



Health-Related Quality of Life (HRQOL) Assessment in Outcome Studies

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GCRC Summer Course

**“The Essentials of Clinical Investigation:
Developing a Research Proposal”**

Gonda Building 1357 (July 13, 2009, 8-9 am)

<http://www.gim.med.ucla.edu/FacultyPages/Hays/>

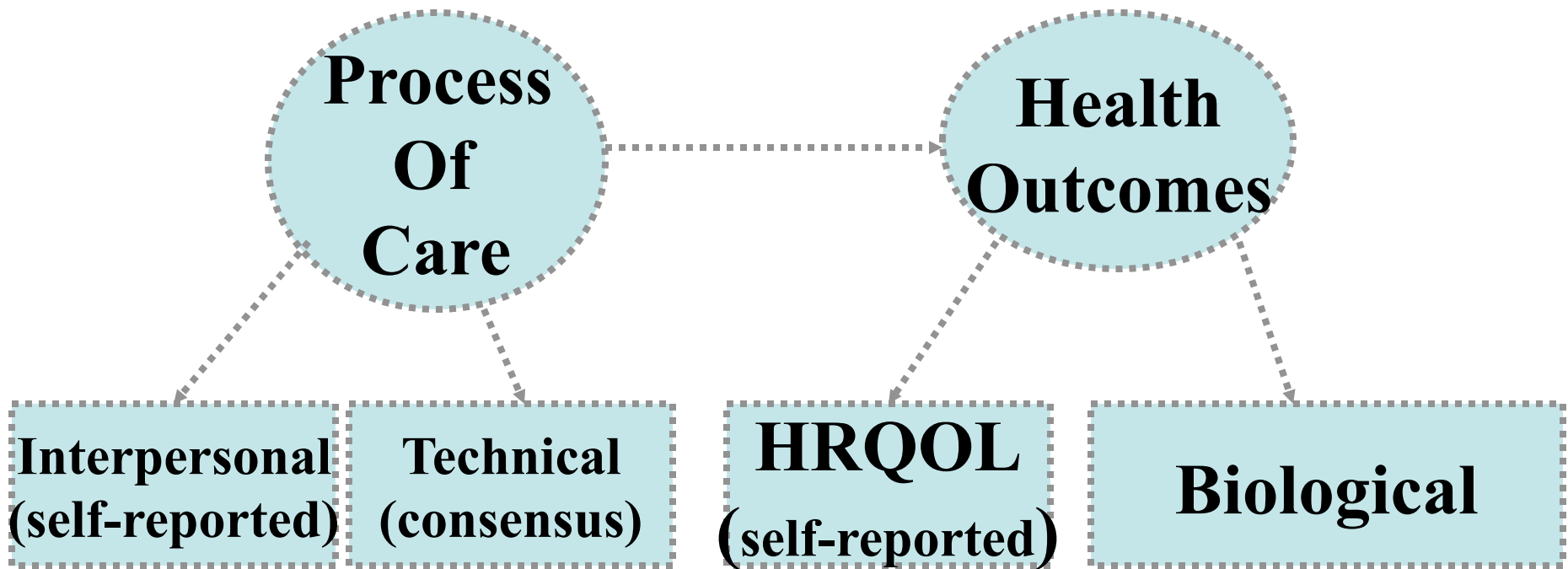
Recent HRQOL Publications

- ✓ Urology. 2009 Jul 7. [Epub ahead of print], **Responsiveness of the University of California-Los Angeles Prostate Cancer Index.** [Bergman J](#), [Saigal CS](#), [Kwan L](#), [Litwin MS](#).
- ✓ Arch Intern Med. 2009 Jun 22;169(12): 1104-12. **The impact of selecting a high hemoglobin target level on health-related quality of life for patients with chronic kidney disease: a systematic review and meta-analysis.** [Clement FM](#), [Klarenbach S](#), [Tonelli M](#), [Johnson JA](#), [Manns BJ](#).

Recent HRQOL Publications

- ✓ J Natl Cancer Inst. 2009 Jun 16;101(12):860-8. Epub 2009 Jun 9. **Impact of cancer on health-related quality of life of older Americans.** [Reeve BB](#), [Potosky AL](#), [Smith AW](#), [Han PK](#), [Hays RD](#), [Davis WW](#), [Arora NK](#), [Haffer SC](#), [Clauser SB](#).
- ✓ N Engl J Med. 2009 Feb 19;360(8):774-83. **Quality of life after late invasive therapy for occluded arteries.** [Mark DB](#), [Pan W](#), [Clapp-Channing NE](#), [Anstrom KJ](#), [Ross JR](#), [Fox RS](#), [Devlin GP](#), [Martin CE](#), [Adlbrecht C](#), [Cowper PA](#), [Ray LD](#), [Cohen EA](#), [Lamas GA](#), [Hochman JS](#); [Occluded Artery Trial Investigators](#).

HRQOL is a Patient-Reported Outcome (PRO)

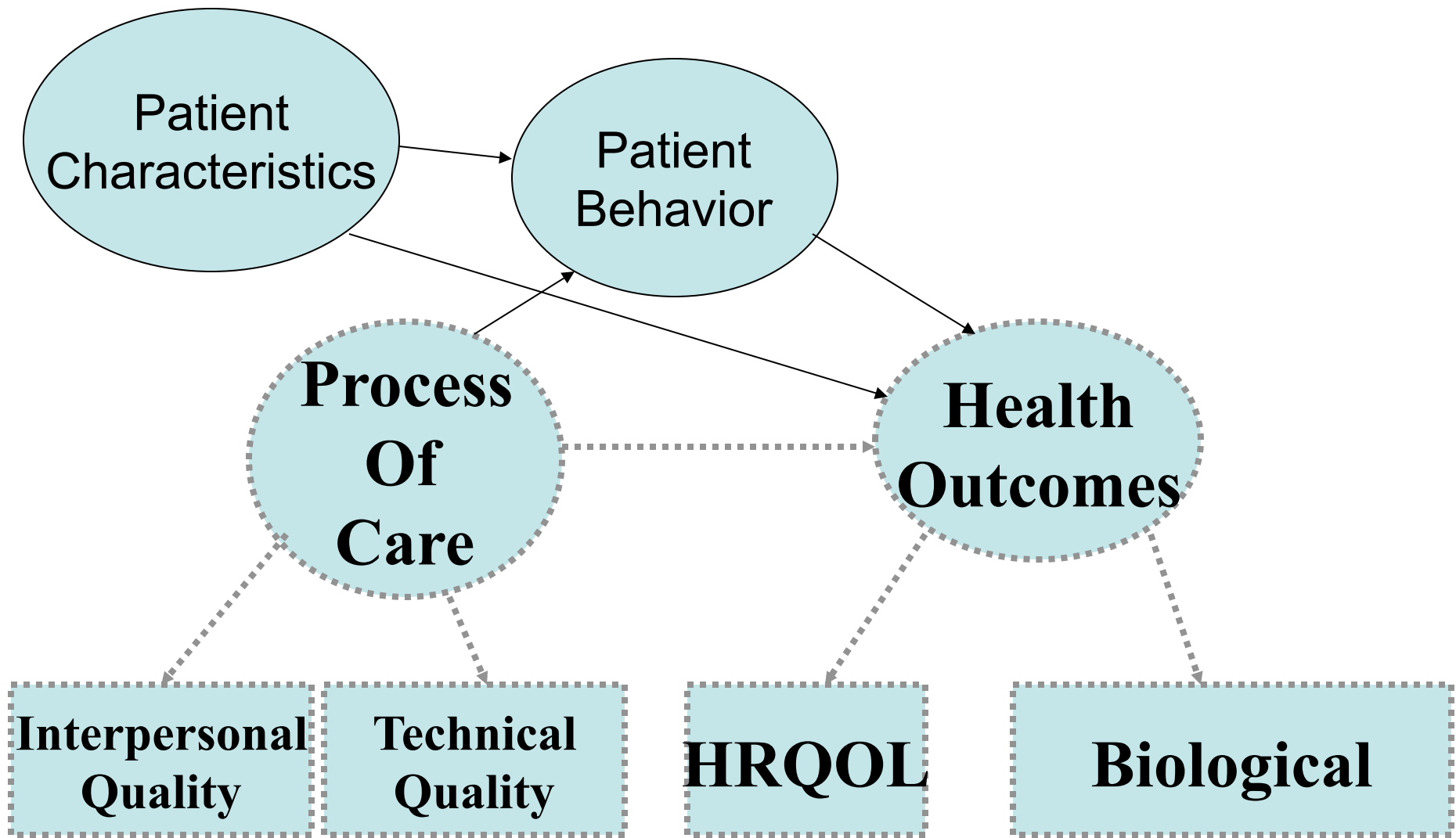


Process of Care

- Technical Quality (expert consensus)
 - Quality of Care “If Then” Indicators
 - % of patients with diabetes with one or more HbA1c tests annually
- Interpersonal Quality (patient reports)
 - In the last 12 months, how often did your doctor explain things in a way that was easy to understand?

Health Outcomes

- Biological
 - % of patients with diabetes with most recent HbA1c level >9.0% (poor control)
- HRQOL
 - In general, would you say that your health is:
 - Excellent
 - Very good
 - Good
 - Fair
 - Poor



Health Services Research

2008 Eisenberg Award

Adobe Acrobat Professional - [Kahn et al HSR 2007.pdf]

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DOI: 10.1111/j.1475-6773.2006.00604.x

Does Ambulatory Process of Care Predict Health-Related Quality of Life Outcomes for Patients with Chronic Disease?

Katherine L. Kahn, Diana M. Tisnado, John L. Adams, Honghu Liu, Wen-Pin Chen, Fang Ashlee Hu, Carol M. Mangione, Ronald D. Hays, and Cheryl L. Damberg

Objective. The validity of quality of care measurement has important implications for practicing clinicians, their patients, and all involved with health care delivery. We used empirical data from managed care patients enrolled in west coast physician organizations to test the hypothesis that observed changes in health-related quality of life across a

Health-Related Quality of Life is:

- How the person FEELS (well-being)
 - Emotional well-being
 - Pain
 - Energy
- What the person can DO (functioning)
 - Self-care
 - Role
 - Social

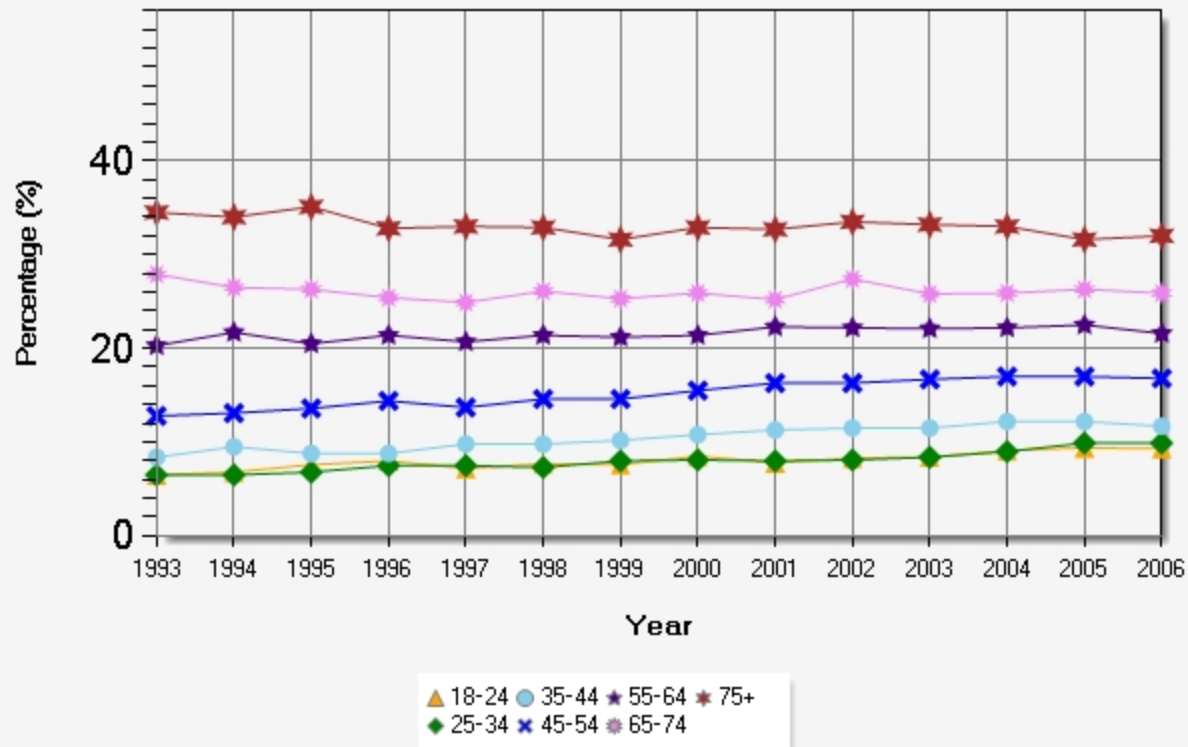
HRQOL is Not

- Quality of environment
- Type of housing
- Level of income
- Social Support



Percentage with fair or poor self-rated health

Nationwide trend: Age Group



**Greater % of fair or poor health reported
by older adults (33% for 75+ versus 9% for 18-34)**

In general, how would you
rate your health?

Poor

Fair

Good

Very Good

Excellent

Does your health now limit you in walking more than a mile?

(If so, how much?)

No, not limited at all

Yes, limited a little

Yes, limited a lot



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



0-100 Scoring of HRQOL Scales

Average or sum all items in the same scale.

0 (worst) to 100 (best) possible range (linear)
transformation

$$X_{0-100} = \frac{(\text{original score} - \text{minimum}) * 100}{(\text{maximum} - \text{minimum})}$$

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 Function

My score today = 100

Event #1:

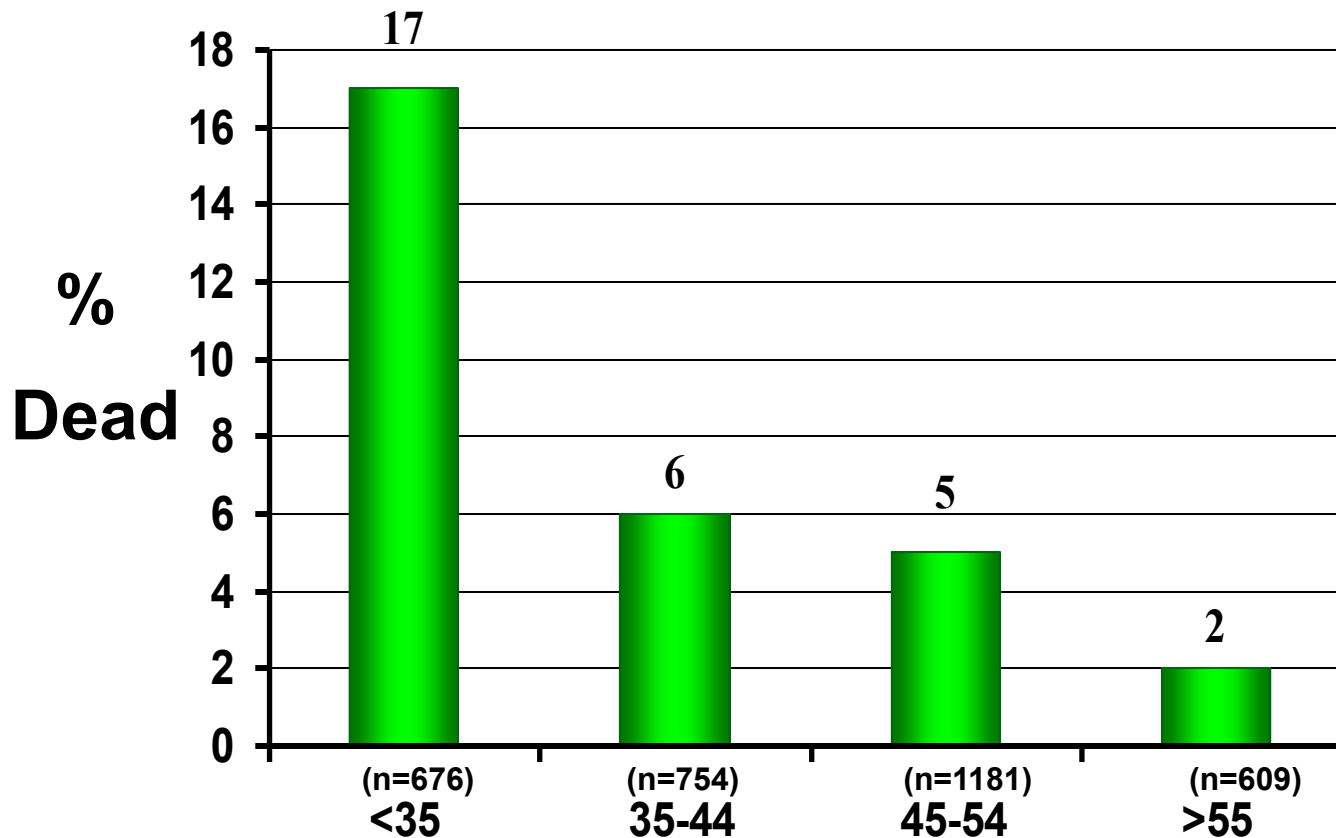
- Hit by **Rock** results in being *limited a little* in vigorous activities
- Post-intervention score: 95 (- 0.25 SD)

Event #2:

- Hit by **Bike** results in me being:
 - *limited a lot* in vigorous activities and in climbing several flights of stairs
 - *limited a little* in moderate activities
- Post-intervention score: 75 (- 1.25 SD)

Mean = 87 (SD = 20)
75th percentile = 100 (U.S. males)

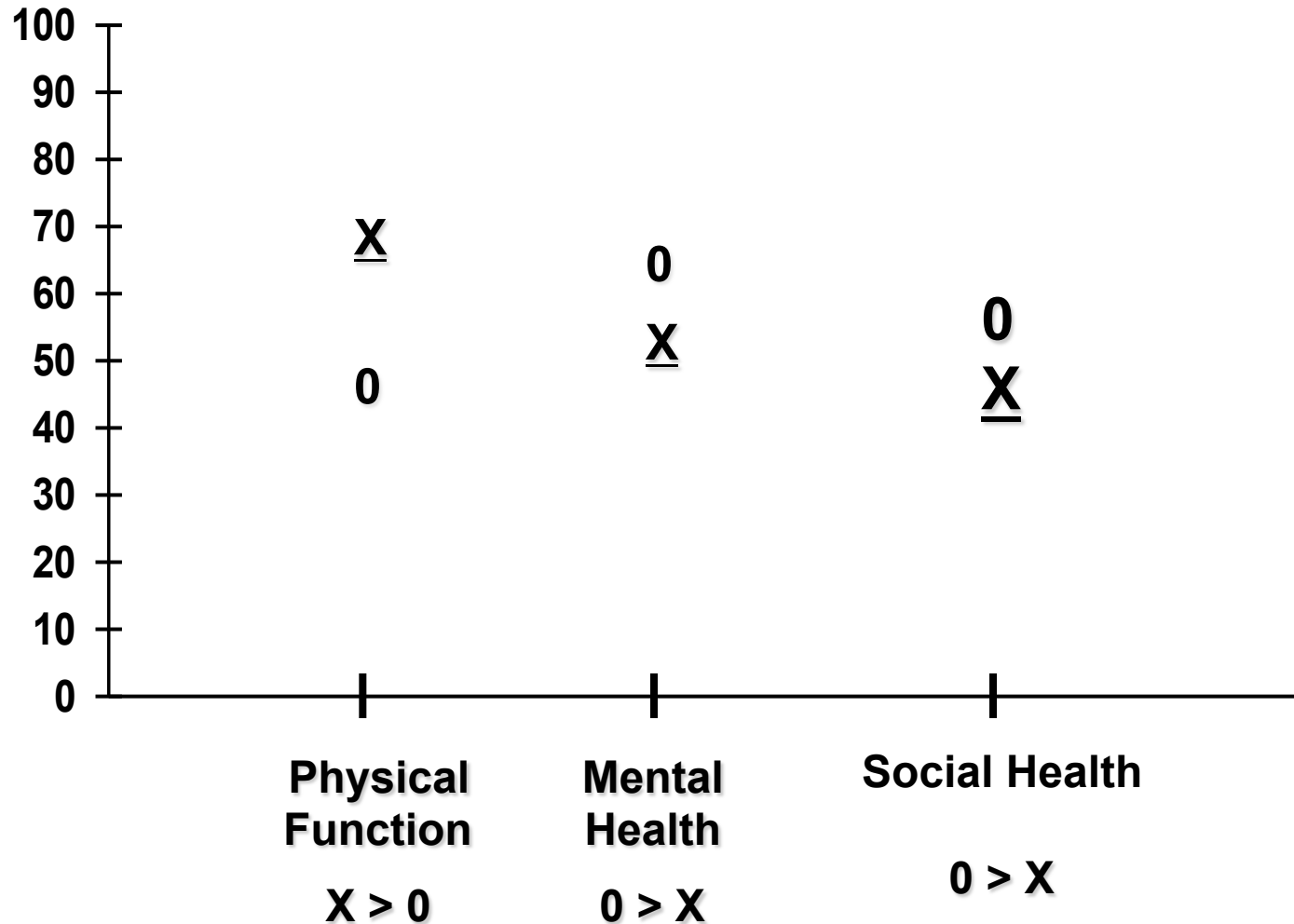
Self-Reported Physical Health Predictive of 5-Year Mortality



SF-36 Physical Health Component Score (PCS)—T score

Ware et al. (1994). SF-36 Physical and Mental Health Summary Scales: A User's Manual.

Is New Treatment (X) Better Than Standard Care (O)?

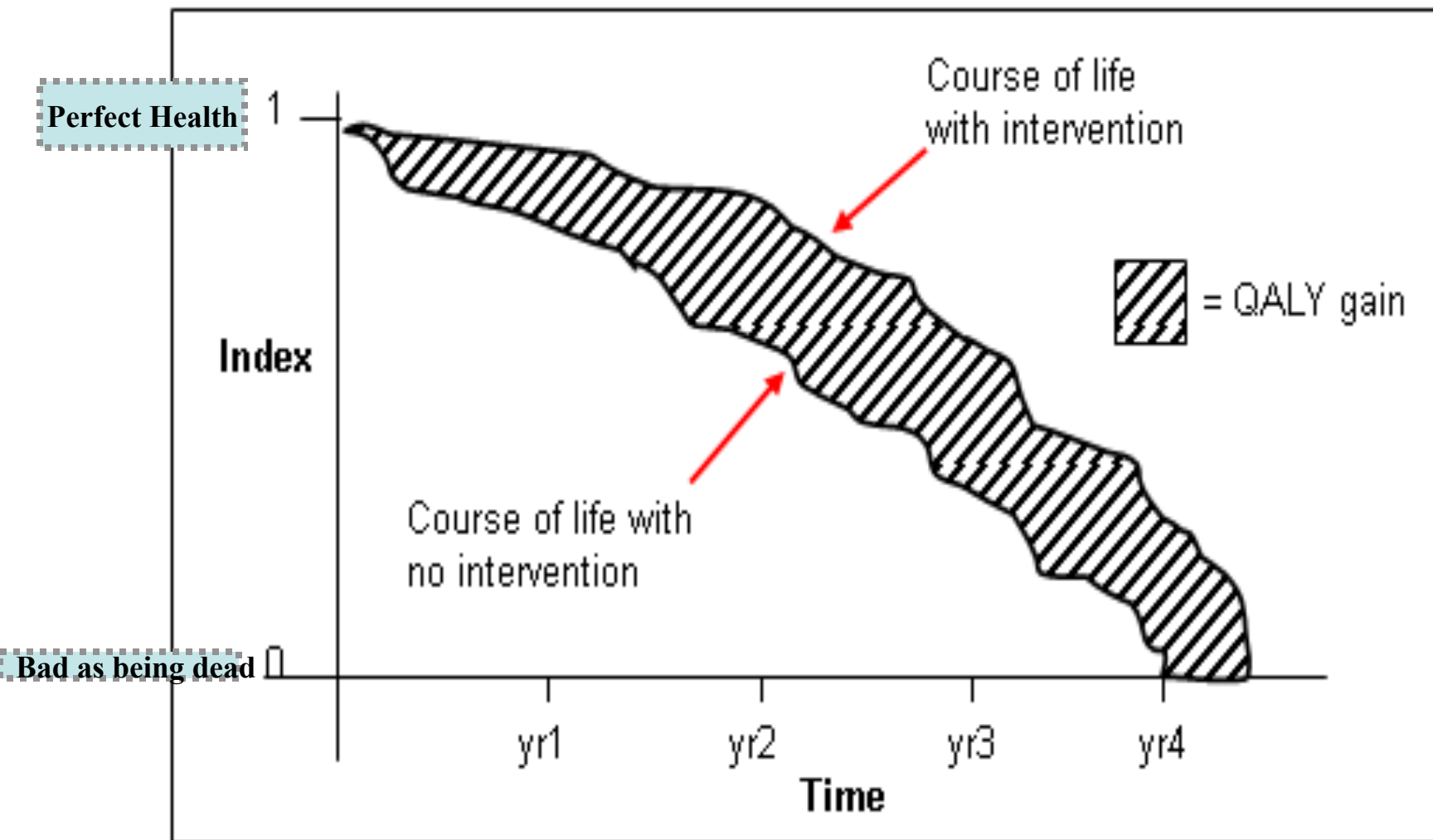


Medicine Use Diminishes HRQOL?

Person	Medication Use	HRQOL (0-100 scale)
1	No	dead
2	No	dead
3	No	50
4	No	75
5	No	100
6	Yes	0
7	Yes	25
8	Yes	50
9	Yes	75
10	Yes	100

Group	n	HRQOL
No Medicine	3	75
Yes Medicine	5	50

Preference-based HRQOL Measure Yields Summary Score



Preference-Based HRQOL Measures

Cost ☐

Effectiveness ☐

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)
- Primary outcome—composite of death, reinfarction, or hospital treatment for class IV heart failure

Health-Related Quality of Life Outcome Measures (baseline, 4, 12 & 24 months)

- Duke Activity Status Index (DASI)
- Medical Outcomes Study 36-Item Short-Form (SF-36) Mental Health Scale (MHI-5)
- Time tradeoff (TTO)

DASI

- Self-administered questionnaire measuring physical functioning (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”

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

Choice #1: Your present state

Life Expectancy: 10 years

Choice #2: Excellent health

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

$$\left[1 - \frac{x}{10} = QALY \right]$$

TTO Estimates

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

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

$$X = 1 \rightarrow QALY = 0.9$$

$$X = 5 \rightarrow QALY = 0.5$$

$$X = 10 \rightarrow QALY = 0$$

$$\left[1 - \frac{X}{10} = QALY \right]$$

Results & Conclusions

- 2-year net cost was \$7,089 for PCI
- DAI at 4 months
 - PCI (37) versus Medical therapy (33)
- 2-year 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.

Thank you

COMMENTS BETTER LEFT UNSAID



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