Health-Related Quality of Life in Outcome Studies

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GCRC Summer Session
July 18, 2011 (8:00-9:00 am)
1st floor Conference Room 1357, UCLA

Health-Related Quality of Life is …

What you can <u>do</u>.

- <u>Functioning</u>
  Self-care
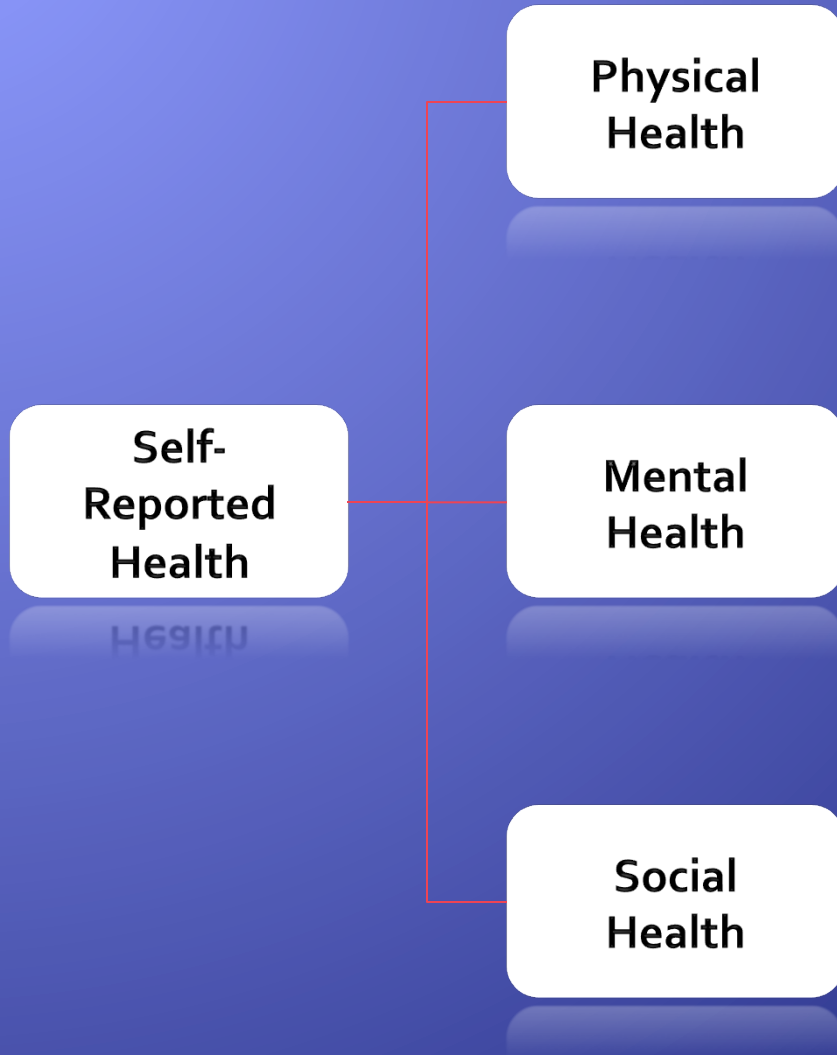 Role
  Social

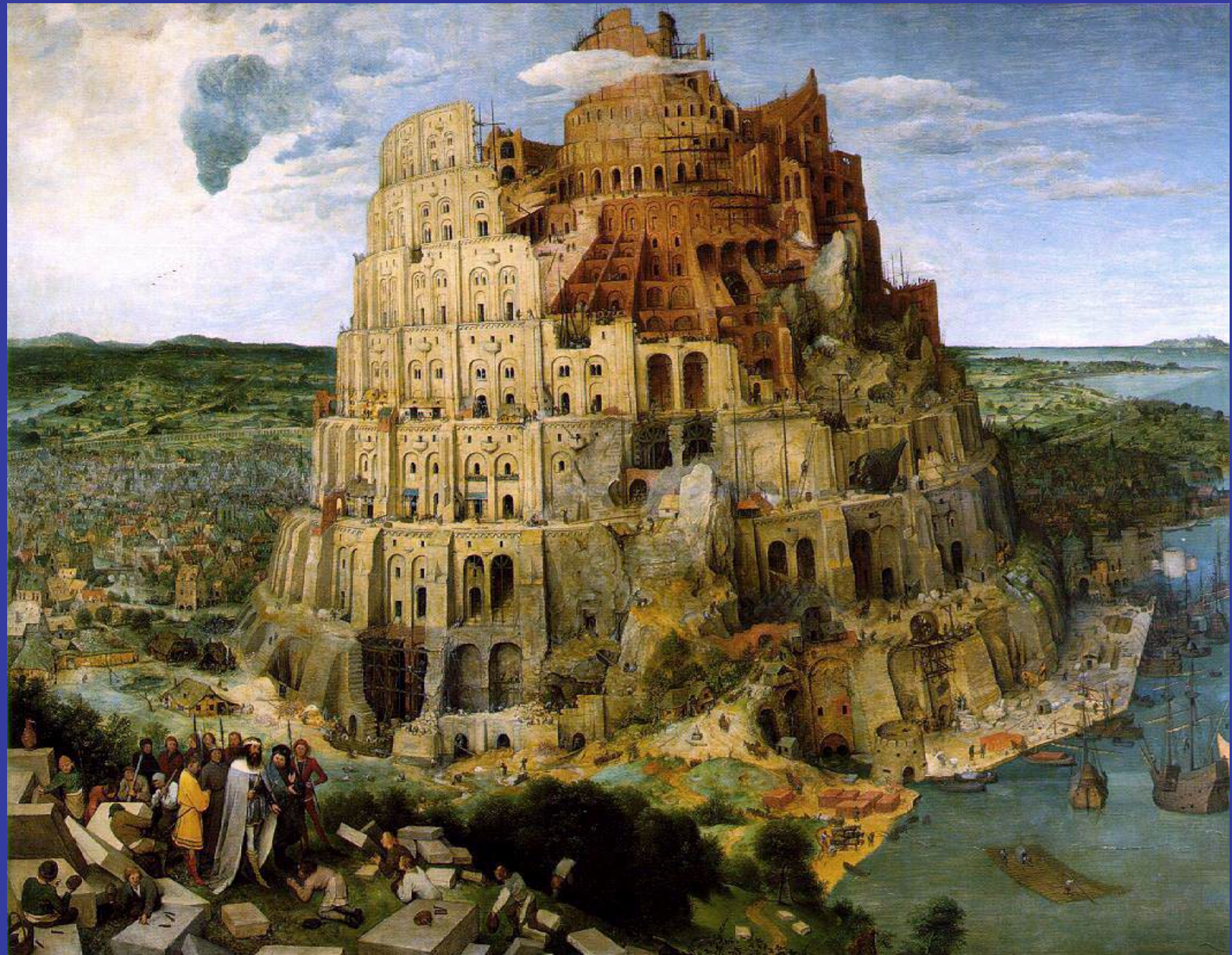## How you <u>feel</u> about your life.

- <u>Well-being</u>
  Emotional well-being
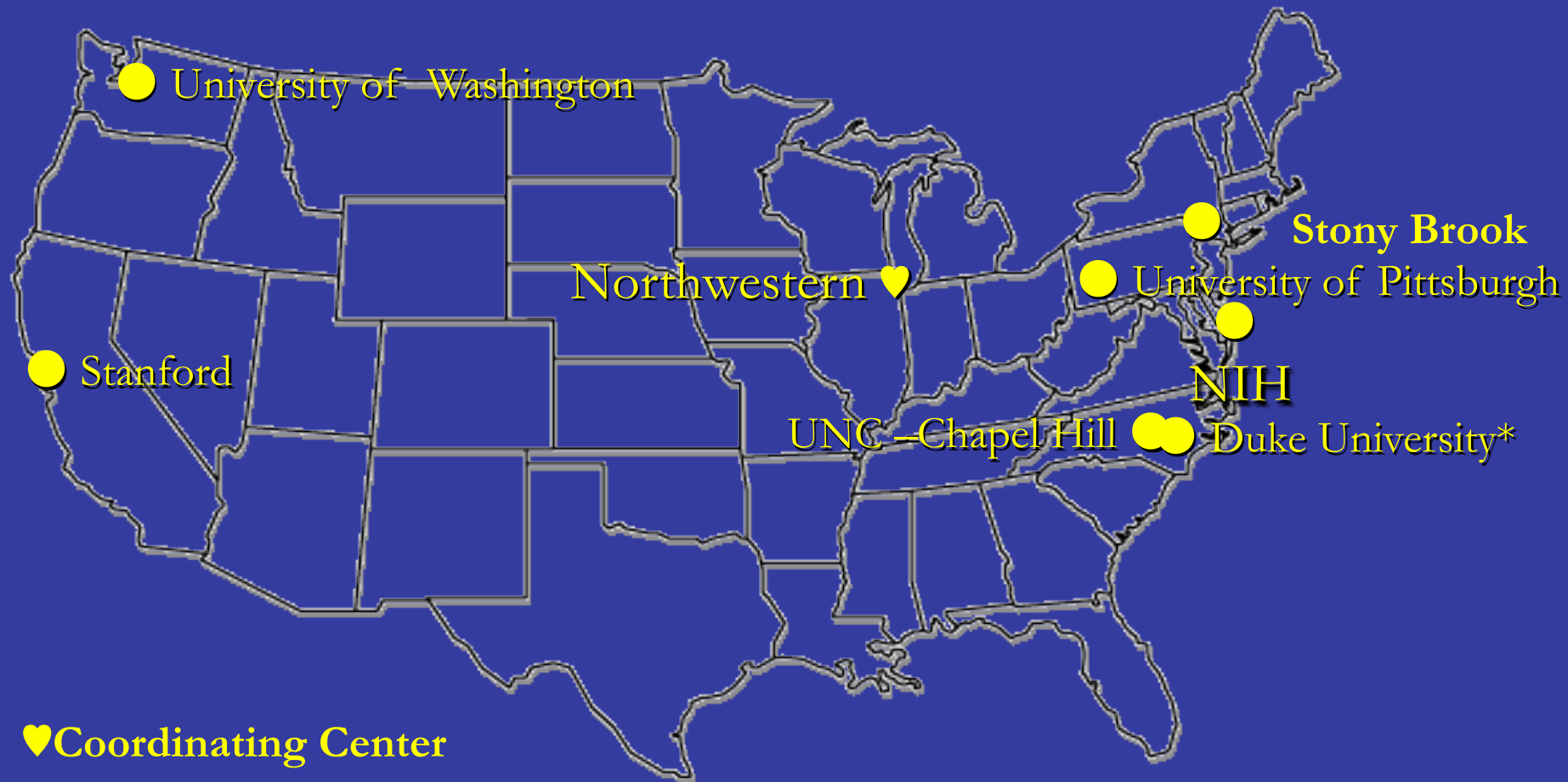 Pain
  Energy

The Tower of Babel (Brueghel, 1563)

4

SF-36®

- 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)

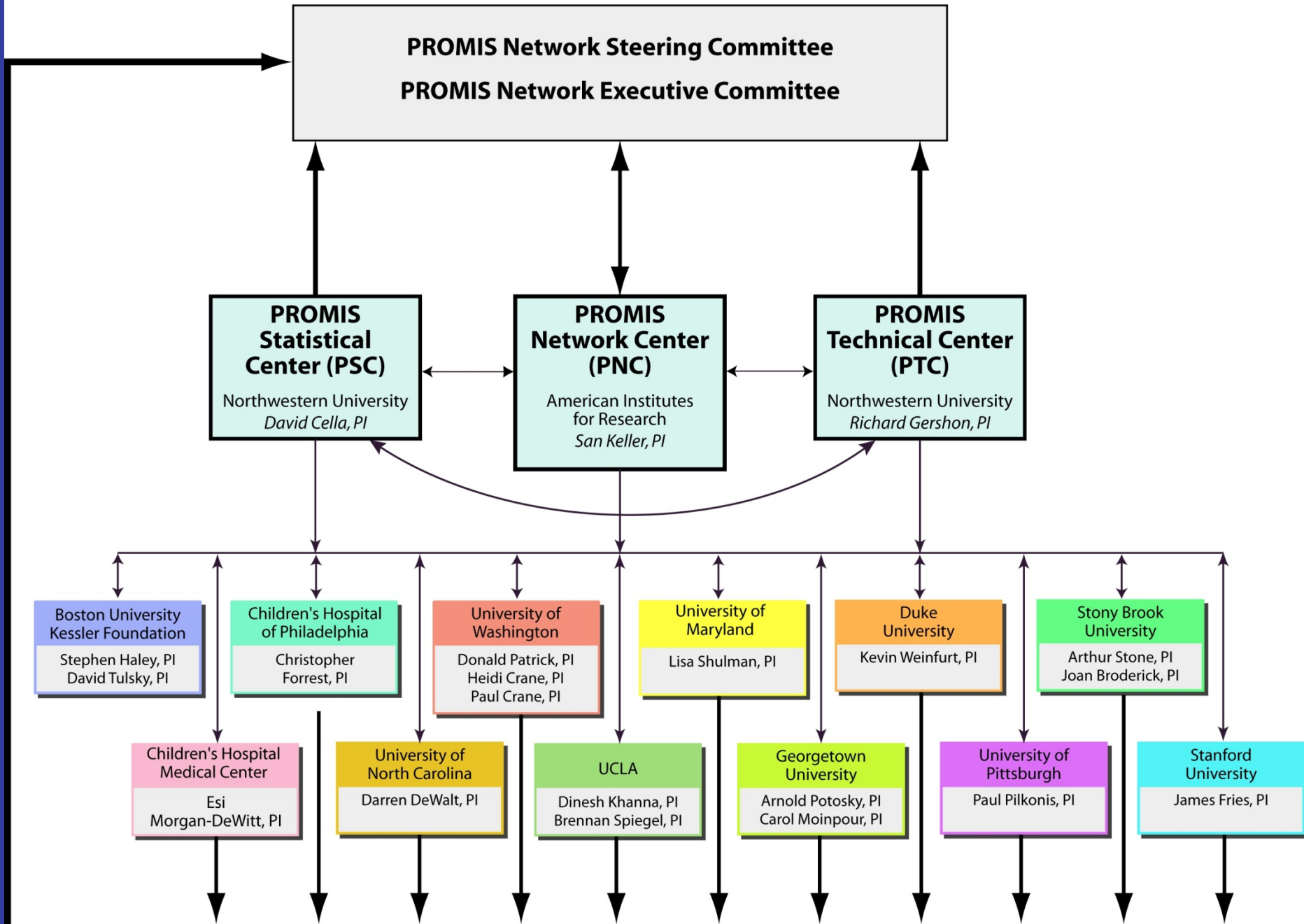- General health perceptions (5 items)

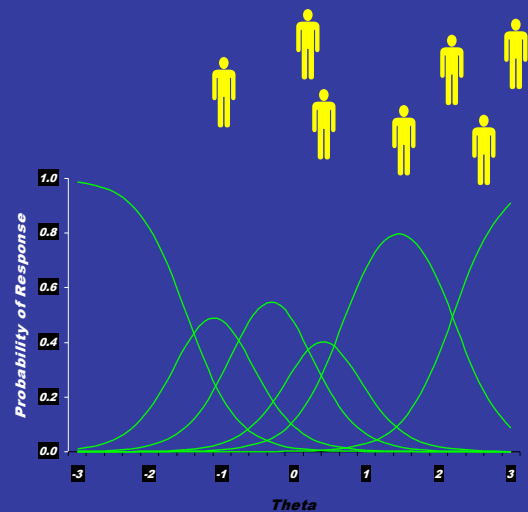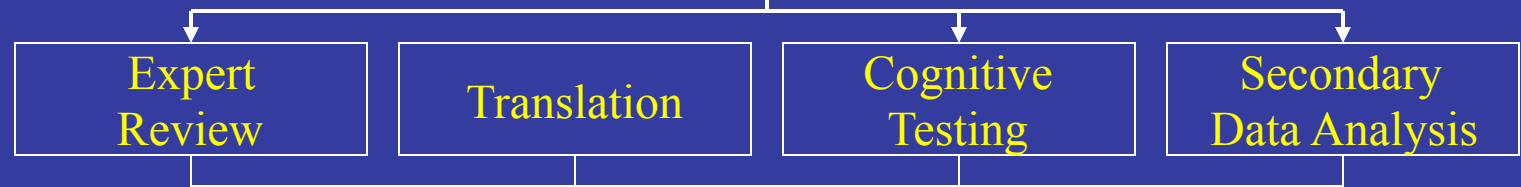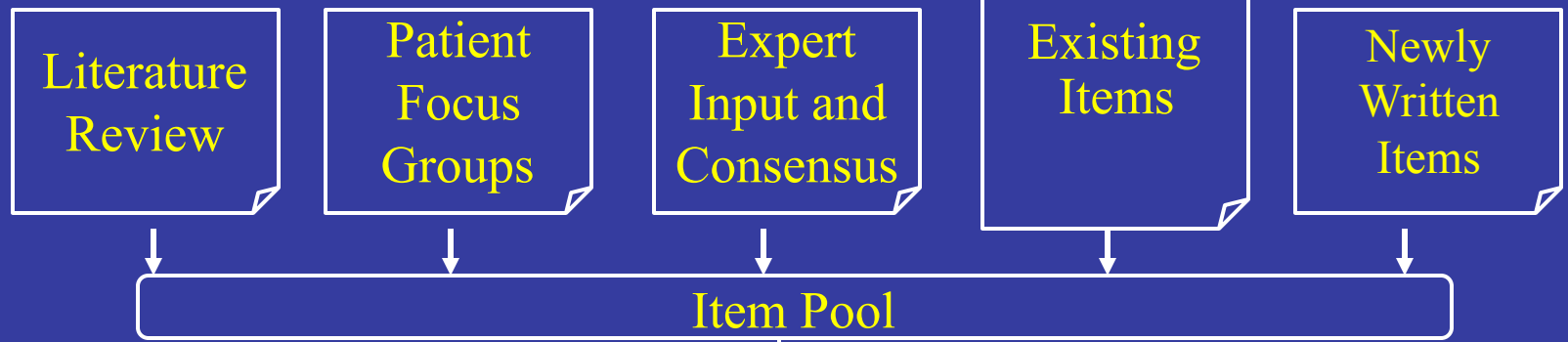# Patient-Reported Outcomes Measurement Information System (PROMIS), 2004-?

- An answer to the "Tower of Babel"
- A commitment of NIH to improve and standardize measurement of patient-reported outcomes (i.e., health-related quality of life)
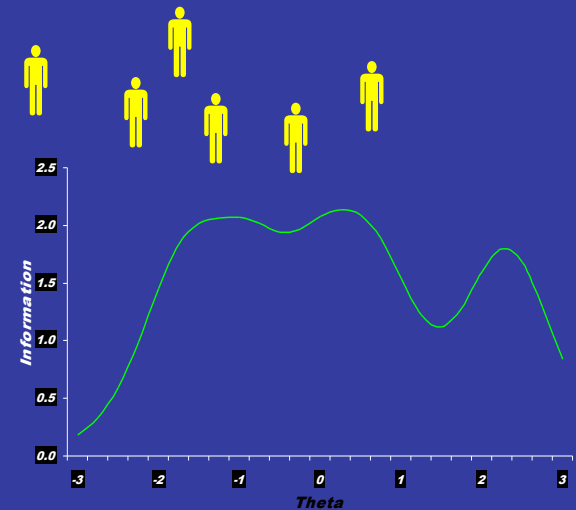
PROMIS-1 Network: 2004-2009

University of Washington

Stony Brook

Northwestern ♥

University of Pittsburgh

Stanford

NIH

UNC –Chapel Hill Duke University*

♥Coordinating Center

PROMIS II Network Diagram

PROMIS Network Steering Committee

PROMIS Network Executive Committee

PROMIS Statistical Center (PSC)
Northwestern University
David Cella, PI

PROMIS Network Center (PNC)
American Institutes for Research
San Keller, PI

PROMIS Technical Center (PTC)
Northwestern University
Richard Gershon, PI

Boston University Kessler Foundation
Stephen Haley, PI
David Tulsky, PI

Children's Hospital of Philadelphia
Christopher Forrest, PI

University of Washington
Donald Patrick, PI
Heidi Crane, PI
Paul Crane, PI

University of Maryland
Lisa Shulman, PI

Duke University
Kevin Weinfurt, PI

Stony Brook University
Arthur Stone, PI
Joan Broderick, PI

Children's Hospital Medical Center
Esi Morgan-DeWitt, PI

University of North Carolina
Darren DeWalt, PI

UCLA
Dinesh Khanna, PI
Brennan Spiegel, PI

Georgetown University
Arnold Potosky, PI
Carol Moinpour, PI

University of Pittsburgh
Paul Pilkonis, PI

Stanford University
James Fries, PI

Physical Functioning Item Bank

| Item 1 | Item 2 | Item 3 | Item 4 | Item 5 | Item 6 | Item 7 | Item 8 | Item 9 | Item n |

50

- Are you able to get in and out of bed?
- Are you able to stand without losing your balance for 1 minute?
- Are you able to walk from one room to another?
- Are you able to walk a block on flat ground?
- Are you able to run or jog for two miles?
- Are you able to run five miles?

PROMIS

Computerized Adaptive Testing (CAT)

- Select questions based on a person's response to previously administered questions.

- Iteratively estimate a person's location on a domain (e.g., fatigue, depressive symptoms)

- Administer most informative items

- Desired level of precision can be obtained using the minimal possible number of questions.

Reliability and SEM

- z-score (mean = 0 and SD = 1)
- T-score = (z-score * 10) + 50
  - Reliability = 1 – SEM^2 (for z-scores)

    = 0.91 (when SEM = 0.30)

    = 0.90 (when SEM = 0.32)
- With 0.90 reliability
  - 95% Confidence Interval for score at mean
    - z-score: - 0.62 →   0.62
    - T-score: 43.8 →   56.2
- www.nihpromis.org

In the past 7 days

I was grouchy

○ Never

○ Rarely

○ Sometimes

○ Often

○ Always

Previous   Next   Exit

Response	Theta	Score	SE
EDANG30=3	0.61	56.1	0.57

In the past 7 days

I felt like I was ready to explode

- ○ Never
- ○ Rarely
- ○ Sometimes
- ○ Often
- ○ Always

Response	Theta	Score	SE
EDANG30=3	0.61	56.1	0.57
EDANG15=1	0.19	51.9	0.48

In the past 7 days

I felt angry

○ Never

○ Rarely

○ Sometimes

○ Often

○ Always

Response	Theta	Score	SE
EDANG30=3	0.61	56.1	0.57
EDANG15=1	0.19	51.9	0.48
EDANG09=2	0.05	50.5	0.39

In the past 7 days

I felt angrier than I thought I should

○ Never

○ Rarely

○ Sometimes

○ Often

○ Always

Response	Theta	Score	SE
EDANG30=3	0.61	56.1	0.57
EDANG15=1	0.19	51.9	0.48
EDANG09=2	0.05	50.5	0.39
EDANG28=1	-0.12	48.8	0.36

In the past 7 days

I felt annoyed

○ Never

○ Rarely

○ Sometimes

○ Often

○ Always

Response	Theta	Score	SE
EDANG30=3	0.61	56.1	0.57
EDANG15=1	0.19	51.9	0.48
EDANG09=2	0.05	50.5	0.39
EDANG28=1	-0.12	48.8	0.36
EDANG35=3	0.01	50.1	0.32

In the past 7 days

I made myself angry about something just by thinking about it

○ Never

◉ Rarely

○ Sometimes

○ Often

○ Always

Response	Theta	Score	SE
EDANG30=3	0.61	56.1	0.57
EDANG15=1	0.19	51.9	0.48
EDANG09=2	0.05	50.5	0.39
EDANG28=1	-0.12	48.8	0.36
EDANG35=3	0.01	50.1	0.32
EDANG06=2	0.02	50.2	0.28

End of Form

CAT assessments can achieve higher precision than fixed forms

PROMIS Profiles

	4	6	8
Anxiety			
Depression			

Mental — Anxiety, Depression

Physical — Fatigue, Pain Interference, Sleep Disturbance, Physical Function
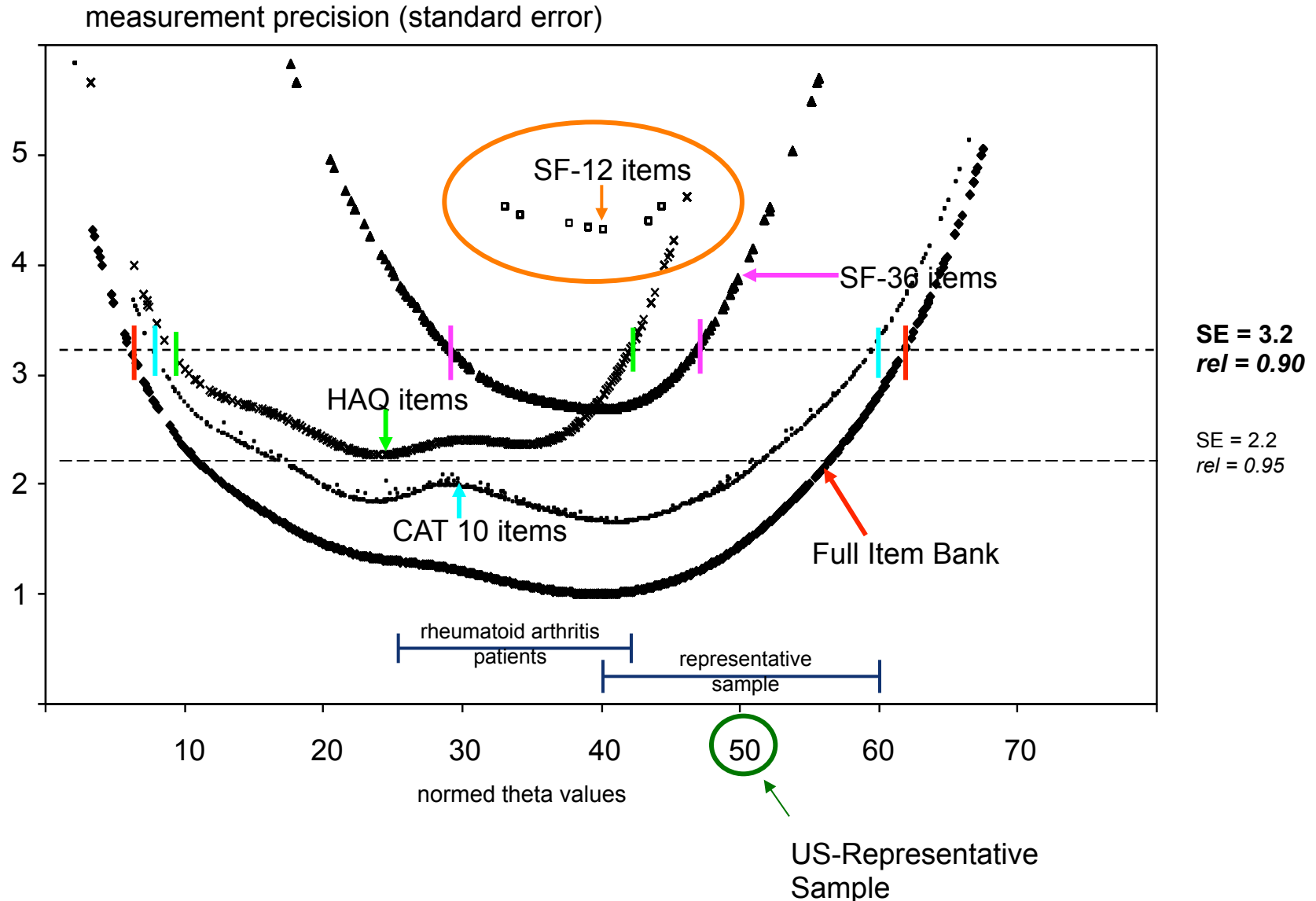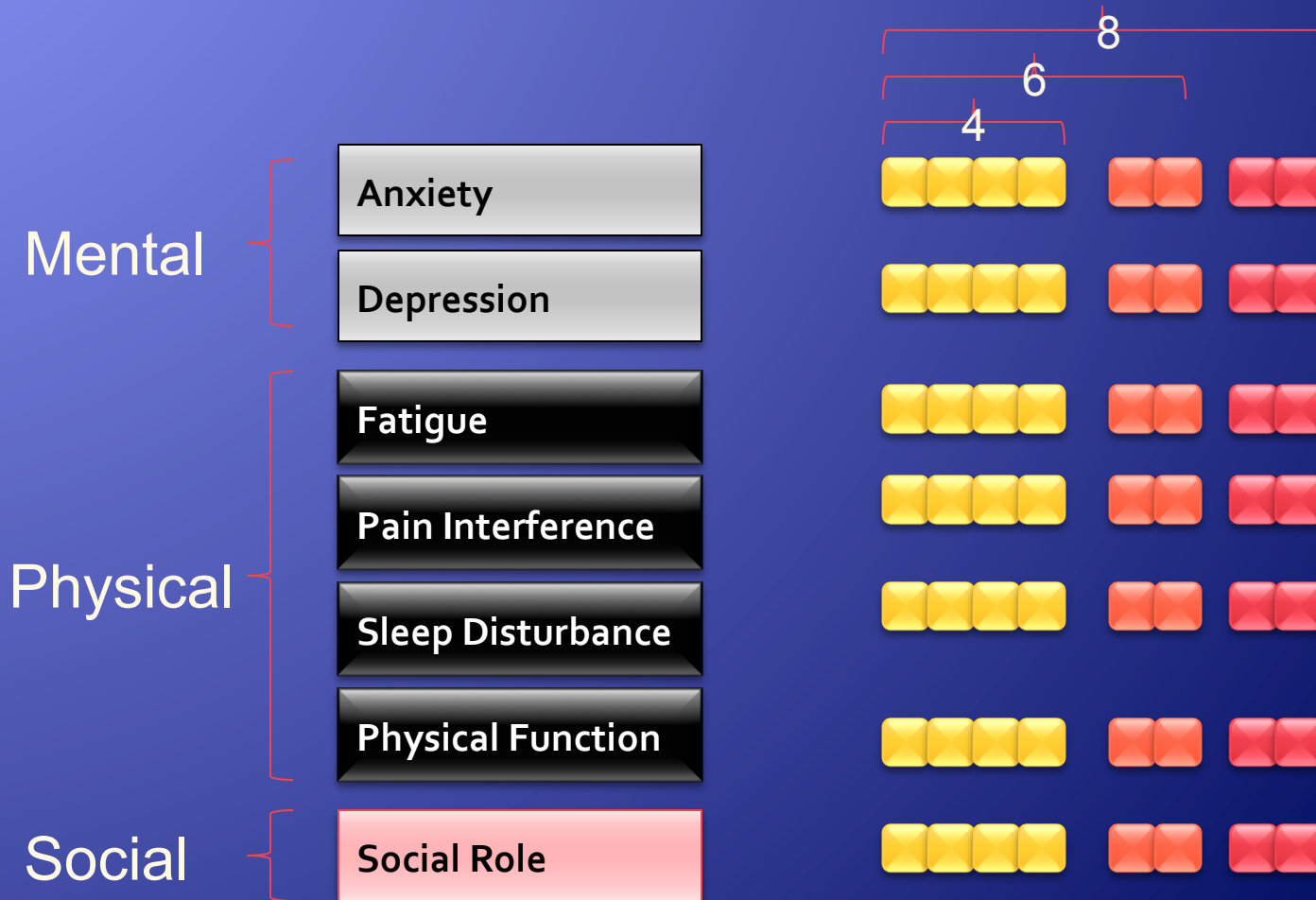
Social — Social Role
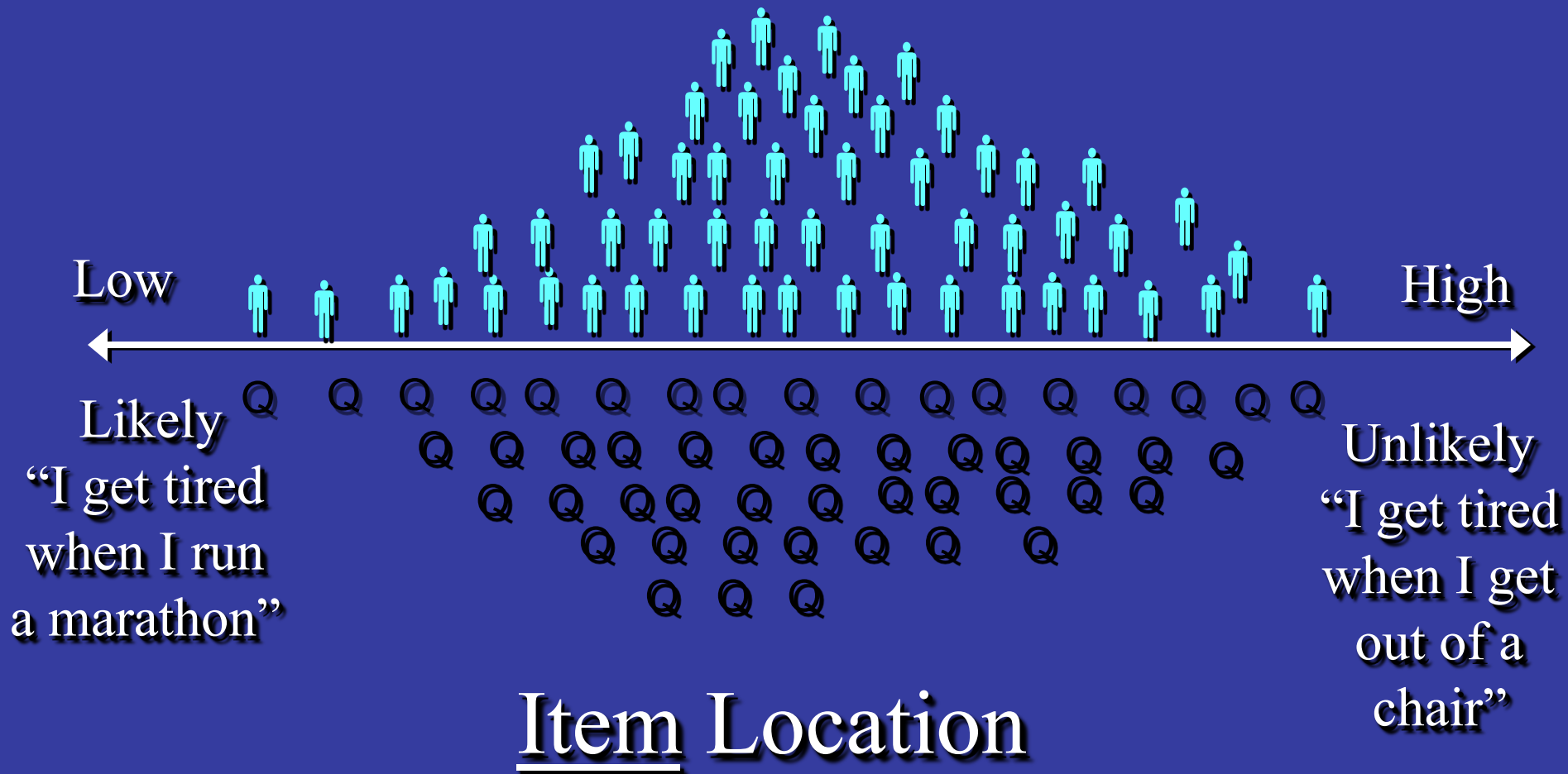
Interpretation Aids
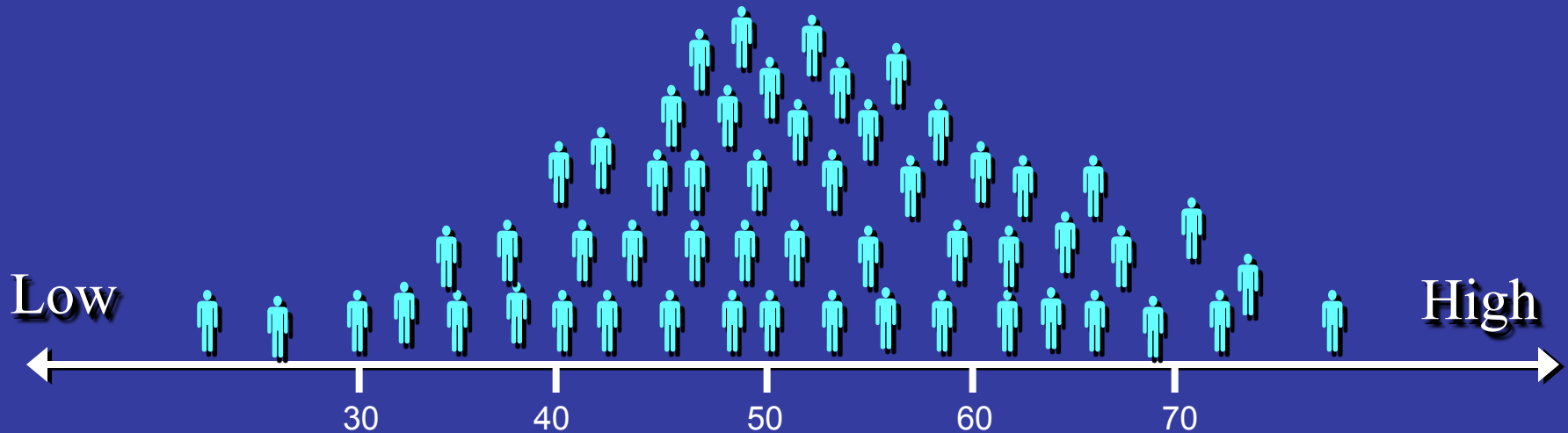
M = 50, SD = 10

T = (z * 10) + 50

Example of high fatigue

Fatigue Score=60

Low ← → High

30   40   50   60   70
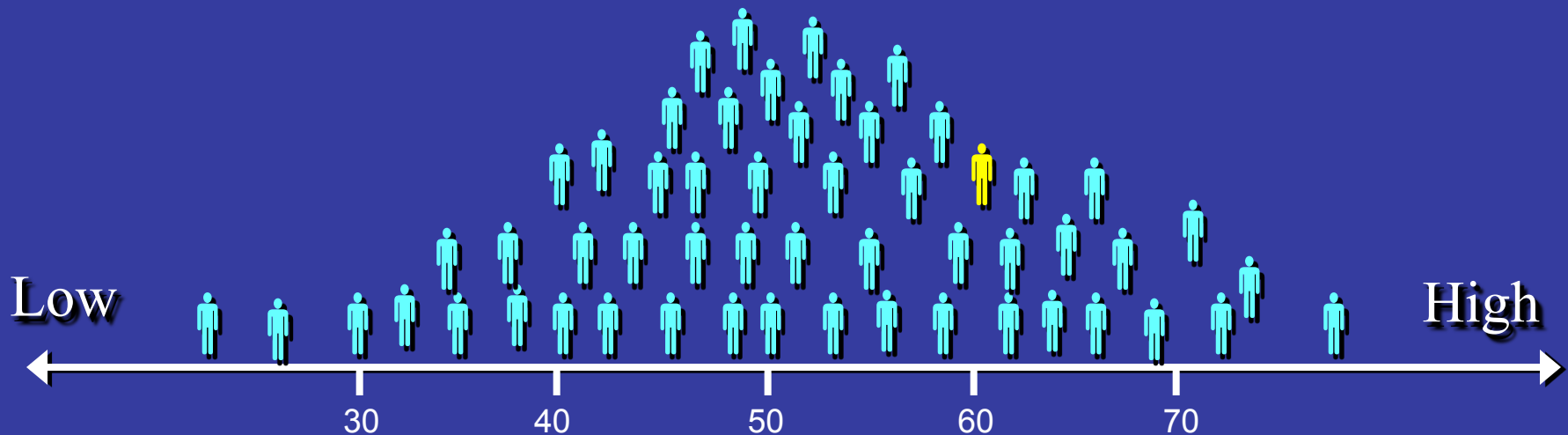
This patient's fatigue score is 60, significantly <u>worse than average</u> (50). People who score 60 on fatigue tend to answer questions as follows:

…"I have been too tired to climb one flight of stairs: VERY MUCH

…"I have had enough energy to go out with my family: A LITTLE BIT

Example of low fatigue

Fatigue Score=40

Low ←   → High

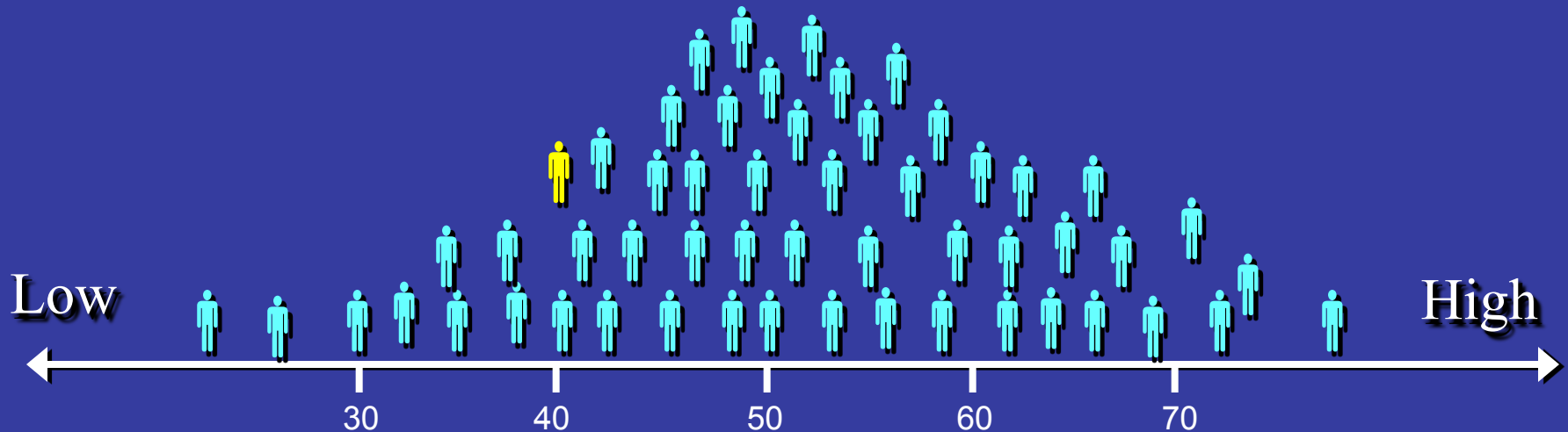30   40   50   60   70

This patient's fatigue score is 40, significantly <u>better than average</u> (50). People who

score 40 on fatigue tend to answer questions as follows:

…"I have been too tired to climb one flight of stairs: NOT AT ALL
…"I have had enough energy to go out with my family: VERY MUCH

Significant Improvement in all but 1 of SF-36 Scales (Change is in T-score metric)

	Change	t-test	prob.
PF-10	1.7	2.38	.0208
RP-4	4.1	3.81	.0004
BP-2	3.6	2.59	.0125
GH-5	2.4	2.86	.0061
EN-4	5.1	4.33	.0001
SF-2	4.7	3.51	.0009
RE-3	1.5	0.96	.3400 ←
EWB-5	4.3	3.20	.0023
PCS	2.8	3.23	.0021
MCS	3.9	2.82	.0067

Defining a Responder:
Reliable Change Index (RCI)

$$\frac{X_2 - X_1}{(\sqrt{2})(SEM)}$$

$$SEM = SD_{bl} \times \sqrt{1 - r_{xx}}$$

Note: SD_{bl} = standard deviation at baseline
r_{xx} = reliability

Amount of Change in Observed Score Needed for Significant Individual Change

Scale	Change	Effect size	Reliability
PF-10	8.4	0.67	0.94
RP-4	8.4	0.72	0.93
BP-2	10.4	1.01	0.87
GH-5	13.0	1.13	0.83
EN-4	12.8	1.33	0.77
SF-2	13.8	1.07	0.85
RE-3	9.7	0.71	0.94
EWB-5	13.4	1.26	0.79
PCS	7.1	0.62	0.94
MCS	9.7	0.73	0.93

7-31% of People in Sample Improve Significantly

	% Improving	% Declining	Difference
PF-10	13%	2%	+ 11%
RP-4	31%	2%	+ 29%
BP-2	22%	7%	+ 15%
GH-5	7%	0%	+ 7%
EN-4	9%	2%	+ 7%
SF-2	17%	4%	+ 13%
RE-3	15%	15%	0%
EWB-5	19%	4%	+ 15%
PCS	24%	7%	+ 17%
MCS	22%	11%	+ 11%

Questions?