Health-Related Quality of Life in Outcome Studies

Ron D. Hays, Ph.D. (<u>drhays@ucla.edu</u>) UCLA Division of General Internal Medicine and Health Services Research, Department of Medicine

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http://twitter.com/RonDHays

http://gim.med.ucla.edu/FacultyPages/Hays/



In general, how would you rate your health?

Poor Fair Good Very Good Excellent

In general, how would you rate your health?

Poor Fair



Health-Related Quality of Life

What you can <u>do</u>.

- Functioning
 - Self-care
 - Role
 - Social

How you feel about your life.

- Well-being
 - Emotional well-being
 - Pain
 - Energy

SF-36 Physical Health



SF-36 Mental Health



The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

- 1. Yes, limited a lot -----> 0
- 2. Yes, limited a little ----> 50
- 3. No, not limited at all -->100
- 1. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports
- 2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf
- 3. Lifting or carrying groceries
- 4. Climbing several flights of stairs
- 5. Climbing one flight of stairs
- 6. Bending, kneeling, or stooping
- 7. Walking more than a mile
- 8. Walking several blocks
- 9. Walking one block
- 10. Bathing or dressing yourself

Change in Physical Functioning

Current Score (not limited at all) = 100

Event #1 (Hit by Rock):

- Leads one to be *limited a little* in vigorous activities
- New score: <u>95</u> (0.25 SD)
- Event #2 (Hit by Bike):
 - Leads one to be:
 - *limited a lot* in vigorous activities <u>and</u> in climbing several flights of stairs
 - *limited a little* in moderate activities
 - New score: <u>75</u> (- 1.25 SD)

Mean = 87 (SD = 20)50th percentile = 95 (U.S. males)

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



Quality of Life after Late Invasive Therapy for Occluded Arteries

- Patients with totally occluded infarct-related artery 3-28 days after MI
- Randomized to:
 - Medical therapy alone (n = 474)
 - Percutaneous coronary intervention (PCI) plus stenting (n = 477)
- N Engl J Med. 2009 Feb 19;360(8):774-83

Health-Related Quality of Life (Baseline, 4, 12, & 24 months)

- Duke Activity Status Index (DASI)
- SF-36 Mental Health Scale (MHI-5)
- Cardiac Symptoms
- Time tradeoff (TTO)

Note: Primary outcome was composite of death, reinfarction, or hospital treatment for class IV heart failure

DASI

12 physical functioning items designed to estimate peak oxygen uptake

- Can you run a short distance?
- Can you do yard work like raking leaves weeding or pushing a power mower?
 - 0-58 score range (higher is better)
 - >=4 is "clinically significant"
 - mL/min = (0.43* DASI) + 9.6

MHI-5

How much of the time during the past 4 weeks:

- Have you been a very nervous person?
- Have you felt so down in the dumps that nothing could cheer you up?
- Have you felt calm and peaceful?
- Have you felt down-hearted and blue?
- Have you been a happy person?
 - 0-100 score range (higher is better)
 - >=5 is "clinically significant"

Cardiac Symptoms

- Rose
 - Angina questionnaire (7 questions)
 - Chest pain and whether provoked by walking and relieved by rest
 - Dyspnea questionnaire (4 questions)

TTO

<u>Choice #1</u>: Your present state

Life Expectancy: 10 years

<u>Choice #2</u>: Excellent health

How many years (x) would you give up in your current state to be able to have perfect health for 10-x years?

TTO Estimates

How many years (x) would you give up in your current state to be able to have excellent health for 10-x years?

$$X = 0 \rightarrow QALY = 1$$

$$X = 1 -> QALY = 0.9$$

$$X = 5 -> QALY = 0.5$$

10

Study Results

- 2-year net cost was \$7,089 for PCI
- DASI at 4 months
 PCI (37) versus Medical therapy (33)
- 2-year Quality-Adjusted Life Years (QALYs)
 ▶1.42 vs.1.45 for PCI and Medical therapy

Does not support common practice of routine PCI in patients in stable condition after MI with occluded infarct-related artery.



FDA Patient-Reported Outcomes Guidance

- Published December 2009
- Use of PRO measures to support claims in product labeling
- Developed by the SEALD group within the Office of New Drugs (OND)
 - Advisory group to all reviewing divisions

http://www.fda.gov/downloads/Drugs/ GuidanceComplianceRegulatory Information/Guidances/UCM193282.pdf



Physical Functioning and Emotional Well-Being at Baseline

for 54 Patients at UCLA-Center for East West Medicine



MS = multiple sclerois; ESRD = end-stage renal disease; GERD = gastroesophageal reflux disease.

Change in SF-36 Scores

Effect Size



Energy = Energy/Fatigue; EWB = Emotional Well-being; Gen H=General Health; MCS =Mental Component Summary; Pain = Bodily Pain; PCS = Physical Component Summary; PFI = Physical Functioning; Role-E = Role-Emotional; Role-P = Role-Physical; Social = Social Functioning



Significance of Group Change (T-scores)

	Change	t-test	prob.		
PF-10	1.7	2.38	.0208		
RP-4	4.1	3.81	.0004		
BP-2	3.6	2.59	.0125		
GH-5	2.4	2.86	.0061		
EN-4	5.1	4.33	.0001		
SF-2	4.7	3.51	.0009		
RE-3	1.5	0.96	.3400 ←		
EWB-5	4.3	3.20	.0023		
PCS	2.8	3.23	.0021		
MCS	3.9	2.82	.0067		

Defining a Responder: Reliable Change Index (RCI)



Note: SD_{hl} = standard deviation at baseline r_{yy} = reliability

Amount of Change in Observed Score Needed for Significant Individual Change

	RCI	Effect size	Cronbach' s alpha
PF-10	8.4	0.67	0.94
RP-4	8.4	0.72	0.93
BP-2	10.4	1.01	0.87
GH-5	13.0	1.13	0.83
EN-4	12.8	1.33	0.77
SF-2	13.8	1.07	0.85
RE-3	9.7	0.71	0.94
EWB-5	13.4	1.26	0.79
PCS	7.1	0.62	0.94
MCS	9.7	0.73	0.93

Significant Change for 54 Cases

	% Improving	% Declining	Difference
PF-10	13%	2%	+ 11%
RP-4	31%	2%	+ 29%
BP-2	22%	7%	+ 15%
GH-5	7%	0%	+ 7%
EN-4	9%	2%	+ 7%
SF-2	17%	4%	+ 13%
RE-3	15%	15%	0%
EWB-5	19%	4%	+ 15%
PCS	24%	7%	+ 17%
MCS	22%	11%	+ 11%



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- Emotional Distress [86]
 - Depression (28)
 - Anxiety (29)
 - Anger (29)
- Pain [80]
 - Behavior (39)
 - Impact (41)
- Fatigue [95]
- Satisfaction with Participation in Discretionary Social Activities (12)
- Satisfaction with Participation in Social Roles (14)
- Sleep Disturbance (27)
- Wake Disturbance (16)

Reliability and SEM

- For z-scores (mean = 0 and SD = 1):
 - Reliability = 1 SEM²
 - = 0.91 (when SEM = 0.30)
 - = 0.90 (when SEM = 0.32)
- With 0.90 reliability
 - 95% Confidence Interval
 - z-score: -0.62 → 0.62
- T-score = (z-score * 10) + 50
 - T-score: $44 \rightarrow 56$

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