

**Comprehensive Assessment
of Health Outcomes
K30 Course on Translational Research**

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Gonda Building Conference Room, 1357

How do we know how the patient is doing?

Temperature

Respiration

Pulse

Weight

Blood pressure



And by asking her or him about ...



Symptoms

**Have you had any of the following
symptoms in the last 4 weeks?**

Fever?

Loss of appetite?

Unintended weight loss?

Dizziness?

Trouble sleeping?

Headache?

Trouble swallowing?

First RCT of Treatment for Newly

*** Watchful waiting**

Versus

*** Radical prostatectomy**

- Trend to reduction in all-cause mortality

(18% versus 15%; RR 0.83, 0.57 to 1.2, $p = 0.31$)

Impact on Symptoms

Reduction in urinary obstruction (weak stream)

- 44% waiting, 28% prostatectomy

Increase in urinary leakage and sexual dysfunction

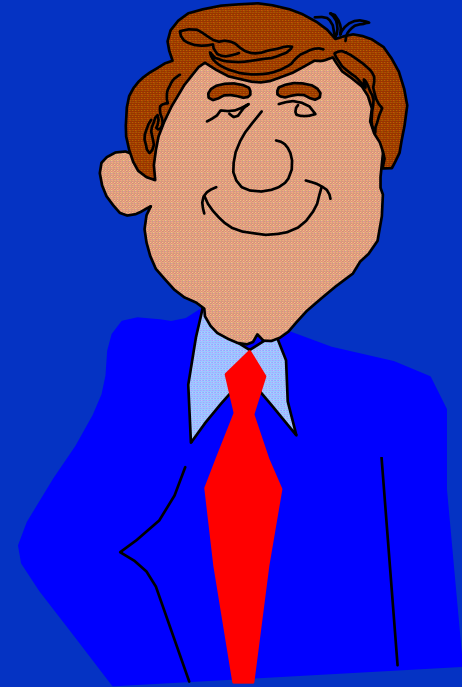
- 49% prostatectomy vs. 21% waiting

- 80% prostatectomy vs. 45% waiting

Also, by asking her or him about ...

What she or he is able to do

And how he or she feels about their life



Does your health now limit you in

(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

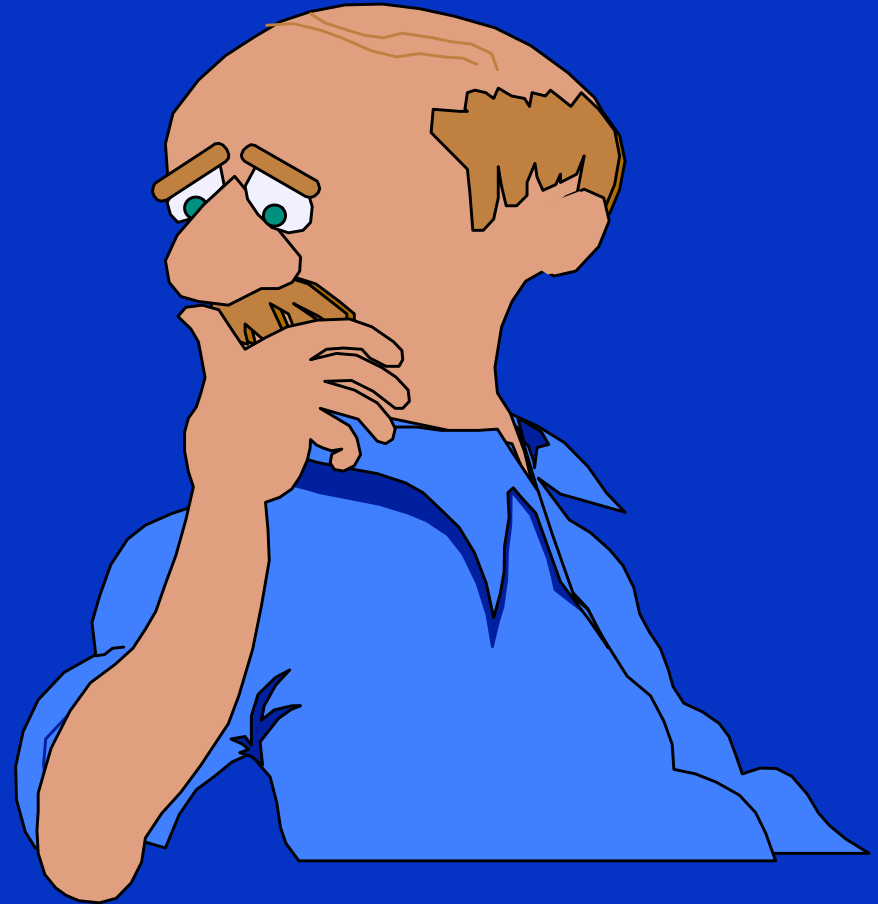
None of the time

A little of the time

Some of the time

Most of the time

All of the time



In general, how would you rate your health?

Excellent

Very Good

Good

Fair

Poor

Are self-reports reliable?

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

Reliability is an issue in

- Do not place the blood pressure cuff over clothing or roll a tight fitting sleeve above the biceps when determining blood pressure as either can cause elevated readings.
- If you have a chance, obtain measurements on the same patient with both a large and small cuff.
- If the reading is surprisingly high or low, repeat the measurement towards the end of your exam.
- These exercises should give you an appreciation for the magnitude of error that can be introduced when improper technique is utilized.

Range of reliability estimates

0.80-0.90 for blood pressure

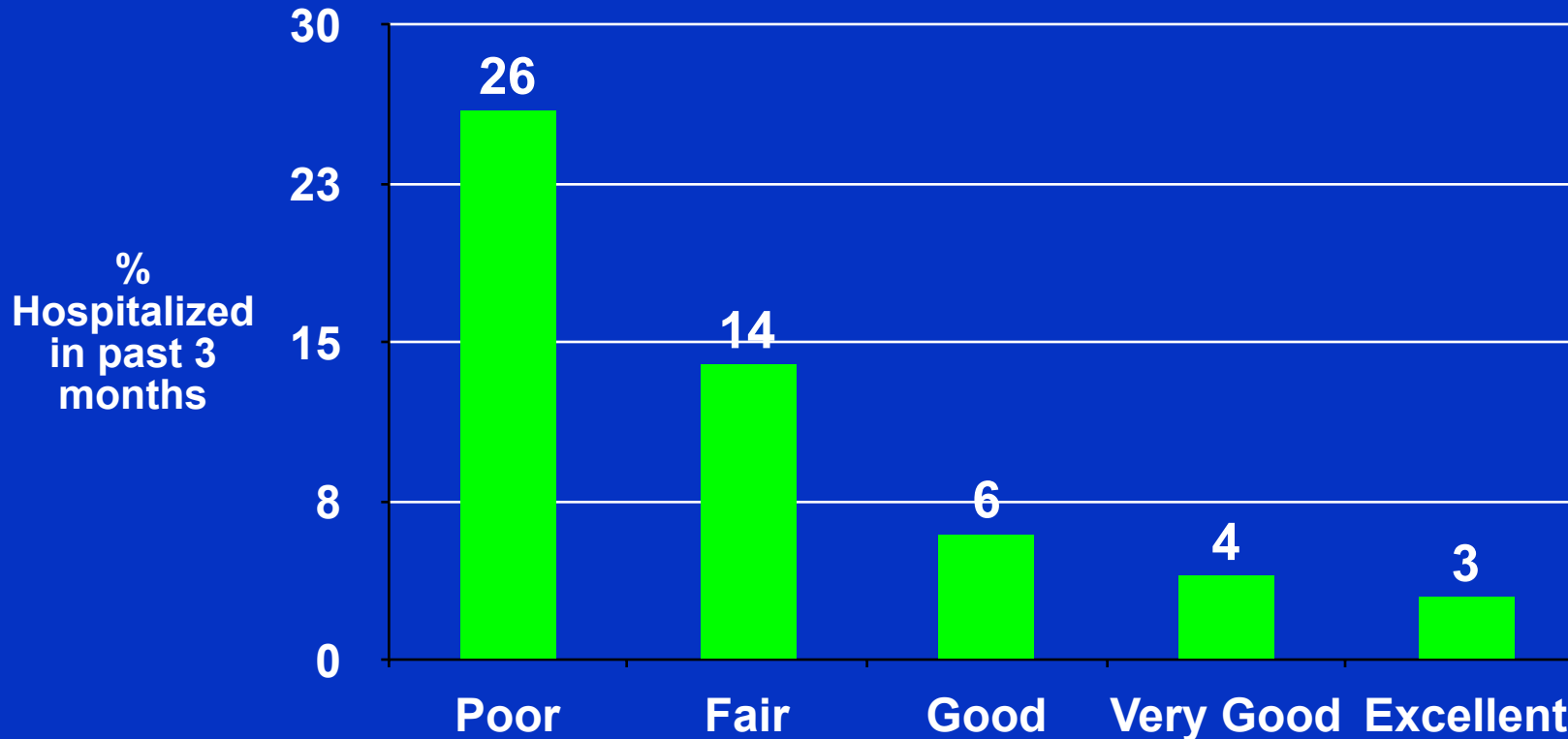
0.70-0.90 for multi-item self-report scales

Are self-reports valid?

Validity—score represents what you are trying to measure rather than something else

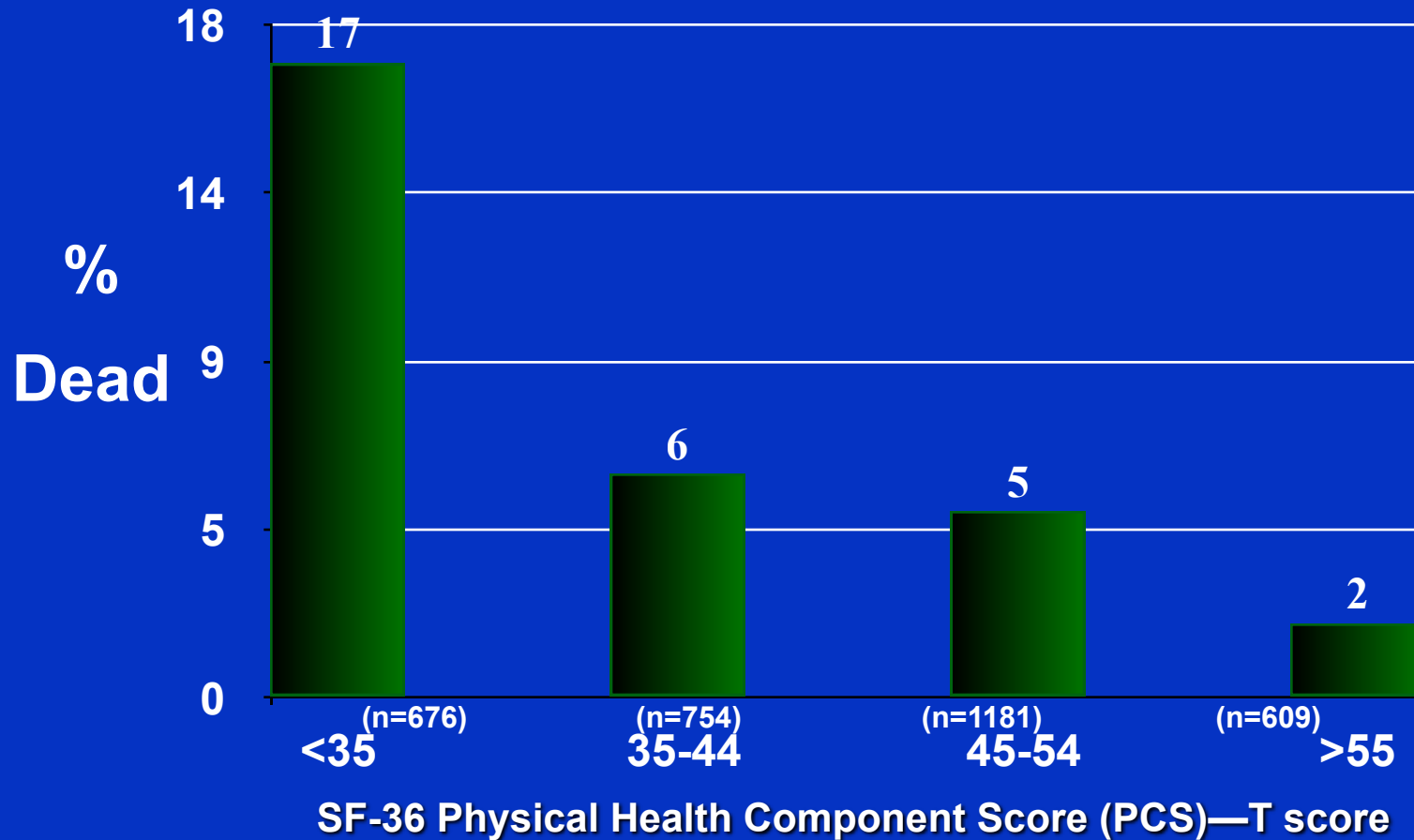
- If possible, measure the blood pressure of a patient who has an indwelling arterial catheter (these patients can be found in the ICU with the help of a preceptor). Arterial transducers are an extremely accurate tool for assessing blood pressure and therefore provide a method for checking your non-invasive technique.
- Make sure the patient has had an opportunity to rest before measuring their BP.
- Instruct her or him to avoid coffee, smoking or any other un-prescribed drug with sympathomimetic activity on the day of the measurement.

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



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

Mark D. Sprenke et al. (Chest, 2004)

**“The Veterans Short Form
36 Questionnaire is
predictive of mortality and
health-care utilization in a
population of veterans
with a self-reported
diagnosis of asthma or
COPD”**



Health-Related Quality of Life is:

How the person FEELS (well-being)

- Emotional well-being
- Pain
- Energy

What the person can DO (functioning)

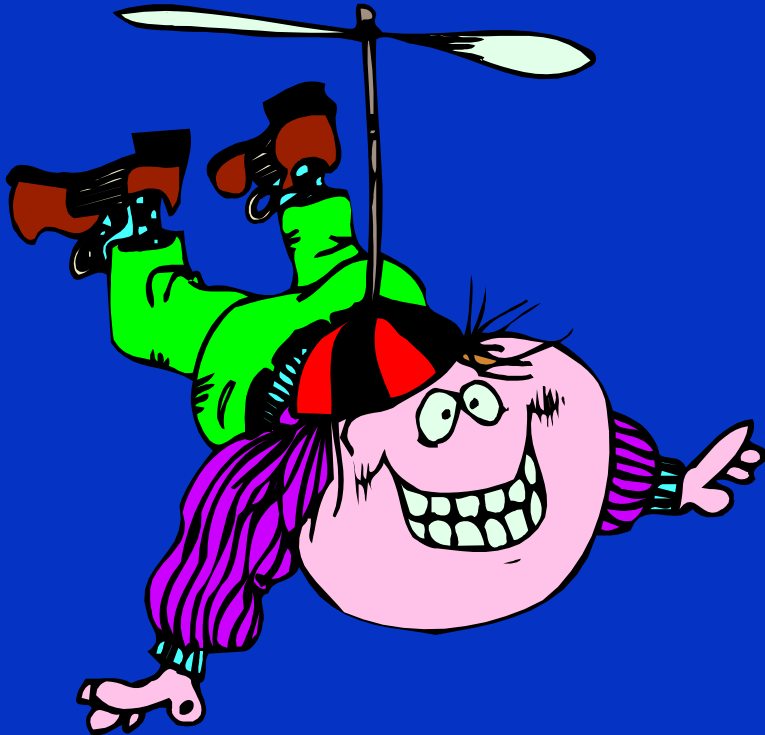
- Self-care
- Role
- Social

HRQOL is Not

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



Types of HRQOL Measures



Profile: Generic vs. Targeted
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)**

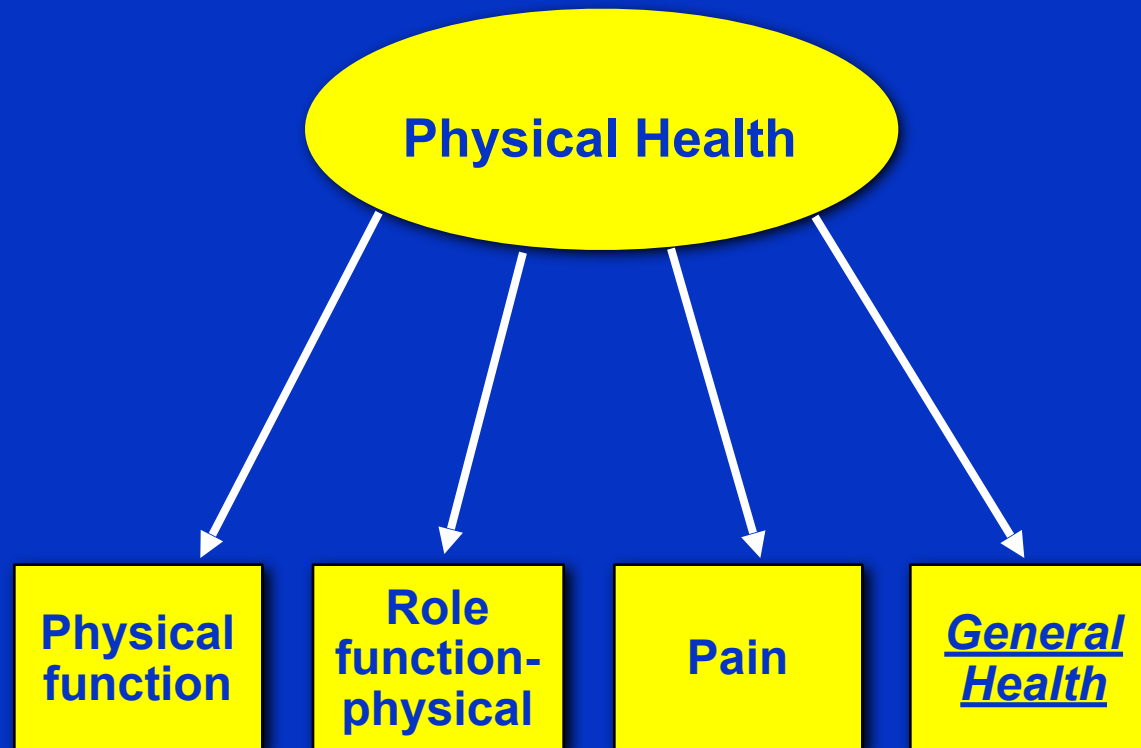
Scoring Generic HRQOL Scales

Average or sum all items in the same scale.

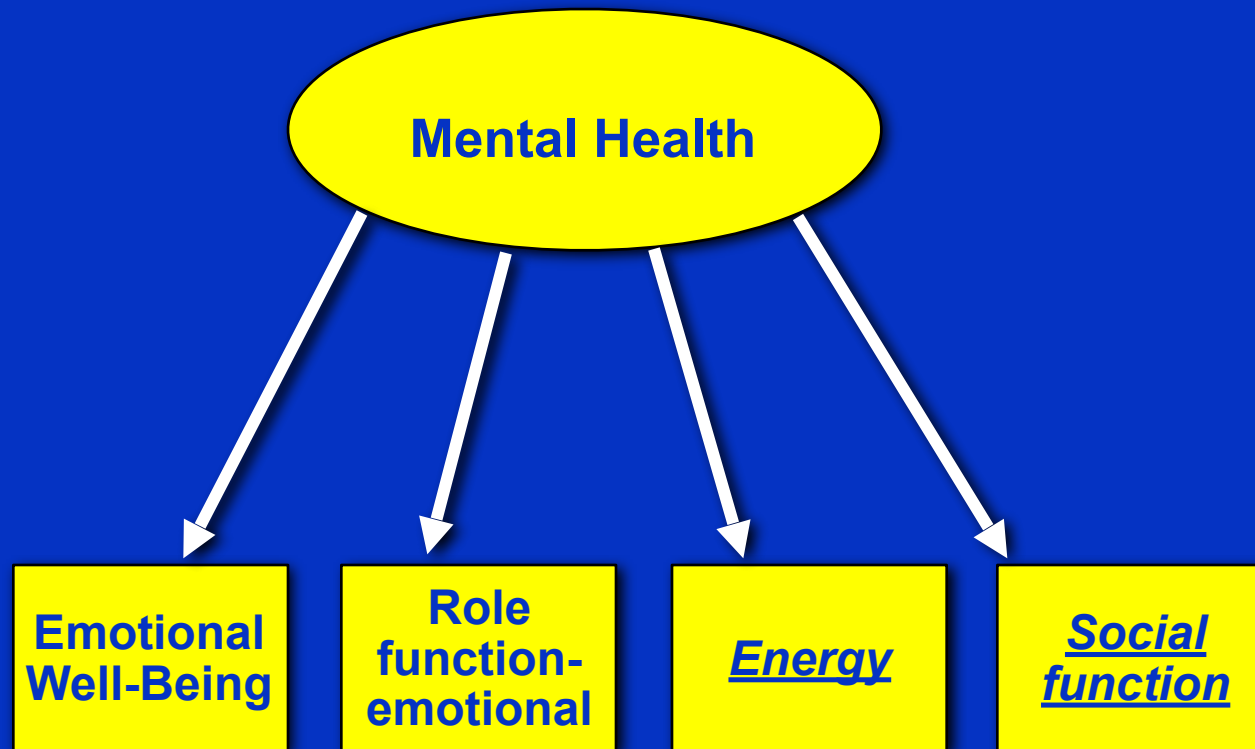
Transform average or sum to

- **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

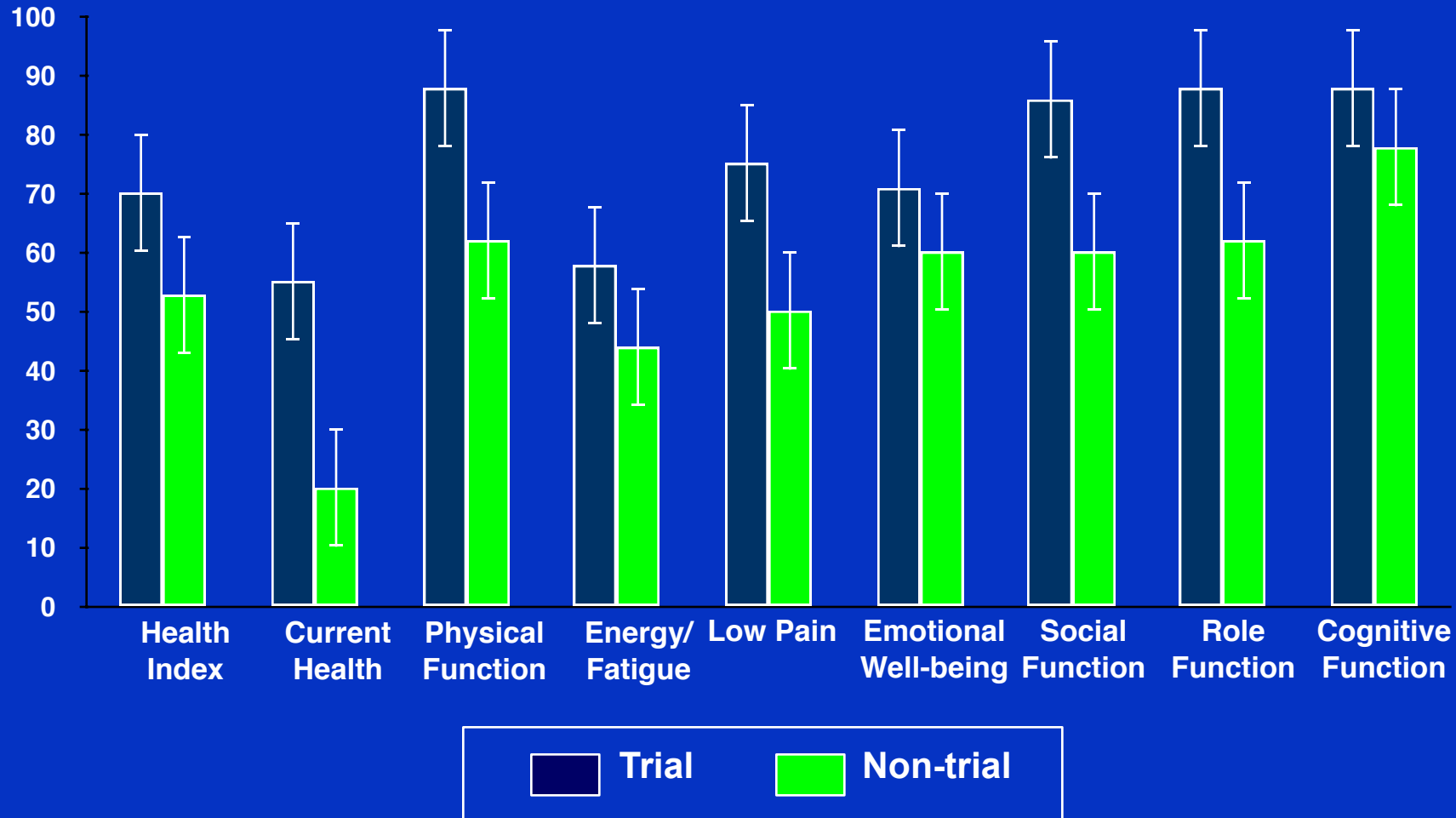
- **Comparison of Same Disease in Different Samples**
- **Profiles of Different Diseases**

Longitudinal

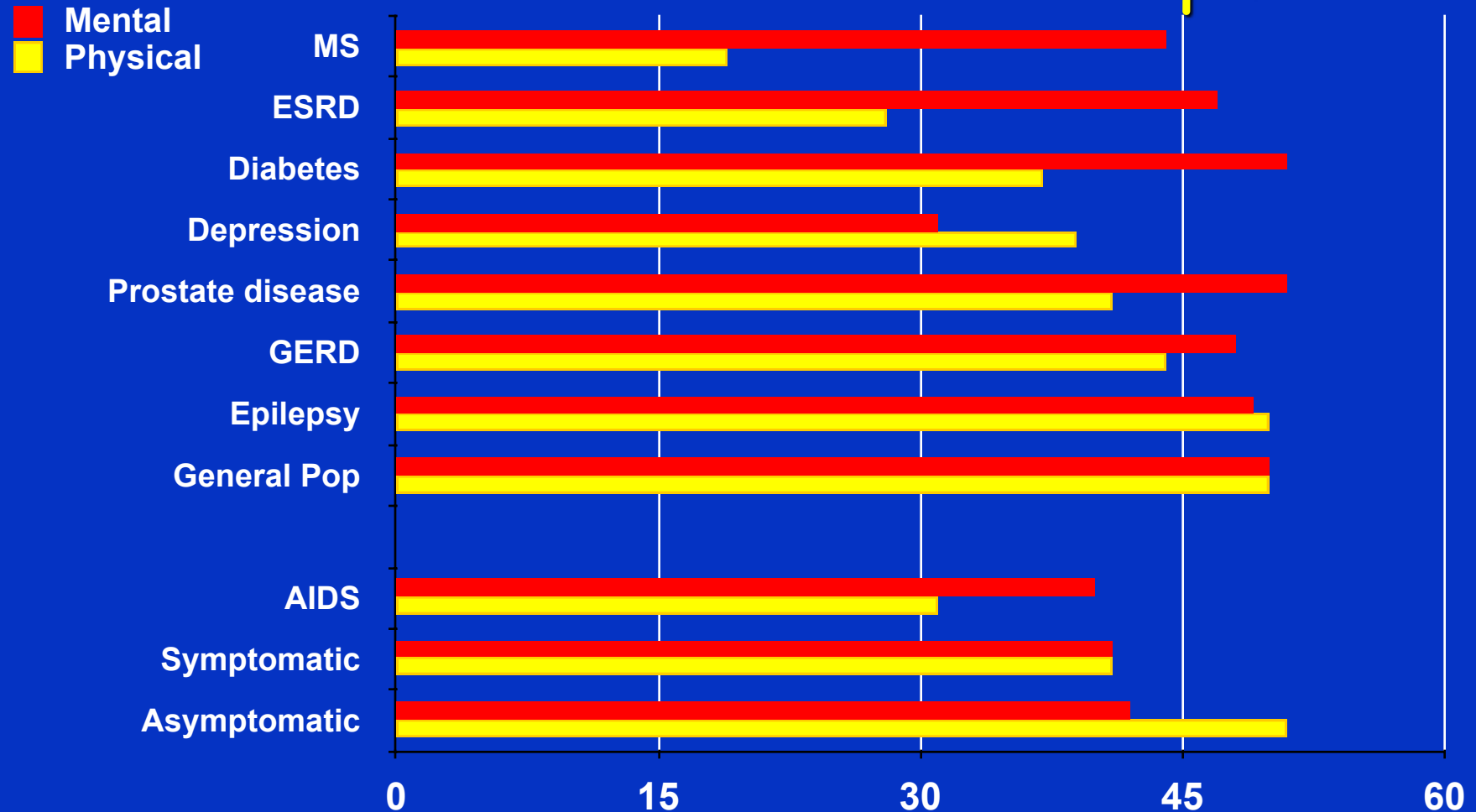
- **Profiles of Different Disease**
- **Identifying Antecedents/Causes of HRQOL**

HRQOL of Patients in ACTG versus Public Hospital Samples

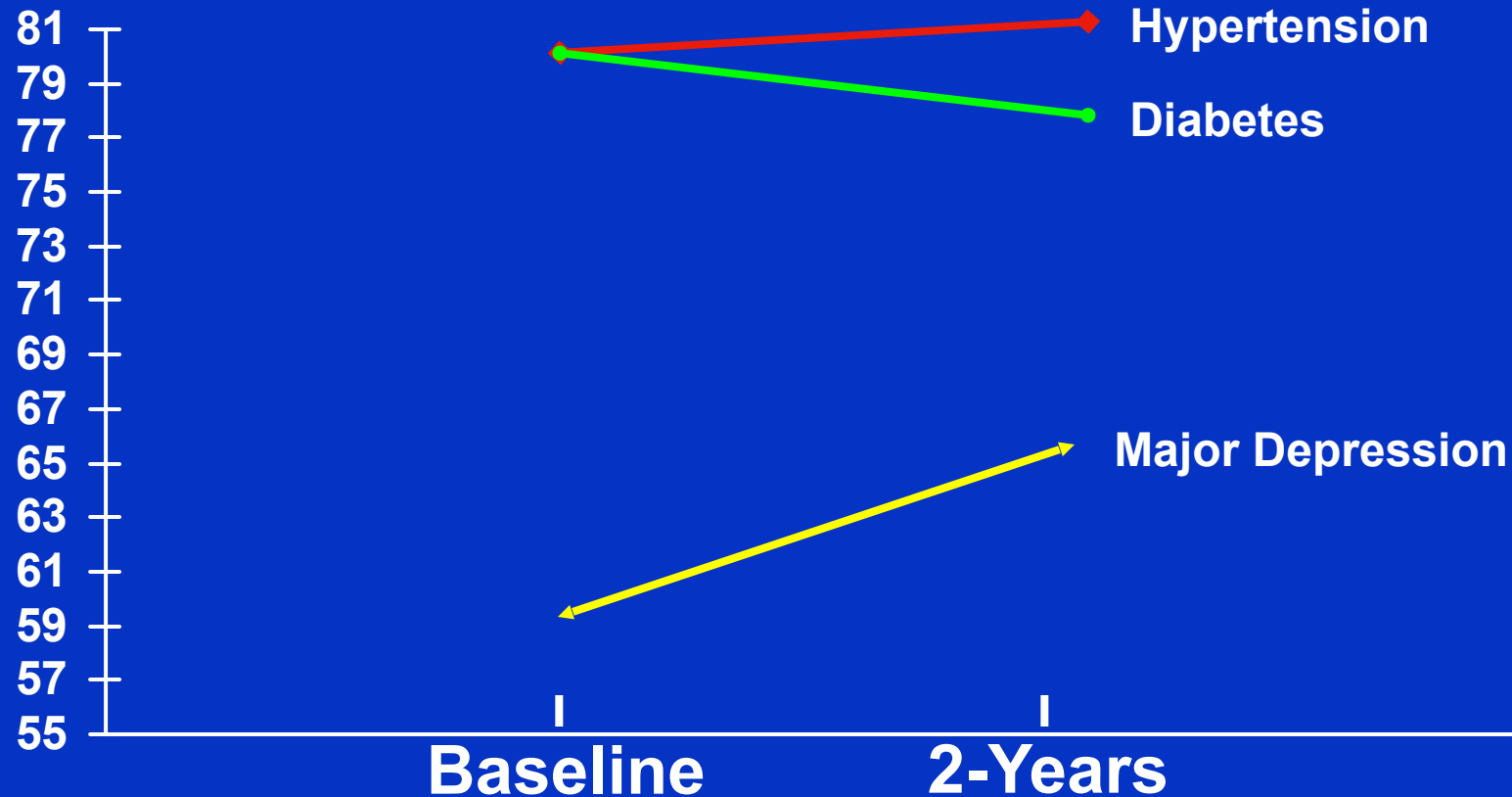
Adjusted Scale Scores (Cunningham et al., 1995)



HRQOL for HIV Compared to other Chronic Illnesses and General Population

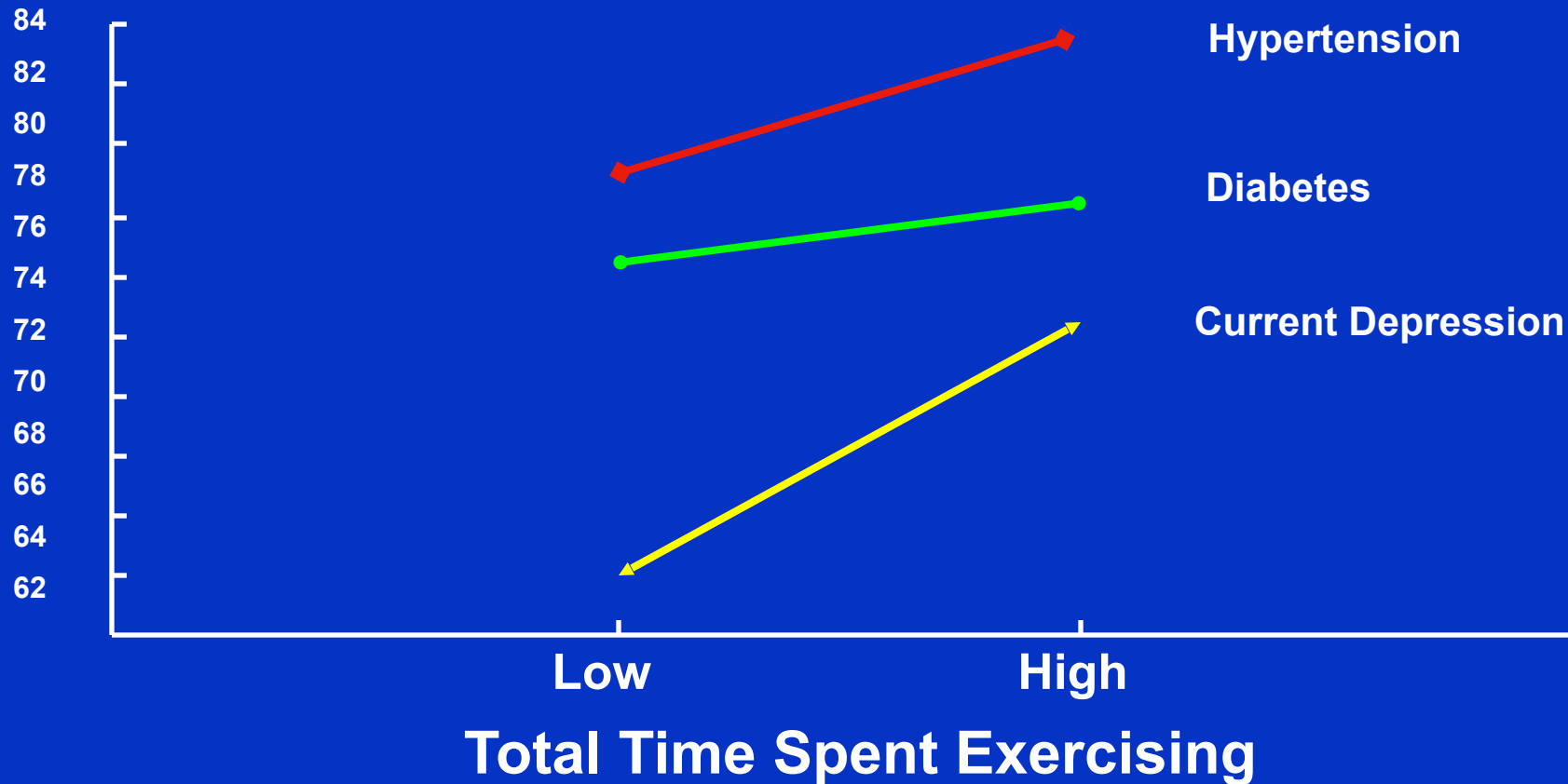


Course of Emotional Well-being Over 2-years for Patients in the MOS General Medical Sector



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, 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
- 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

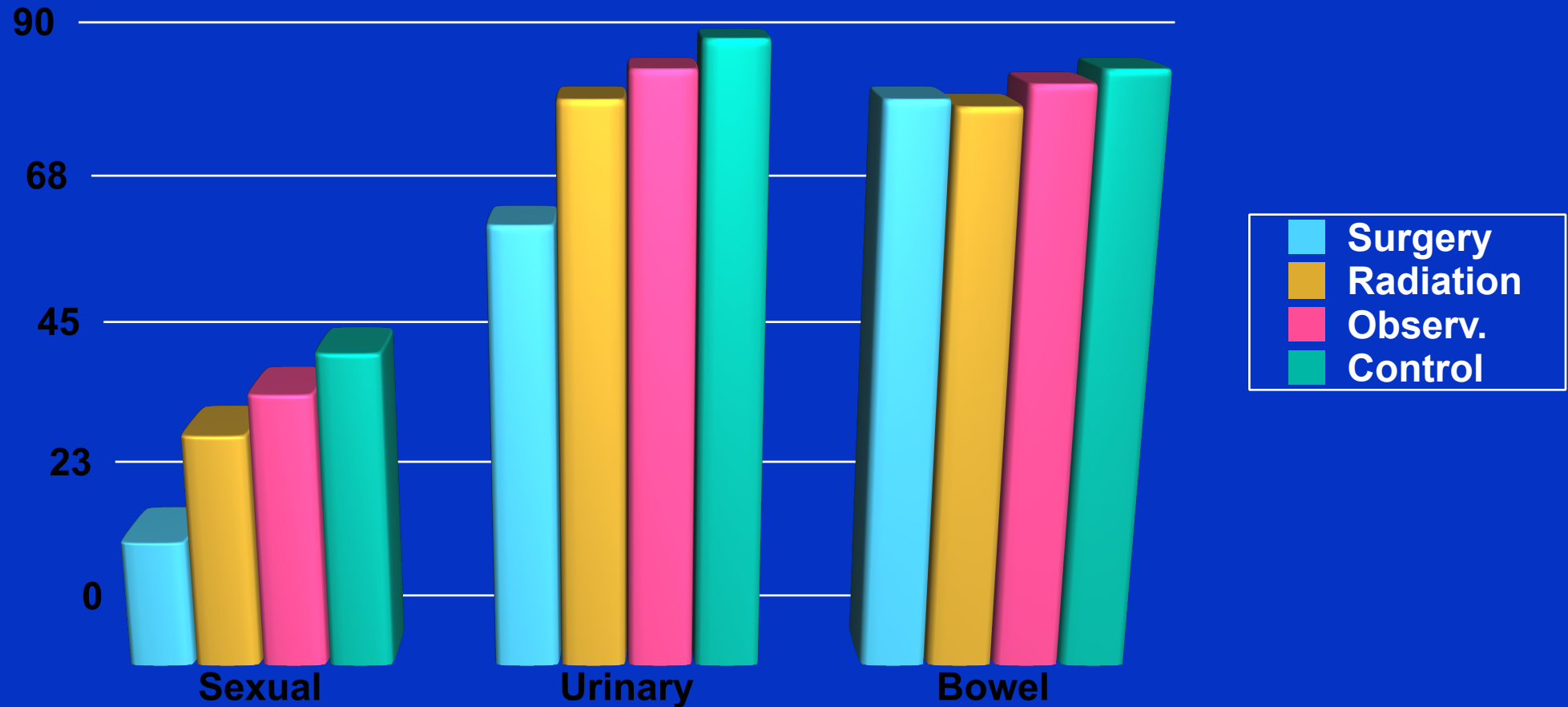
Cross-sectional study of 214 men with prostate cancer

- 98 radical prostatectomy
- 56 primary pelvic irradiation
- 60 observation alone

273 age/zip matched pts. without cancer

JAMA, 1995

Sexual, Urinary and Bowel Function

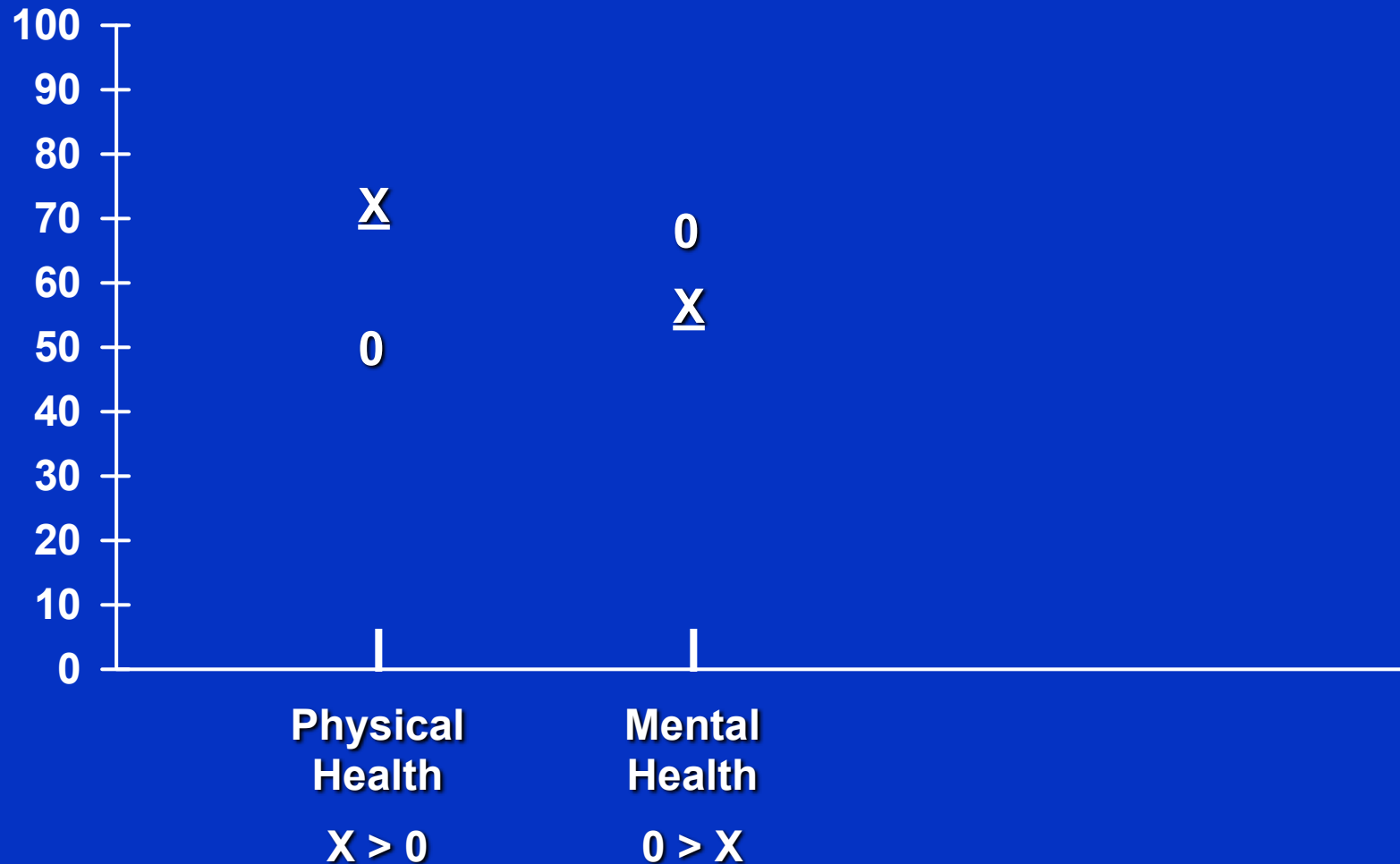


Ultimate Use of HRQOL Measures-- Helping to Ensure Access to Cost-Effective Care

Cost \hat{a}

Effectiveness \hat{a}

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



Do a Survival Analysis?

Marathoner and person in coma = 1.0



Preference-Based Measure-- Quality of Well-Being Scale

- Summarize HRQOL in QALYs
 - Physical activity (PAC)
 - Mobility (MOB)
 - Social activity (SAC)
 - Symptom/problem complexes (SPC)



- Well-Being Formula $w = 1 + PAC + MOB + SAC + SPC$

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**.

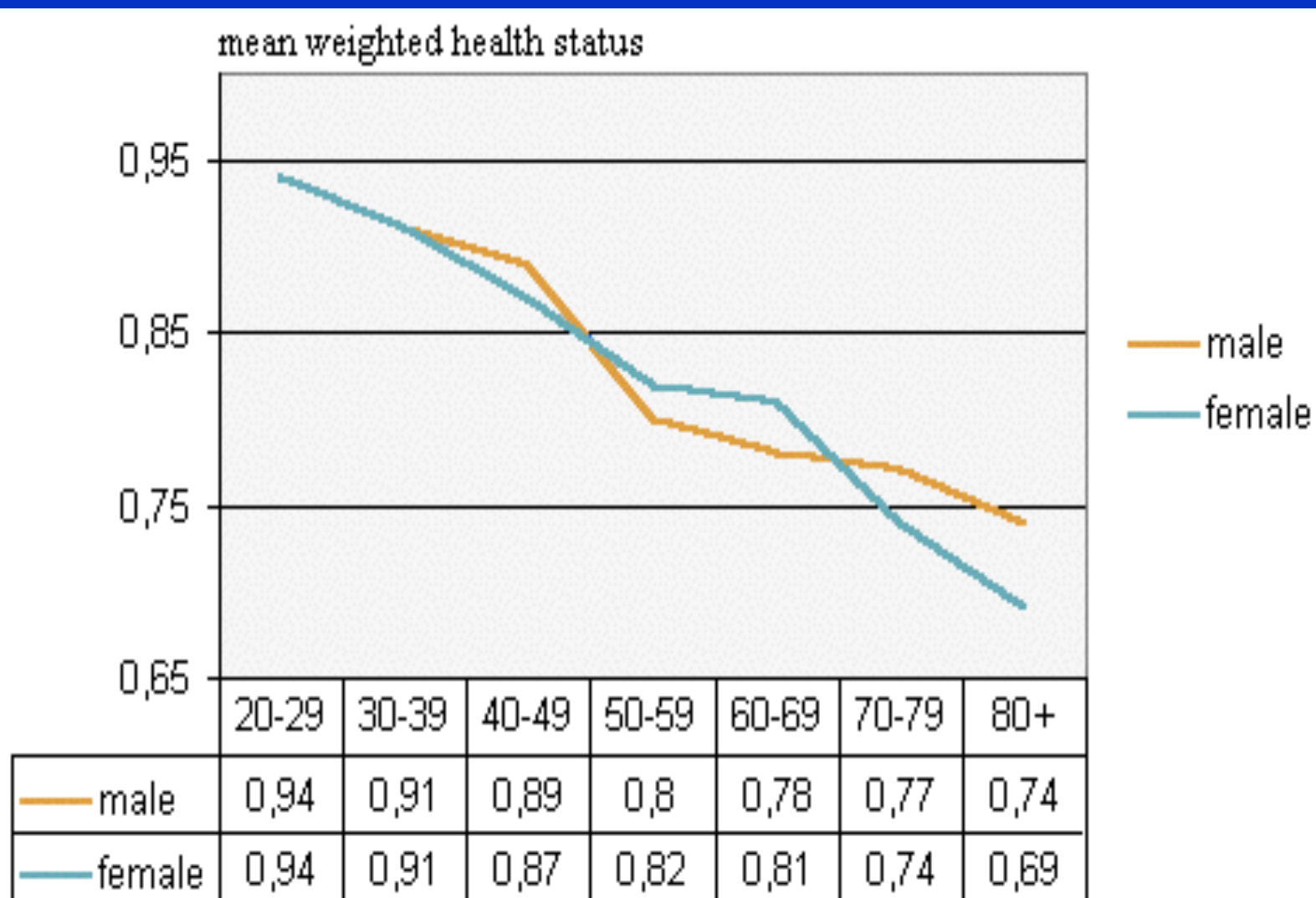
Your health limits your **social activities** (like visiting friends or close relatives) a little or none of the time

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

EQ-5D in UK by age and gender



For further information

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

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

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

www.sf-36.com

Appendix: Transforming Scores

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

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

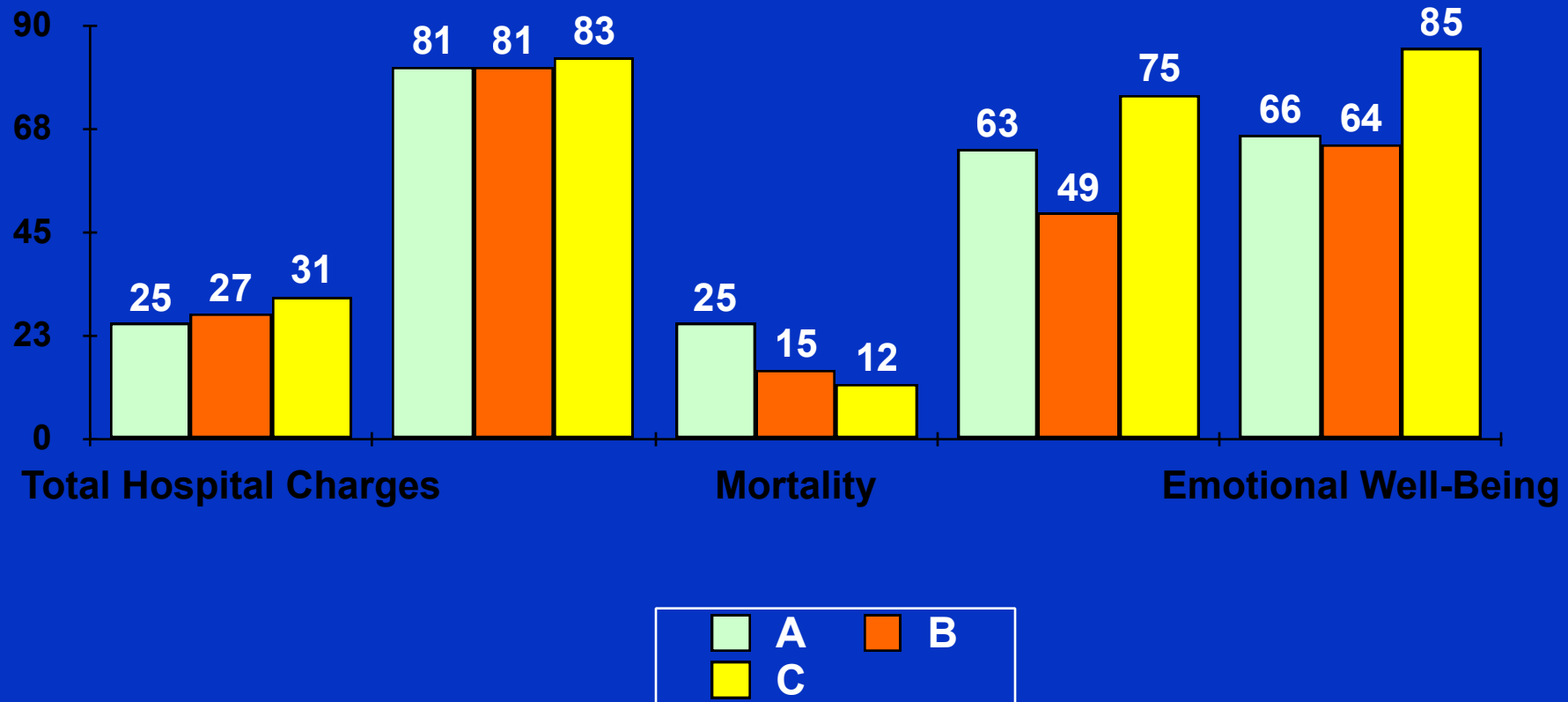
$$Z_x = \frac{(X - \bar{X})}{SD_x}$$

Appendix: Is Medicine Related to Worse 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

Appendix: Profile + Mortality

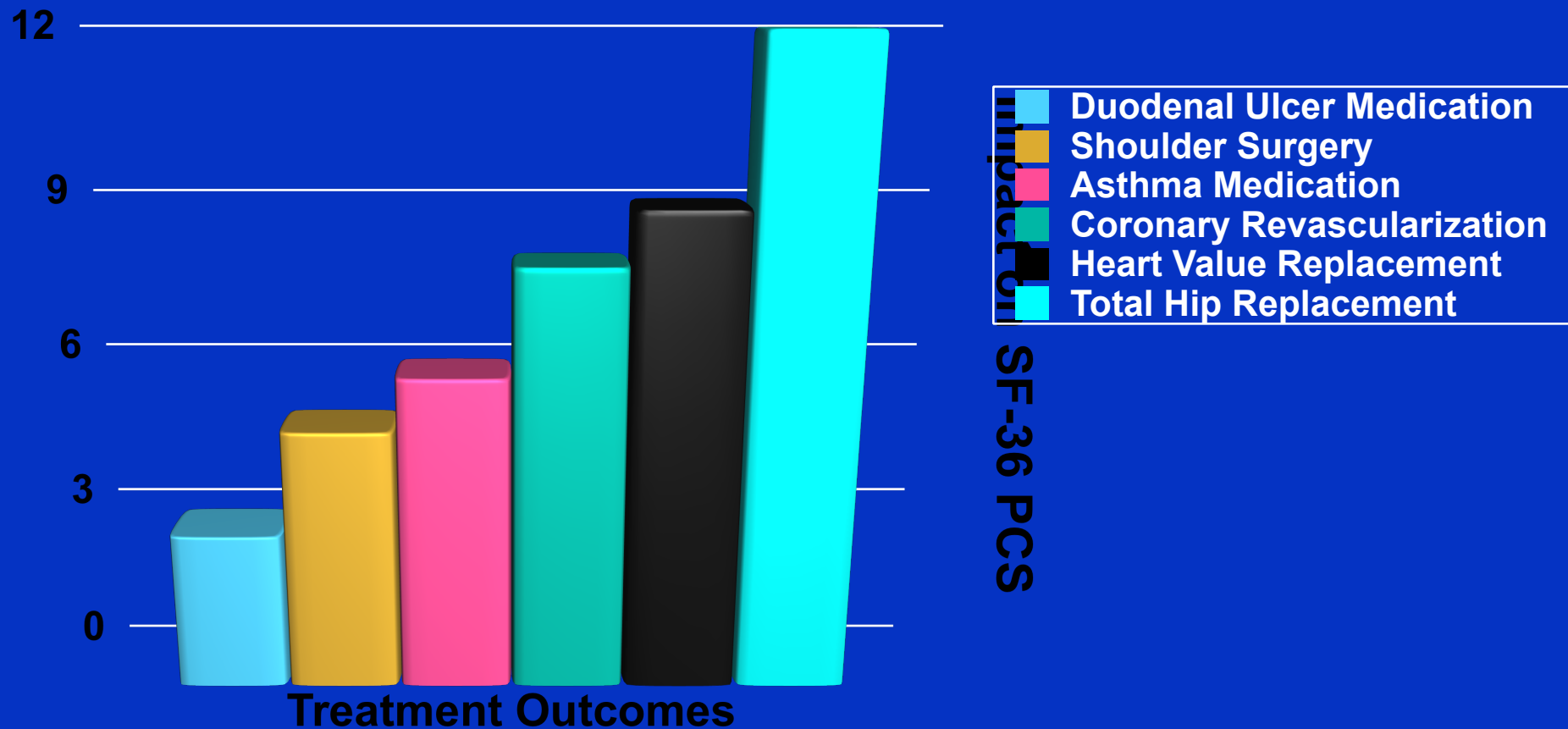
Outcomes for Acute MI (n = 133)



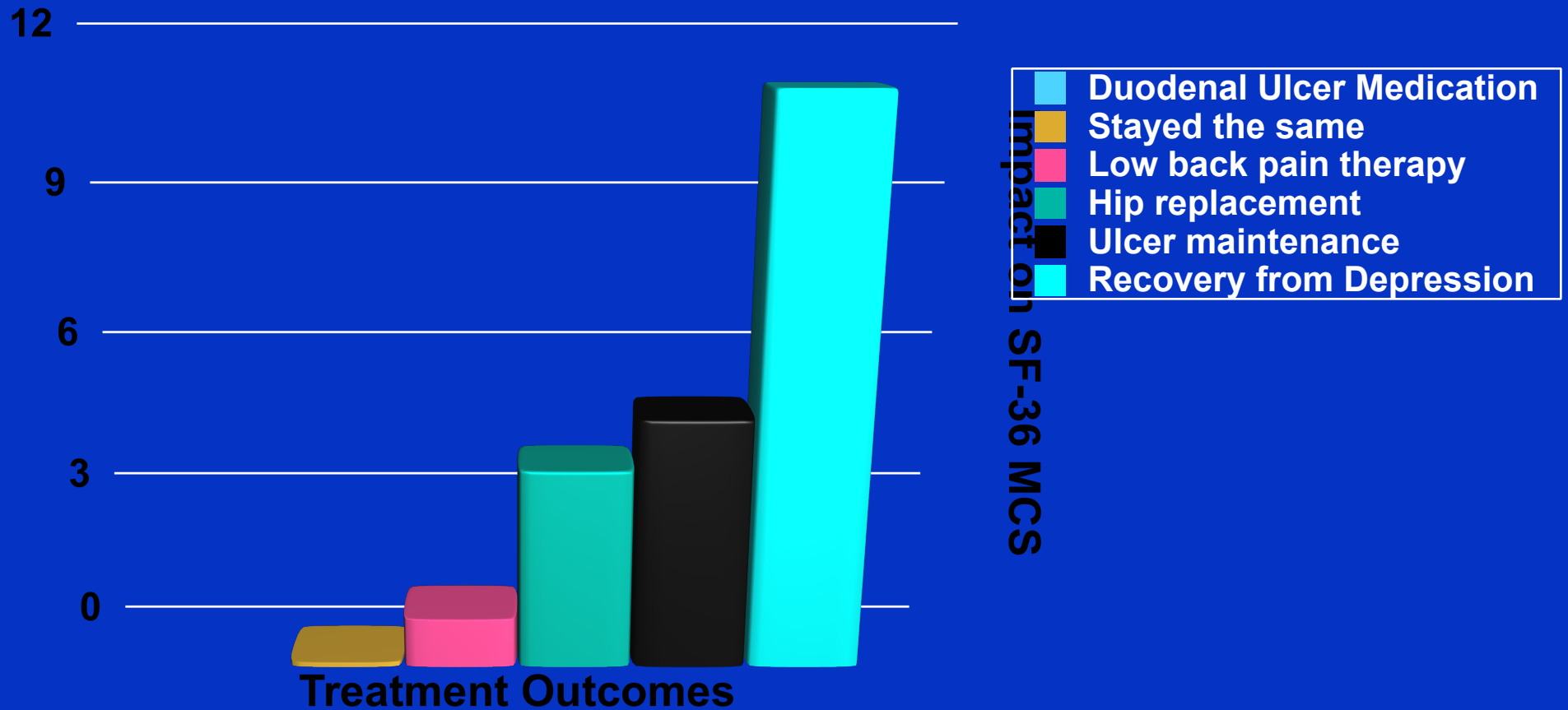
Appendix: Generic Child Health Measures

**Landgraf, J. M., & Abetz, L. N. (1996).
Measuring health outcomes in pediatric
populations: Issues in psychometrics and
application. In B. Spilker (ed.), Quality of life
and pharmacoeconomics in clinical trials,
Second edition. Lippincott-Raven Publishers.**

Appendix: Impact on Physical Health



Appendix: Impact on Mental Health



EQ-5D

Mobility

Self-care

Usual activities

Pain/discomfort

Anxiety/depression

- **243 states, 3 levels per attribute**

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

HUI-3

Vision

Hearing

Speech

Ambulation

Dexterity

Cognition

Pain and discomfort

Emotion

- 972,000 states, 5-6 levels per attribute