Health-Related Quality of Life Assessment as an Indicator of Quality of Care

Ron D. Hays, Ph.D.
HS249F

January 31, 2007 (3:30-6:30 pm)
RAND Conference Room, 5312
Questions

• What is the difference between symptoms and health-related quality of life?

• How does one estimate the minimally important difference in health-related quality of life measures?

• How do you know if a measure is responsive to change?
Contact Information

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http://gim.med.ucla.edu/FacultyPages/Hays/
How do you know how the patient is doing?

Temperature
Respiration
Pulse
Weight
Blood pressure
Also, by talking to her or him about ... 

Symptoms

- Have you had a fever in the last 7 days?
  
  No
  
  Yes

What they are able to do

And how they feel about their life
First RCT of Treatment for Newly Diagnosed Prostate Cancer (NEJM, 2002)

Radical prostatectomy vs. watchful waiting

- Trend to reduction in all-cause mortality

(18% versus 15%; RR 0.83, 0.57 to 1.2, p = 0.31)
Impact on Symptoms

+ Urinary obstruction (weak stream)
  -> 44% waiting, 28% prostatectomy (+)

- Sexual dysfunction
  -> 80% prostatectomy (-) vs. 45% waiting

- Urinary leakage
  -> 49% prostatectomy (-) vs. 21% waiting
“Outcomes”--How is the Patient Doing?

**Physiological**

- Vital signs (pulse, BP, temperature, respiration)
- Hematocrit
- Albumin

**Physician observation**

- Physical performance

**Self-report indicators**

- Functioning and well-being
Health-Related Quality of Life (HRQOL) is:

What the person can DO (functioning)

- Self-care
- Role
- Social

How the person FEELs (well-being)

- Emotional well-being
- Pain
- Energy
HRQOL is Multi-Dimensional

HRQOL

- Physical
- Mental
- Social
In general, how would you rate your health?

- Excellent
- Very Good
- Good
- Fair
- Poor
Does your health now limit you in walking more than a mile?

(If so, how much?)

Yes, limited a lot

Yes, limited a little

No, not limited at all
How much of the time during the past 4 weeks have you been happy?

- None of the time
- A little of the time
- Some of the time
- Most of the time
- All of the time
HRQOL is Not

- Quality of environment
- Type of housing
- Level of income
- Social Support
Are self-reports reliable?

Reliability—extent to which you get the same score on repeated assessments
Reliability is an issue in blood pressure measurement

- Do not place the blood pressure cuff over clothing or roll a tight fitting sleeve above the biceps when determining blood pressure as either can cause elevated readings.
- If you have a chance, obtain measurements on the same patient with both a large and small cuff.
- If the reading is surprisingly high or low, repeat the measurement towards the end of your exam.
- These exercises should give you an appreciation for the magnitude of error that can be introduced when improper technique is utilized.
Range of reliability estimates

0.80-0.90 for blood pressure

0.70-0.90 for multi-item self-report scales
Are self-reports about HRQOL valid?

Validity—score represents what you are trying to measure rather than something else

In general, how would you rate your health?

   Excellent
   Very Good
   Good
   Fair
   Poor
Hospitalized Patients Report Worse General Health (n = 20,158)

<table>
<thead>
<tr>
<th>Health Status</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor</td>
<td>26%</td>
</tr>
<tr>
<td>Fair</td>
<td>14%</td>
</tr>
<tr>
<td>Good</td>
<td>6%</td>
</tr>
<tr>
<td>Very Good</td>
<td>4%</td>
</tr>
<tr>
<td>Excellent</td>
<td>3%</td>
</tr>
</tbody>
</table>

Self-Reports of Physical Health Predictive of Five-Year Mortality Rates

“The Veterans Short Form 36 Questionnaire is predictive of mortality and health-care utilization in a population of veterans with a self-reported diagnosis of asthma or COPD”
Types of HRQOL Measures

Profile: Generic vs. Targeted
Preference Measure
SF-36 Generic Profile Measure

- Physical functioning (10 items)
- Role limitations/physical (4 items)
- Role limitations/emotional (3 items)
- Social functioning (2 items)
- Emotional well-being (5 items)
- Energy/fatigue (4 items)
- Pain (2 items)
- General health perceptions (5 items)
Persons with mobility impairments object to SF-36 physical functioning items:

Does your health now limit you in (if so, how much) …

- climbing several flights of stairs
- climbing one flight of stairs
- walking more than a mile
- walking several hundred yards
- walking one hundred yards

Andresen & Meyers (2000, Archives of Physical Medicine and Rehabilitation)
Scoring Generic HRQOL Scales

Average or sum all items in the same scale.

Transform average or sum to

• 0 (worse) to 100 (best) possible range
• z-score (mean = 0, SD = 1)
• T-score (mean = 50, SD = 10)
Formula for Transforming Scores

\[ X = \frac{\text{original score} - \text{minimum}}{\text{maximum} - \text{minimum}} \times 100 \]

\[ Y = \text{target mean} + (\text{target SD} \times Z_x) \]

\[ Z_x = \frac{(X - \bar{X})}{SD_x} \]
<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
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<tbody>
<tr>
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<td>0</td>
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<td>-1.26491</td>
<td>37.3509</td>
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<td></td>
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<td>-0.63246</td>
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<tr>
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<td>39.5285</td>
<td>0</td>
<td>50</td>
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<td></td>
</tr>
<tr>
<td>4</td>
<td>4</td>
<td>75</td>
<td>39.5285</td>
<td>0.63246</td>
<td>56.3246</td>
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<td>39.5285</td>
<td>1.26491</td>
<td>62.6491</td>
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<tr>
<td>6</td>
<td>raw</td>
<td>x</td>
<td>SDx</td>
<td>Zx</td>
<td>T-score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SF-36 PCS and MCS

PCS = (PF_Z * .42402) + (RP_Z * .35119) +
     (BP_Z * .31754) + (GH_Z * .24954) +
     (EF_Z * .02877) + (SF_Z * -.00753) +
     (RE_Z * -.19206) + (EW_Z * -.22069)

MCS = (PF_Z * -.22999) + (RP_Z * -.12329) +
     (BP_Z * -.09731) + (GH_Z * -.01571) +
     (EF_Z * .23534) + (SF_Z * .26876) +
     (RE_Z * .43407) + (EW_Z * .48581)
T-score Transformation

PCS = (PCS_z*10) + 50

MCS = (MCS_z*10) + 50
SF-36 Survey Version 1


http://www.sf-36.org/demos/SF-36v2.html
Example Uses of Generic HRQOL Measures

Cross-Sectional

- Comparison of Same Disease in Different Samples
- Profiles of Different Diseases

Longitudinal

- Profiles of Different Disease
- Identifying Antecedents/Causes of HRQOL
HRQOL of Patients in ACTG versus Public Hospital Samples

Adjusted Scale Scores (Cunningham et al., 1995)
HRQOL for HIV Compared to other Chronic Illnesses and General Population

Hays et al. (2000), American Journal of Medicine
Course of Emotional Well-being Over 2-years for Patients in the MOS General Medical Sector

Physical Functioning in Relation to Time Spent Exercising 2-years Before

Targeted HRQOL Measures

• Designed to be relevant to particular group.

• Sensitive to small, clinically-important changes.

• Important for respondent cooperation.

• More familiar and actionable.
Kidney-Disease Targeted Items

During the last 30 days, to what extent were you bothered by each of the following?

- Cramps during dialysis
- Washed out or drained

Not at all bothered
Somewhat bothered
Moderately bothered
Very much bothered
Extremely bothered
During the last 4 weeks, how often were you angry about your irritable bowel syndrome?

- None of the time
- A little of the time
- Some of the time
- Most of the time
- All of the time
HRQOL in Men Treated for Localized Prostate Cancer

Cross-sectional study of managed care pop.

214 men with prostate cancer
- 98 radical prostatectomy
- 56 primary pelvic irradiation
- 60 observation alone

273 age/zip matched pts. without cancer

Litwin et al. (1995, JAMA)
Sexual, Urinary and Bowel Function

The bar chart shows the comparison of Sexual, Urinary, and Bowel function across different treatment methods:

- **Surgery**
- **Radiation**
- **Observ.**
- **Control**

The chart indicates the percentage of function for each category, with Sexual, Urinary, and Bowel functions measured on the x-axis and the percentage on the y-axis.
HRQOL Measures Helpful in Ensuring Access to Cost-Effective Care

Cost ↓

|   |   |   |   |   |   |   |   |

Effectiveness ↑
HRQOL Outcomes

Summarize overall results of health care:

Cost

ρ HRQOL
SF-36 Physical Health

Physical Health

- Physical function
- Role function - physical
- Pain
- General Health
SF-36 Mental Health

Mental Health

- Emotional Well-Being
- Role function-emotional
- Energy
- Social function
Treatment Impact on Physical Health

Impact on SF-36 PCS

Treatment Outcomes

- Duodenal Ulcer Medication
- Shoulder Surgery
- Asthma Medication
- Coronary Revascularization
- Heart Value Replacement
- Total Hip Replacement
Impact on SF-36 MCS

- Stayed the same
- Low back pain therapy
- Hip replacement
- Ulcer maintenance
- Recovery from Depression

Treatment Outcomes
Debate About Summary Scores

Weights

Summary scores for SF-36 derived from uncorrelated (orthogonal) two factor (physical and mental health) solution introduces – and + weights into scoring algorithm

PCS-z = (PF-z* .42) + (RP-z* .35) + (BP-z* .32) + (GH-z* .25)
+ (EN-z* .03) + (SF-z* -.01) + (RE-z* -.19) + (MH-z* -.22)

MCS-z = (PF-z* -.23) + (RP-z* -.12) + (BP-z* -.10) +
(GH-z* -.12) + (EN-z* .24) + (SF-z* .27) + (RE-z* .43) +
(MH-z* .48)
536 Primary Care Patients Initiating Antidepressant Tx

≥3-month improvements in physical functioning, role—physical, pain, and general health perceptions ranging from 0.28 to 0.49 SDs.

Yet SF-36 PCS did not improve.

Simon et al. (Med Care, 1998)
Four scales improve 0.28-0.49 SD, but physical health summary score doesn’t change
n = 194 with Multiple Sclerosis

≥ Lower scores than general population on
  " Emotional well-being (↓ 0.3 SD)
  " Role—emotional (↓ 0.7 SD)
  " Energy (↓1.0 SD)
  " Social functioning (↓1.0 SD)

≥ Yet SF-36 MCS was only 0.2 SD lower.
≥ RAND-36 mental health was 0.9 SD lower.

Nortvedt et al. (Med Care, 2000)
Four scales 0.3-1.0 SD lower, but mental health summary score only 0.2 SD lower
Farivar et al. alternative weights

\[
\text{PCS}_z = (\text{PF}_z \times 0.20) + (\text{RP}_z \times 0.31) + (\text{BP}_z \times 0.23) + \\
(\text{GH}_z \times 0.20) + (\text{EF}_z \times 0.13) + (\text{SF}_z \times 0.11) + \\
(\text{RE}_z \times 0.03) + (\text{EW}_z \times -0.03)
\]

\[
\text{MCS}_z = (\text{PF}_z \times -0.02) + (\text{RP}_z \times 0.03) + (\text{BP}_z \times 0.04) + \\
(\text{GH}_z \times 0.10) + (\text{EF}_z \times 0.29) + (\text{SF}_z \times 0.14) + \\
(\text{RE}_z \times 0.20) + (\text{EW}_z \times 0.35)
\]
Is New Treatment (X) Better Than Standard Care (O)?

Physical Health

Mental Health

$X > 0$

$0 > X$
### Single Weighted Combination of Scores

**Perceived Health Index (n = 1,862; reliability = 0.94)**

<table>
<thead>
<tr>
<th>Highest</th>
<th>Lowest</th>
<th>Quartile on Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>35%</td>
<td>84%</td>
<td>at least 1 moderate symptom</td>
</tr>
<tr>
<td>7%</td>
<td>70%</td>
<td>at least 1 disability day</td>
</tr>
<tr>
<td>1%</td>
<td>11%</td>
<td>hospital admission</td>
</tr>
<tr>
<td>2%</td>
<td>14%</td>
<td>performance of invasive diagnostic procedure</td>
</tr>
</tbody>
</table>

Perceived Health Index = 0.20 Physical functioning + 0.15 Pain + 0.41 Energy + 0.10 Emotional well-being + 0.05 Social functioning + 0.09 Role functioning.

Is Use of Medicine Related to Worse HRQOL?

<table>
<thead>
<tr>
<th>Person</th>
<th>Medication Use</th>
<th>HRQOL (0-100 scale)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No dead</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>No dead</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>No 50</td>
<td>75</td>
</tr>
<tr>
<td>4</td>
<td>No 75</td>
<td>100</td>
</tr>
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<td>No 100</td>
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</tr>
<tr>
<td>6</td>
<td>Yes 0</td>
<td>25</td>
</tr>
<tr>
<td>7</td>
<td>Yes 25</td>
<td>50</td>
</tr>
<tr>
<td>8</td>
<td>Yes 50</td>
<td>75</td>
</tr>
<tr>
<td>9</td>
<td>Yes 75</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Yes 100</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>HRQOL</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Medicine</td>
<td>3</td>
<td>75</td>
</tr>
<tr>
<td>Yes Medicine</td>
<td>5</td>
<td>50</td>
</tr>
</tbody>
</table>
Do a Survival Analysis?

Marathoner and person in coma = 1.0
http://www.ukmi.nhs.uk/Research/pharma_res.asp
Overall Health Rating Item

Overall, how would you rate your current health?
(Circle One Number)

- 0: Worst possible health (as bad or worse than being dead)
- 1: Half-way between worst and best
- 2: Best possible health

0 1 2 3 4 5 6 7 8 9 10
Overall Quality of Life Item

Overall, how would you rate your quality of life?

Worst possible quality of life (as bad or worse than being dead)

Half-way between worst and best

Best possible quality of life
Brazier et al. SF-6D

≥ Brazier et al. (1998, 2002)

" 6-dimensional classification
  ▪ Collapsed role scales, dropped general health
  ▪ Uses 11 SF-36 items (8 SF-12 and 3 additional physical functioning items)

" 18,000 possible states

" 249 states rated by sample of 836 from UK general population
Health State 11111

Health state 11111

Your health does not limit you in **vigorous activities** (e.g. running, lifting heavy objects, participating in strenuous sports).

You have **no** problems with your work or other regular daily activities as a result of your **physical health or any emotional problems**.

Your health limits your **social activities** (like visiting friends or close relatives) **a little or none of the time**

You have **no pain**

You feel **tense or downhearted and low** a **little or none of the time**.

You have a lot of **energy all of the time**
Health state 424421 (0.59)

- Your health limits you a lot in moderate activities (such as moving a table, pushing a vacuum cleaner, bowling or playing golf)
- You are limited in the kind of work or other activities as a result of your physical health
- Your health limits your social activities (like visiting friends, relatives etc.) most of the time.
- You have pain that interferes with your normal work (both outside the home and housework) moderately
- You feel tense or downhearted and low a little of the time.
- You have a lot of energy all of the time
Indirect Preference Measures--Quality of Well-Being Scale

• Summarize HRQOL in QALYs

  -- Physical activity (PAC)
  – Mobility (MOB)
  – Social activity (SAC)
  - Symptom/problem complexes (SPC)

• Well-Being Formula $w = 1 + \text{PAC} + \text{MOB} + \text{SAC} + \text{SPC}$
Quality of Well-Being Weighting Procedure

Each page in this booklet tells how an imaginary person is affected by a health problem on one day of his or her life. I want you to look at each health situation and rate it on a ladder with steps numbered from zero to ten. The information on each page tells 1) the person's age group, 2) whether the person could drive or use public transportation, 3) how well the person could walk, 4) how well the person could perform the activities usual for his or her age, and 5) what symptom or problem was bothering the person.

Example Case #1

Adult (18-65)
Drove car or used public transportation without help
Walked without physical problems
Limited in amount or kind of work, school, or housework
Problem with being overweight or underweight

<table>
<thead>
<tr>
<th>10 Perfect Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
</tr>
<tr>
<td>8</td>
</tr>
<tr>
<td>7</td>
</tr>
<tr>
<td>6</td>
</tr>
<tr>
<td>5</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>0 Death</td>
</tr>
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</table>
## Quality of Well-Being States and Weights

<table>
<thead>
<tr>
<th>Component</th>
<th>Measures</th>
<th>States</th>
<th>Weights</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical activity</td>
<td>Physical function</td>
<td>In bed, chair, couch, or wheelchair*</td>
<td>-.077</td>
</tr>
<tr>
<td></td>
<td></td>
<td>In wheelchair* or had difficulty lifting, stooping, using stairs, walking, etc.</td>
<td>-.060</td>
</tr>
<tr>
<td>Mobility</td>
<td>Ability to get around or transport oneself</td>
<td>In hospital, nursing home, or hospice.</td>
<td>-.090</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Did not drive car or use public transportation</td>
<td>-.062</td>
</tr>
<tr>
<td>Social activity</td>
<td>Role function and self-care</td>
<td>Did not feed, bath, dress, or toilet</td>
<td>-.106</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Limited or did not perform role</td>
<td>-.061</td>
</tr>
<tr>
<td>Symptom/problem</td>
<td>Physical symptoms and complexes problems</td>
<td>Worst symptom from loss of consciousness to breathing smog or unpleasant air</td>
<td>-.407</td>
</tr>
</tbody>
</table>

* moved vs. did not move oneself in wheelchair
On each dimension, respondent gets three choices of level.
EQ-5D

Mobility

Self-care

Usual activities

Pain/discomfort

Anxiety/depression

- 243 states, 3 levels per attribute
HUI-3

Vision
Hearing
Speech
Ambulation
Dexterity
Cognition
Pain and discomfort
Emotion

- 972,000 states, 5-6 levels per attribute
Quality-adjusted life-years (QALYs)

Tengs, T. Presented at Health Services Research Seminar, VA Hospital, San Diego, July, 2000
Quality of Life for Individual Over Time
Direct Preference Measures
Time Tradeoff (TTO)

• Choice between two certain outcomes
• Years of life traded for quality of life
• Simple to administer alternative to SG
Time Trade-off approach:

Alternative 1: intermediate health state x, for time t, followed by death.
Alternative 2: full health for time s where s<t, followed by death.

Time t is given and the individual is asked to state s. The preference score is then worked out as s/t.
**Time Tradeoff**

**Choice #1:** Your present state (e.g., paralysis)

**Life Expectancy:** 10 years

**Choice #2:** Complete mobility

How many years (x) would you give up in your current state to be able to have complete mobility?

\[
\left[ 1 - \frac{X}{10} = \text{QALY} \right]
\]
How many years (x) would you give up in your current state to be able to have complete mobility?

\[
X = 0 \rightarrow QALY = 1 \\
X = 1 \rightarrow QALY = 0.9 \\
X = 5 \rightarrow QALY = 0.5 \\
X = 10 \rightarrow QALY = 0 \\
\]

\[
[1 - \frac{X}{10} = QALY]
\]
Standard Gamble

Classical method of assessing preferences

• Choose between certain outcome and a gamble

• Conformity to axioms of expected utility theory

• Incorporates uncertainty (thus, more reflective of treatment decisions).
Standard Gamble approach

- **Alternative 1**: probability \((p)\) of living full health for individual’s remaining life expectancy otherwise immediate death.

- **Alternative 2**: the certainty of living in a given intermediate health state \(x\).

Diagram:

- Full health
  - Alternative 1: Death
  - Alternative 2: Health state \(x\)
Standard Gamble (SG)

Choice #1: Your present state (e.g., paralysis)

Choice #2: X probability of complete mobility
           1-X probability of death

Preference Value: Point at which indifferent between choices, varying X

[ X = QALY ]
Standard Gamble (SG)

X probability of complete mobility

X = 1.00 → QALY = 1.00
X = 0.50 → QALY = 0.50
X = 0.00 → QALY = 0.00
Questions?
For further information

http://hs214.med.ucla.edu/modules/news/
http://gim.med.ucla.edu/FacultyPages/Hays/
http://www.rand.org/health/surveys.html
http://www.qolid.org/
www.sf-36.com
http://www.nihpromis.org/
https://www.editorialmanager.com/qure/
http://www.chime.ucla.edu/measurement/measurement.htm
http://www.dartmouth.edu/~coopproj/morc_charts.html
http://medicine.ucsd.edu/fpm/hoap/index.html
http://www.mapivalues.com/
http://healthmeasurement.org/
http://www.facit.org/
http://www.eortc.be/
Appendix: Generic Child Health Measures

Comprehensive Geriatric Assessment (n = 363 community-dwelling older persons) lead to improvements in SF-36 energy, social functioning, and

" Physical functioning (4.69 points) in 64 weeks

" Cost of $746 over 5 years beyond control group

Is CGA worth paying for?

Change in QALYs associated with 4.69 change in SF-36 physical functioning

- $r = 0.69 \rightarrow b = .003$
- $\rho QWB = 4.69 \times .003 = .014$
- $.014 \times 5 \text{ yrs.} = 0.07 \text{ QALYs}$
- Cost/QALY: $10,600+$

<=$20,000 \text{ per QALY worthwhile}$
Limitations of Preference Measures

Complexity of task

Coarseness of health states

Sensitivity to method of elicitation
### Hypothetical Health States

#### Physical Health

<table>
<thead>
<tr>
<th>P3</th>
<th>0.00</th>
<th>High</th>
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</thead>
<tbody>
<tr>
<td>P2</td>
<td>-0.20</td>
<td>Medium</td>
</tr>
<tr>
<td>P1</td>
<td>-0.50</td>
<td>Low</td>
</tr>
</tbody>
</table>

#### Mental Health

<table>
<thead>
<tr>
<th>M3</th>
<th>0.00</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>M2</td>
<td>-0.30</td>
<td>Medium</td>
</tr>
<tr>
<td>M1</td>
<td>-0.40</td>
<td>Low</td>
</tr>
</tbody>
</table>
Mapping Health States into Quality of Life

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<th>Exists</th>
<th>Measured</th>
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<tr>
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Perfect QOL

| 0.9 |
| 0.8 |
| 0.7 |
| 0.6 |
| 0.5 |
| 0.4 |
| 0.3 |
| 0.2 |
| 0.1 |

Dead