Quality of life: What is it, how is it measured, and how are the results used?

JOEL TSEVAT, MD, MPH

UNIVERSITY OF PITTSBURGH  ANNUAL MEDICAL ETHICS CONFERENCE – 2019
29 MARCH 2019
Disclosures

None
Objectives

1. Compare various definitions and concepts of quality of life
2. Describe various approaches to measuring quality of life
3. Understand uses of quality of life data in health care
What is quality of life?

- According to the WHO, QOL is an “individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.”

- QOL encompasses
  - HRQOL
  - Environment
  - Family
  - Work
  - Etc.

Conceptualizations of QOL, a simple yet complex paradigm

- Quality of life is a simple yet complex paradigm
- Philosophers (e.g., Plato, Aristotle, Bentham, Kant, Mill, Marx, Nietzsche, many others)
- Ethicists
- Sociologists
- Psychologists
- Economists (e.g., Sen)
- Theologians
- Clinicians
- Health services researchers
- Lawyers
- Urban planners
- Poets, playwrights, novelists, artists
- Lay persons
Constitutes a comprehensive reference work on quality of life, spanning different fields of research

> see more benefits
Health-related quality of life

- “The extent to which one’s usual or expected physical, emotional, and social well-being are affected by a medical condition or its treatment”

- Incorporates
  - Subjectivity
  - Multidimensionality

Patient-reported outcomes

- “Any report of the status of a patient’s health condition that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone other party.”

- Includes (among many others)
  - HRQoL
  - Other attributes – productivity at home and in the workplace

Quality of Life

Social and Role

Physical and Mental

Health-Related Quality of Life

Biologic

Wilson and Cleary Model

Relationships among measures of patient outcome in a health-related quality of life conceptual model.

DETERMINANTS OF HEALTH

This diagram is a model of all factors correlated with health outcomes for an individual.

- Physical Environment: 7%
- Medical Care: 11%
- Individual Behavior: 36%
- Social Circumstances: 24%
- Genetics and Biology: 22%

Adapted from: https://www.goinvo.com/features/determinants-of-health/
## Risk factors for suicide

<table>
<thead>
<tr>
<th>Health-related/treatable</th>
<th>Not health-related</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychiatric disorders, history of previous attempts</td>
<td>Rural residence</td>
</tr>
<tr>
<td>Hopelessness</td>
<td>Marital status (not married)</td>
</tr>
<tr>
<td>General medical illnesses (e.g., chronic pain, TBI)</td>
<td>Sexual minority</td>
</tr>
<tr>
<td>Antidepressant therapy</td>
<td>Occupation (unskilled)</td>
</tr>
<tr>
<td>Firearms</td>
<td>Military veterans</td>
</tr>
<tr>
<td></td>
<td>Childhood adversity</td>
</tr>
<tr>
<td></td>
<td>Family history/genetics</td>
</tr>
</tbody>
</table>

Measuring QOL and HRQOL

- How?
- Why?
- Can we?
Art Rating Scale

Best Art

The Pits
Why measure HRQOL?

- If you can’t measure it, you can’t improve it
- Want comparable (quantifiable) subjective outcomes on impact of disease and treatment in addition to objective parameters such as mortality
- Embedded in CDC’s mission: “To promote health and quality of life by preventing and controlling disease, injury, and disability.”
- FDA requires an improvement in patient-reported outcome measure(s) to support claims in medical product labeling
Approaches to assessing HRQOL

- Health status: describes states of health and their impact on function and disability
- Utility/value/preference: ascertains the value or desirability of a health state vs. an external metric
Health Status
- Describes health states, impact on function and disability
  - Objective
    - Joint count
    - Exercise tests
    - Visual acuity
  - Subjective
    - Reports, ratings
    - Functional capacity
    - Symptoms
    - Feelings
    - Behavior
- Generic
- Disease-specific

Value, Preference
- Global value assigned to health state
  - Rating scale
  - Time trade-off
  - Standard gamble
  - Health state classification system

General health status measures

- Early prototype: Sickness Impact Profile
  - 136 items
  - Physical and Psychosocial dimensions

- Later: SF-36v2™ or SF-12v2™
  - Physical functioning
  - Social functioning
  - Mental health
  - Role-physical
  - Role-emotional
  - Vitality
  - Pain
  - General health perceptions

- Now: PROMIS®
  - Based on item response theory
  - Short forms or computerized adaptive testing
PROMIS® Adult Self-Reported Health

Physical Health
- Fatigue
- Pain Intensity
- Pain Interference
- Physical Function
- Sleep Disturbance

Mental Health
- Anxiety
- Depression

Social Health
- Ability to Participate in Social Roles & Activities

PROMIS Profile Domains

PROMIS Additional Domains
- Dyspnea
- Gastrointestinal Symptoms
- Itch
- Pain Behavior
- Pain Quality
- Sexual Function
- Sleep-related Impairment

Companionship
- Satisfaction with Social Roles & Activities
- Social Isolation
- Social Support

http://www.healthmeasures.net/explore-measurement-systems/promis/intro-to-promis
Disease-specific health status measures

- **Examples**
  - PHQ-9, GAD-7
  - Asthma QoL Questionnaire
  - Skindex
  - Knee Injury and Osteoarthritis Outcome Score (KOOS) – 5 subscales, each scored from 0 (worst) - 100 (best)

- **Advantages**
  - Relevance
  - Responsiveness to change

- **Disadvantages**
  - Can’t compare across conditions
  - May miss unanticipated effects
Uses of health status measures

- Health services research
- Describing natural history of disease
- Monitoring populations (e.g., Institute for Healthcare Improvement’s 100 Million Healthier Lives initiative)
- Case finding
- Casemix adjustment
- Quality assurance/continuous quality improvement
- Clinical encounters
- Clinical trials
- Guidelines
- Value-based payment metric
Valuing health states

- Which state(s)?
  - Own health state
  - Described health state
    - Written
    - Video

- By whom?
  - General public (recommended)
  - Healthcare providers
  - Patients
  - Surrogate decision makers
Ethical argument: who are we (non-patients) to judge?

- Many studies have shown that the general public’s, providers’, and even surrogates’ utilities for health states are lower than those who have those health states.

- In the context of gene editing for potentially heritable diseases: “No parents ... wish disability on their children. Yet many people who live with disability perceive their quality of life to be as high as that of people without disability.”

- Ethan Weiss: “You can’t know ... until you know.”

Health utility assessment methods

- Rating scale (not a true utility)
- Time tradeoff
- Standard gamble
- Willingness to pay
- Discrete-choice experiment
- Health state classification systems
Uses of health utilities

- Decision analysis
  - Individual clinical decision making
  - Policy-level analyses
- Cost-effectiveness (cost-utility analysis)
- Clinical trials
Rationing of Health Care in the United States
An Inevitable Consequence of Increasing Health Care Costs

Howard Bauchner, MD

The modern era of medicine began in the 1960s. Health care coverage expanded with the passage of Medicare and Medicaid and the increasing availability of employee-based health insurance. Scientific and clinical advances began to occur at a far more rapid pace. Physicians became more specialized and began to focus on acute care dominated by cardiovascular disease, diabetes, and cancer rather than infectious diseases, and there was increasing recognition of the importance of chronic diseases. With more data available, it became possible to measure variation in the delivery and quality of care, along with disparities and rationing in the provision of care. Health care costs per person more than doubled between 1960 and 1970, beginning their 5-decade increase.

Rationing and cost of care are inextricably linked, although measuring the amount and extent of rationing and defining rationing is difficult. There are many types of rationing, including rationing by access (type of insurance), by cost (out-of-pocket expenses), by restriction (the service is not available or paid for by a third party), or by long waits (Canada and parts of the United States). Broadly, rationing refers to approaches that are used to allocate resources and potentially restrict access to effective therapies. Rationing is linked to poverty, race, and ethnicity, and it inevitably leads to differences in the care that certain groups of individuals receive.

Rationing of care often is part of the larger discussion of disparities in health care. Healthy People 2020 defines a health disparity as "a particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage. Health disparities adversely affect groups of people who have systematically experienced greater obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion." Disparity in health
Rating Scale

Perfect Health ➔ -100
-90
-80
-70
-60
-50 ➔ 1–Current Health
-40
-30
-20
-10

Death ➔ -0

50
Time Tradeoff

CHOICES:
1 - Live for 5 years in Current Health, then die.
2 - Live for 4.9 years in Perfect Health, then die.
= - No preference.

Loss of 0.1 years  U = 99.0
McTaggart’s version of time tradeoff

• 20th century British philosopher

• Compared the life of an oyster – characterized by very little consciousness and very little excess pleasure over pain – vs. the life of a human being with all of its vicissitudes

• Concludes that the full oyster-like life is preferable to a shorter human life

Kraut R. The Quality of Life: Aristotle Revisited. Oxford Scholarship Online; Sep 2018
Standard Gamble
Willingness to pay

- Asks how much one would be willing to pay to improve health
  - In the form of direct payments
  - In the form of higher insurance premiums

- Converse is willingness to receive
  - The average Facebook user would require >$1000 to deactivate their account for 1 yr

- Perhaps most useful for short-term health state utility assessment

Health state classification systems

- Assess health status on several domains, then use community-derived utilities to transform health status to utility

- Measures
  - EuroQoL (EQ-5D-3L and EQ-5D-5L): 5 domains
    - Collected as part of MEPS and other large population surveys
    - Allows scores < 0
  - Health Utilities Index (HUI2 and HUI3): 6 or 8 domains
    - Allows scores < 0
  - SF-6D: 6 domains
    - Score range: 0.29-1.00
    - MID: 0.041
  - Quality of Well-Being scale – Self-Administered (QWB-SA): 3 domains + symptoms/problems
    - Score range: 0.09-1.00
  - Health and Activities Limitations index (HALex): 2 domains
  - PROPr: 7 domains
    - Score range: -0.022 to 1.0
EuroQoL descriptive system

- Mobility
  1. No problems in walking about
  2. Some problems in walking about
  3. Confined to bed

- Self-care
  1. No problems with self-care
  2. Some problems washing or dressing self
  3. Unable to wash or dress self

- Usual activity *
  1. No problems with usual activity
  2. Some problems with usual activity
  3. Unable to perform usual activity

- Pain / discomfort
  1. No pain or discomfort
  2. Moderate pain or discomfort
  3. Extreme pain or discomfort

- Anxiety / depression
  1. Not anxious or depressed
  2. Moderately anxious or depressed
  3. Extremely anxious or depressed

FIG. 1. Classification of health states.

Slide courtesy of Janel Hanmer, MD, PhD
Time tradeoff method
EQ-5D scoring

- First scored on UK sample, using TTO
- Other countries have derived their own weights, using either RS or TTO
- US weights
  - Derived on sample of 4048 adults
  - 45 EQ-5D health states valued, using TTO
  - Values for other states derived mathematically

http://www.euroqol.org
PROPr Development

\[ \bar{u}(\Theta) = \frac{1}{c} \prod_{i=1}^{7} \left(1 + c \cdot c_i \cdot \bar{u}_i(\theta_i)\right) \]

Range -0.022 to 1.0

Histogram from an online US panel survey representative of the US population. N=4142

Slide courtesy of Janel Hanmer, MD, PhD
So, what’s a QALY?

- A measure of length of life weighted by its quality, on a scale anchored by dead (0.0) and perfect health (1.0)

- 1 QALY
  - = 1 year in perfect health
  - = 2 years in a health state valued at 0.5
  - = 5 years in a health state valued at 0.2
  - ...

- Valuing states of health
  - Visual analog scale
  - Time tradeoff
  - Standard gamble
  - New: PROPr
Cost-saving interventions include:

- Hep A vaccination for children in high-prevalence areas
- Subsidizing fruits & veggies with SNAP
- Bevacizumab for metastatic colorectal cancer

More costly interventions include:

- Tyrosine kinase inhibitors for NSCLC
- PCSK9 inhibitors

Cost-effectiveness is indicated by the ratio of cost to Quality-Adjusted Life Years (QALY). The thresholds are:

- $50k/QALY
- $100k/QALY
- $200k/QALY
- $500k/QALY

Source: Tufts Medical Center CEA Registry, www.cearegistry.org
CEA in the US

1976

Hypertension

1977

SPECIAL ARTICLE

FOUNDATIONS OF COST-EFFECTIVENESS ANALYSIS FOR HEALTH AND MEDICAL PRACTICES

1996

COST-EFFECTIVENESS in HEALTH and MEDICINE

Harvard University Press
CEA in the US

Institute for Clinical and Economic Review

2006  2008  2016
Role of QALYs in comparative effectiveness research

• “[PCORI] 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 Medicare.”

• Illegal!
Institute for Clinical and Economic Review (ICER)

- **Independent** health technology assessment group whose reviews are funded by non-profit foundations

- Develop **publicly available value assessment reports** on medical tests, treatments, and delivery system innovations

- Use cost-effectiveness analysis to determine **value-based price benchmarks**

- Convene regional independent **appraisal committees** for public hearings on each report
Use of ICER Assessments: Payers and Providers

• Medicaid programs
• VA using ICER reports to negotiate prices
• Private payers and PBMs
• CVS new benefit design: “Reducing launch price using comparative effectiveness”
  • Drugs with a price that fails to reach a cost-effectiveness level of $100K/QALY are a non-covered benefit
  • Newly launched drugs
  • Breakthrough drugs excluded
What do utilities measure?

Sharp, or fuzzy?

Quality of Life

Social and Role

Physical and Mental

Health-Related Quality of Life

Biologic

Acknowledgement

Thanks to Dinesh Khanna, MD and Janel Hanmer, MD, PhD for use of some slides