



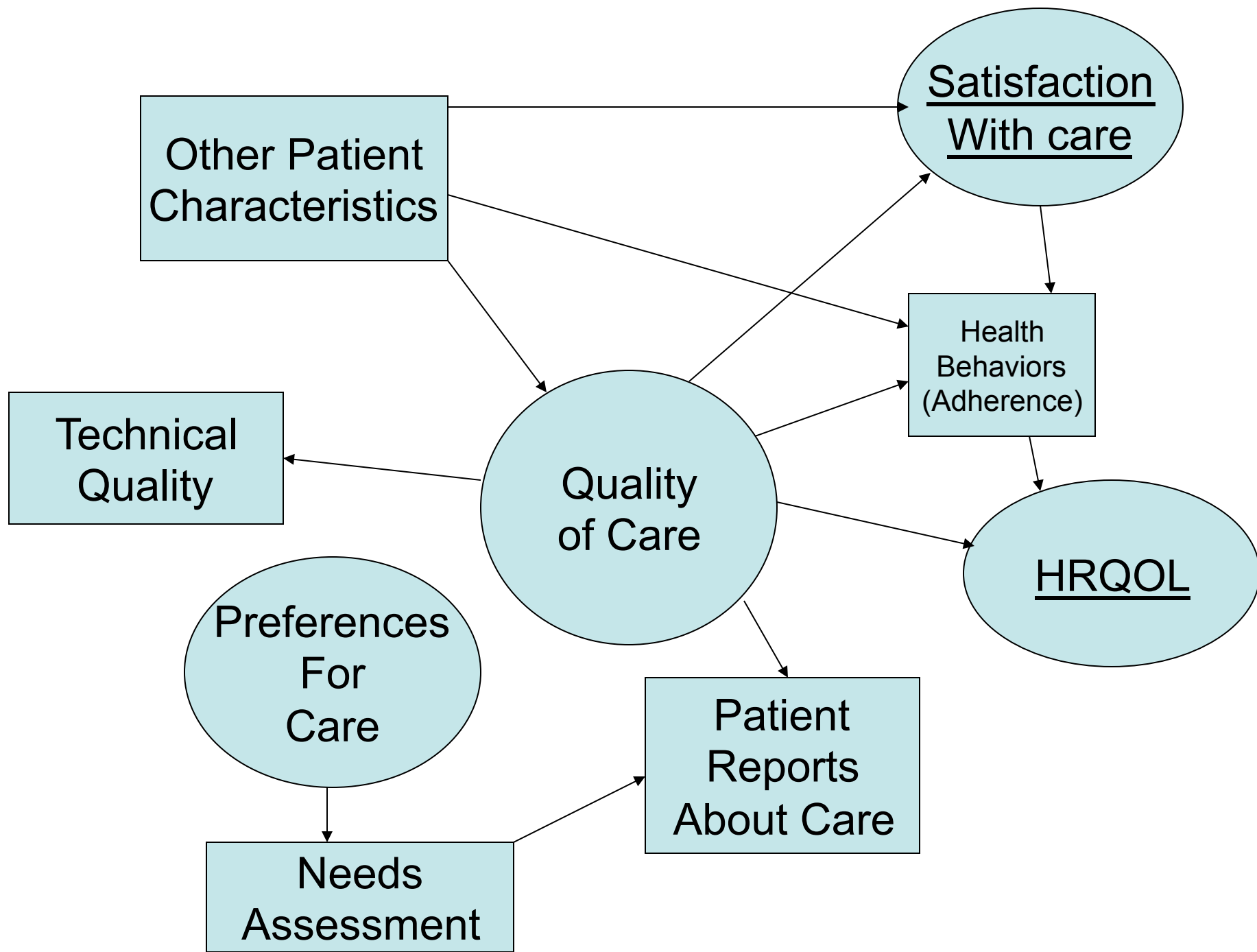
Health-Related Quality of Life Assessment in Outcome Studies

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

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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 2.5-year window reflecting process of care.

Data Sources/Study Setting. Patient self-report data as well as clinically detailed medical record review regarding 963 patients with chronic disease associated with managed care from three west coast states.

Study Design. Prospective cohort study of change in health-related quality of life scores across 30 months as measured by change in SF-12 physical component scores.

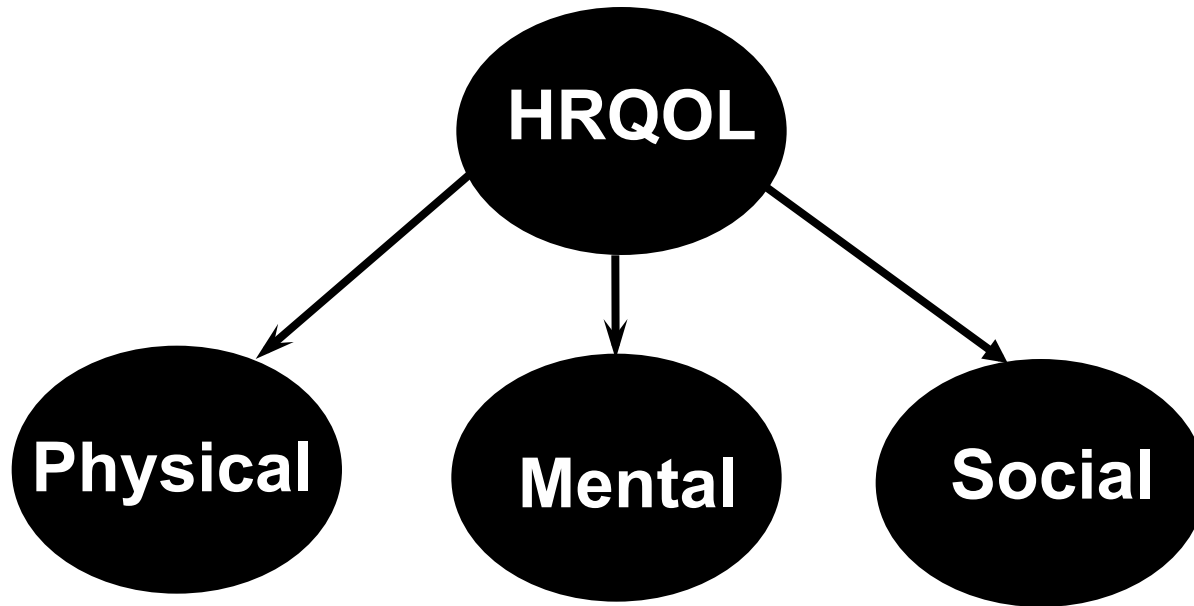
Data Collection/Extraction Methods. Patient self-report and medical record abstraction.

Principal Findings. We found a positive relationship between better process scores and higher burden of illness ($p < .05$). After adjustment for burden of illness, using an instrumental variables approach revealed better process is associated with smaller declines in SF-12 scores across a 30-month observation window ($p = .014$). The application of the best quartile of process of care to patients currently receiving poor process

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 Multi-Dimensional



HRQOL is Not

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



SF-36 Generic Profile Measure

- Functioning
 - Physical functioning (10 items)
 - Role limitations/physical (4 items)
 - Role limitations/emotional (3 items)
 - Social functioning (2 items)
- Well-being
 - Emotional well-being (5 items)
 - Energy/fatigue (4 items)
 - Pain (2 items)
 - General health perceptions (5 items)

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



Scoring HRQOL Scales

- Average or sum all items in the same scale.
- 0 (worst) to 100 (best) possible range (linear) transformation
- Fix mean and SD in sample or with respect to a reference population
 - z-score (mean = 0, SD = 1)
 - T-score (mean = 50, SD = 10)

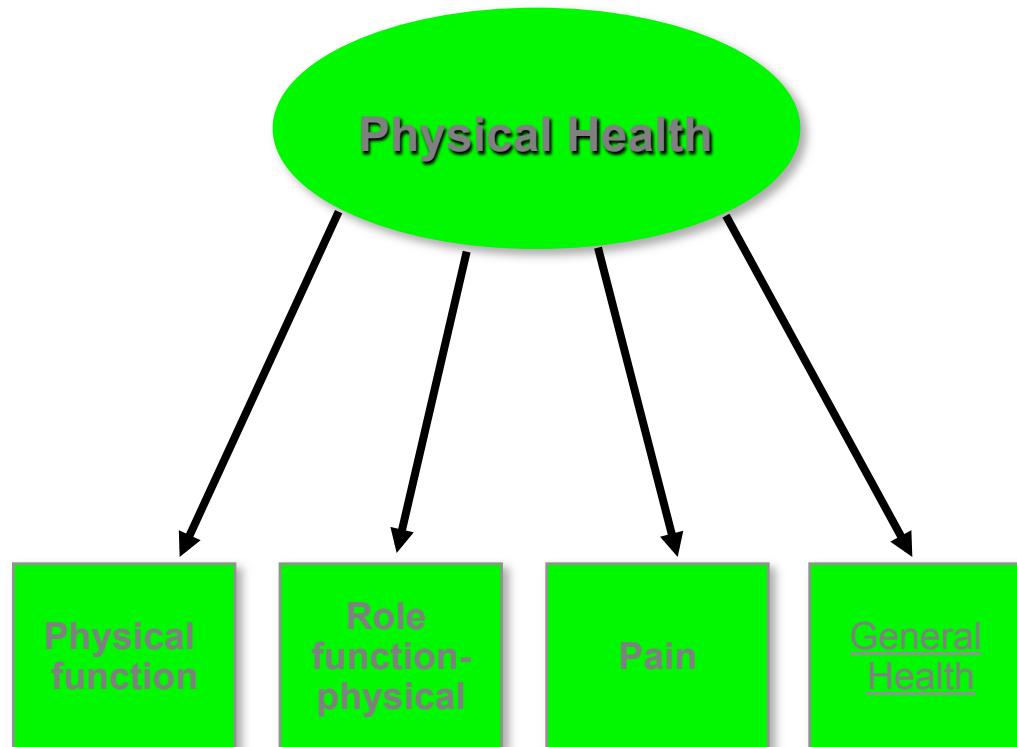
Formula for Transforming Scores

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

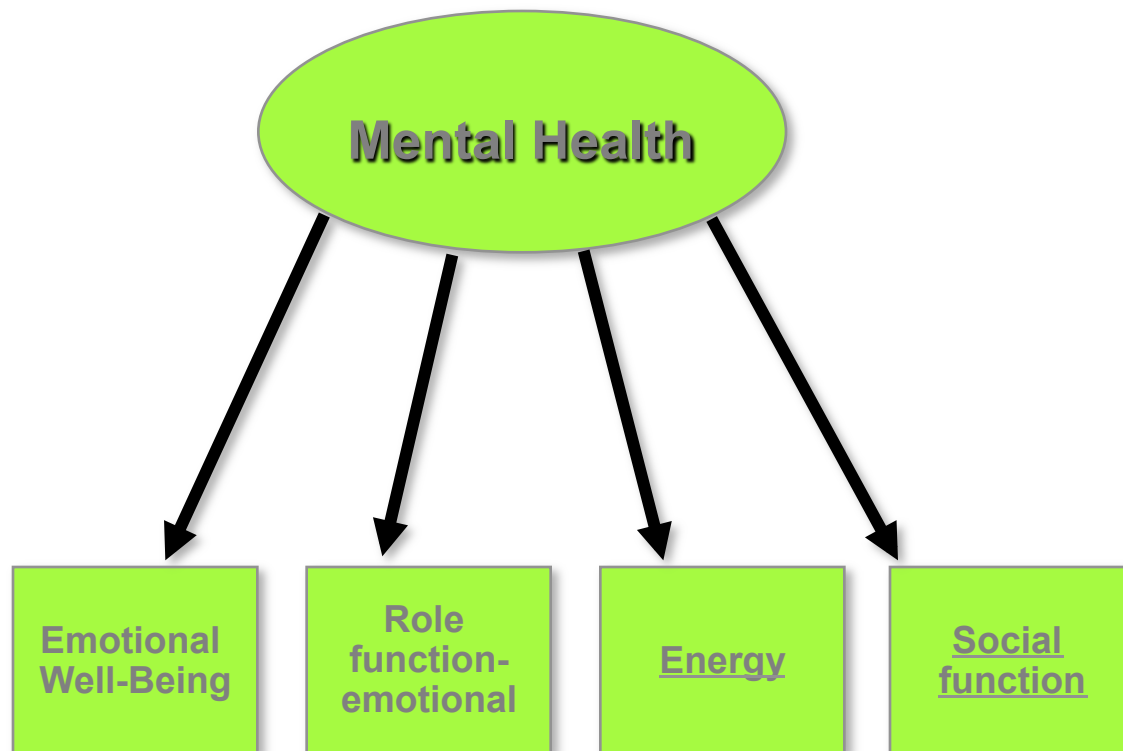
$$Y = \text{target mean} + (\text{target SD} * Zx)$$

$$Z_{\text{score}} = \frac{(X - \text{sample or population mean})}{SD_x}$$

SF-36 Physical Health



SF-36 Mental Health



SF-36 Physical Health (PCS) & Mental Health (MCS) Summary Scores

$$\begin{aligned} \text{PCS} = & (\text{PF_Z} * .42402) + (\text{RP_Z} * .35119) + \\ & (\text{BP_Z} * .31754) + (\text{GH_Z} * .24954) + \\ & (\text{EF_Z} * .02877) + (\text{SF_Z} * -.00753) + \\ & (\text{RE_Z} * -.19206) + (\text{EW_Z} * -.22069) \end{aligned}$$

$$\begin{aligned} \text{MCS} = & (\text{PF_Z} * -.22999) + (\text{RP_Z} * -.12329) + \\ & (\text{BP_Z} * -.09731) + (\text{GH_Z} * -.01571) + \\ & (\text{EF_Z} * .23534) + (\text{SF_Z} * .26876) + \\ & (\text{RE_Z} * .43407) + (\text{EW_Z} * .48581) \end{aligned}$$

T-score Transformation

$$PCS = (PCS_z * 10) + 50$$

$$MCS = (MCS_z * 10) + 50$$

Reliability Minimum Standards

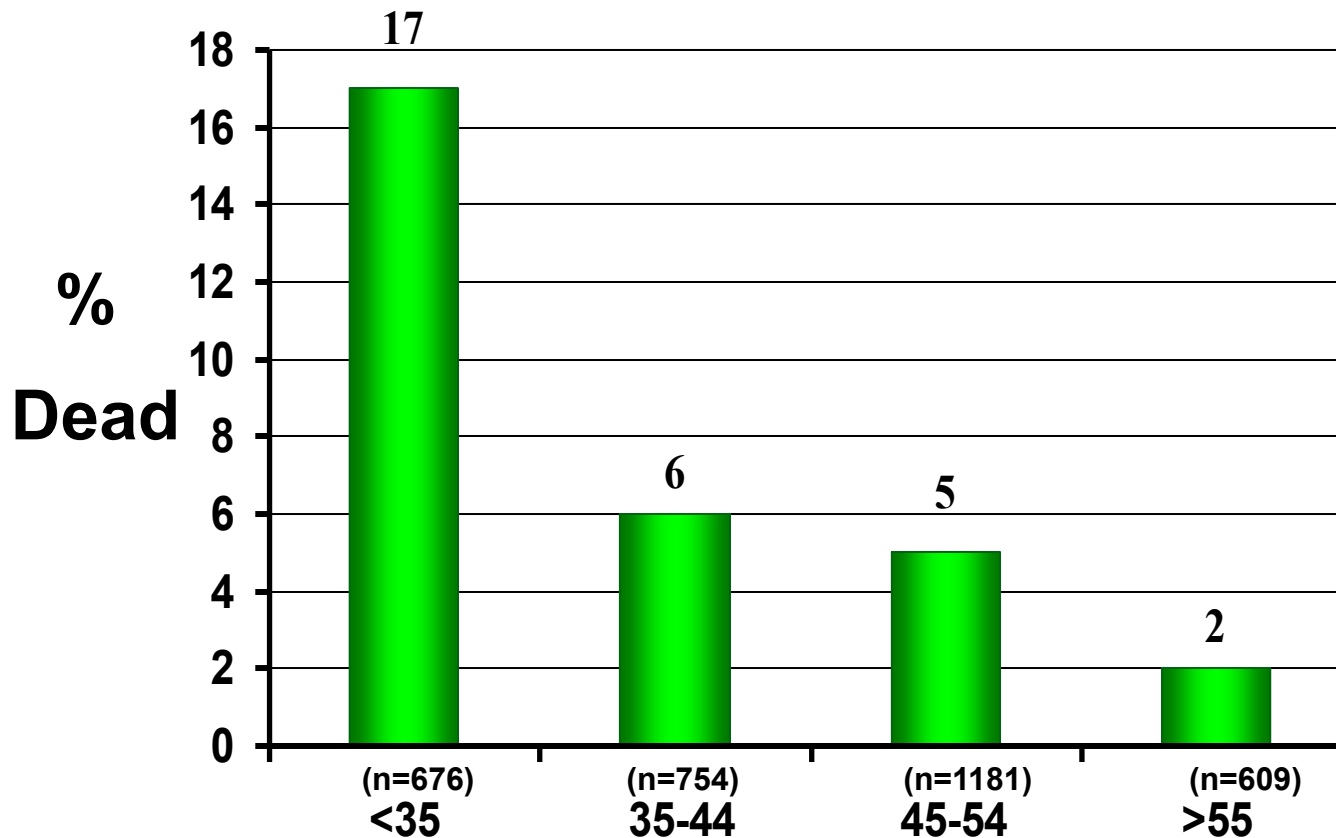
0.70 or above (for group comparisons)

Hahn, E. A., Cella, D., Chassany, O.,
Fairclough, D. L., Wong, G. Y., & Hays,
R. D. (in press). A comparison of the
precision of health-related quality of life
data relative to other clinical measures.
Mayo Clinic Proceedings.

Construct Validity

- Does measure relate to other measures in ways consistent with hypotheses?
- Responsiveness to change including minimally important difference

PCS Predictive of 5-Year Mortality



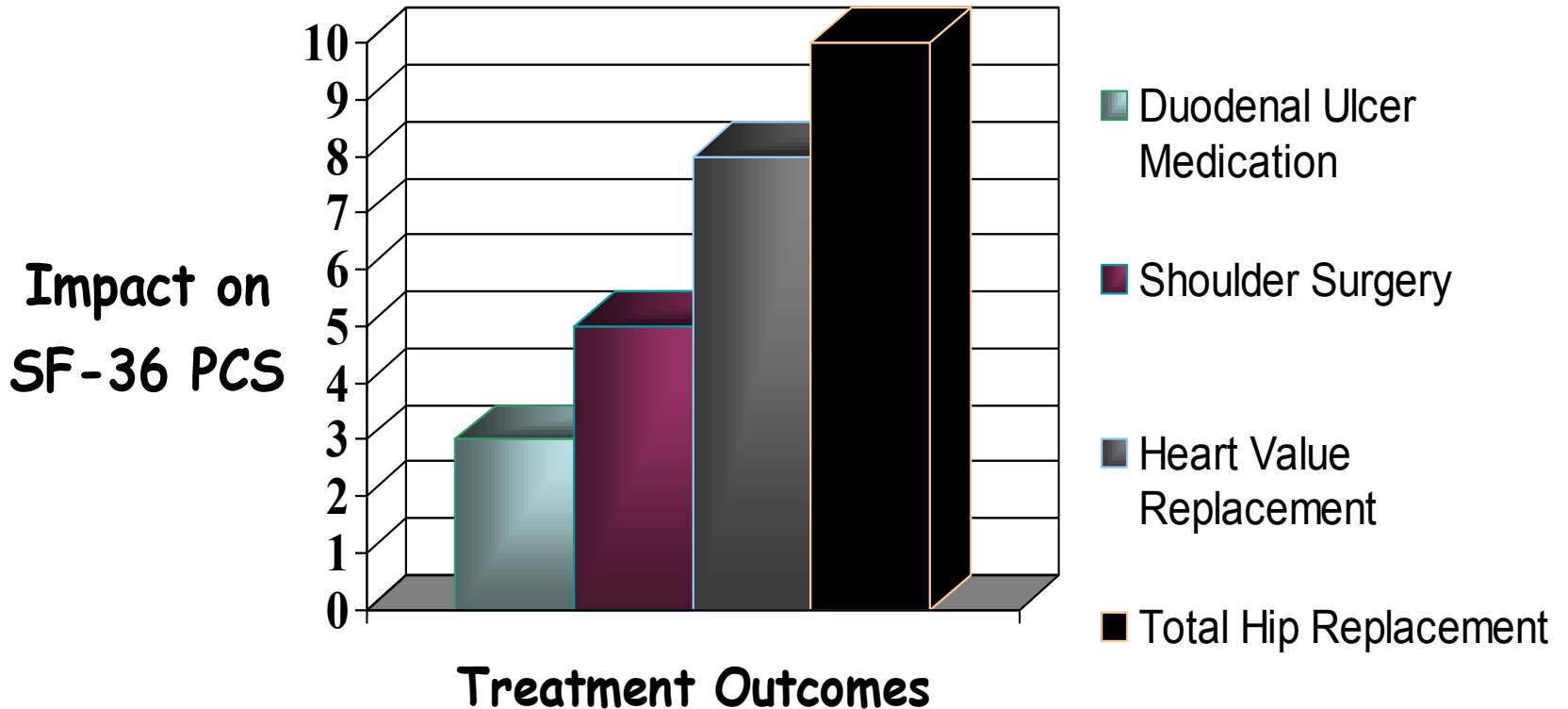
SF-36 Physical Health Component Score (PCS)—T score

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

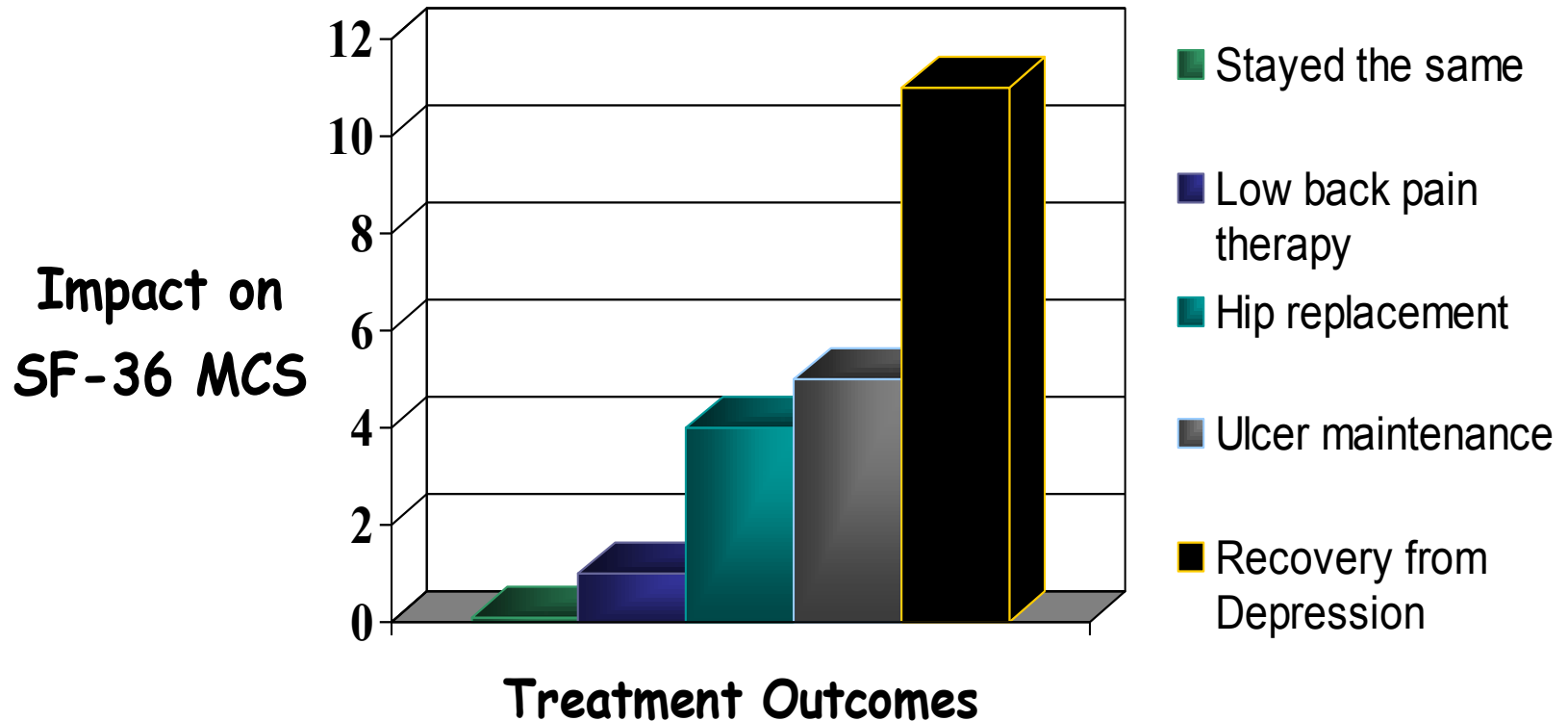
Responsiveness to Change and Minimally Important Difference (MID)

- HRQOL measures should be responsive to interventions that change HRQOL
- Evaluate change on HRQOL measures for those who have changed on external indicators of change (anchors).
 - HRQOL change among people who have changed a “minimal” amount on anchors is used to estimate MID.

Treatment Impact on PCS



Treatment Impact on MCS



Effect Size Benchmarks

- Small: 0.20->0.49
- Moderate: 0.50->0.79
- Large: 0.80 or above



Responsiveness Indices

- (1) Effect size (ES) = D/SD
- (2) Standardized Response Mean (SRM) = D/SD^{\dagger}
- (3) Guyatt responsiveness statistic (RS) = D/SD^{\ddagger}

D = raw score change in “changed” group;

SD = baseline SD;

SD^{\dagger} = SD of D;

SD^{\ddagger} = SD of D among “unchanged”

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. Vigorous activities, such as running, lifting heaving 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

Yes, limited a lot (0)/Yes, limited a little (50)/No, not limited at all (100)
Mean = 87; 75th percentile = 100 for U.S. males

Change in Physical Function from Baseline

Mean for U.S. males = 87 (SD = 20)

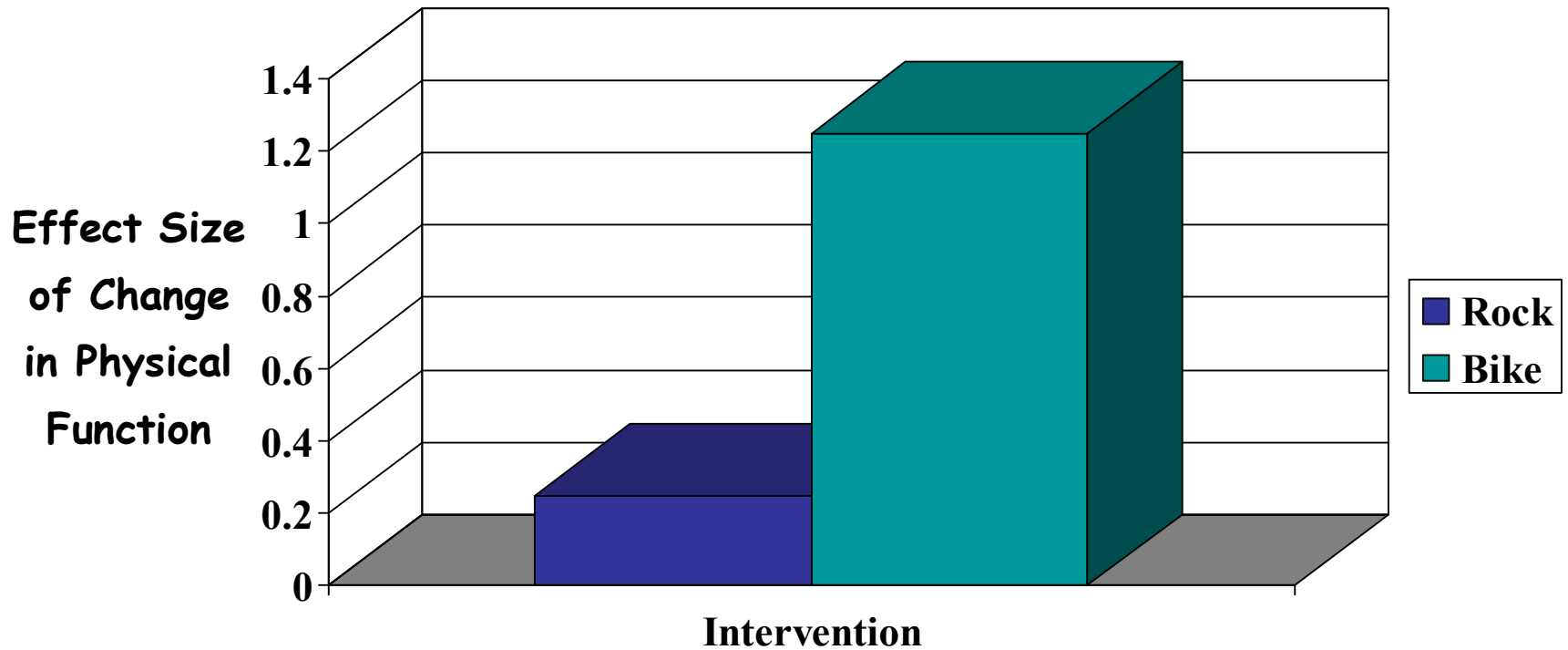
My baseline score = 100

Post-baseline:

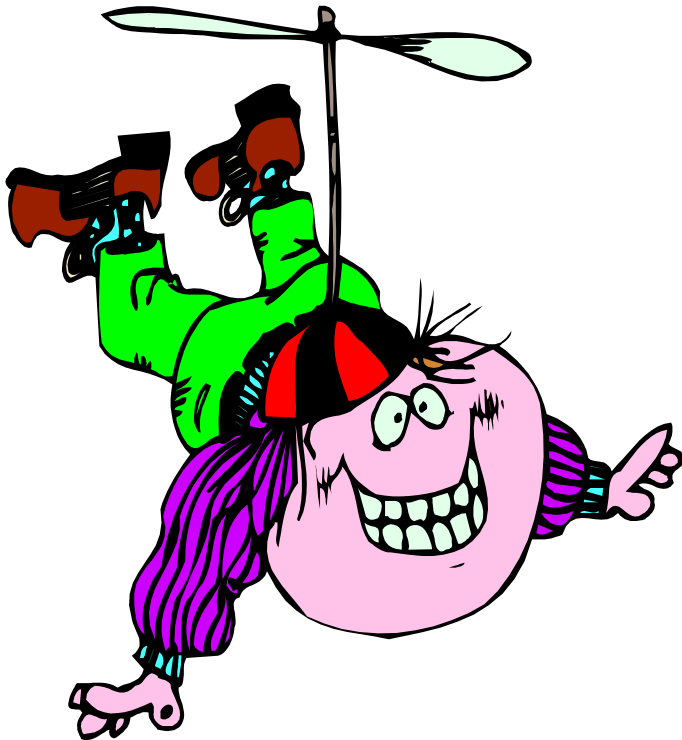
- Hit by **Bike** causes me to be *limited a lot* in vigorous activities, *limited a little* in moderate activities, and *limited a lot* in climbing several flights of stairs. Physical functioning drops to 75 (- 1.25 SD)
- Hit by **Rock** causes me to be *limited a little* in vigorous activities and physical functioning drops to 95 (- 0.25 SD)

Getting Hit By Bike is > Minimal

Getting Hit by Rock is Closer to MID



HRQOL Profile Measures



Generic

Targeted

Targeted HRQOL Measures

- Designed to be relevant to particular group.
- Sensitive to small, but clinically-important changes.
- More familiar and actionable for clinicians.
- Enhance respondent cooperation.

Kidney-Disease Targeted Items

- During the last 30 days, to what extent were you bothered by each of the following.
 - Cramps during dialysis ?
 - Feeling washed out or drained?

Not at all bothered

Somewhat bothered

Moderately bothered

Very much bothered

Extremely bothered

IBS-Targeted Item

- 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

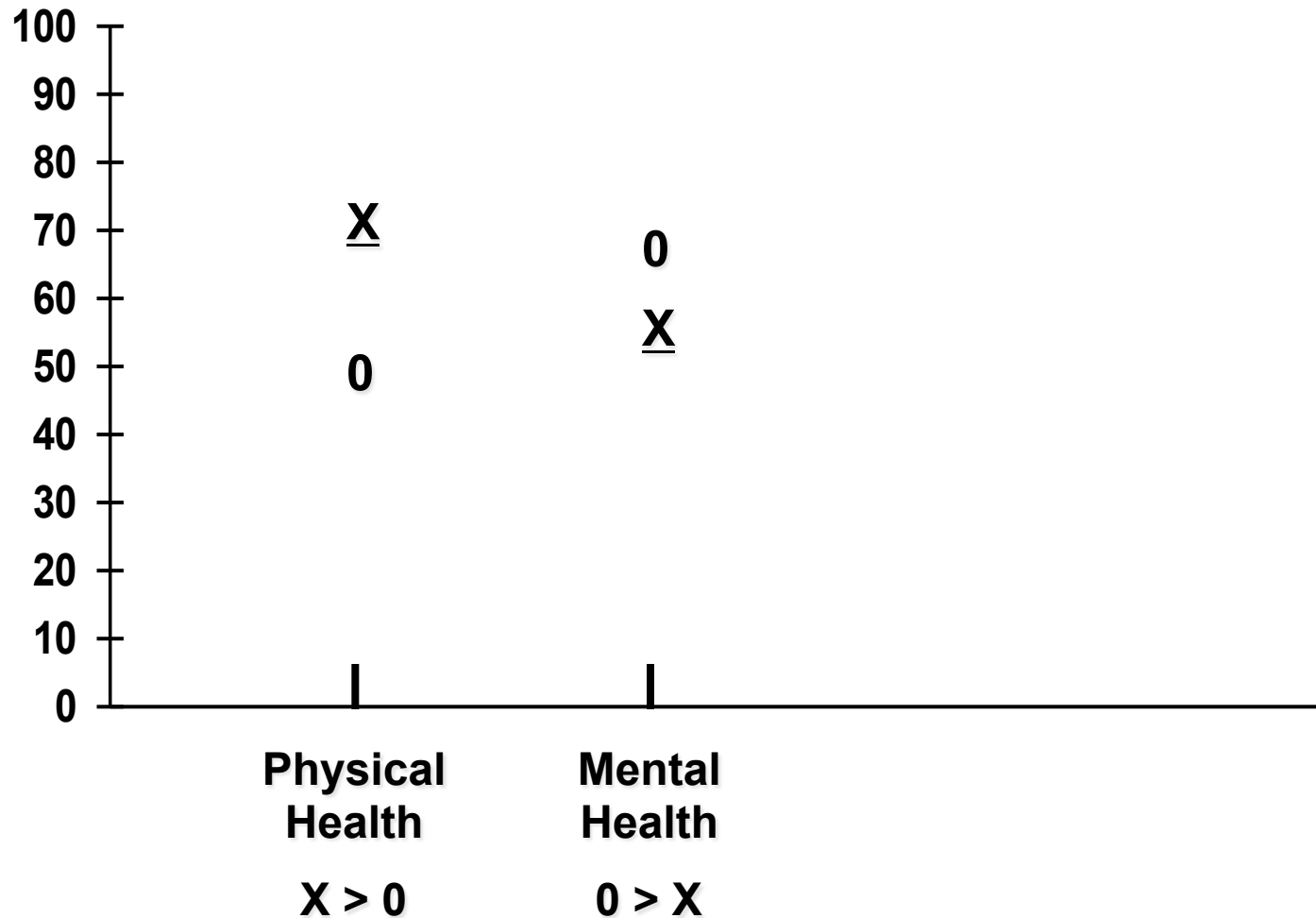
All of the time

Use of HRQOL Measures-- Cost-Effective Health Care

Cost ☐

Effectiveness ☐

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

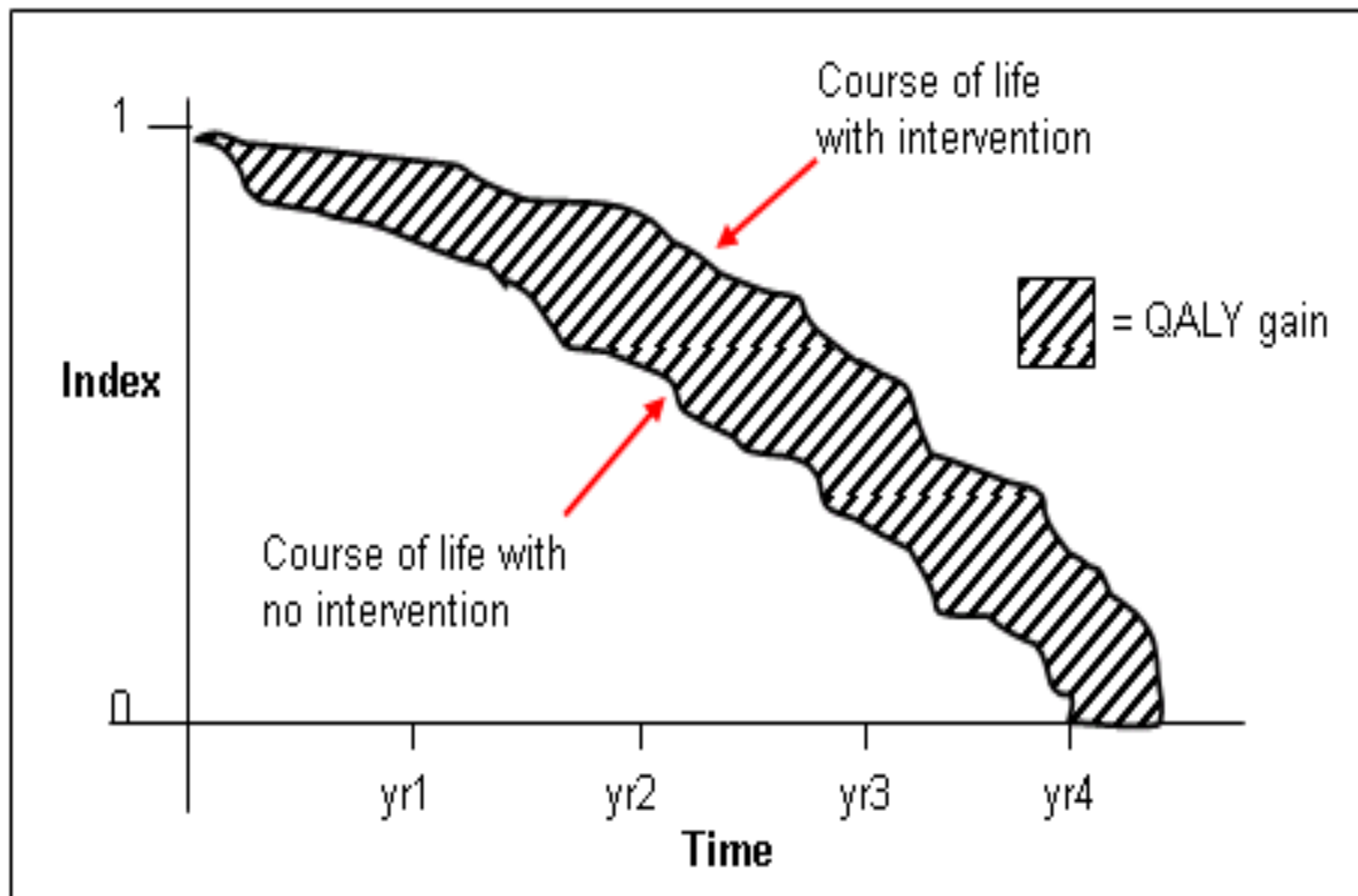
Group	n	HRQOL
No Medicine	3	75
Yes Medicine	5	50

Survival Analysis

Marathoner 1.0

Person in coma 1.0





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

Quality of Life for Individual Over Time

