Health-Related Quality of Life Assessment

Ron D. Hays, Ph.D. (hays@rand.org)

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Problems with US Health Care

Health costs increasing despite managed care

Number of cardiologists has doubled and number of radiologists increased 5-fold in past 2 decades

Despite much greater growth in costs of health care in the US, no evidence that health has improved more than other G7 countries

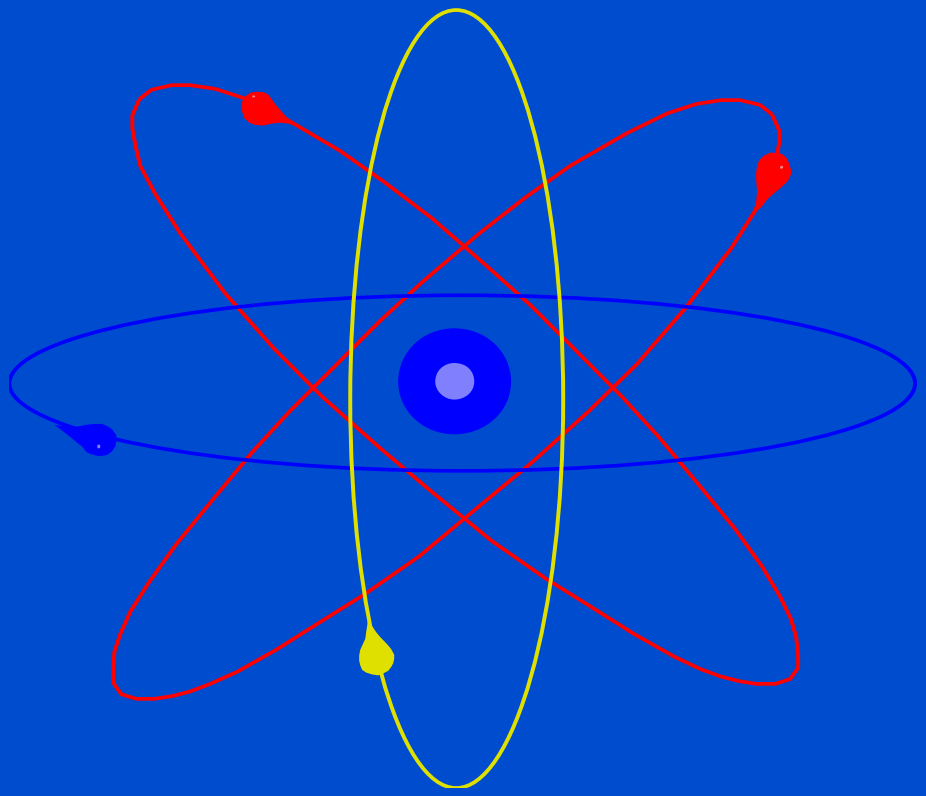
With more doctors and better technology, we have found that more people are sick

New spiral CT scans can detect hepatic lesions of 2mm. In 1982, only 20mm lesions could be detected.

MRI can detect abnormalities of the knee in 25% of healthy young men.

MRI can find lumbar disc bulge in 50% of adults, many who have no back pain.

Health Care System Concerns



Access

Affordability

Accountability

Cost Effective Care

$$\frac{\text{Cost } ?}{\text{Effectiveness } ?}$$

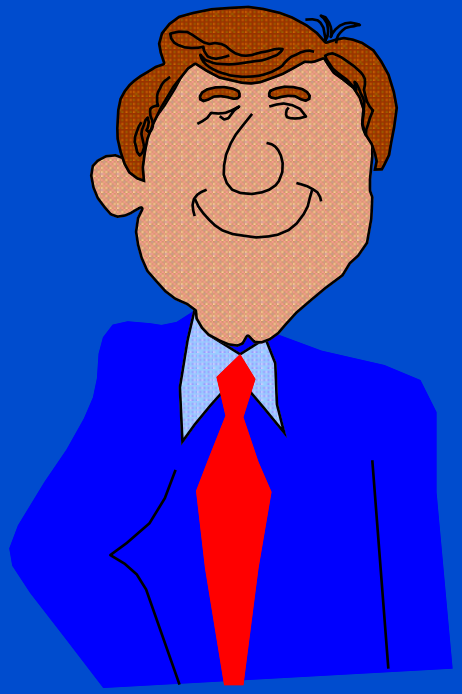
What is Effective Care?

- Maximizes desired outcomes
- Outcomes serve as markers of effective care.

How is the Patient Doing

Biological indicators

- Hematocrit
- Albumin



Self-report indicators

- Functioning
- Well-being (including symptoms)

Health-Related Quality of Life is:

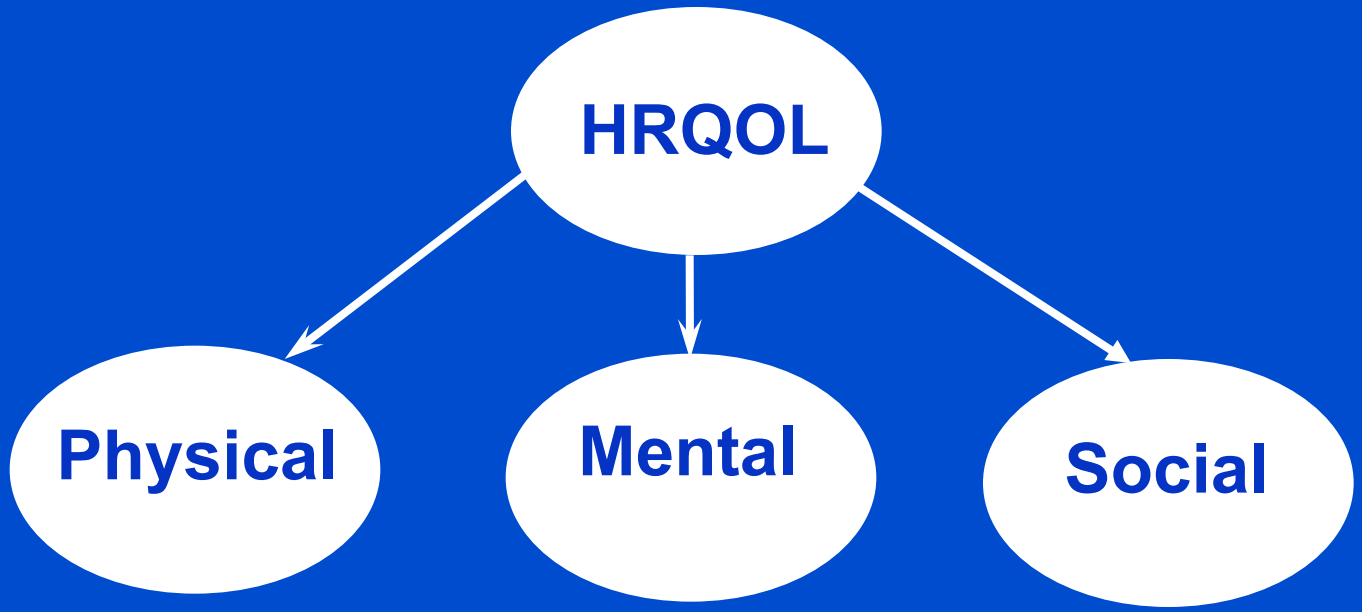
What the person can DO (functioning)

- Self-care
- Role
- Social

How the person FEELs (well-being)

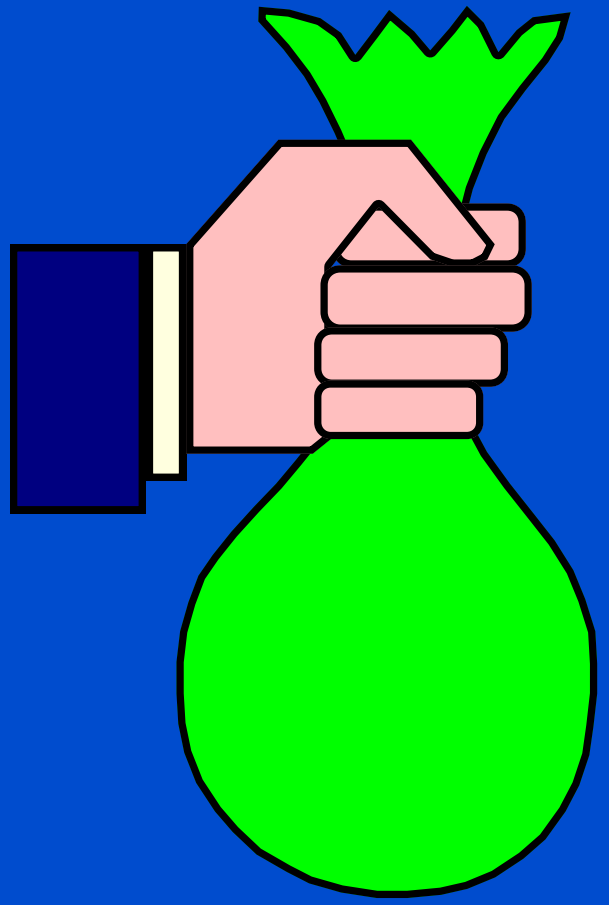
- Emotional well-being
- Pain
- Energy

HRQOL is Multi-Dimensional



HRQOL is Not

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



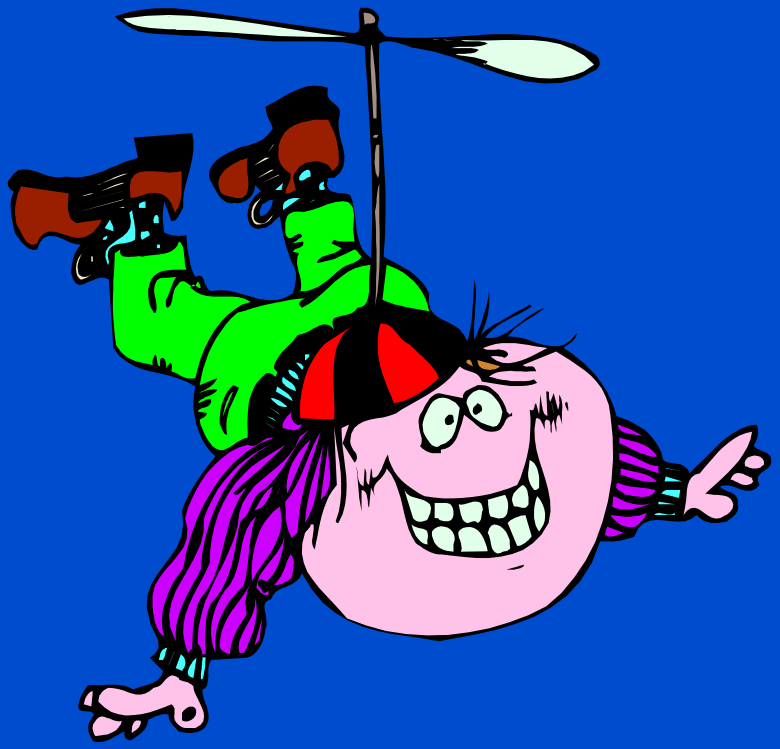
HRQOL Outcomes

Matter more to patients than biological indicators.

Can summarize overall effects:

$$\frac{\text{Cost}}{\triangle \text{ HRQOL}}$$

Types of HRQOL Measures



Profile

- **Generic**
- **Targeted**

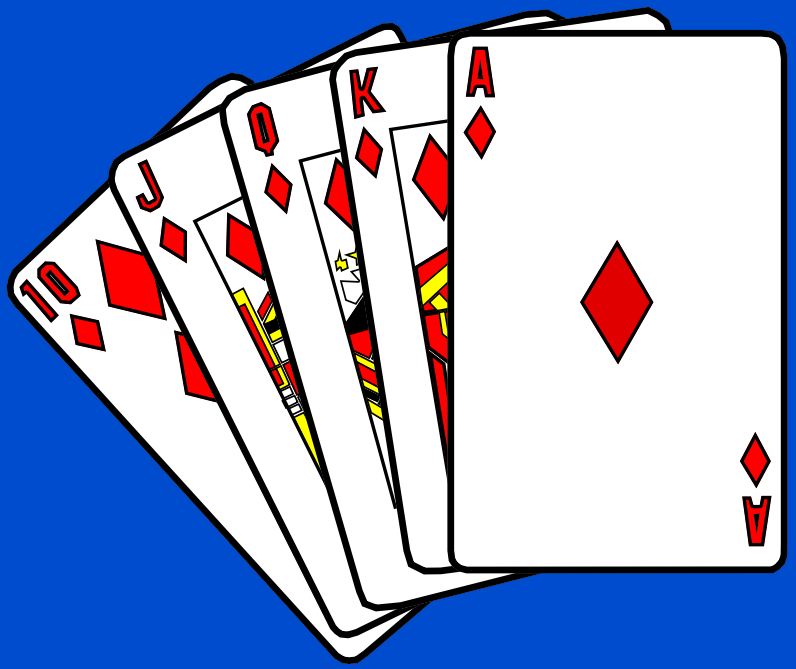
Preference-based

Example Generic Item

Has your child had difficulty running?

Never
Sometimes
Often

Generic HRQOL Item



In general, would you say Bob Brook's health is:

Excellent

Very Good

Good

Fair

Poor

Generic HRQOL Scales (Items)

- 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)

Physical Functioning Item

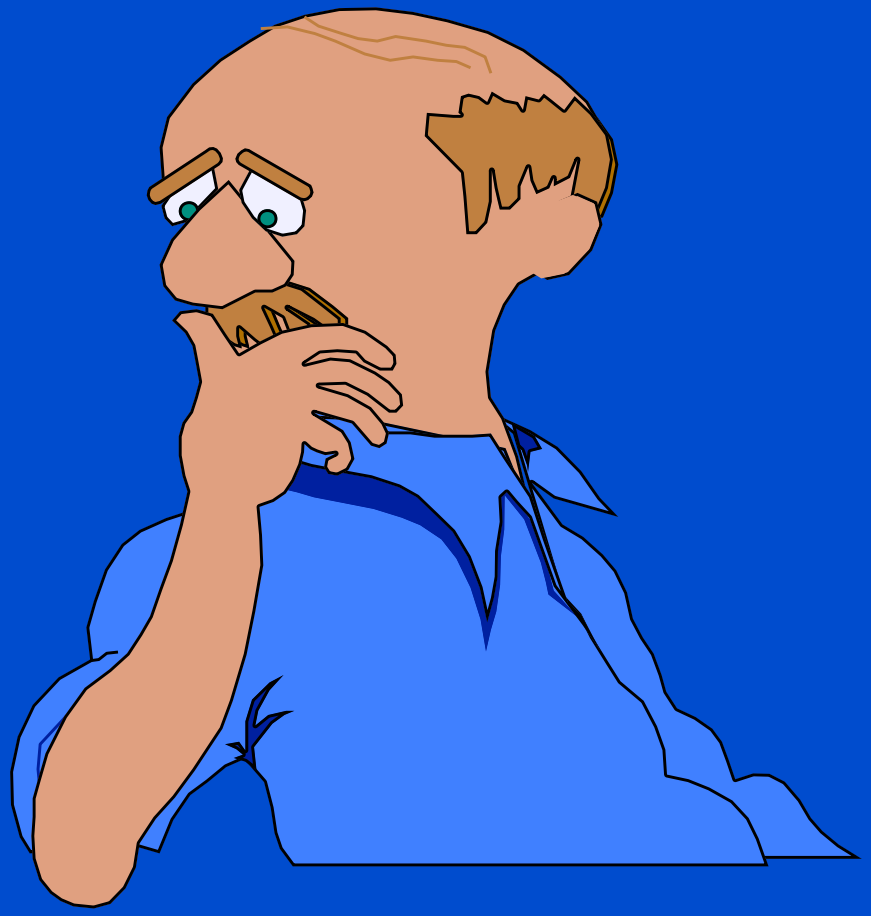
Does your health now limit you in bathing or dressing yourself?

Yes, limited a lot

Yes, limited a little

No, not limited at all

Emotional Well-Being Item



How much of the time during the past 4 weeks have you been a very nervous person?

None of the time; A little of the time; Some of the time; A good bit of the time; Most of the time; All of the time

Advantages of Generic Measures

Allow comparisons across different people

- Across disease groups
- Sick versus well
- Young versus old

Can detect unexpected side effects

Scoring Generic HRQOL Scales

Average or sum all items in the same scale.

Transform raw average or sum linearly to

- 0-100 possible range
- T-score metric

www.sf-36.com

Version 2

Norm based scoring

Formula for Transforming Scores

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

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

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

Some Uses of Generic Measures

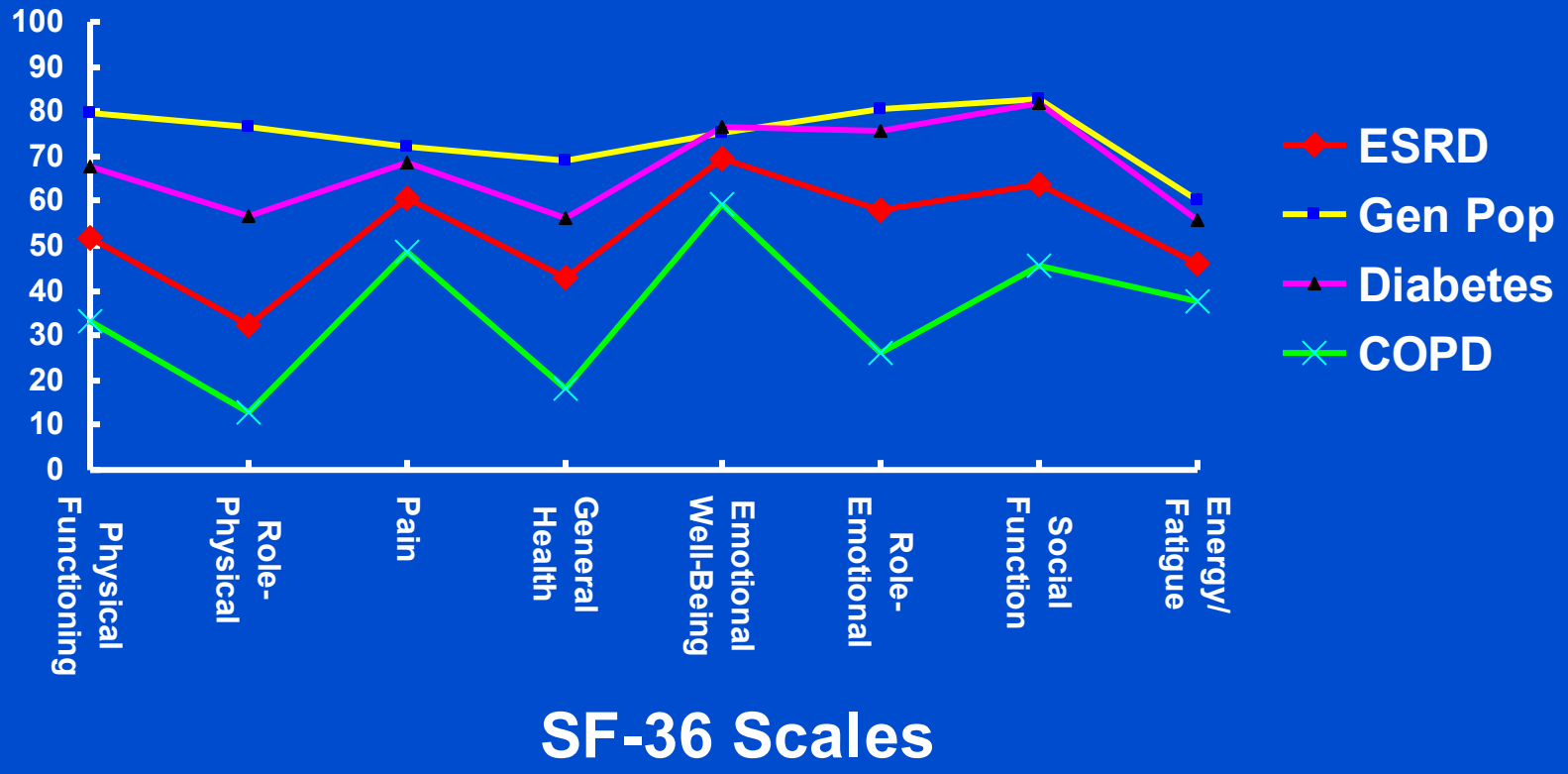
Cross-Sectional

- Profiles of Different Diseases
- Comparison of Different Samples
- Profiles by Medical Group

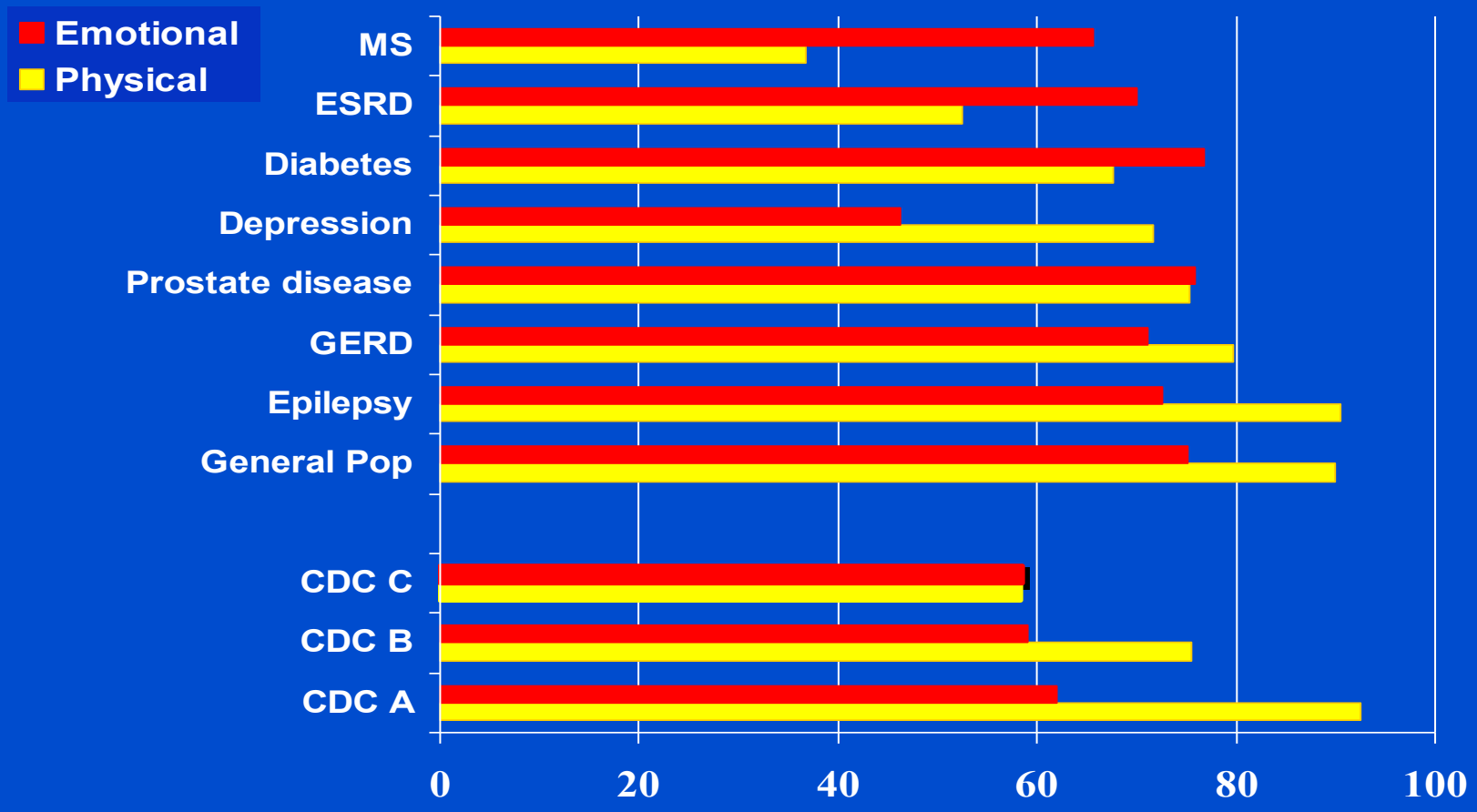
Longitudinal

- Profiles of Different Disease
- Examining Antecedents of HRQOL

Comparison of SF-36 Scores for Different Patient Populations

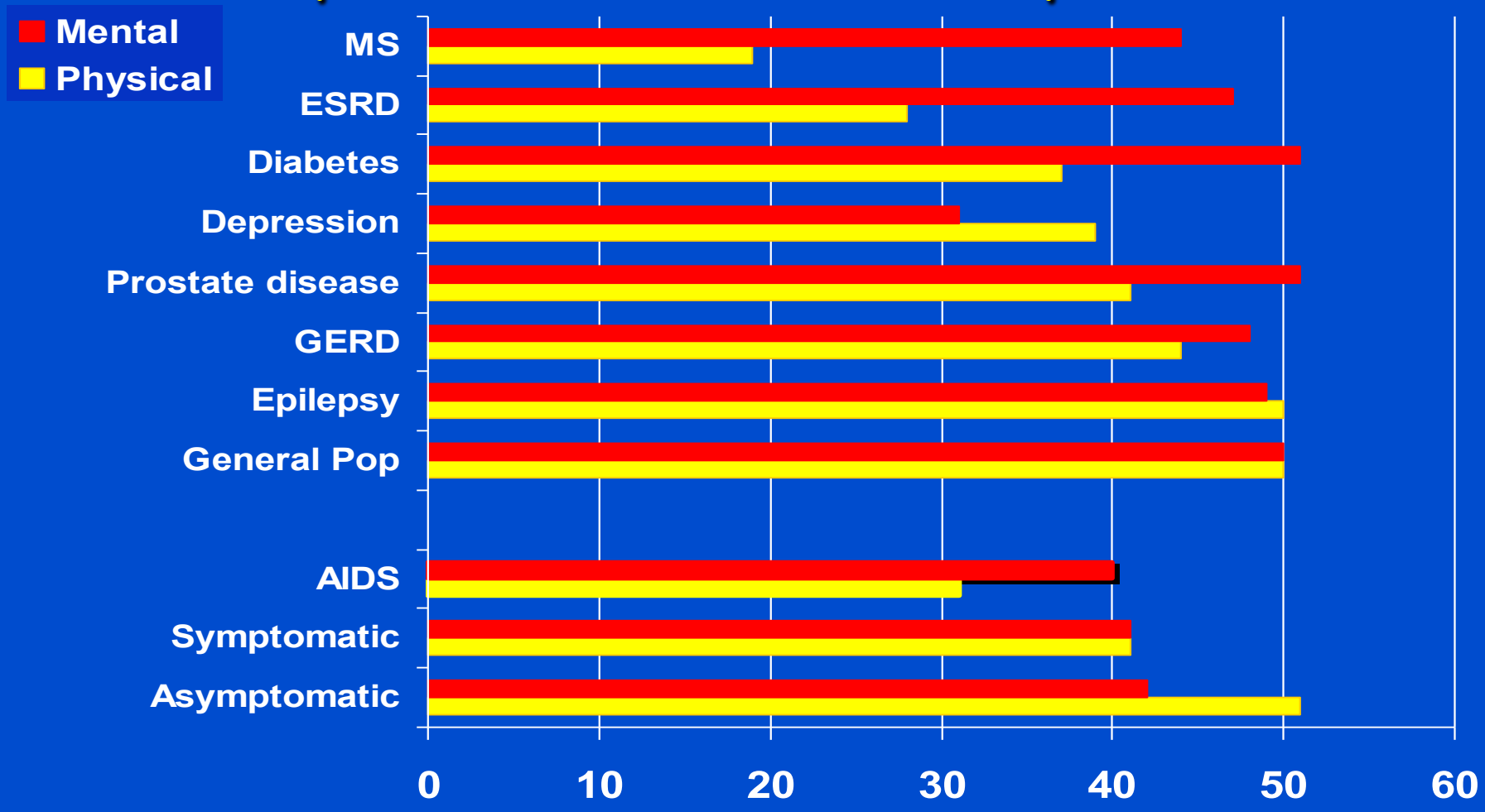


HRQOL of HIV Infected Adults



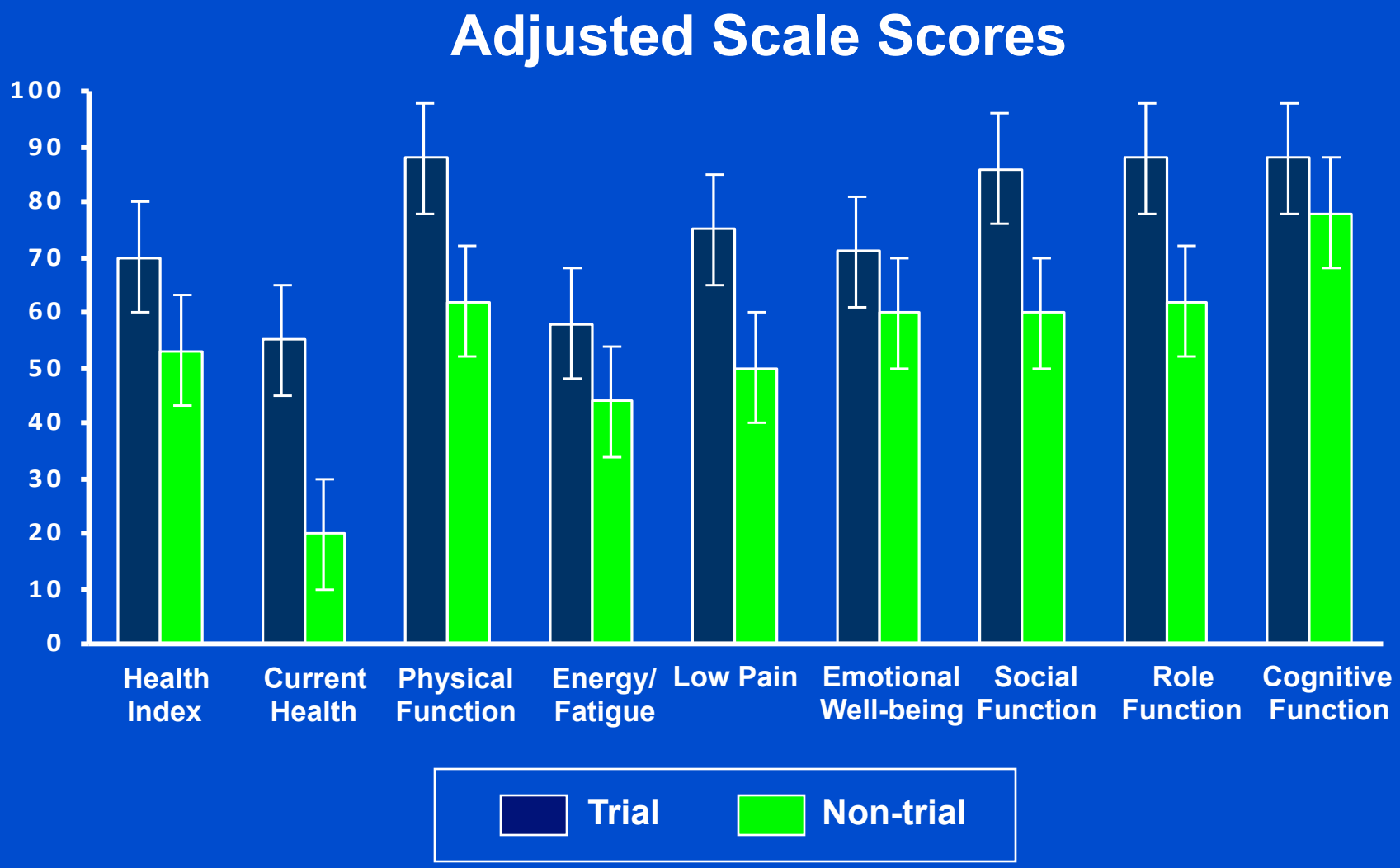
Hays, Cunningham, Sherbourne, et al (2000, AJ Medicine)

HRQOL of Those with Chronic Illness Compared to General Population

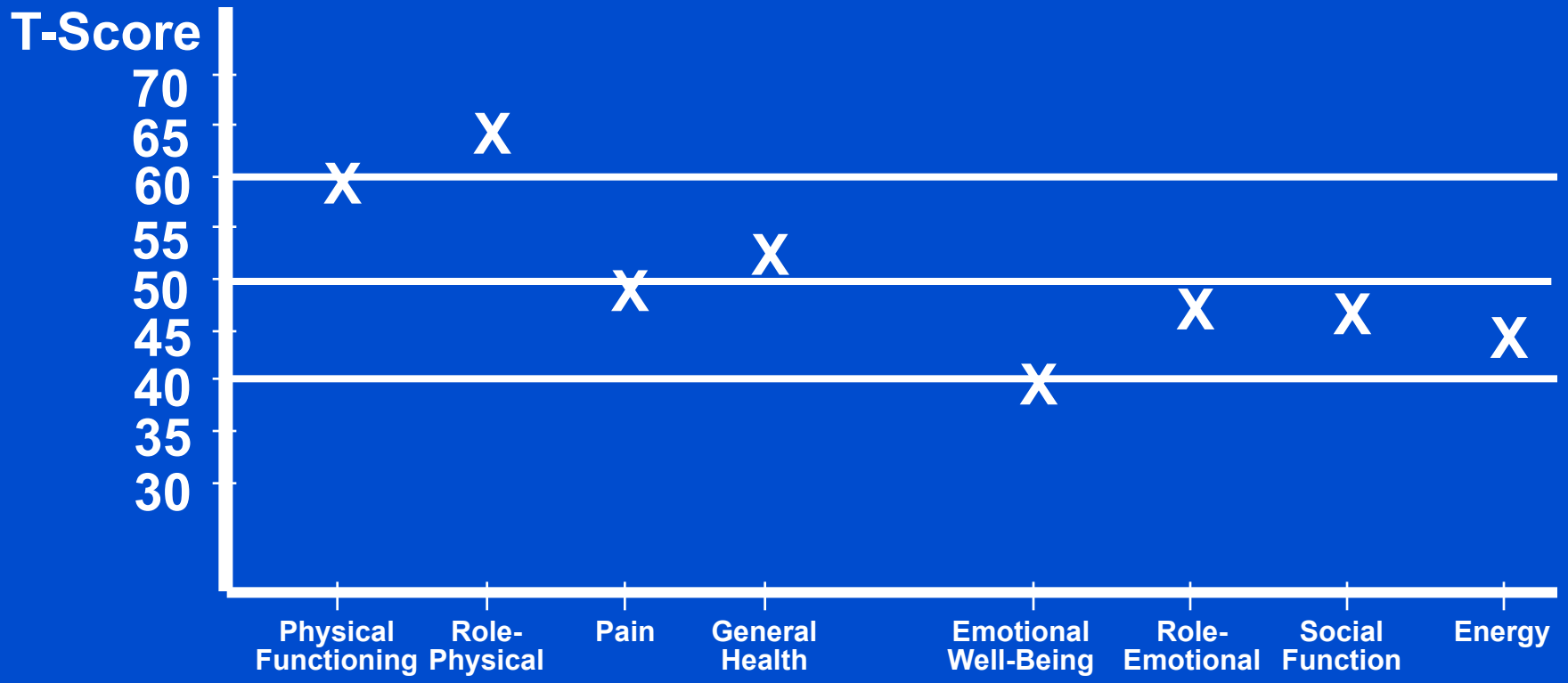


Hays, et al. (2000), American Journal of Medicine

HRQOL Scores of Patients with HIV Infection in Clinical Trial and Non-Clinical Trial Samples

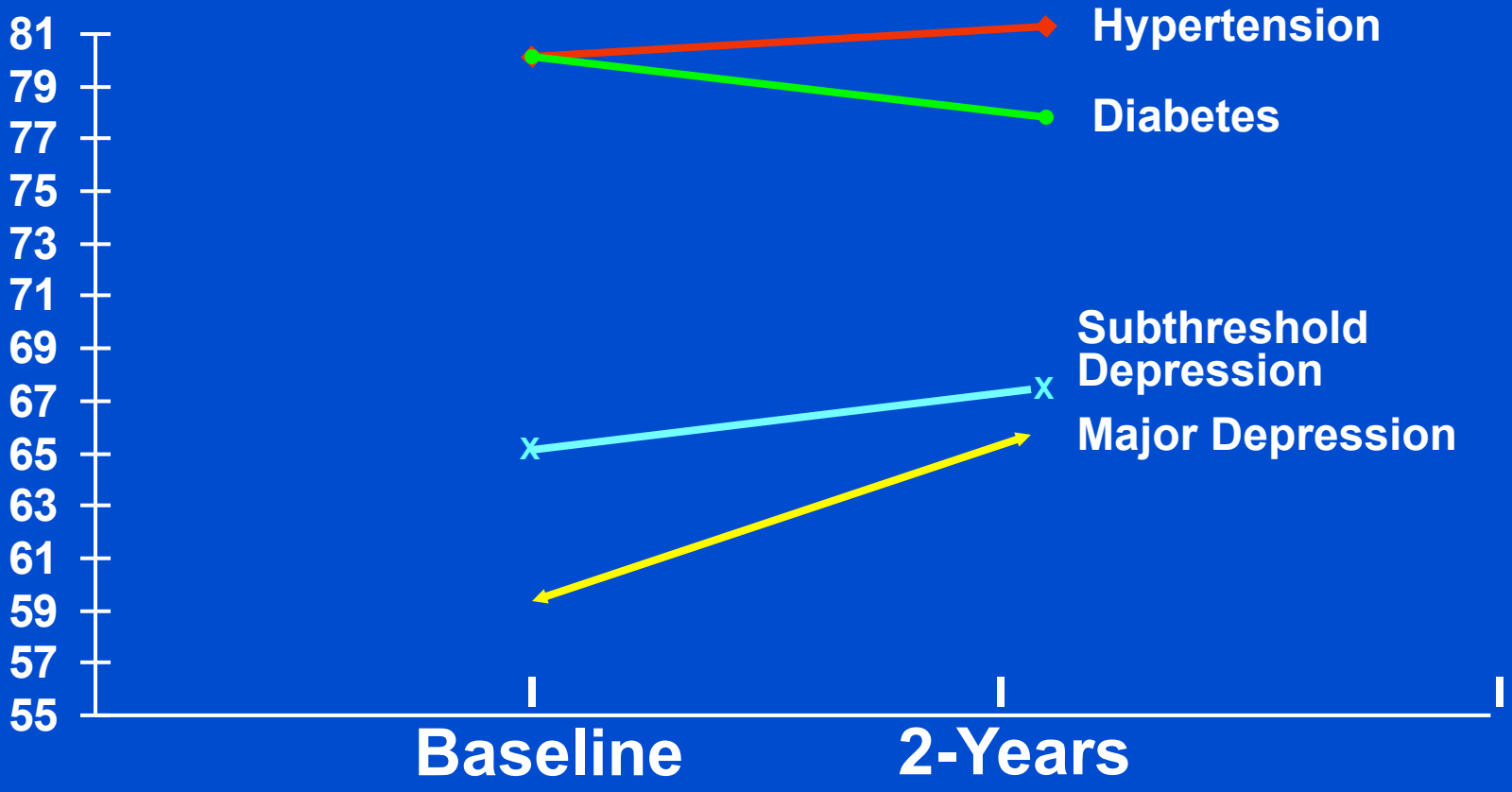


SF-36 Health Profiles for Medical Group



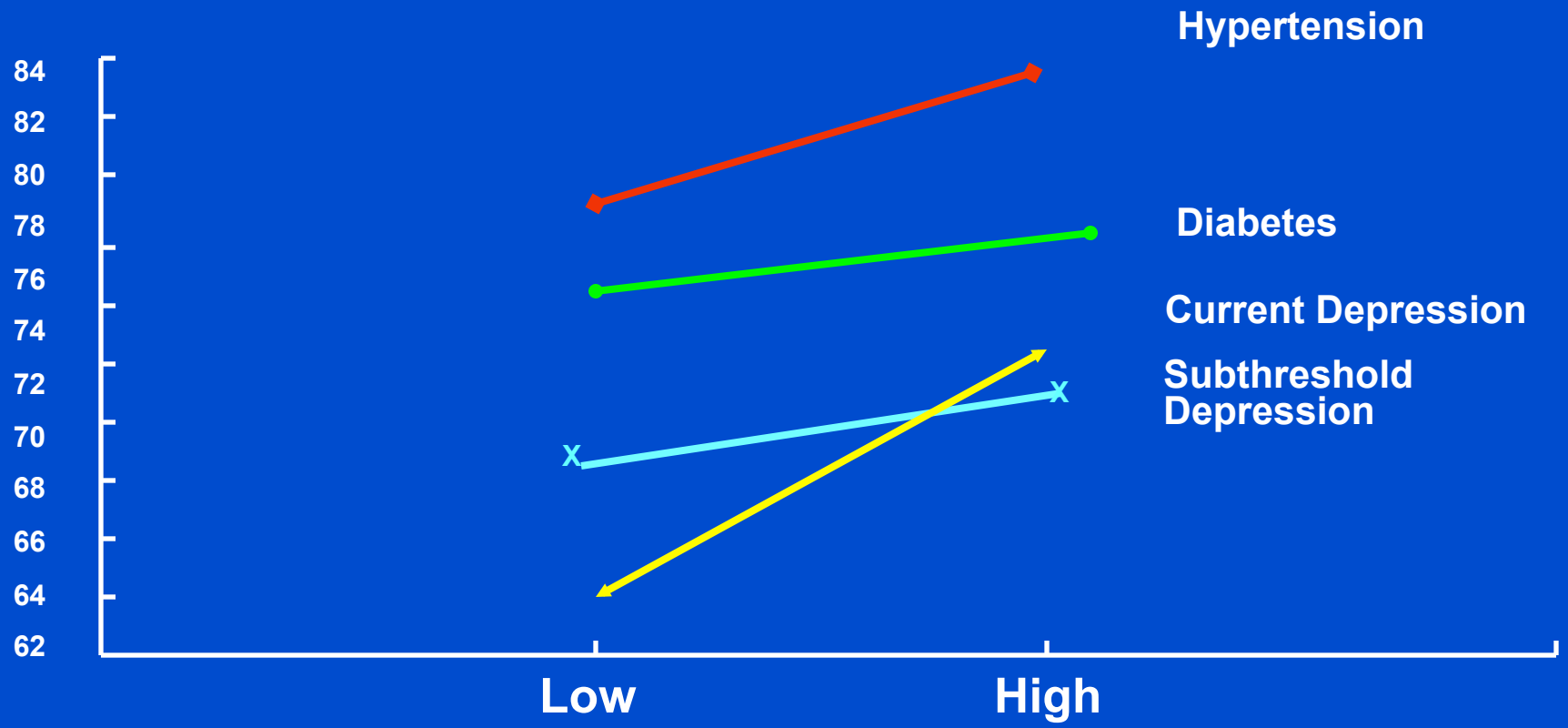
WHAT THIS FIGURE SHOWS: X's denote average SF-36 score for a sample of 200 members from your medical group. Average score across all 48 medical groups is 50 (standard deviation is 10).

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



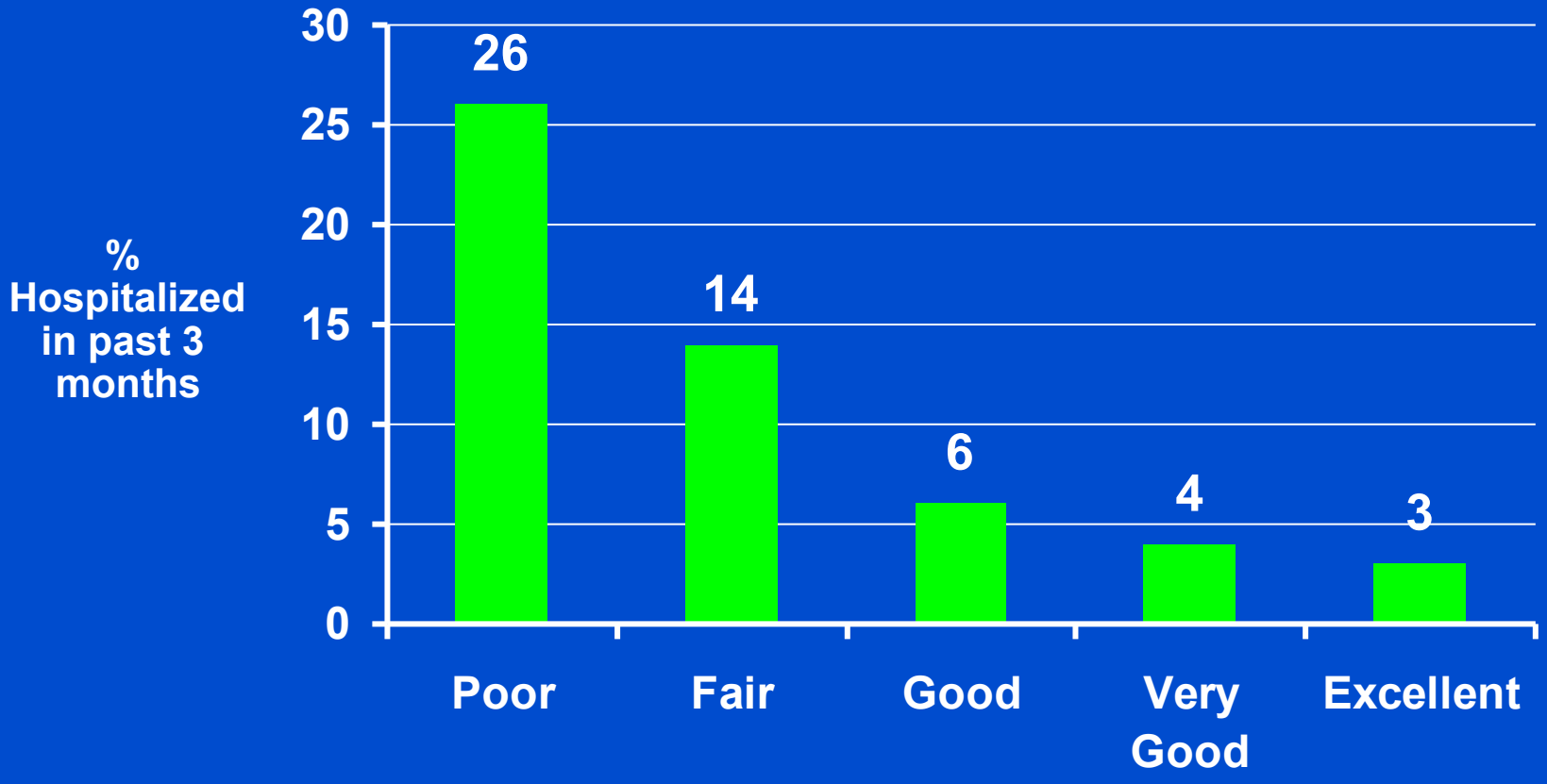
Hays, R.D., Wells, K.B., Sherbourne, C.D., Rogers, W., & Spritzer, K. (1995). Functioning and well-being outcomes of patients with depression compared to chronic medical illnesses. Archives of General Psychiatry, 52, 11-19.

Association of Exercise with Physical Functioning 2-years After Baseline in the MOS



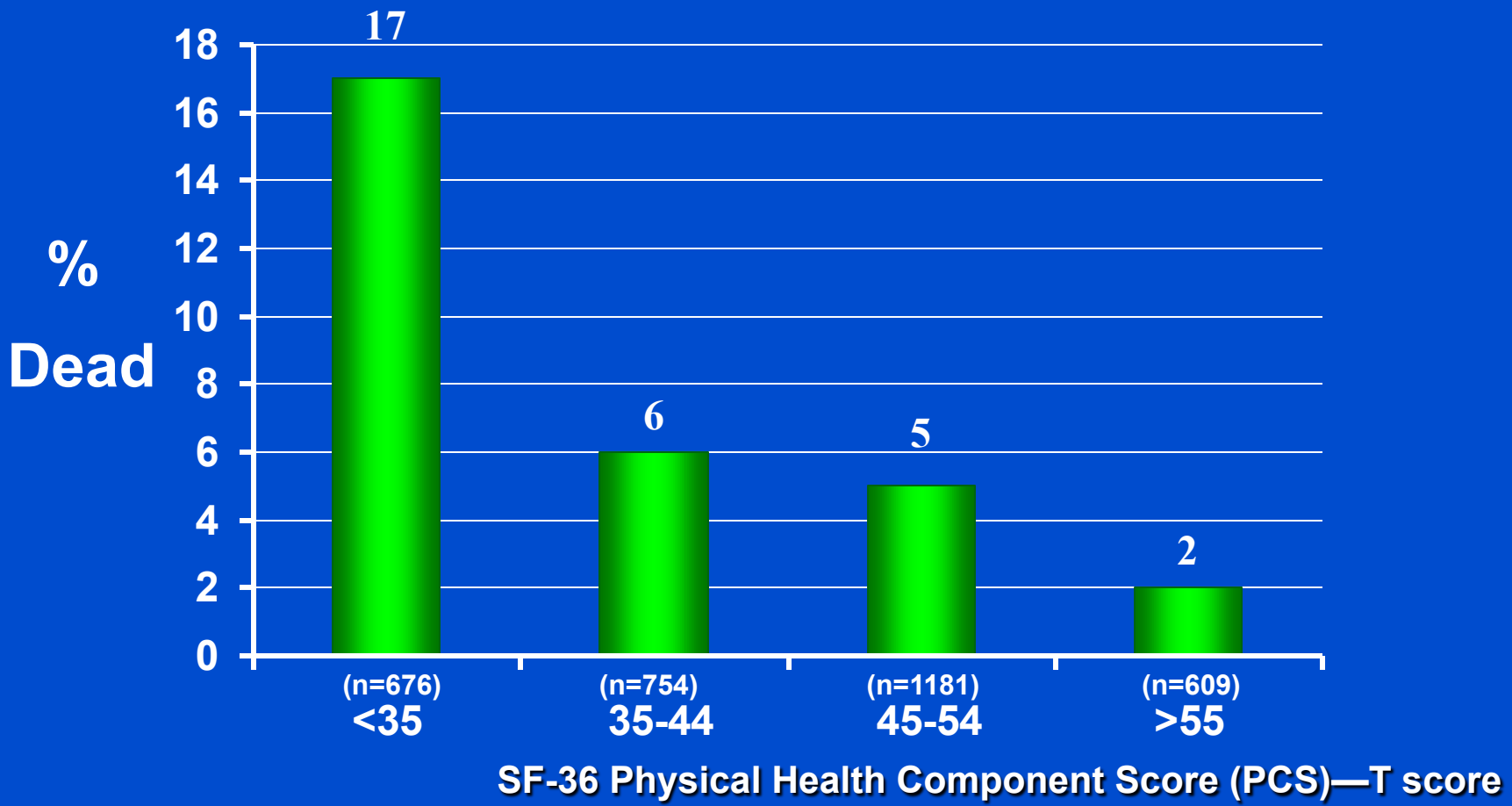
Stewart, A.L., Hays, R.D., Wells, K.B., Rogers, W.H., Spritzer, K.L., & Greenfield, S. (1994). Long-term functioning and well-being outcomes associated with physical activity and exercise in patients with chronic conditions in the Medical Outcomes Study. Journal of Clinical Epidemiology, 47, 719-730.

Generic Health Ratings Associated with Hospitalizations (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.

Five-Year Mortality Rates by Levels of Physical Health



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

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* to *Extremely*)

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

KDQOL-SF™ (80 items)

Generic core: SF-36™ health survey

Kidney disease-targeted items (43 items)

One overall health item

KDQOL-SF™
Kidney Disease-Targeted Scales

- Symptoms/problems (12 items)
- Effects of kidney disease (8 items)
- Burden of kidney disease (4 items)
- Work status (2 items)
- Cognitive function (3 items)
- Quality of social interaction (3 items)
- Sexual function (2 items)
- Sleep (4 items)

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

HRQOL Measures for Prostate Cancer Study

Generic

SF-36

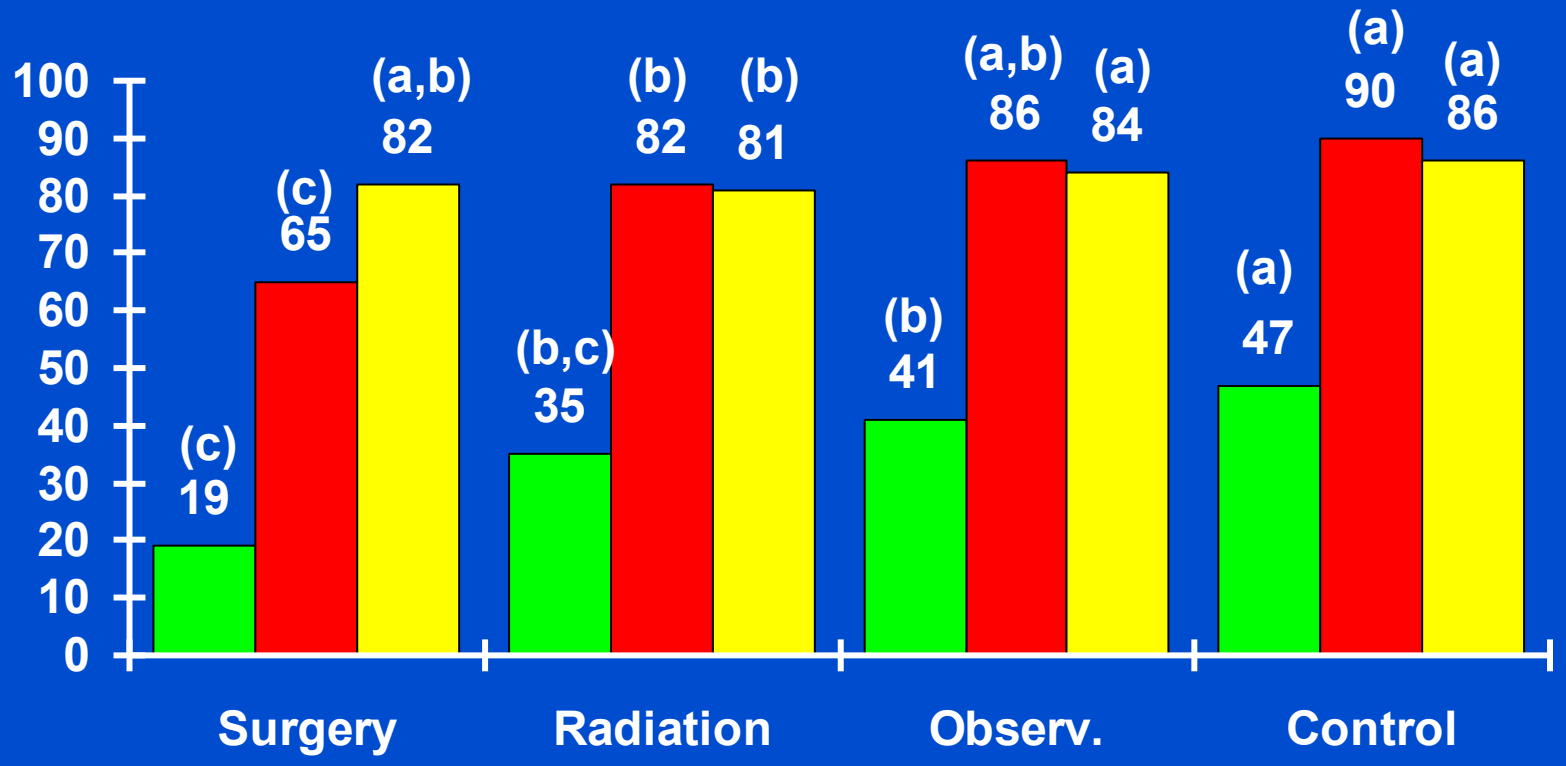
Intermediate

Cancer Rehabilitation Evaluation System (CARES)
Functional Assessment of Cancer Therapy (FACT)

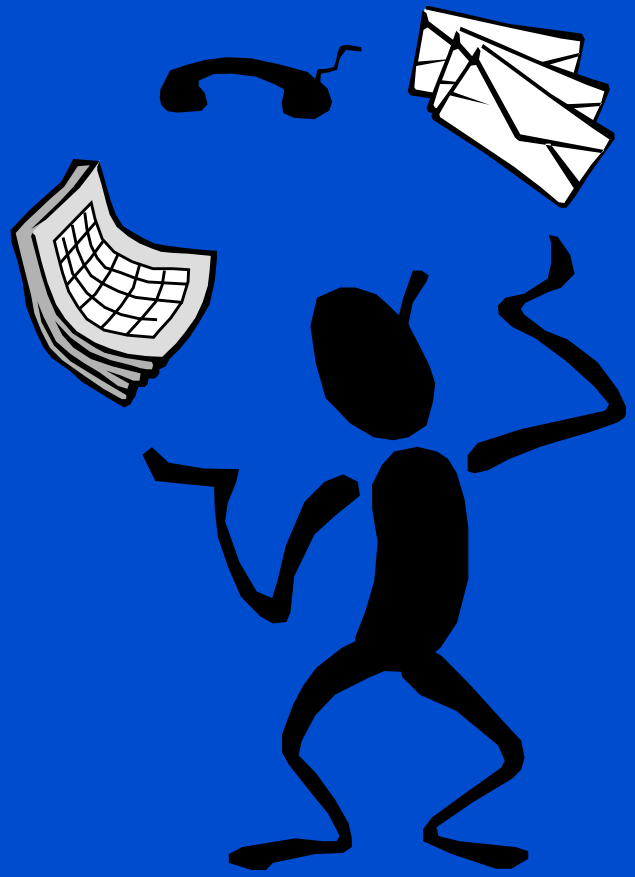
Disease-Targeted

Sexual, Urinary, Bowel Function/Distress

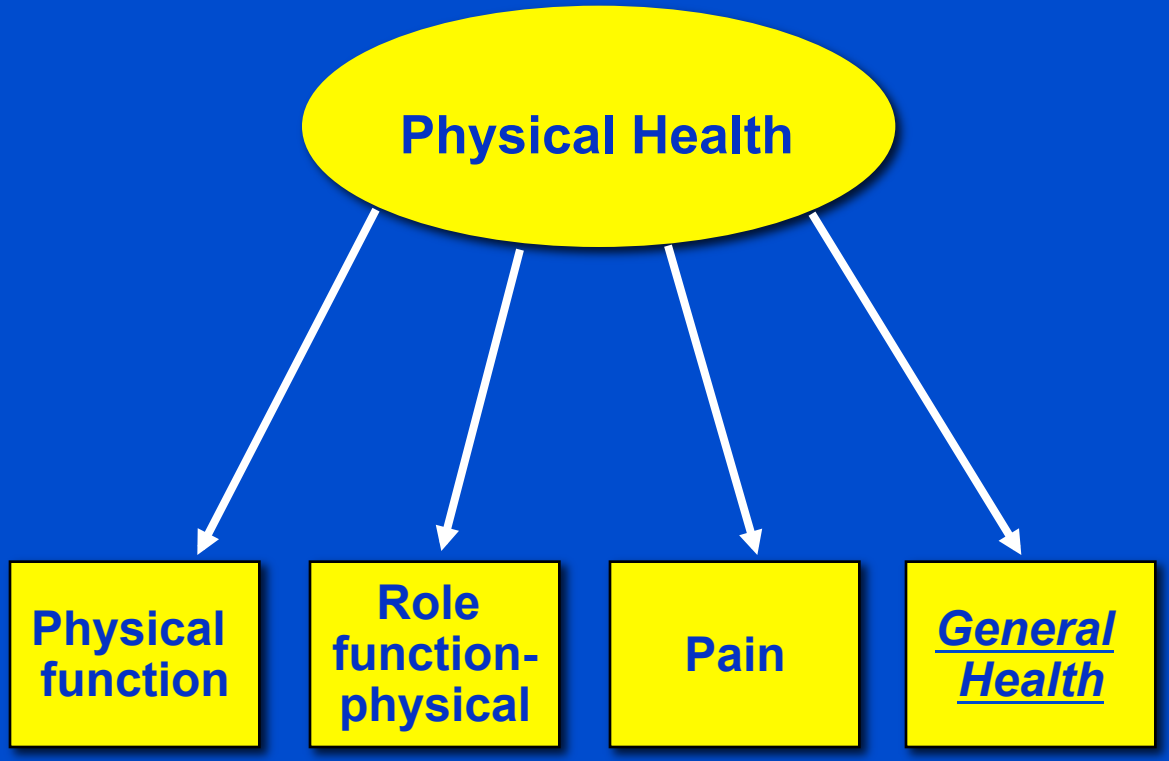
Sexual, Urinary, and Bowel Function Outcomes



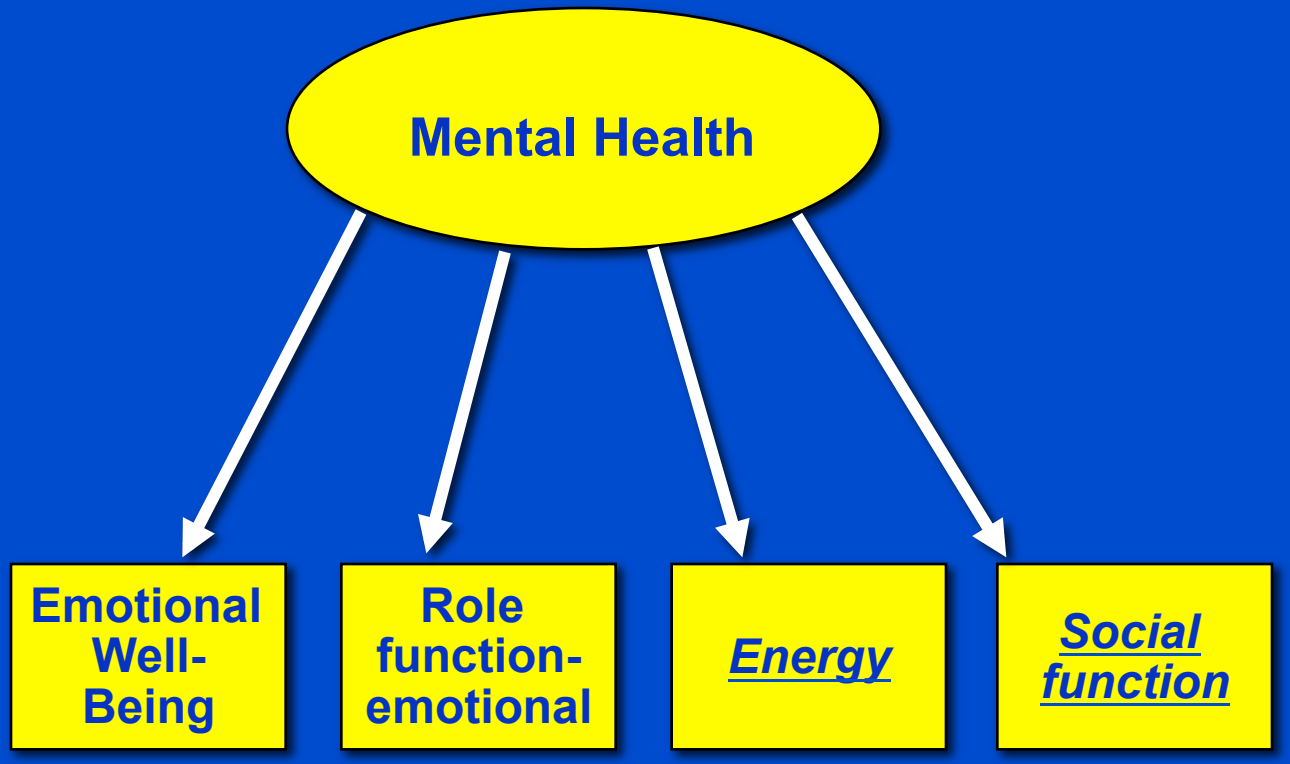
How do you summarize HRQOL?



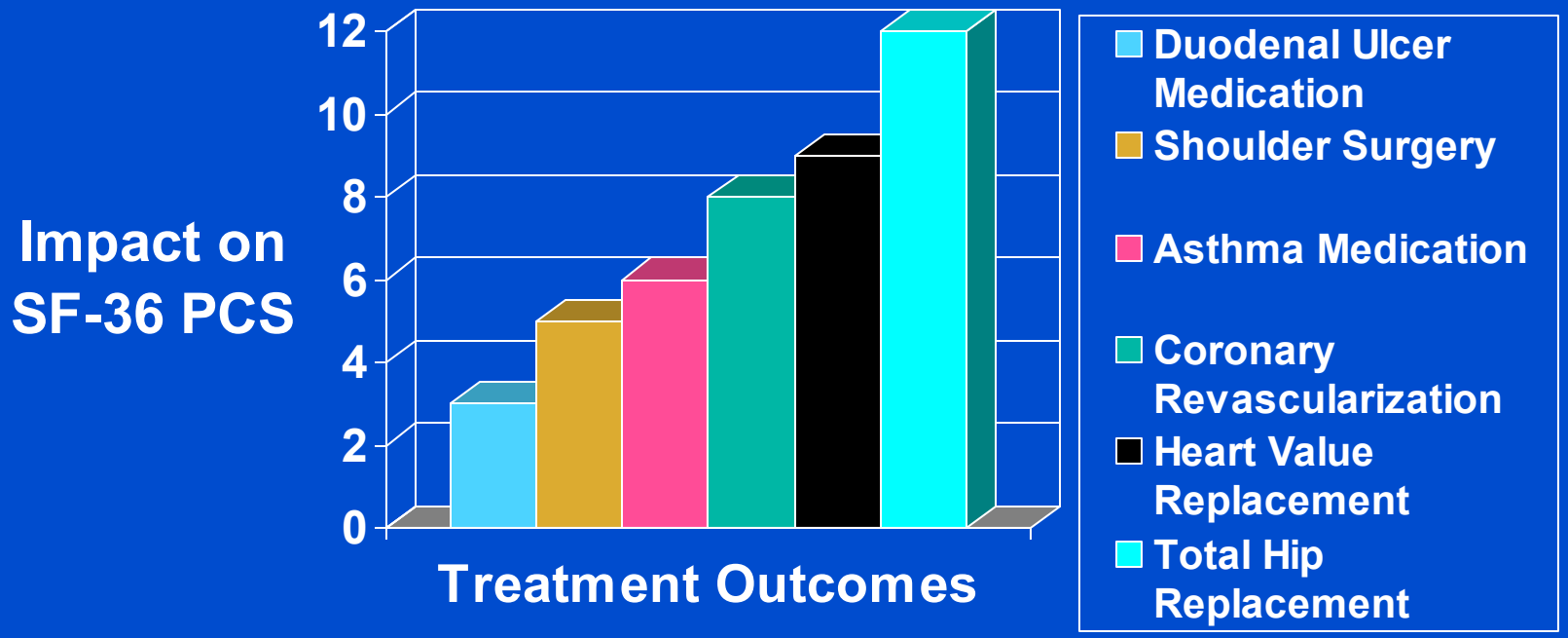
Physical Health



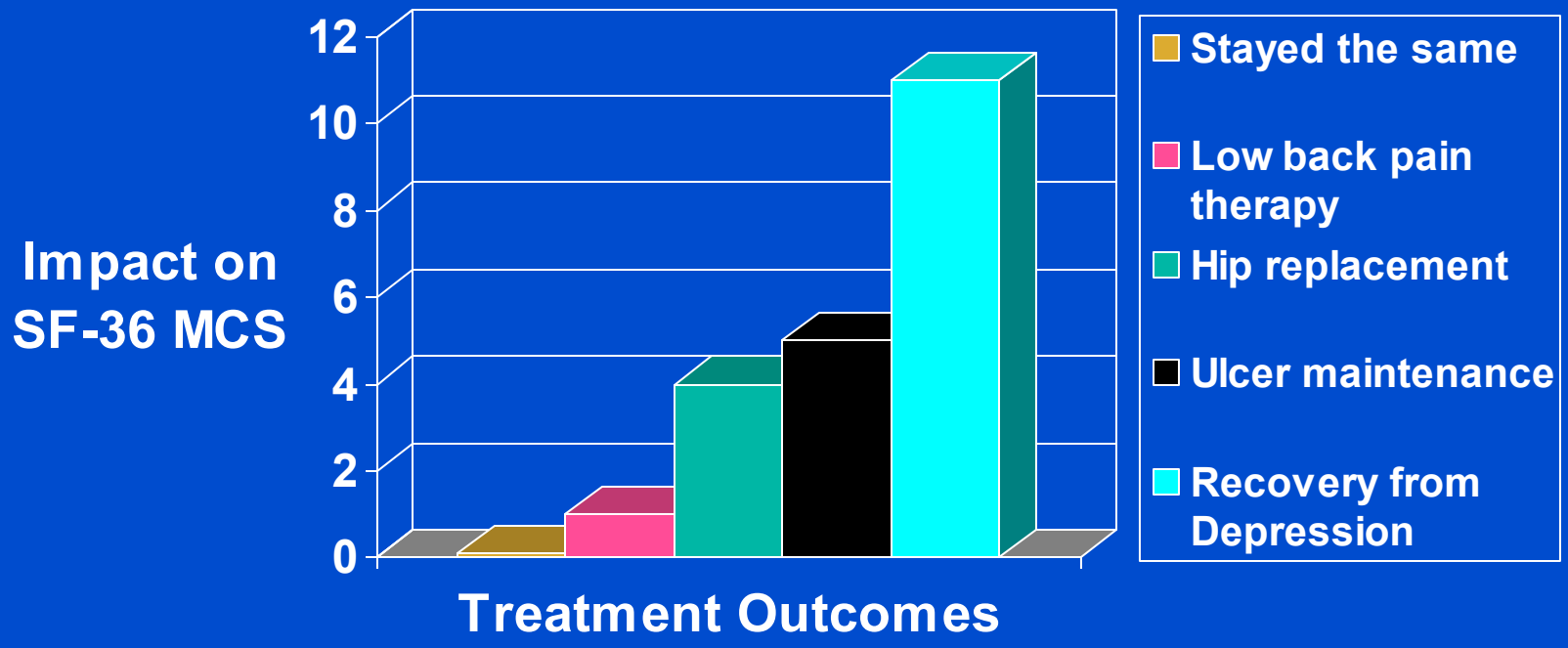
Mental Health



Treatment Impact on PCS



Treatment Impact on MCS



Physical and Mental Health Summary Scores

- SF-36 PCS & MCS uncorrelated (r = 0.00)
- RAND-36 Physical Health & Mental Health Composites correlated (r = 0.66)

Hays, R. et al. (1998), RAND-36 Health Status Inventory.

536 Primary Care Patients Initiating Antidepressant Tx

- 3-month improvements in physical functioning, role—physical, pain, and general health perceptions ranging from 0.28 to 0.49 SDs.

- Yet SF-36 PCS did not improve.

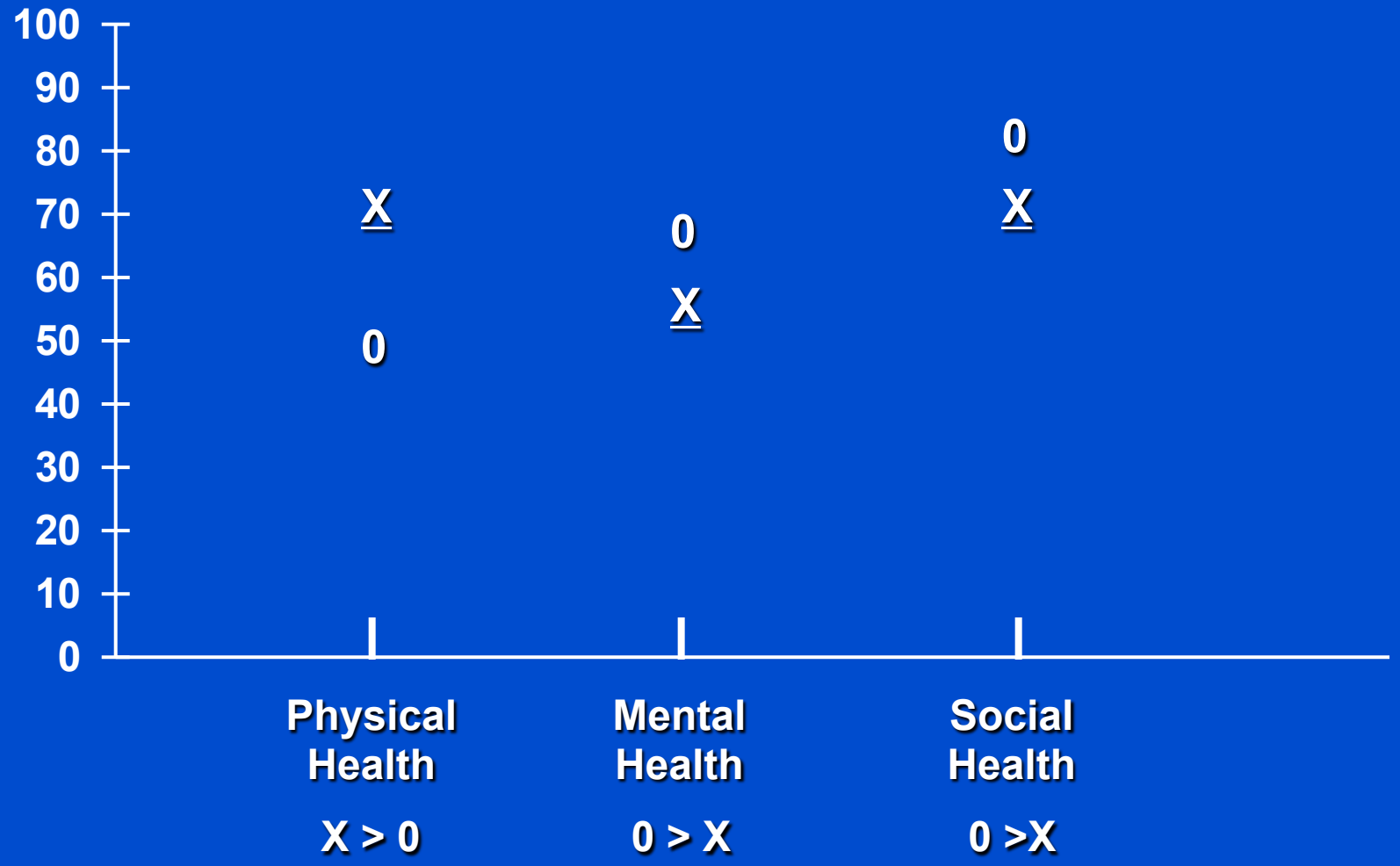
Simon et al. (Med Care, 1998)

n = 194 with Multiple Sclerosis

- Lower scores than general population on
  - Emotional well-being (↓ 0.3 SD)
  - Role—emotional (↓ 0.7 SD)
  - Energy (↓1.0 SD)
  - Social functioning (↓1.0 SD)
- Yet SF-36 MCS was only 0.2 SD lower.
- RAND-36 mental health was 0.9 SD lower.

Nortvedt et al. (Med Care, 2000)

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



Is Use of 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

HRQOL Summary Options

Ignore mortality

- *Single score--weighted combination*

Profile and mortality information

Preference score

Single Weighted Combination of Scores

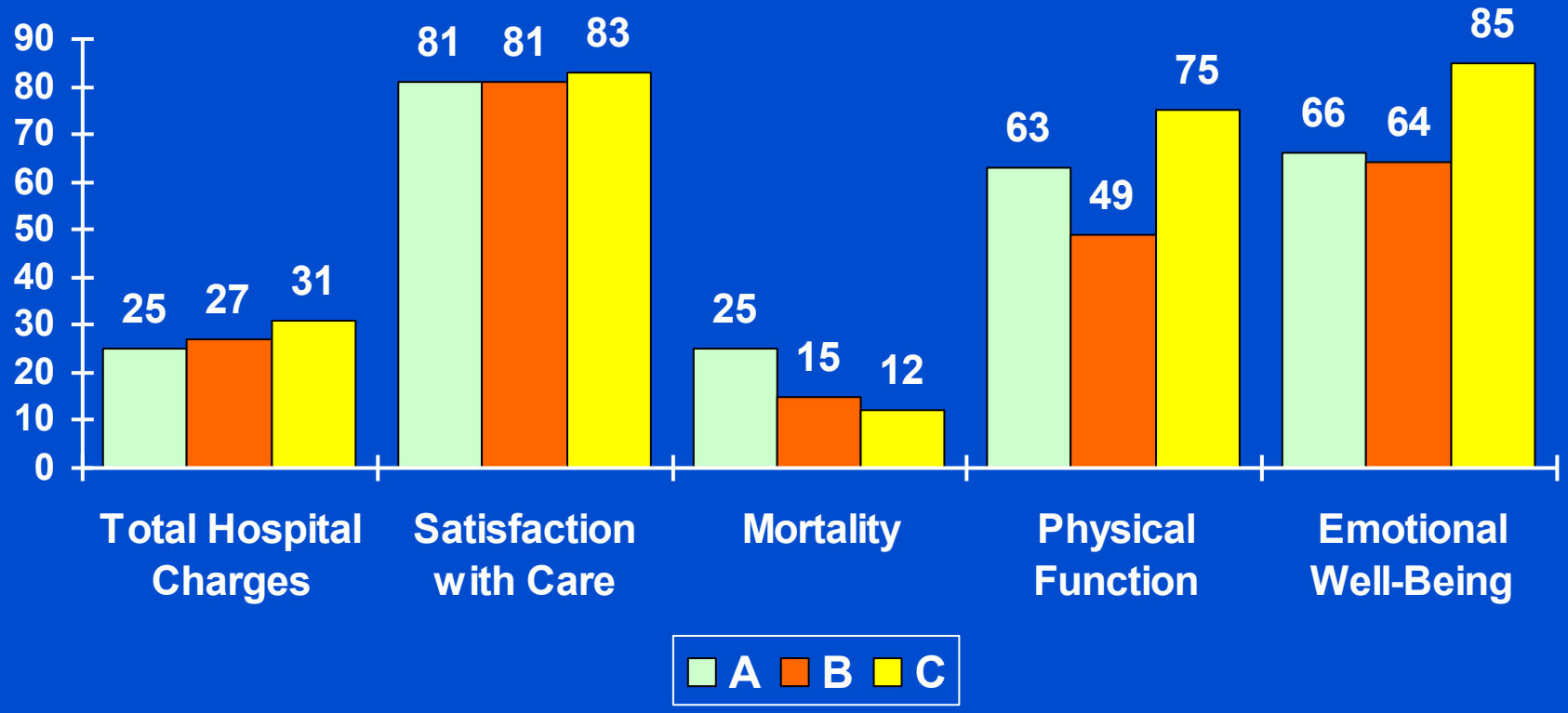
Quartile on Perceived Health Index (reliability = 0.94)

Highest	Lowest	(n = 1,862)
35%	84%	at least 1 moderate symptom
7%	70%	at least 1 disability day
1%	11%	hospital admission
2%	14%	performance of invasive diagnostic procedure

Perceived Health Index = 0.20 Physical functioning + 0.15 Pain + 0.41 Energy + 0.10 Emotional well-being + 0.05 Social functioning + 0.09 Role functioning.

Bozzette, S.A., Hays, R.D., Berry, S.H., & Kanouse, D.E. (1994). A perceived health index for use in persons with advanced HIV disease: Derivation, reliability, and validity. Medical Care, 32, 716-731.

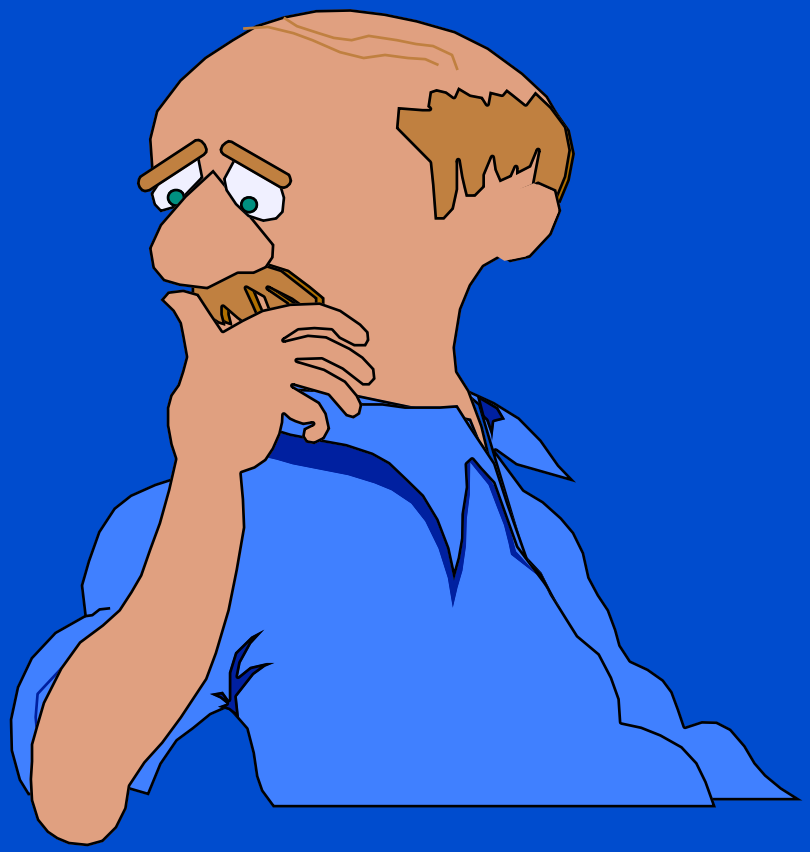
Profile + Mortality Outcomes for Acute MI (n = 133)



Problem with Survival Analysis

Marathoner 1.0

Person in coma 1.0

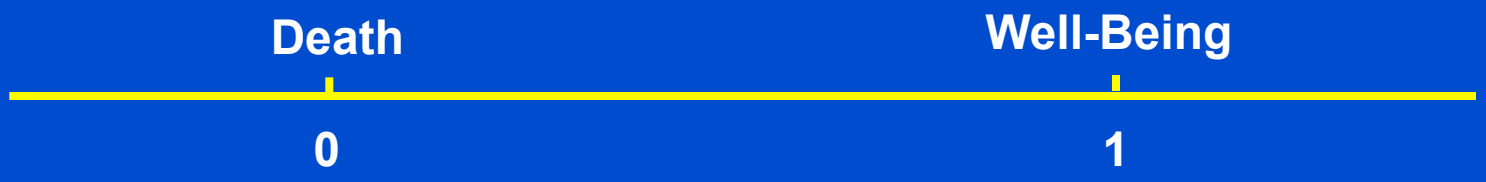


Types of Preference Measures

- Societal Preferences (Multi-attribute Utility)
  - QWB
  - HUI
  - EQ-5D
- Individual Preferences
  - Standard Gamble
  - Time Tradeoff

Quality of Well-Being Scale

- 15 Minute Structured Interview
  - Physical activity (PAC)
  - Mobility (MOB)
  - Social activity (SAC)
  - Symptom/problem complexes (SPC)
- Summarizes Health in Quality-adjusted Life Years



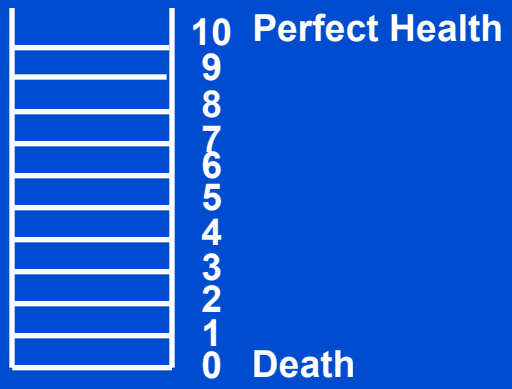
- Well-Being Formula $w = 1 + PAC + MOB + SAC + SPC$

Quality of Well-Being Weighting Procedure

Each page in this booklet tells how an imaginary person is affected by a health problem on one day of his or her life. I want you to look at each health situation and rate it on a ladder with steps numbered from zero to ten. The information on each page tells 1) the person's age group, 2) whether the person could drive or use public transportation, 3) how well the person could walk, 4) how well the person could perform the activities usual for his or her age, and 5) what symptom or problem was bothering the person.

Example Case #1

Adult (18-65)
Drove car or used public transportation without help
Walked without physical problems
Limited in amount or kind of work, school, or housework
Problem with being overweight or underweight



QWB Physical Activity Levels

1) Dead
2) In bed, chair, couch, or wheelchair*
3) In wheelchair** or had difficulty
   - lifting
   - stooping
   - using stairs
   - walking, etc.
4) None of the above

---

* Did not move oneself

** Moved oneself

QWB Mobility Levels

1) Dead
2) In hospital, nursing home, or hospice
3) Did not drive car or use public transportation
4) None of the above

QWB Social Activity Levels

1) Dead

2) Did not feed, bath, dress, or toilet oneself

3) Limited or did not perform role activities

4) None of the above

QWB Symptom/Problem Complexes

Worst Symptom/problem complex experienced

Loss of consciousness –> breathing smog

Quality of Well-Being States and Weights

Component	Measures	States	Weights
Physical activity	Physical function	In bed, chair, couch, or wheelchair*	-.077
		In wheelchair* or had difficulty lifting, stooping, using stairs, walking, etc.	-.060
Mobility	Ability to get around or transport oneself	In hospital, nursing home, or hospice.	-.090
		Did not drive car or use public transportation	-.062
Social activity	Role function and self-care	Did not feed, bath, dress, or toilet f	-.106
		Limited or did not perform role	-.061
Symptom/problem	Physical symptoms and complexes problems	Worst symptom from loss of consciousness to breathing	-.407
			-.101
			smog or
unpleasant air			

* moved vs. did not move oneself in wheelchair

HUI-3

(5-6 levels/attribute, 972,000 unique states)

Vision

Hearing

Speech

Ambulation

Dexterity

Cognition

Pain and discomfort

Emotion

EQ-5D
(3 levels/dimension, 243 states)

Mobility

Self-care

Usual activities

Pain/discomfort

Anxiety/depression

Ad Hoc Preference Score Estimates

Comprehensive Geriatric Assessment (n = 363 community-dwelling older persons) lead to improvements in SF-36 energy, social functioning, and

- Physical functioning (4.69 points) in 64 weeks
- Cost of $746 over 5 years beyond control group

Is CGA worth paying for?

Change in QALYs associated with 4.69 change in SF-36 physical functioning

- r = 0.69 -> b = .003 x 4.69 =.014 (△QWB)
- .014 x 5 yrs. = 0.07 QALYs
- Cost/QALY: $10,600+

<$20,000 per QALY worthwhile

Latest Preference Score

Brazier et al. (1998, in press)

- 6-dimensional classification
  - Collapsed role scales, dropped general health
- 9000 possible states

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

Standard Gamble

Classical method of assessing preferences

- Choose between certain outcome and a gamble
- Conformity to axioms of expected utility theory
- Incorporates uncertainty (thus, more reflective of treatment decisions).

Standard Gamble (SG)

Choice #1: Your present state (e.g., paralysis)

Choice #2: X probability of complete mobility
1-X probability of death

Preference Value: Point at which indifferent between choices, varying X

[X = QUALY]

Time Tradeoff (TTO)

- Choice between two certain outcomes
- Years of life traded for quality of life
- Simple to administer alternative to SG

Time Tradeoff

Choice #1: Your present state (e.g., paralysis)

Life Expectancy: 10 years

Choice #2: Complete mobility

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

$$[\ 1 - \frac{X}{10} = \text{QUALY}\ ]$$

Limitations of Preference Measures

Sensitivity to Method

Societal

- **Coarseness of health states**

Individual

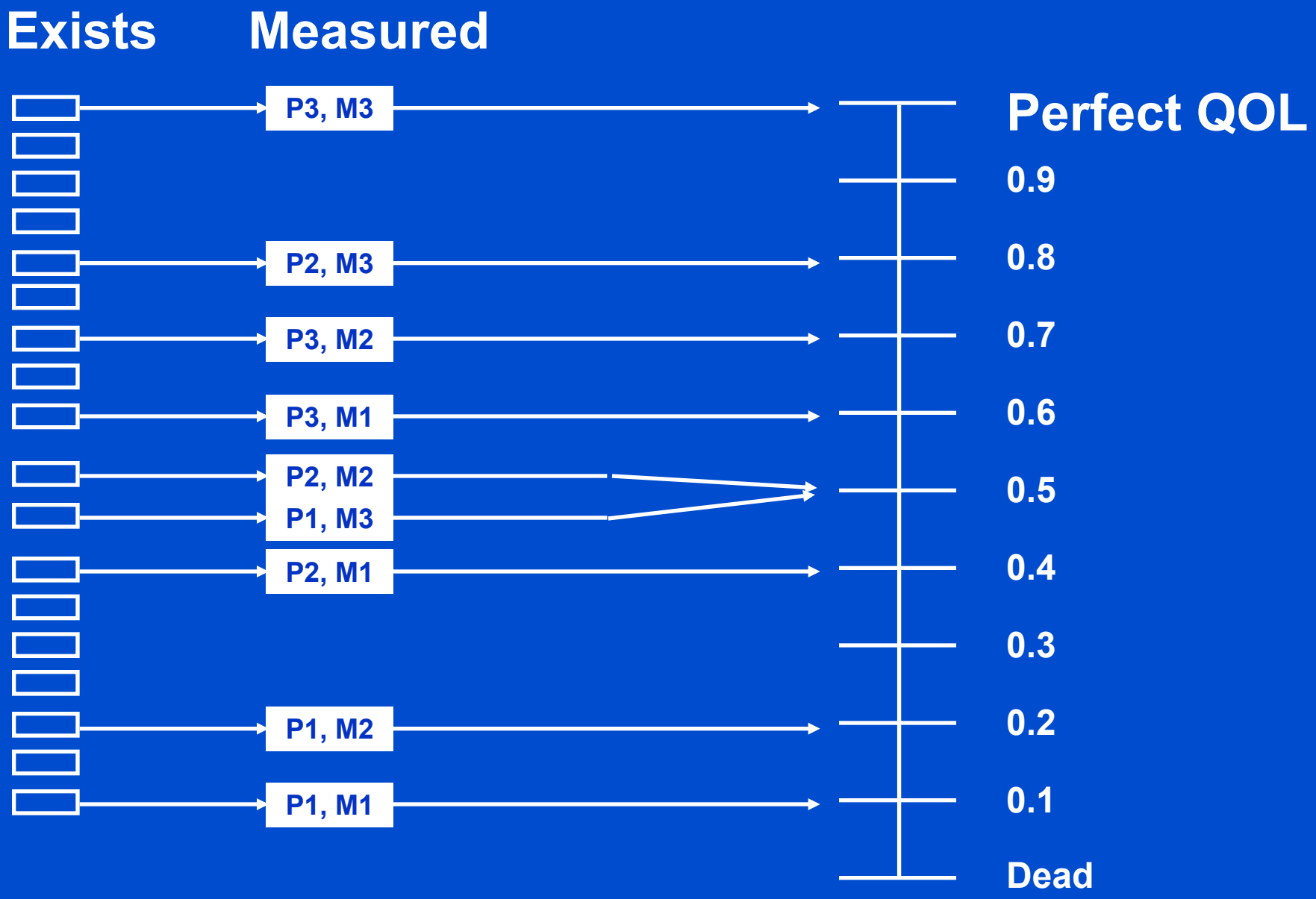
- **Complexity of task**

Hypothetical Health States

Physical Health		
P3	0.00	High
P2	-0.20	Medium
P1	-0.50	Low

Mental Health		
M3	0.00	High
M2	-0.30	Medium
M1	-0.40	Low

Mapping Health States into Quality of Life



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.

Child Measures

Child Health and Illness Profile (CHIP)

- Starfield et al., Medical Care, 1995

COOP Charts

- Baribeau, P. et al., 1991 (final report)

Functional Status II-R

- Stein & Jessop, Medical Care, 1990

Child Health Questionnaire

- Landgraf, Abetz, & Ware (2000)

Summary

Optimal HRQOL Assessment

- Generic Profile
- Targeted Profile
- Preference-Based Summary Measure