

• **Age weighting**
  – life years of children and old people are counted less
The World Bank evaluates the "Relative Value of a Year of Life"

Data source: World Bank (1993)
Justice Equity

The DALY approach has been criticised for discriminating

- the young (age weight)
- the elderly (age weight)
- future generations (discounting)
- future health benefits (discounting)
- Women (age weight & LE)
- the disabled (discrimination)
Article 2 Definitions

... discrimination on the basis of disability means any distinction, exclusion or restriction on the basis of disability which has the purpose or effect of impairing or nullifying the recognition, enjoyment or exercise, on an equal basis with others, of all human rights and fundamental freedoms in the political, economic, social, cultural, civil or any other field. It includes all forms of discrimination, including denial of reasonable accommodation;...

Some remarks with respect to the theory and the practice of QoL scaling

„.. the challenge in measuring quality of life lies in its uniqueness to individuals.“

General problems of QoL validity

- What is “Quality of Life” or “Disability Weighting of Life Years”? 
- Can Quality of Life be measured in a single and precise number? 
- Can Quality of Life be measured in a linear additive scale? 
- Does the same health problem have equal impact on different persons or groups? 
- Is there a general agreement to underlying value choices: discounting, age weighting and choice of life expectancy
General problems of QoL validity

A fundamental part of the definition of a high QoL is a large degree of freedom in thinking and behaviour that includes personal subjective feelings.

As a result, the cornerstones of science—which include objectivity, universality, reproducibility, and logical consistency—can no longer be totally applied.

Unless a logical and scientific way of assessing personal feelings is established, QoL simply cannot be evaluated using scientific analysis and numeric expression.

Observation, Measurement or Interaction Protocol

Reality
- Counts
  - e.g. Incidence
- Numeric
  - e.g. Body weight
- Quality
  - e.g. QoL

Information flow
- Measurement information
- Response information

Observation protocol
- e.g. Counts/rates

Measurement protocol
- e.g. Values/distributions

Interaction Protocol
- At best: Ordinal qualities

Influence of context, questions, and “measurement instruments”
What we are talking about?
The content of a one-dimensional QoL scale

The Ratings for many endpoints and many attributes of a state of health are converted to a health utility score using a scoring algorithm based on the preferences of the general adult public or subgroups of it. But what is the content of that scale? Has it a unit? Is it additive? Is it useful/justified to use it multiplication?
“One of the other fundamental problems with eliciting patient preferences is the assumption that one-dimensional preferences already exist in the patient's mind, ..

.. the problems of translation the preference into a question / interview is very difficult to sustain in the real-world interaction in a physician's office.”

→ Validity problems
The process of eliciting preferences and utilities

- Standard Gamble
- Time-Trade-Off
- Rating-Scale-Approaches
- Multi-Attribute-Utility-Scales
  - HRQL/HUI Inc.
  - EuroQual
- Magnitude-Estimation-Approach
- Equivalence-Approach
- Willingness-To-Pay
- … and some more

- General Quality Remarks
The Standard Gamble Approach ~ Indifference of utility

The participant of the study is asked to decide between two alternatives or to signal indifference. The investigator is changing the assigned probabilities of alternative B until indifference is found.

Alternative A

- Defined state of health „As it is“

Alternative B\textsubscript{1..n}

- Treatment with probability $p$
  - Complete Health

- Treatment with probability $1 - p$
  - Death

Model assumptions: $(U_{\text{Death}} = 0, U_{\text{Complete Health}} = 1) \Rightarrow$

For $Util_A = Util_B \Rightarrow p \star Util_{\text{Complete Health}} + (1 - p) \star U_{\text{Death}} = p$
Imagine that you are told that you are ill (with a specific disease) and you have 10 years left to live. In connection with this you are also told that you can choose to live these 10 years in your current health state or that you can choose to give up some life years to live for a shorter period in full health.

Indicate with a cross on the line the number of years in full health that you think is of equal value to 10 years in your current health state.

Model assumption

10 \( [y] \) * Current State of health \([ \] \) = \( x [y] \) * State of „Full Health“ \([ \] \)
The Time-Trade-Off (TTO) scheme (2)

Response
Assignment of a number position (e.g. 4) on a line of length (e.g. 10 units)

\[ 0 \quad \times \quad 5 \quad \times \quad 10 \quad [\text{years}] \]

Quality of Life Weight “Measure QoL”
Indicated value (e.g. in range 0 to 10) / Length of TTO line's range (e.g. 10)

Calculation of a QALY from QoL index

QALYs lived in one year  = 1 * QoL  = e.g. 4/10 = 0.4 with QoL ≤ 1

Quality adjusted Residual Life Span

\[
\text{QALE} = \sum_{t=a}^{\text{Residual}(LE)} Q_t
\]
Face and Content Validity problems

- Forced impossibility to answer that all individuals and all years of life are equally valuable (acceptance of experimental context)
- Not easy to answer since the investigator gives a promise that he or she might never keep.
- Forced consistency with respect to comparibility between the two situations that are essentially different
- Lack of simplicity, lack of uniform diagnostic criteria, difficult to understand: give an answer for disease's values without personal experience (→ prejudice)
- Assumption of an artificial "all-or-nothing" process
- The "expert panel" will not represent the values of other people
- The investigators never ask for "Do you agree to the consequences of your adjustment that ..?"
The multi-attribute utility functions provide all the information required to calculate single-summary scores of health-related quality of life (HRQL) for each health state defined by the classification systems.

**Utility Measurement Theory**

There are two main approaches to measuring utilities, direct measurement and the use of multi-attribute systems. In the multi-attribute approach used for HUI, a respondent completes a questionnaire providing information about an individual's health status that is then scored using a multi-attribute scoring function derived from community preference measures for health states.
# Multi-Attribute Health Status Classification System:
## Health Utilities Index Mark 2 (HUI2)

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Levels</th>
<th>Min / Max description of the Attribute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensation</td>
<td>4</td>
<td>Able to see, hear, and speak normally for age. Blind, deaf, or mute</td>
</tr>
<tr>
<td>Mobility</td>
<td>5</td>
<td>Able to walk, bend, lift, jump, and run normally for age. Unable to control or use arms and legs.</td>
</tr>
<tr>
<td>Emotion</td>
<td>5</td>
<td>Generally happy and free from worry. Extremely fretful, angry, irritable, anxious, or depressed usually requiring hospitalization or psychiatric institutional care.</td>
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<tr>
<td>Cognitive</td>
<td>4</td>
<td>Learns and remembers school work normally for age. Unable to learn and remember</td>
</tr>
<tr>
<td>Self-Care</td>
<td>4</td>
<td>Eats, bathes, dresses, and uses the toilet normally for age Requires the help of another person to eat, bathe, dress, or use the toilet.</td>
</tr>
<tr>
<td>Pain</td>
<td>5</td>
<td>Free of pain and discomfort. Severe pain. Pain not relieved by drugs and constantly disrupts normal activities</td>
</tr>
<tr>
<td>Fertility</td>
<td>3</td>
<td>Able to have children with a fertile spouse. Unable to have children with a fertile spouse</td>
</tr>
</tbody>
</table>
• The major criterion for selecting attributes for the HUI systems was the importance that members of the general public placed on each attribute. Attribute levels were defined to cover the full range of possible abilities/disabilities and to be clearly distinguishable from one another. HUI utility scores represent mean community preferences.

• The HRQL score for each health state is calculated using a mathematical formula (utility function) developed from preference scores measured in accordance with von Neumann-Morgenstern utility theory. Subjects were asked to rate states on a 100-point visual analogue scale (VAS), then to assess a series of health states using a standard gamble chance board (SG). This combination of preference measures ensures appropriate ranking of scores among health states and provides a direct link to the fundamental axioms of utility theory.

EQ-5D: A standardised instrument for use as a measure of health outcome

- „Dimensions“ of the EQ-5D scale
  - mobility,
  - self-care,
  - usual activities,
  - pain/discomfort,
  - anxiety/depression


By placing a check-mark in one box in each group below, please indicate which statement best describes your own state of health today.

**Mobility**
- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

**Self-Care**
- I have no problems with self-care
- I have some problems washing or dressing
- I am unable to wash or dress myself

**Usual Activities** *(e.g. work, study, household, leisure activities)*
- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

**Pain/Discomfort**
- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

**Anxiety/Depression**
- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed
What is the QoL? Questions

- What they meant by Quality of Life?
- Domains wanted to measure as components of Quality of Life?
- Reasons for choosing the instruments used?
- Aggregating the results from multiple items, domains, or instruments into a single Composite Score for Quality of Life?
- Were patients asked to give their own Global Rating for Quality of Life?
- Was Overall Quality of Life distinguished from Health-Related Quality of Life?
- Were patients invited to supplement the items listed in the instruments offered by the investigators?
  - If so, were these supplemental items incorporated into the final rating?
- Were patients asked to indicate which items (either specified by the investigator or added by the patients) were personally important to them?
  - If so, were these importance ratings incorporated into the final rating?

Because quality of life is a uniquely personal perception, denoting the way that individual patients feel about their health status and/or nonmedical aspects of their lives, most measurements of quality of life in the medical literature seem to aim at the wrong target.

Self-assessment for the Quality of Life generates no measurement data!

- The **Quality of Scale** containing subjective estimates is unknown, it is at best ordinal.
- The **Reference System** will be at best pseudo-numeric for each individual, but might be better assumed to vary from person to person.
- The **Response** will show high instability over time, resulting in low reliability.
- The **Unit of the Scale** is not defined. **Equality of Scale Intervals** is violated. In consequence, the validity of numerical operations like addition and multiplication is invalid.
- The **Dimensionality of the QoL Scale** is at least health state dependent. There might be other influences on the attributes structure like age, sex, experience, coping, cultural back-ground among others.
Critical points with respect to „Data and Methods“

Some remarks on measurement
DALY/QALY estimates have no measurement qualities, they are at best values calculated by convention!

- **Reality**
  - Mortality
  - Morbidity
  - Duration
  - Attributes

- **Measurement**
  - Observation
  - Life expectancy
  - Life years lost
  - Adjusting by factors

**Information**

- Period/Cohort data
- Prognosis/Norm
- Period data

**Disability**

- Disability time
- QoL
- Disability

**Attributes**

- Weight factor
- Discounting
- Age factor

"Weigh enough!"
Summary:
Application of SMPH in Health Economy
Some remarks on application

„The ability to compare directly the dollar cost of different health outcomes is attractive to the decision-maker.“
McGregor M: Cost-utility analysis: Use QALY only with great caution.
## Evaluating Costs and Utilities / Values of benefit

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<th>Costs</th>
<th>Result</th>
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<tr>
<td>Cost-minimisation-study (CM)</td>
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<tr>
<td>Cost-effectiveness-analysis (CEA)</td>
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<td>Outcome</td>
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<tr>
<td>Willingness-to-pay (WTP)</td>
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<td>Outcome</td>
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<td>Cost-benefit-analysis (CBA)</td>
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<td>Risk-Risk-Comparison</td>
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<tr>
<td>Health-Health-Comparison</td>
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<td>Outcome</td>
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</tbody>
</table>

Thanks for your audience and patience!

Clarify: About what and about whom we talk?
Aggregation errors, simplified scales and the danger of injustice

Level of description
- Quality of life
- Quality of disease
- Value of age (life years)

Population health and Population Quality of Life

Individual Health and Individual Quality of Life

Intervention

Effect

Disease Free Survival

Diseases LE DALY QALY ....

Decisions about Allocation

Ressources

Many Influences

Age

Envir.

Sex

Social

Many Qualities

QoL

Many Qualities

0 1

Health Quality

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