

# Comprehensive Approach to Measuring Health Outcomes

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**UCLA GIM & HSR**

October 23, 2006 (3:15-4:45 pm)

**MacDonald Research Building (MRL)**

**Room 2740**

# How do you know how the patient is doing?

Temperature

Respiration

Pulse

Weight

Blood pressure



# Also, by talking to her or him about ...

## Symptoms

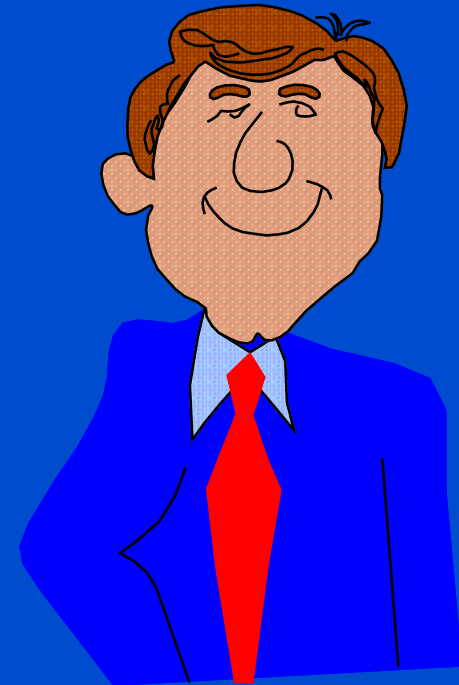
- Have you had a fever in the last 7 days?

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 +

## Urinary leakage

- 49% prostatectomy - vs. 21% waiting

## Sexual dysfunction

- 80% prostatectomy - vs. 45% waiting

# **Woman's Health Initiative (NEJM, 2003)**

**Effects of hormone therapy on HRQOL (n = 16,608;  
1,511 with HRQOL data)**

**Postmenopausal women 50-79 randomized to either:**

**Placebo or estrogen plus progestin**

**No difference on general health, energy, emotional well-being, and sexual satisfaction.**

**Significant but small difference favoring treatment for physical functioning, pain, and sleep disturbance**

# Archives of Internal Medicine (2006)

RAND appropriateness method applied to 784 undergoing total hip replacement and 792 undergoing total knee replacement.

Appropriate candidates for *total hip joint replacement* demonstrated greater improvement than those judged inappropriate in terms of:

physical functioning (34 vs. 20) , role–physical (35 vs. 9),  
bodily pain (33 vs. 6), and social function (27 vs. 7).

Appropriate candidates for *total knee replacement* had greater improvement in social functioning than those deemed inappropriate candidates (20 vs. 8).

# 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



**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?

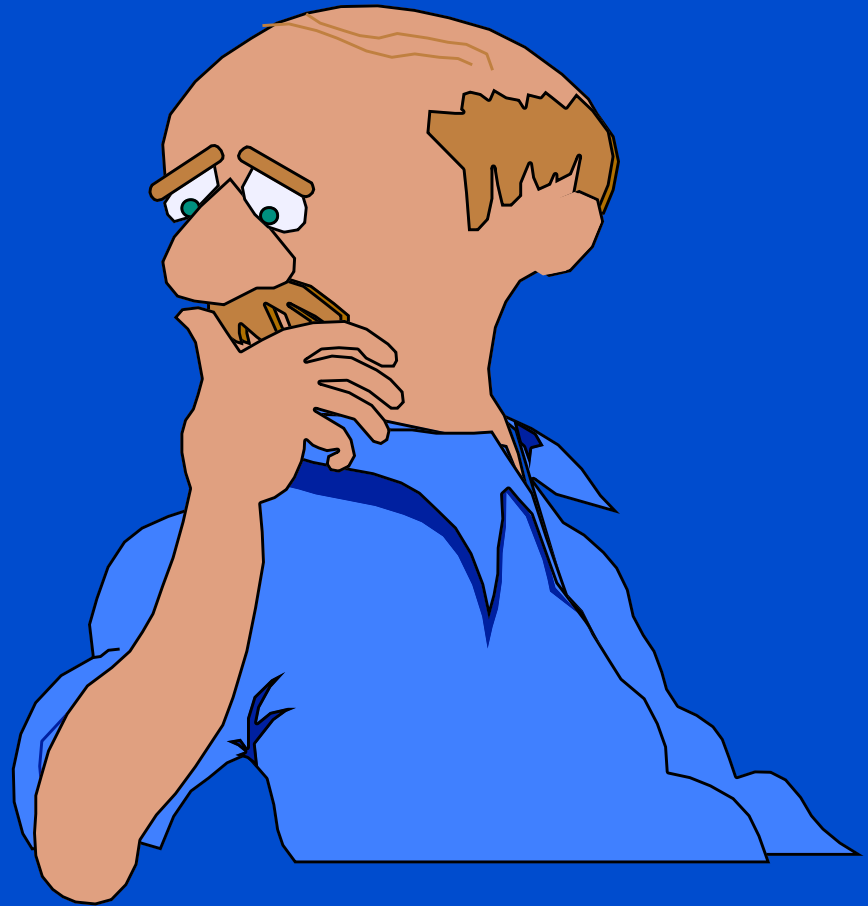
*None of the time*

*A little of the time*

*Some of the time*

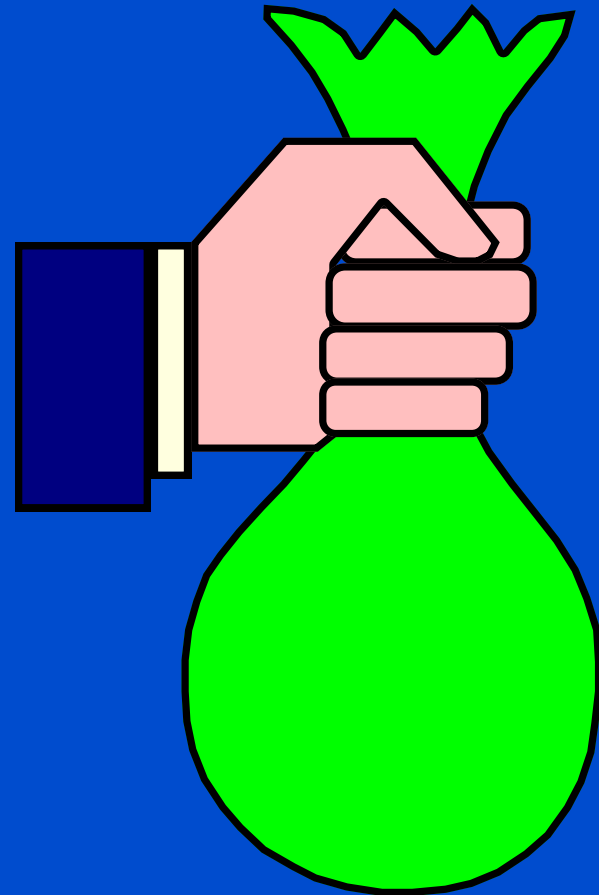
*Most of the time*

*All of the time*



# HRQOL is Not

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



# Reliability estimates

**Reliability—extent to which you get the same score on repeated assessments**

**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**

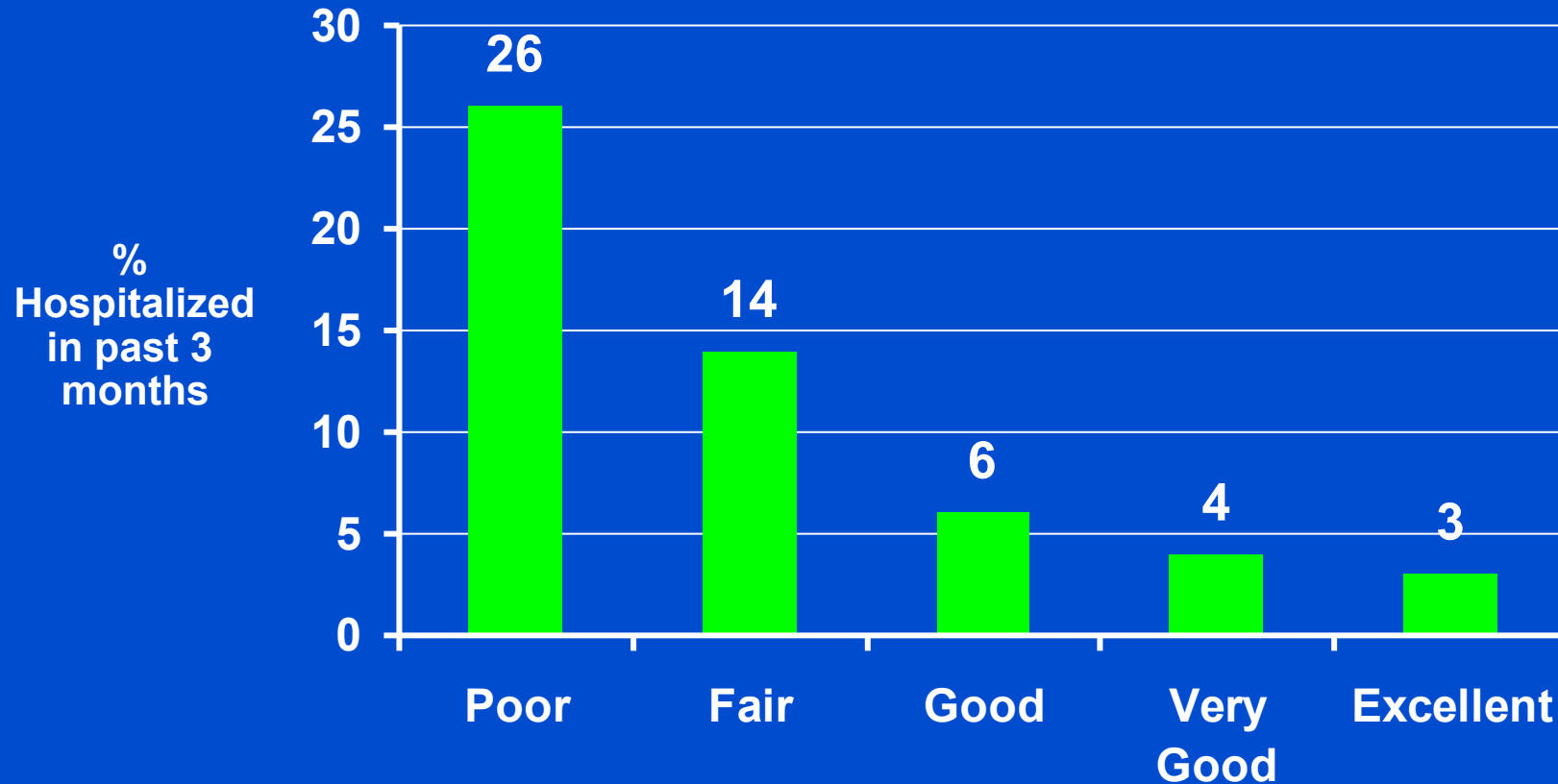
**Very Good**

**Good**

**Fair**

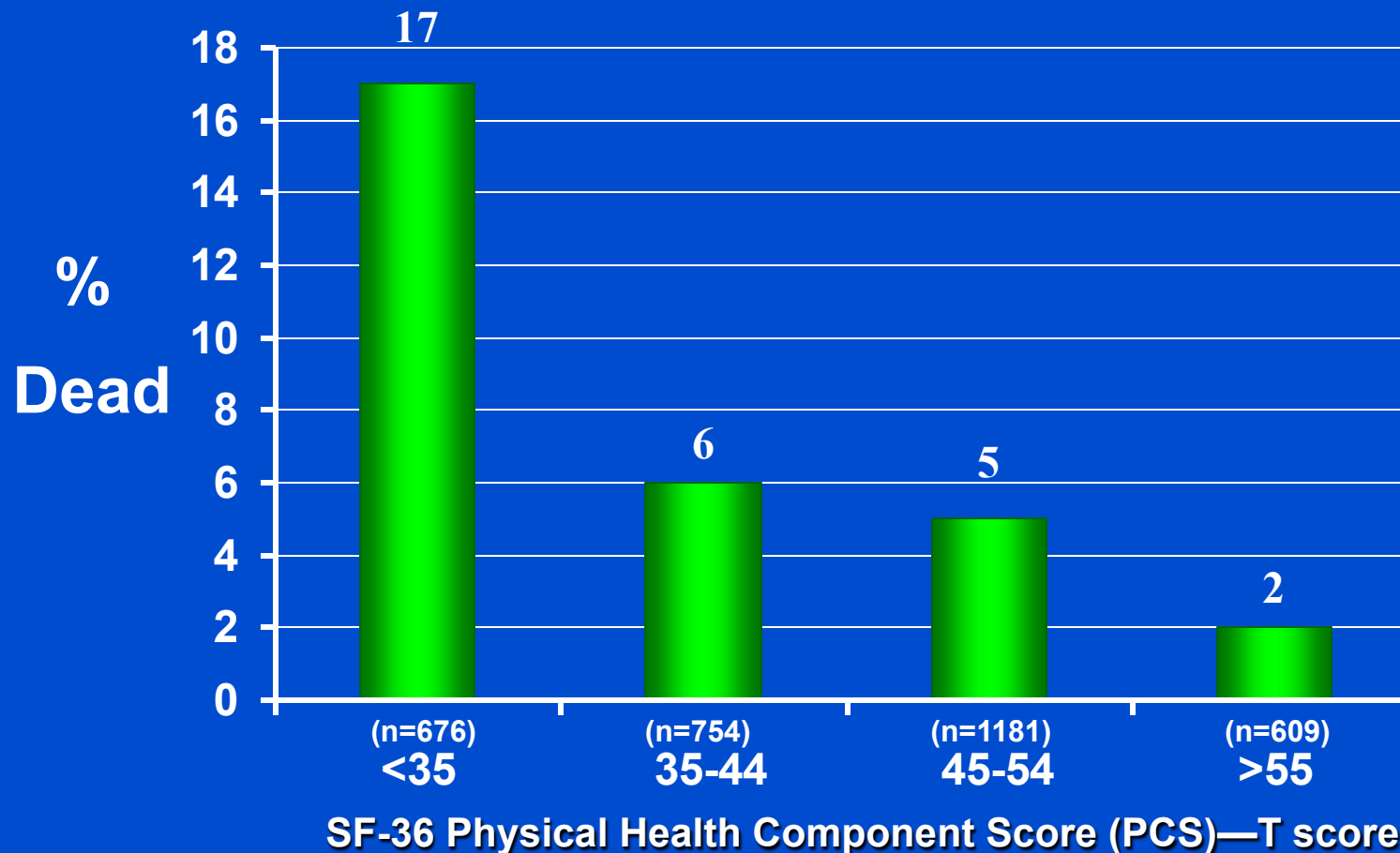
**Poor**

# Hospitalized Patients Report Worse General Health (n = 20,158)



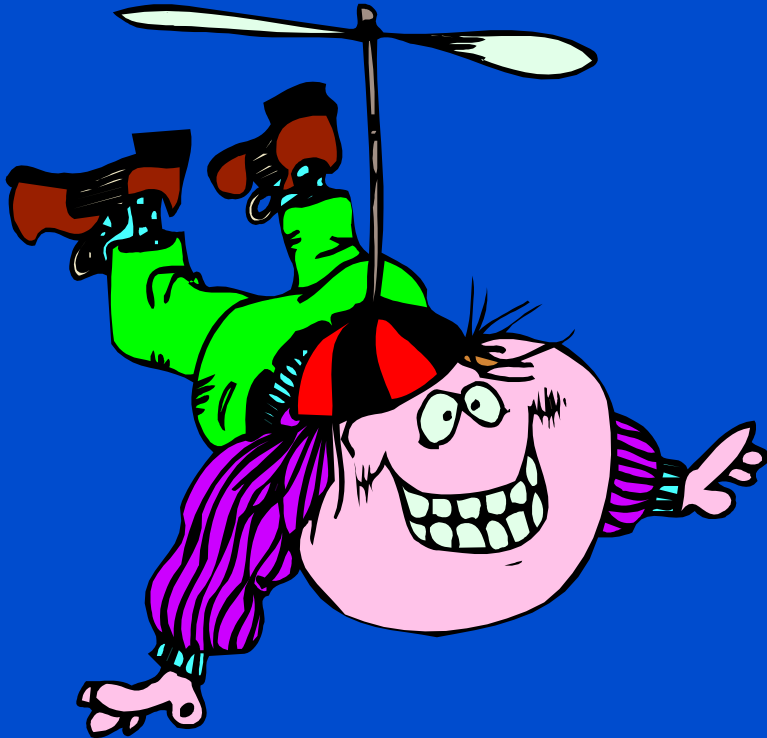
Kravitz, R. et al. (1992). Differences in the mix of patients among medical specialties and systems of care: Results from the Medical Outcomes Study. *JAMA*, 267, 1617-1623.

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



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

# Types of HRQOL Measures



Generic Profile

Targeted Profile

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)

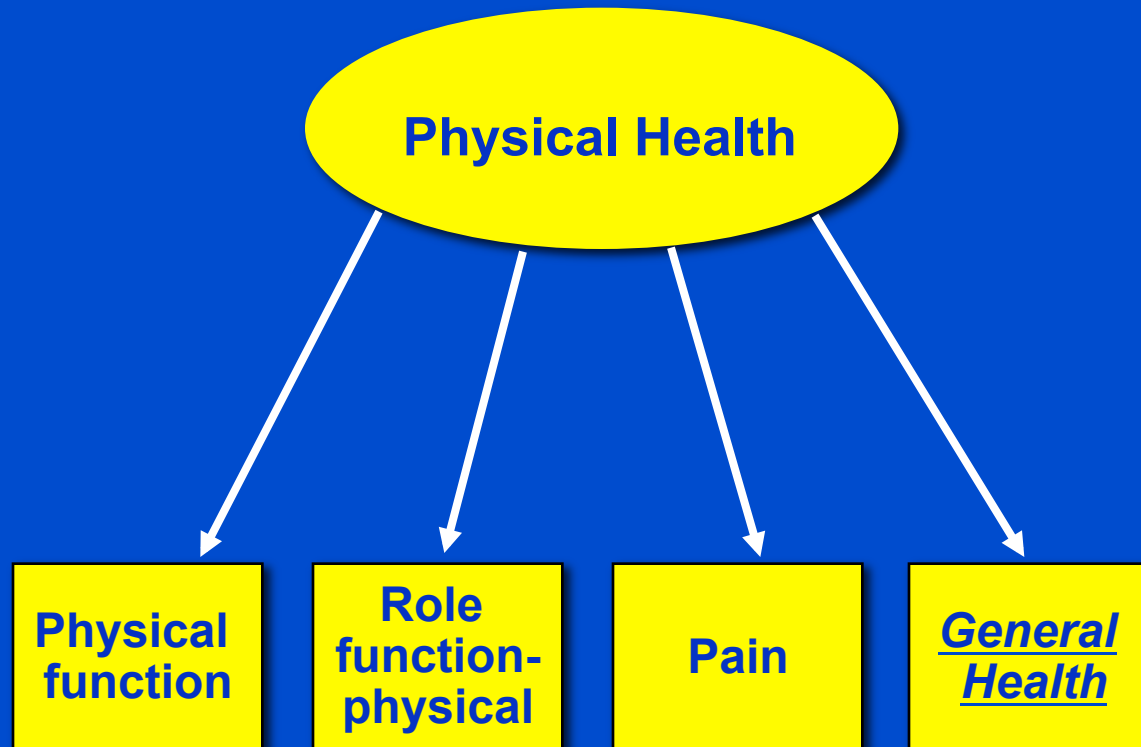
# Scoring Generic HRQOL Scales

Average or sum all items in the same scale.

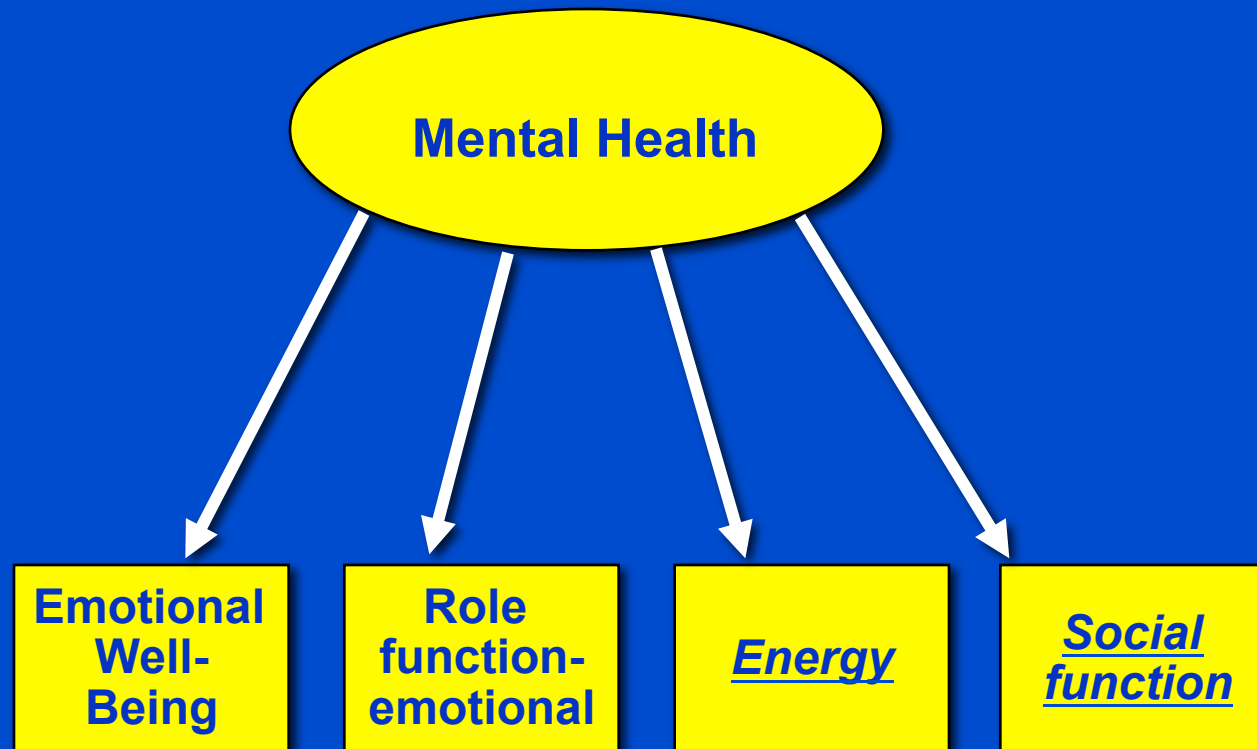
Transform average or sum to

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

# Physical Health



# Mental Health



# Example Uses of Generic HRQOL Measures

## Cross-Sectional

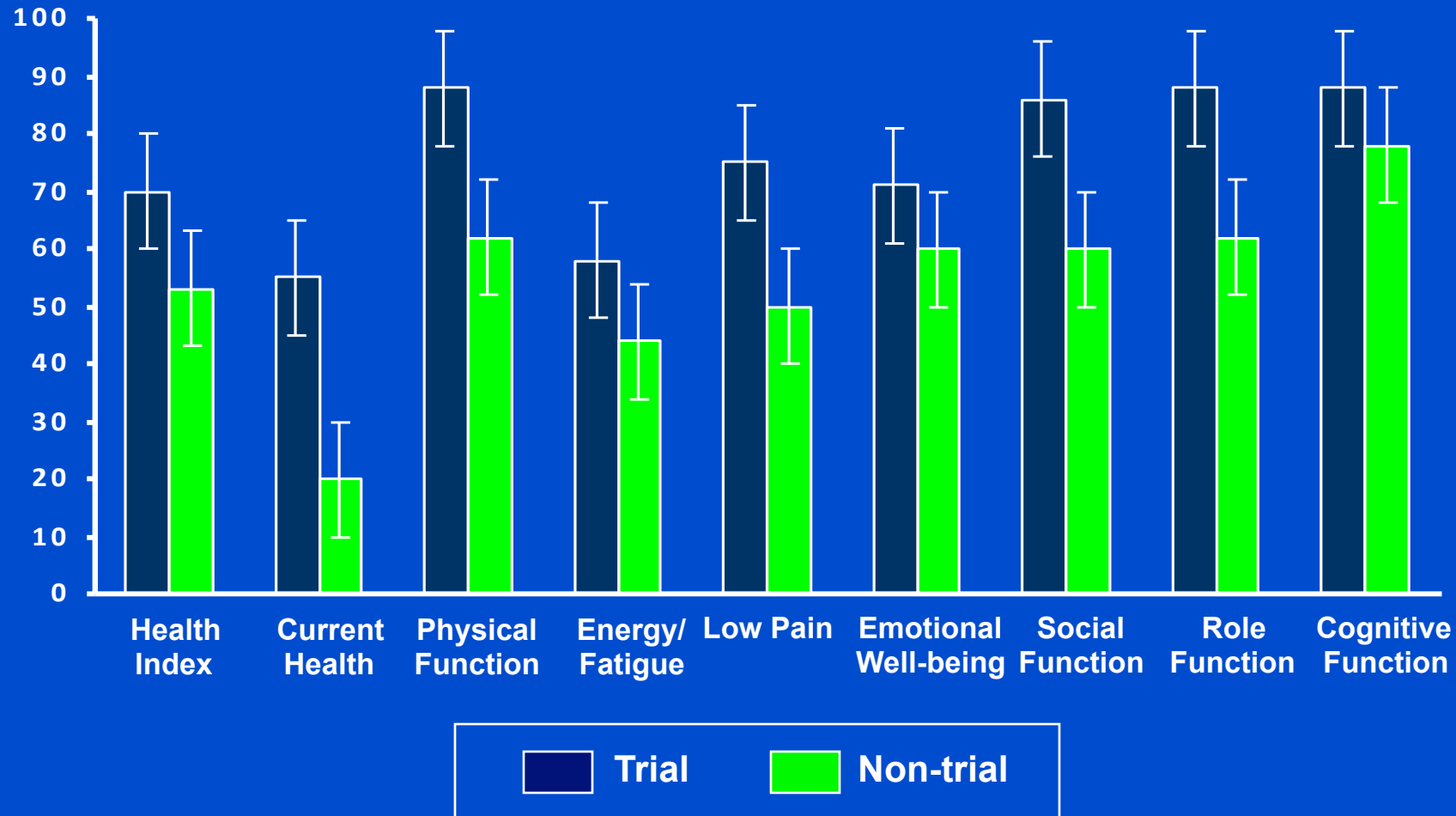
- Comparison of Same Disease in Different Samples
- Profiles of Different Diseases

## Longitudinal

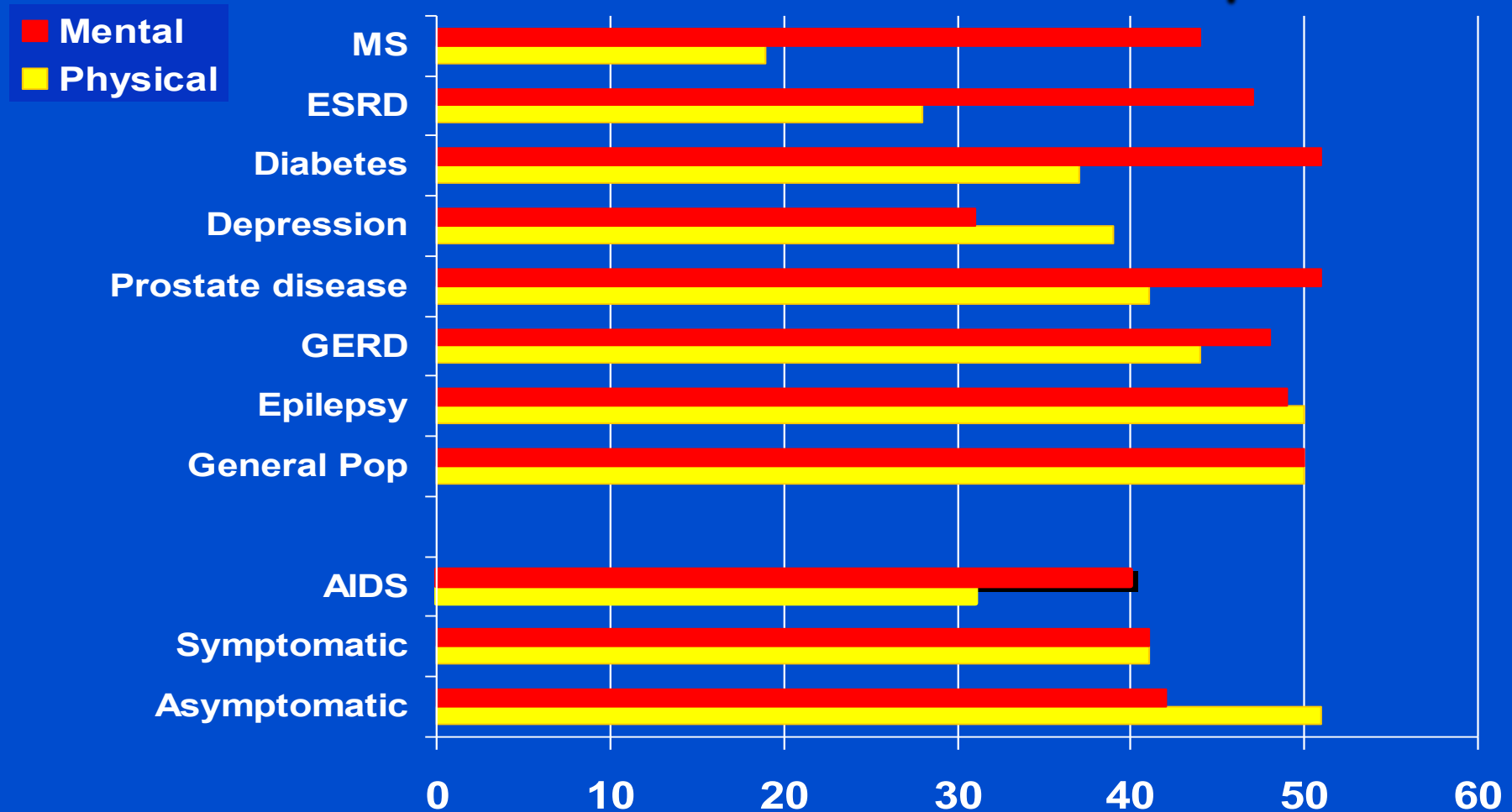
- Profiles of Different Disease
- Identifying Antecedents/Causes of HRQOL

# HRQOL of Patients in ACTG versus Public Hospital Samples

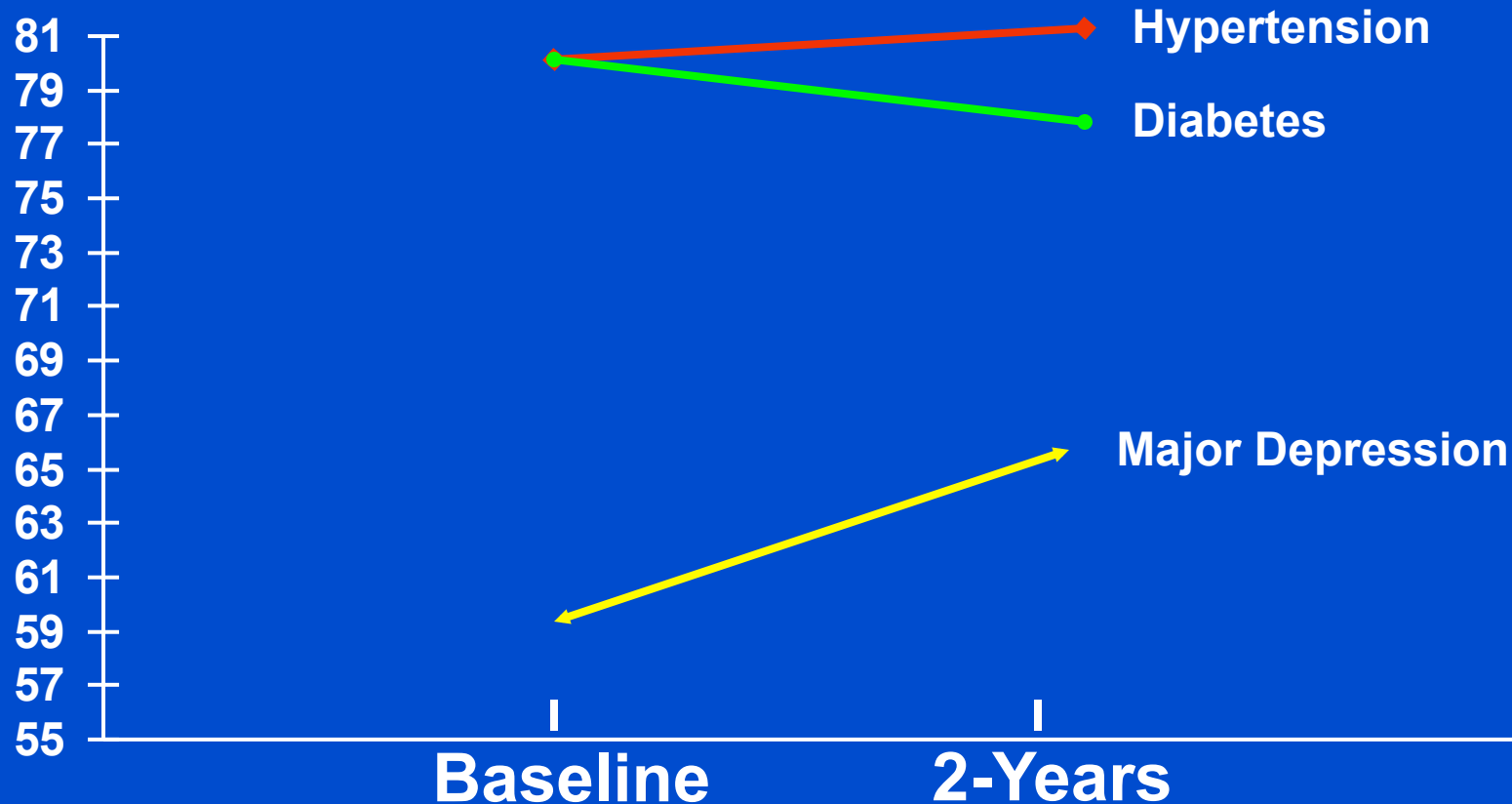
Adjusted Scale Scores (Cunningham et al., 1995)



# HRQOL for HIV Compared to other Chronic Illnesses and General Population



# Course of Emotional Well-being Over 2-years for Patients in the MOS General Medical Sector



Hays, R.D., Wells, K.B., Sherbourne, C.D., Rogers, W., & Spritzer, K. (1995).  
Functioning and well-being outcomes of patients with depression compared  
to chronic medical illnesses. *Archives of General Psychiatry*, 52, 11-19.



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



Stewart, A.L., Hays, R.D., Wells, K.B., Rogers, W.H., Spritzer, K.L., & Greenfield, S. (1994). Long-term functioning and well-being outcomes associated with physical activity and exercise in patients with chronic conditions in the Medical Outcomes Study. *Journal of Clinical Epidemiology*, *47*, 719-730.

# 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*

# 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*

# HRQOL in Men Treated for Localized Prostate Cancer

Cross-sectional study of managed care pop.

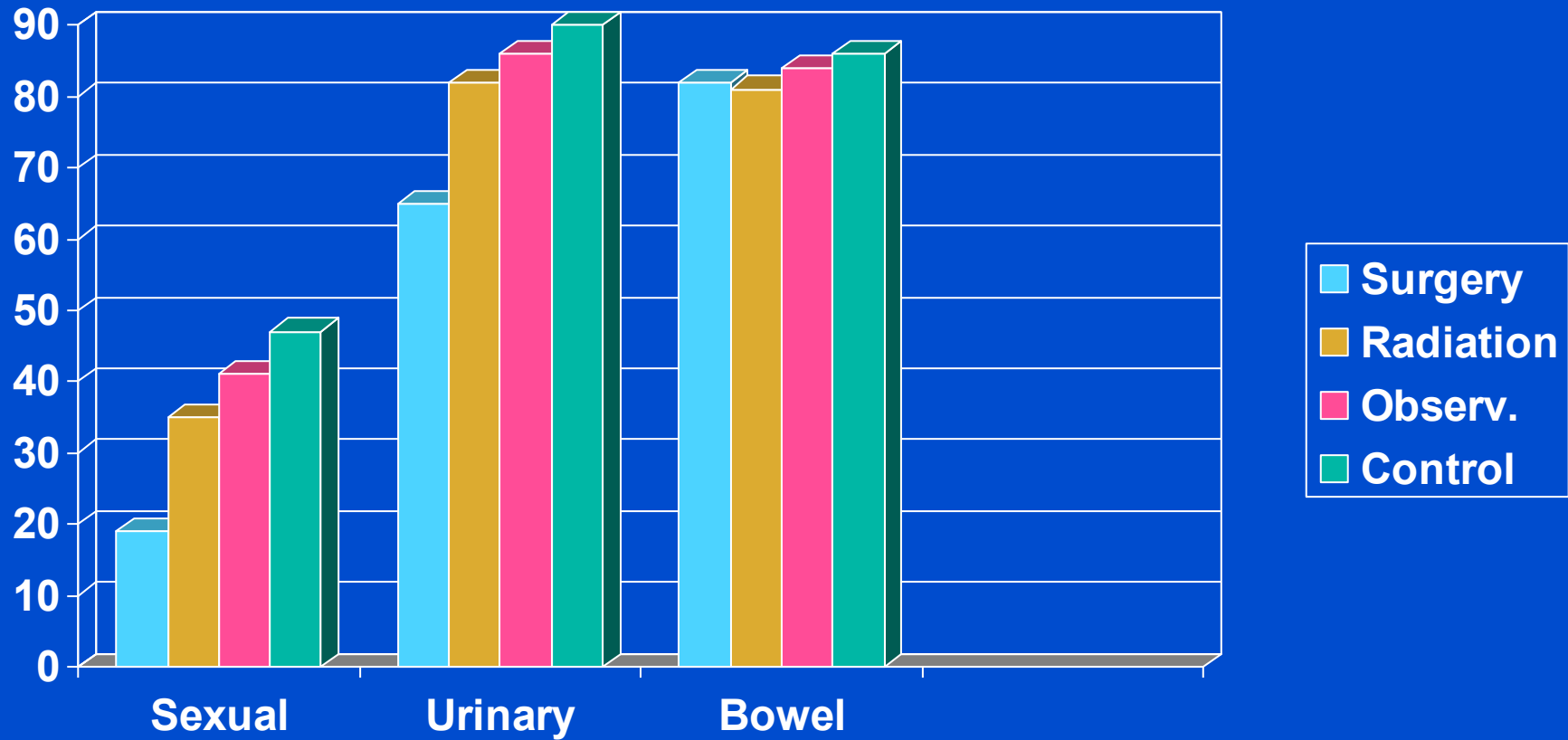
214 men with prostate cancer

- 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



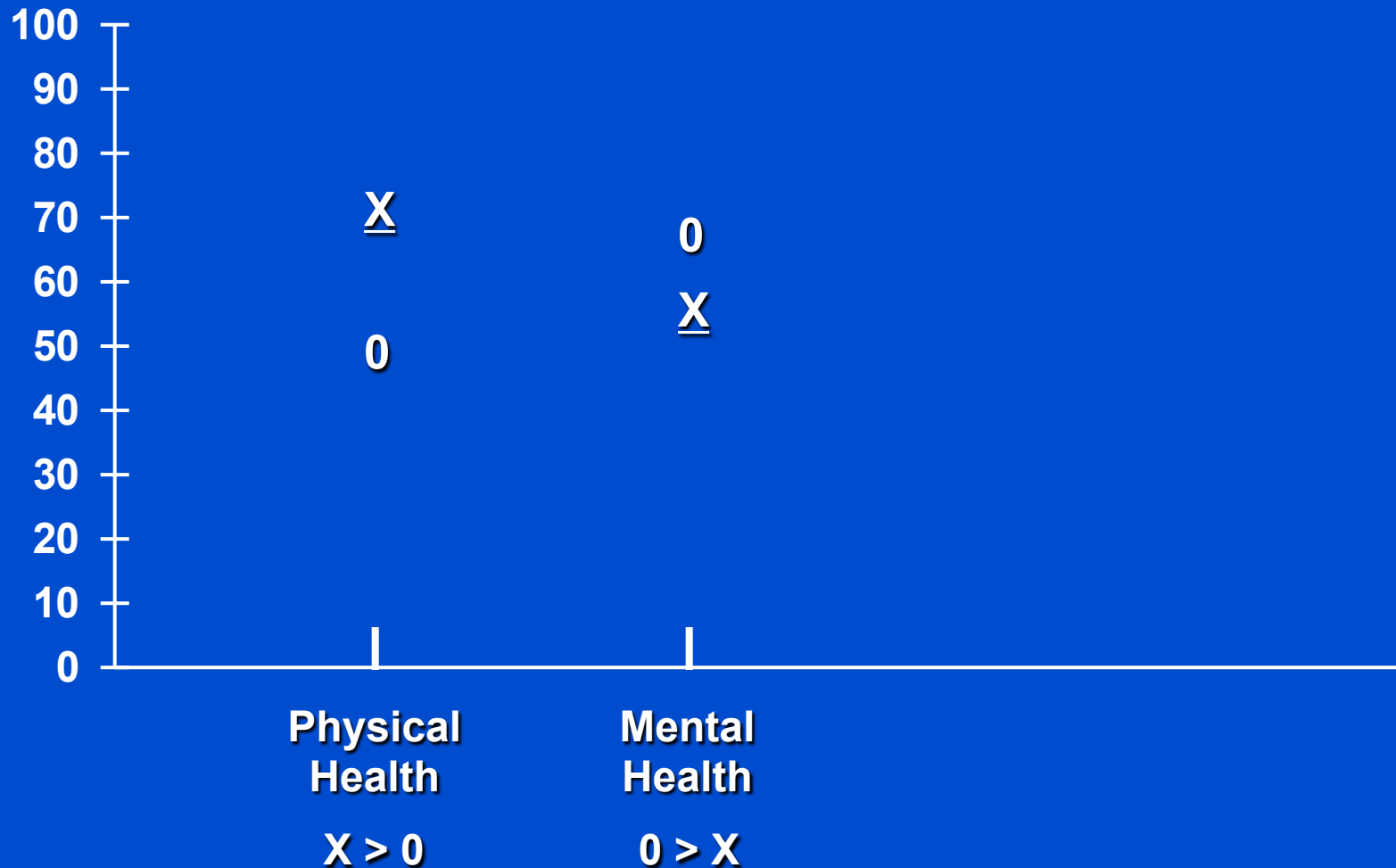
# HRQOL Measures Helpful in Ensuring Access to Cost-Effective Care

Cost ☐



Effectiveness ☐

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



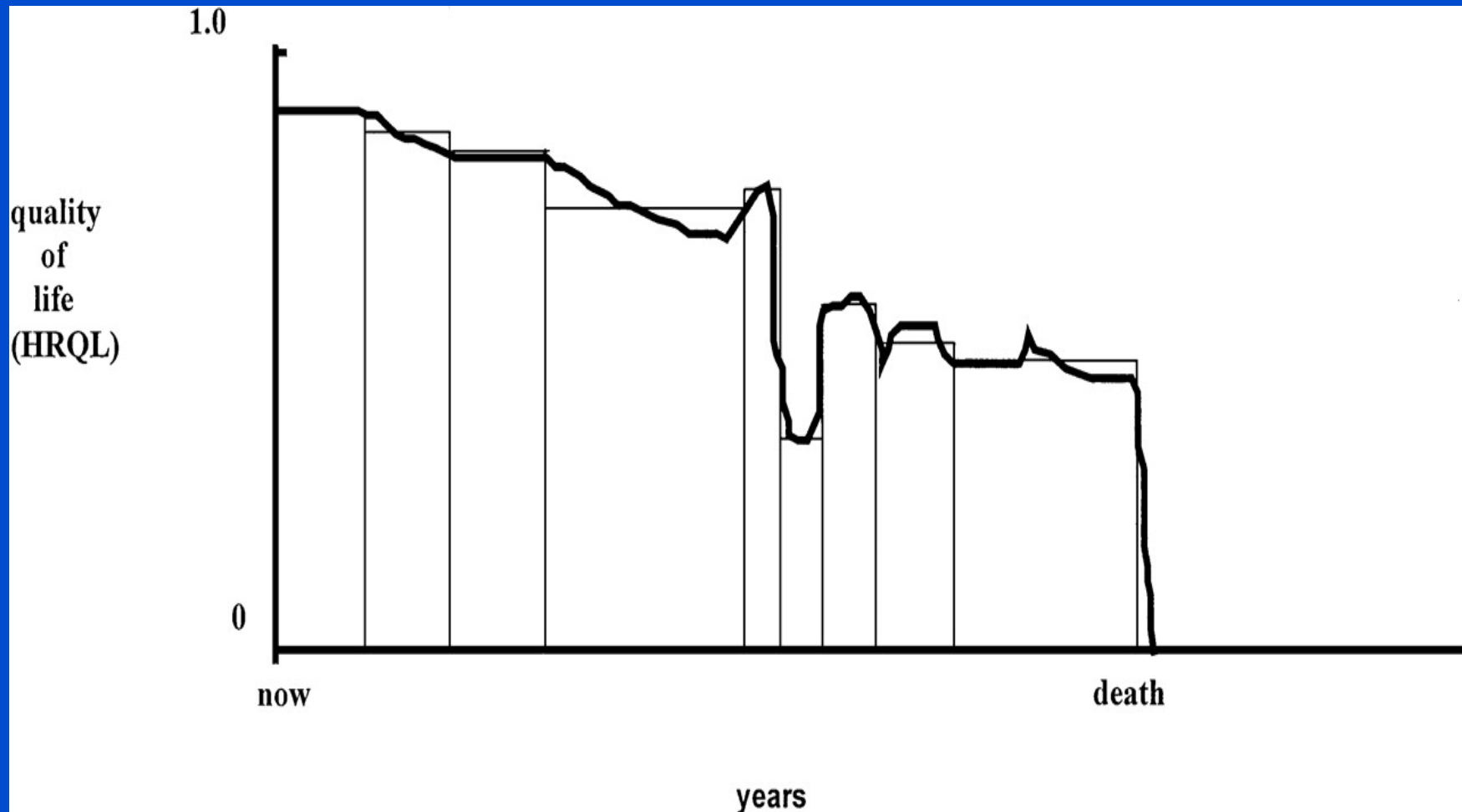


# Do a Survival Analysis?

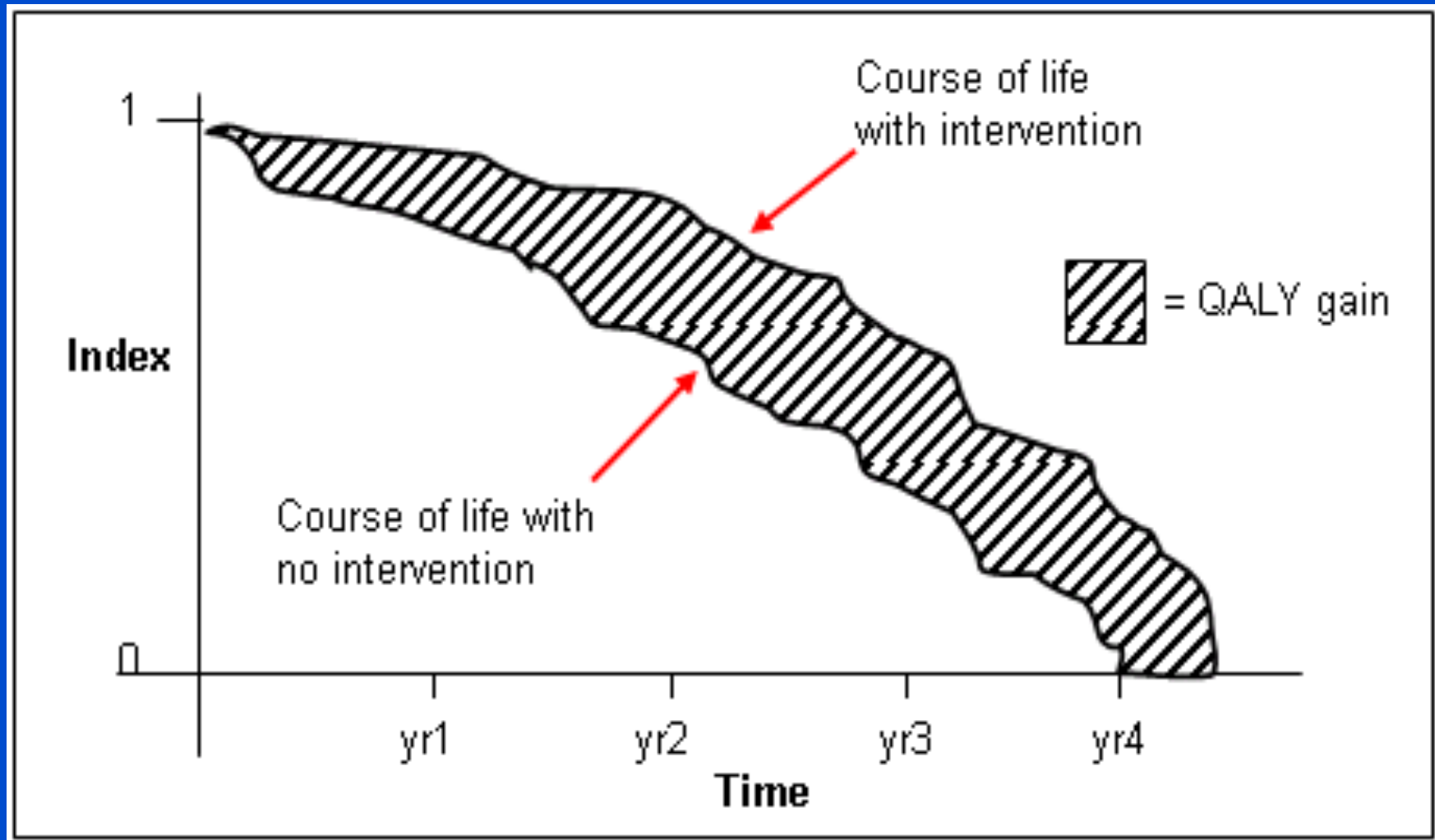
Marathoner and person in coma = 1.0



# Quality of Life for Individual Over Time



[http://www.ukmi.nhs.uk/Research/pharma\\_res.asp](http://www.ukmi.nhs.uk/Research/pharma_res.asp)



# Health State 111111

## Health state 111111

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

# 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

# Hot HRQOL Issues

**Use of HRQOL in clinical practice**

**Item response theory and computerized adaptive testing**

**Minimally important differences (MID)**

**Use of HRQOL in labeling of drugs (FDA)**

# Questions?



# For further information

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

<http://www.rand.org/health/surveys.html>

<http://www.chime.ucla.edu/measurement/measurement.htm>

<http://www.proqolid.org/>

[www.sf-36.com](http://www.sf-36.com)



# Quality of Life Research

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# **Assessing Quality of Life in Clinical Trials: Methods and Practice, 2<sup>nd</sup> Edition**

**Peter Fayers and Ron Hays, Eds.**

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464 pages**