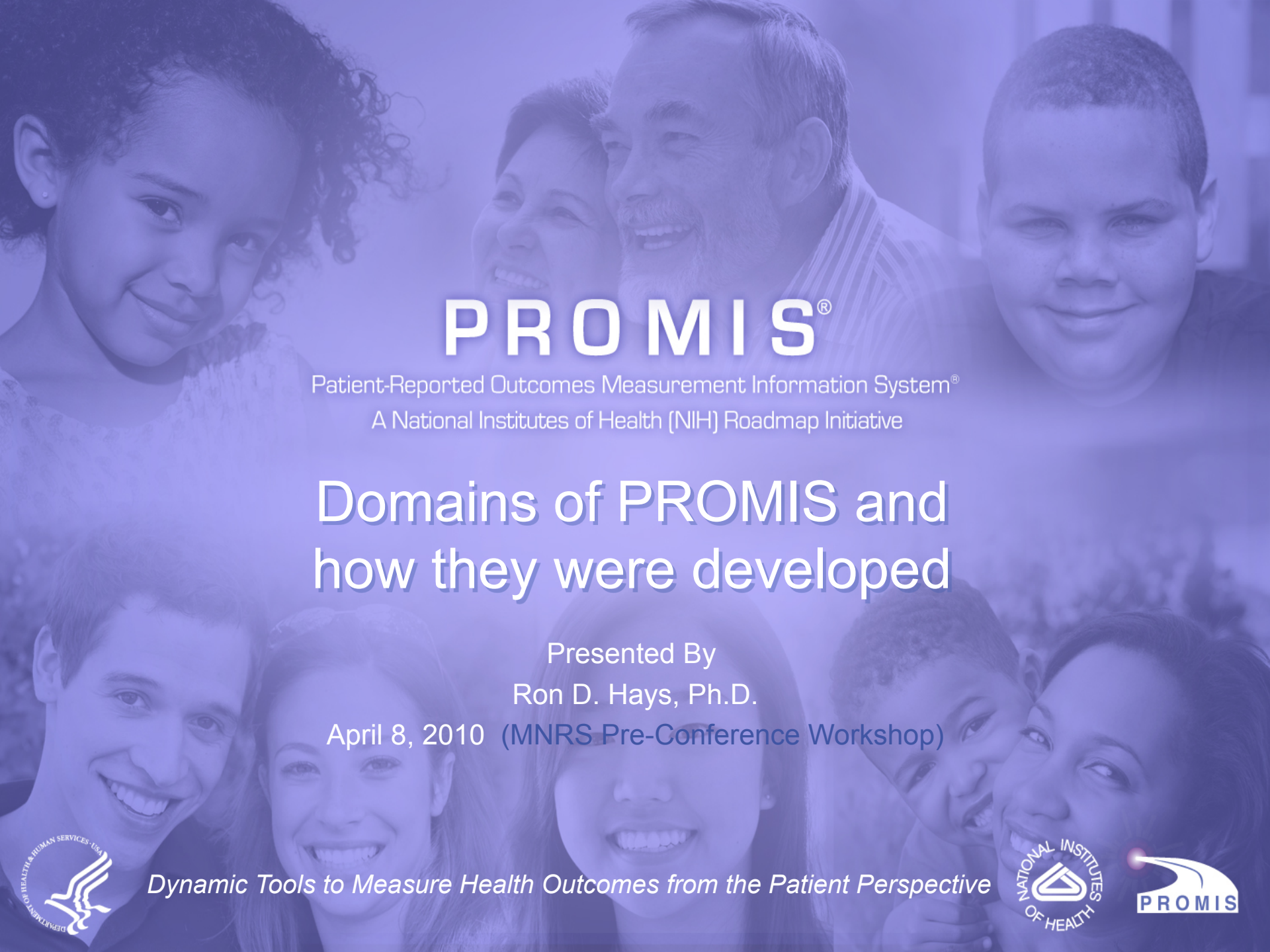


PROMIS®

Patient-Reported Outcomes Measurement Information System®

A National Institutes of Health (NIH) Roadmap Initiative

Domains of PROMIS and how they were developed

Presented By

Ron D. Hays, Ph.D.

April 8, 2010 (MNRS Pre-Conference Workshop)

Dynamic Tools to Measure Health Outcomes from the Patient Perspective

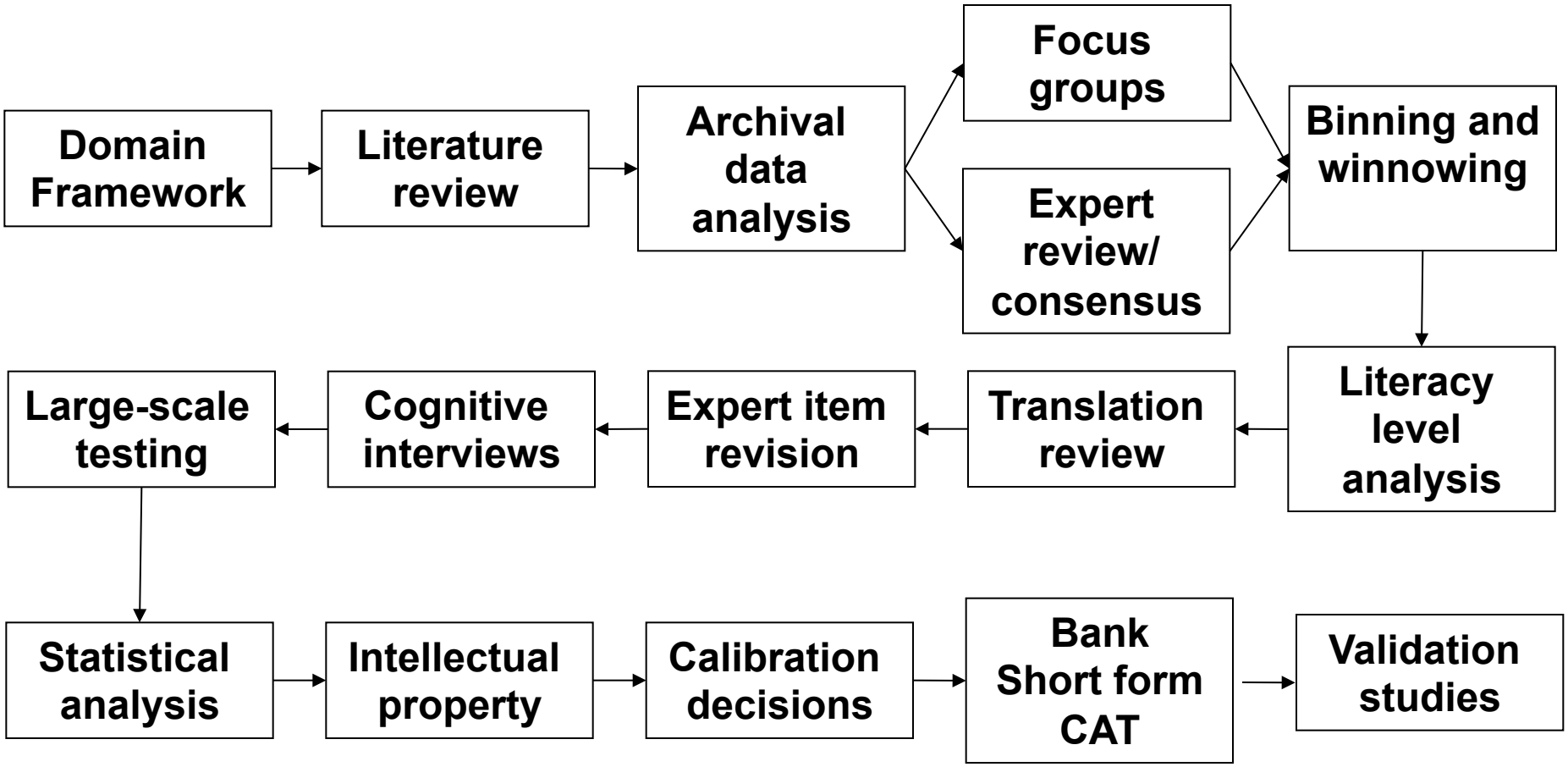
Developing Instruments for Use in Research and in Clinical Practice that:

- Reduce response burden.
- Improve measurement precision.
- Provide the ability to compare or combine results from multiple studies.
- Use computer-based administration, scoring, and reporting.

“Item Bank”

- A large collection of items measuring one thing in common
- Items in the same bank are linked on a common metric
- Basis for Computer Adaptive Testing (CAT) and short forms tailored to the target population

The Life Story of a PROMIS Item

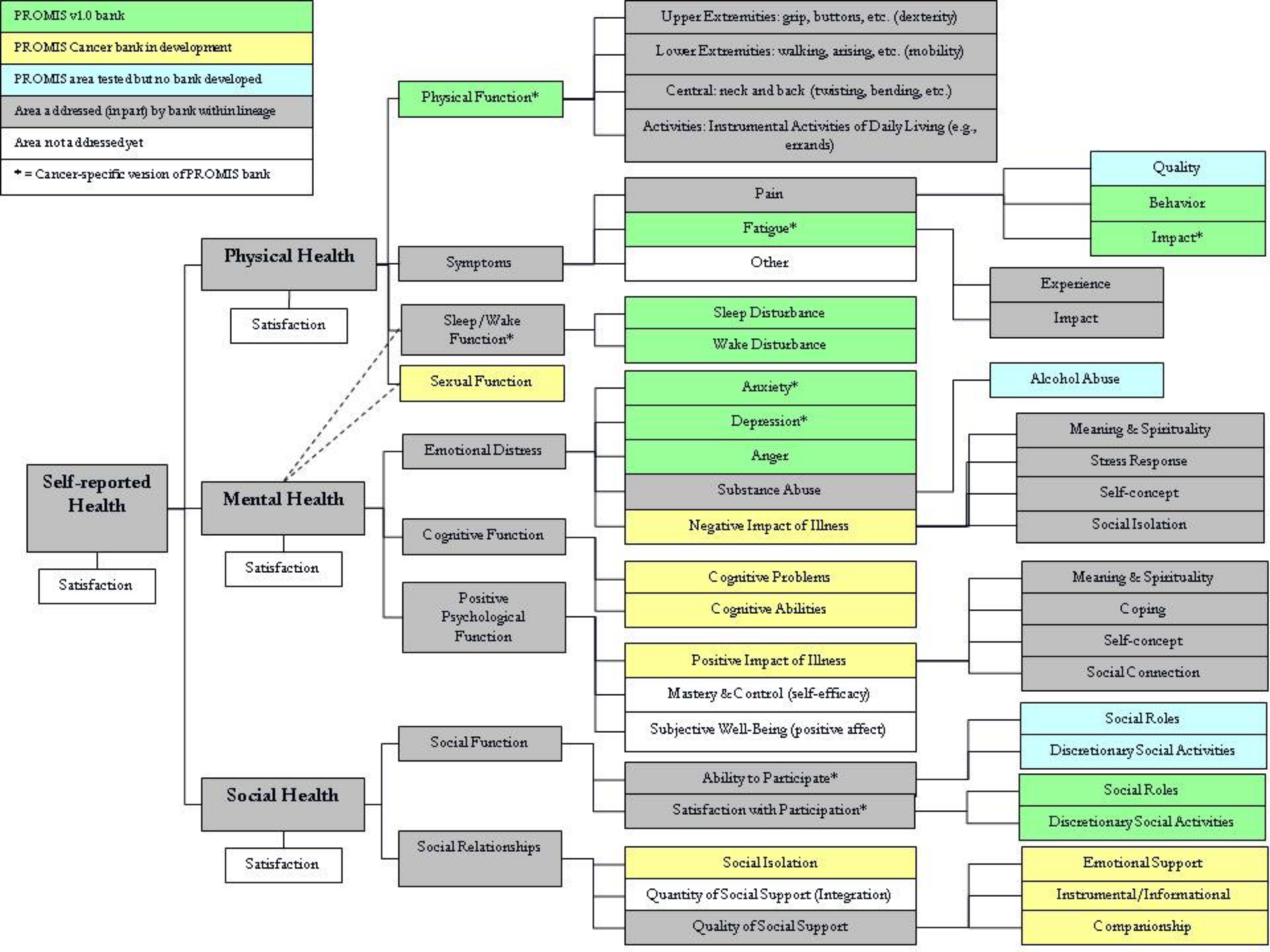


PROMIS Wave 1 Banks (454 items)

- Physical Function [124]
- Fatigue [95]
- Emotional Distress [86]
  - Depression (28)
  - Anxiety (29)
  - Anger (29)
- Pain [80]
  - Behavior (39)
  - Impact (41)
- Sleep Disturbance (27)
- Wake Disturbance (16)
- Satisfaction with Participation in Discretionary Social Activities (12)
- Satisfaction with Participation in Social Roles (14)

2010 PROMIS Banks

Domains	Items in Bank	Items in Short Form
Emotional Distress – Anger	29	8
Emotional Distress – Anxiety	29	7
Emotional Distress – Depression	28	8
Fatigue	95	7
Pain – Behavior	39	7
Pain – Interference	41	6
Physical Function	124	10
Satisfaction with Discretionary Social Activities	12	7
Satisfaction with Social Roles	14	7
Sleep Disturbance	27	8
Sleep-Related Impairment	16	8
Global Health		10


PROMIS v1.0 bank
PROMIS Cancer bank in development
PROMIS area tested but no bank developed
Area addressed (in part) by bank within lineage
Area not addressed yet
* = Cancer-specific version of PROMIS bank
Self-reported Health
Satisfaction
Physical Health
Satisfaction
Mental Health
Satisfaction
Social Health
Satisfaction
Physical Function*
Upper Extremities: grip, buttons, etc. (dexterity)
Lower Extremities: walking, arising, etc. (mobility)
Central: neck and back (twisting, bending, etc.)
Activities: Instrumental Activities of Daily Living (e.g., errands)
Symptoms
Pain
Fatigue*
Other
Quality
Behavior
Impact*
Experience
Impact
Sleep/Wake Function*
Sleep Disturbance
Wake Disturbance
Sexual Function
Emotional Distress
Anxiety*
Depression*
Anger
Substance Abuse
Negative Impact of Illness
Alcohol Abuse
Meaning & Spirituality
Stress Response
Self-concept
Social Isolation
Cognitive Function
Cognitive Problems
Cognitive Abilities
Positive Psychological Function
Positive Impact of Illness
Mastery & Control (self-efficacy)
Subjective Well-Being (positive affect)
Meaning & Spirituality
Coping
Self-concept
Social Connection
Social Function
Ability to Participate*
Satisfaction with Participation*
Social Roles
Discretionary Social Activities
Social Roles
Discretionary Social Activities
Social Relationships
Social Isolation
Quantity of Social Support (Integration)
Quality of Social Support
Emotional Support
Instrumental/Informational
Companionship

Additional Domain Development

- Supplementary projects
  - Modified item banks for patients using wheelchairs and assistive devices
  - Parent-proxy item banks that parallel the pediatric item banks
- Collaborations with other federally-funded initiatives
  - DBDR/NHLBI AscQ-me project (sickle cell)
  - NINDS NeuroQOL (neurological conditions)
  - NIH Toolbox (Sensory, Motor, Cognitive, Emotional)
- Cancer PROMIS Supplement (CaPS)

"Validation" of PROMIS Banks

- Assessment of construct validity (including sensitivity to change) is in progress in various PROMIS projects
  - COPD
  - Depression
  - Back Pain
  - Heart Failure
  - Arthritis
- Mode of administration
- Minimally important differences

Applications of PROMIS

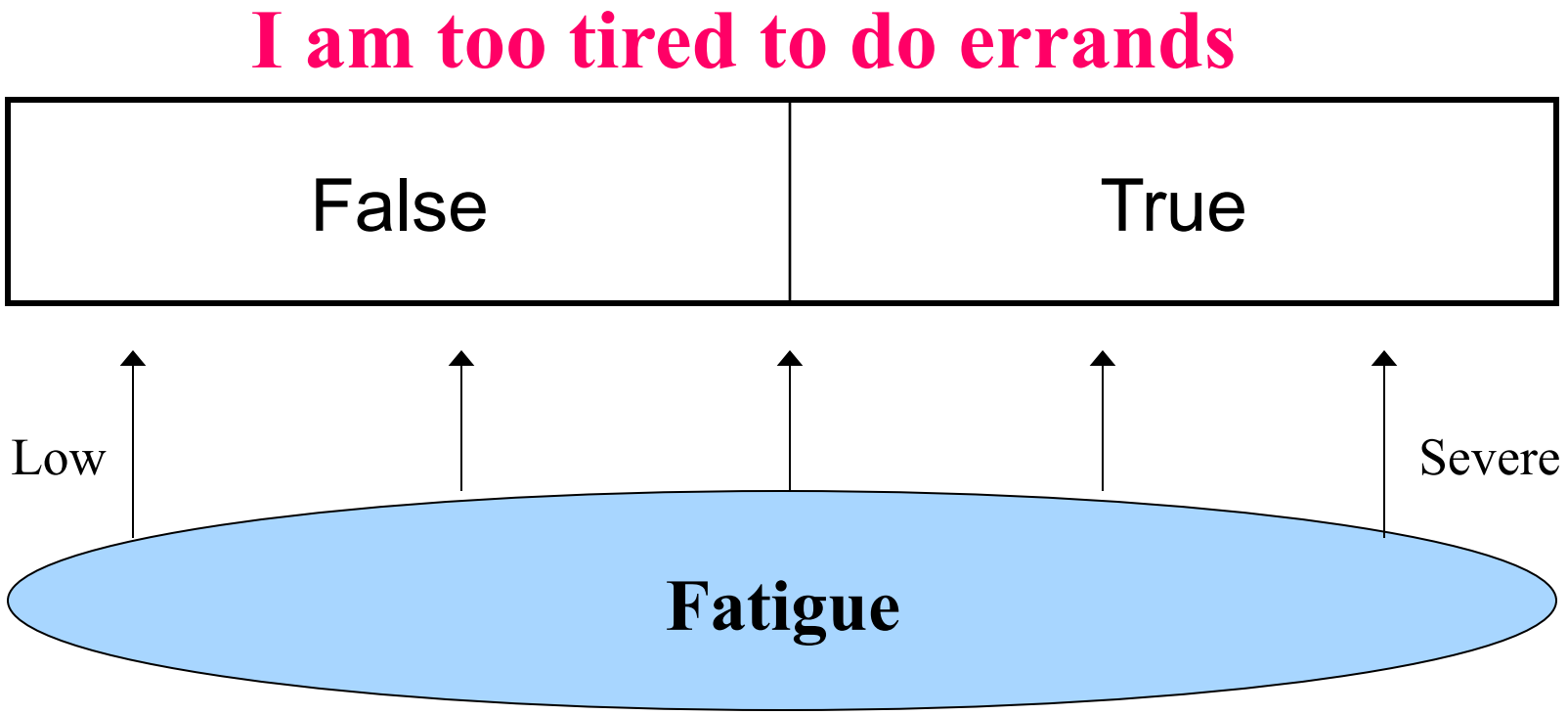
- Adoption by Clinical Trial Groups
  - Gynecological Oncology Group approved Phase III study comparing outcomes from surgical intervention in cervical cancer
- PROMIS Global Health Scale to be included on core 2010 NHIS (possible for 2015, 2020)
- HealthyPeople 2020 QOL Goals
- Contracts and Grants: Integrating PROMIS measures into cancer care settings (including integration with EMRs)
- DSM-V

Am. Psychiatric A. DSM-5

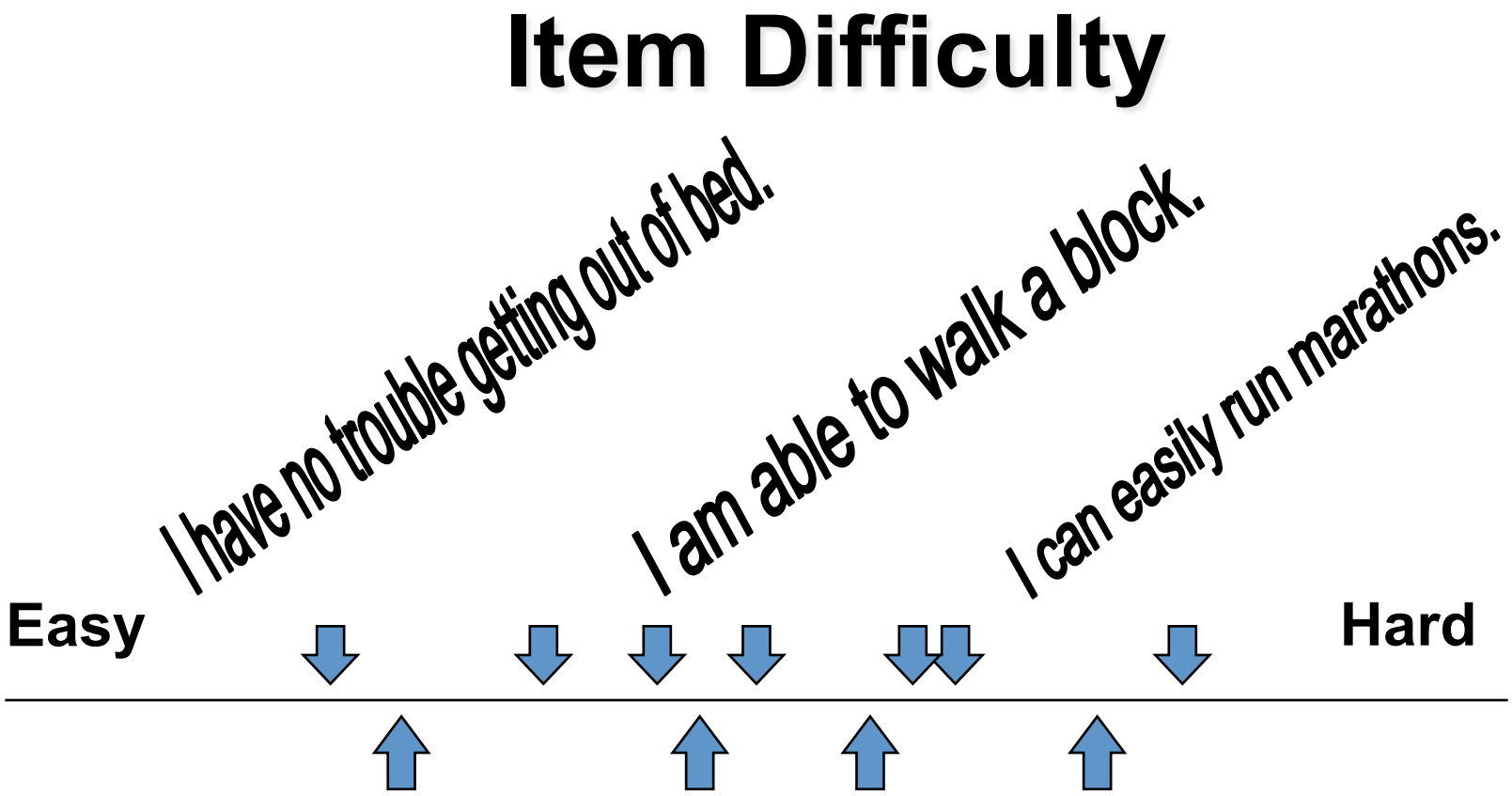
"As part of a roadmap for clinical research, the NIH began an effort to produce a Patient-Reported Outcome Measurement Information System™ (PROMIS) that "aims to revolutionize the way patient-reported outcome tools are selected and employed . . . . PROMIS™ aims to develop ways to measure patient-reported symptoms . . . . across a wide variety of chronic diseases and conditions." www.nihpromis.org PROMIS™ has developed assessments for a number of clinical domains that have been identified by the DSM-5 Task Force as areas on which quantitative ratings would be useful for this cross-cutting assessment. One advantage for using the scales developed by the PROMIS™ initiative is that they are short. Further, the initiative has developed computerized adaptive testing methods that can be used to establish a patient's rating by comparison to national norms with as few questions as possible. For the DSM-5 field trials, a simpler approach, using the paper and pencil fixed-item "short forms" for each PROMIS™ domain, will be available although a computer assisted version may also be used. The short forms focus on a single domain, such as depressed mood, and use a set of questions identified using item response theory to place an individual's response along a unidimensional continuum based on population norms. Relevant short forms that could be included in DSM-5 include the scales for depressed mood, anxiety, anger, sleep problems, and perhaps fatigue and pain impact."

IRT Modeling is Latent Trait Modeling

A latent trait is an *unobservable* latent dimension that gives rise to observed item responses.



Respondents and items are represented on the same scale



One-Parameter Model

- Most parsimonious model
- Only item parameter estimated is “difficulty”

Two-Parameter Model

- Item “difficulty” and “discrimination” parameters
- PROMIS used graded response model
  - Extension of dichotomous model to multiple response categories

One- Parameter Logistic Model

$$P_{1,0} = \frac{e^{(ability - difficulty)}}{1 + e^{(ability - difficulty)}}$$

When the difficulty of a given item exactly matches the respondent's level on the construct, then the person has 50% chance of answering high versus low:

$$P_{1,0} = \frac{e^{(0)}}{1 + e^{(0)}} = \frac{1}{2} = .50$$

Two-Parameter Logistic Model

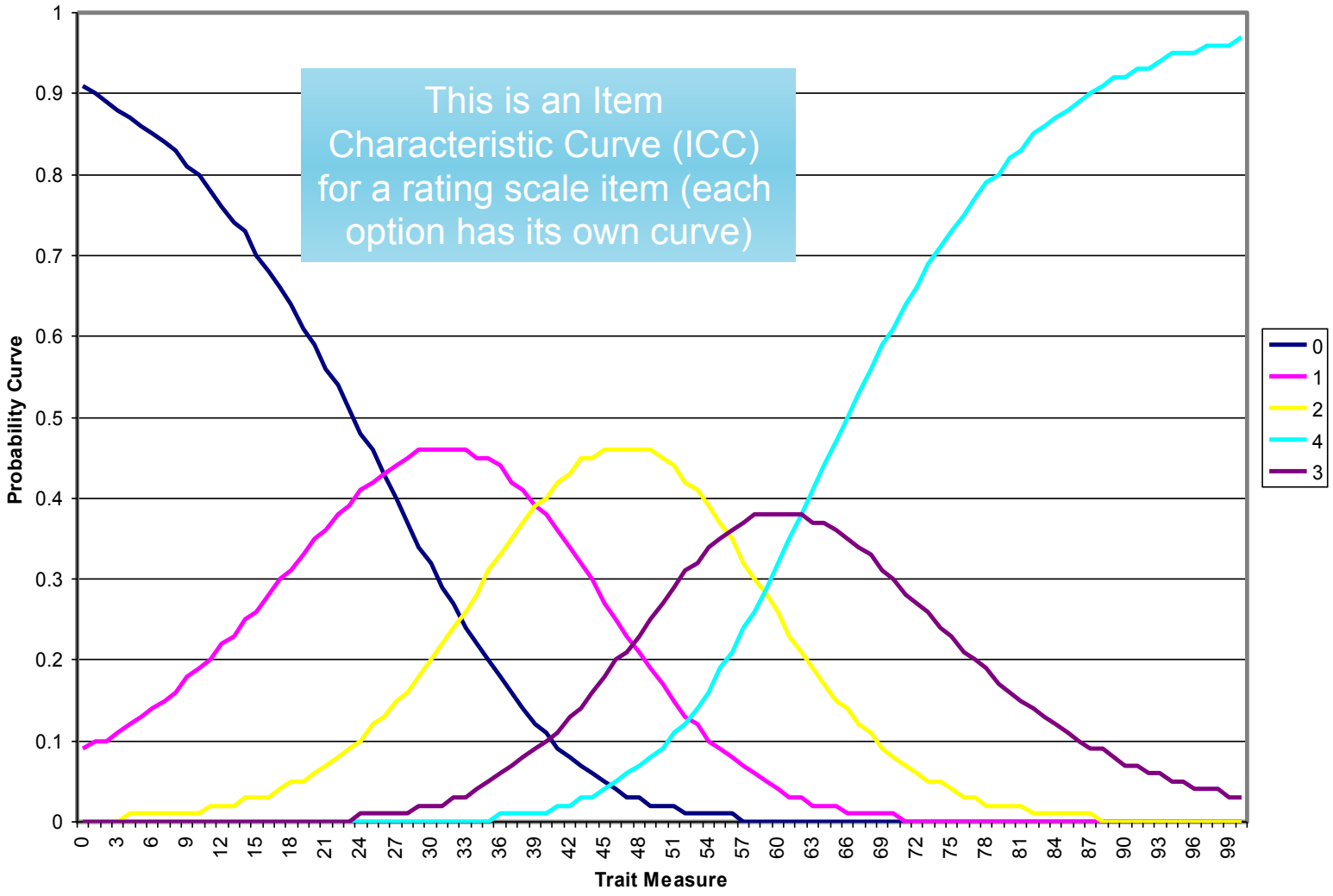
$$P_{1,0} = \frac{e^{a\,(ability - b)}}{1 + e^{a\,(ability - b)}}$$

Two parameters

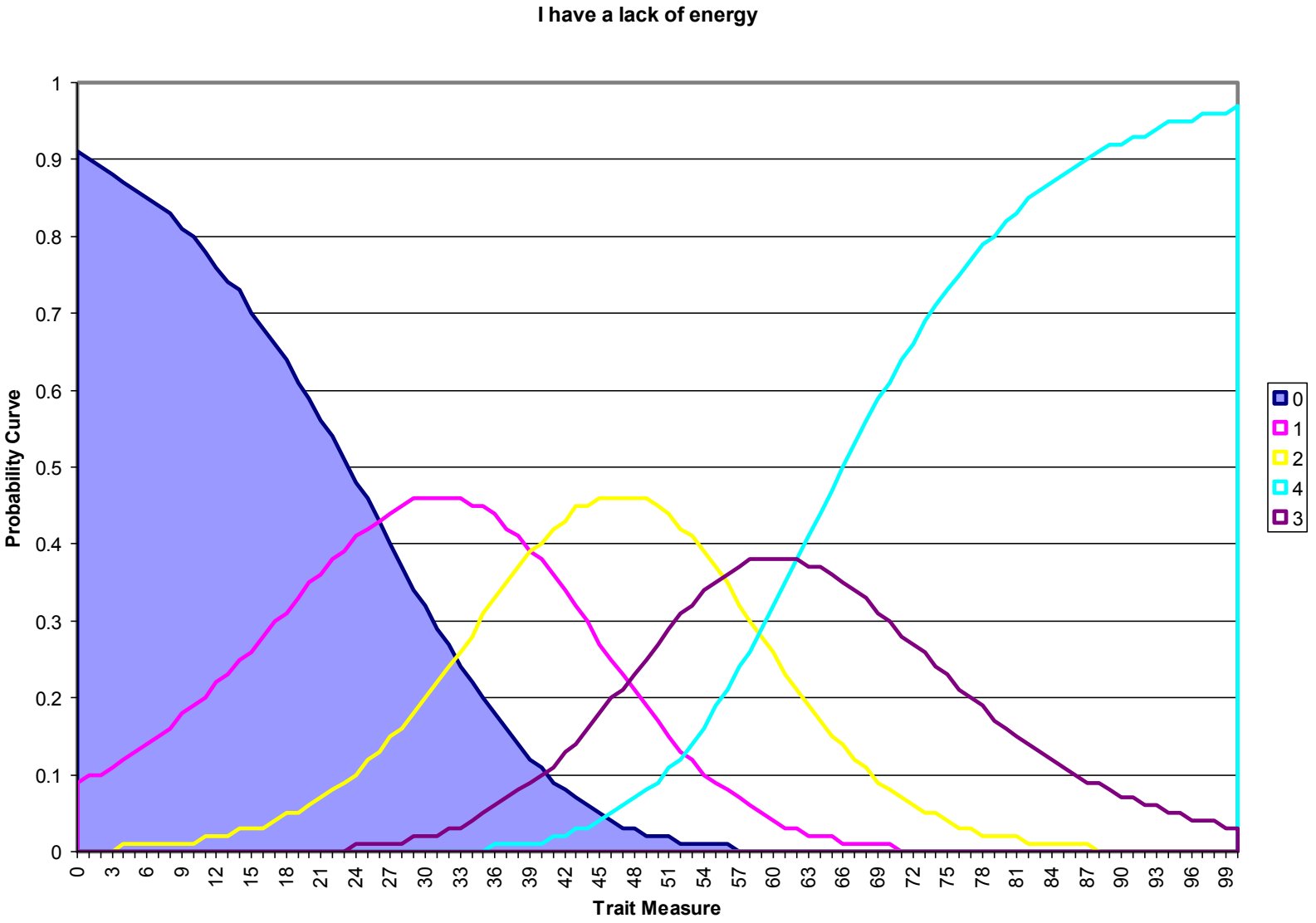
a=Discrimination

b=Item Difficulty

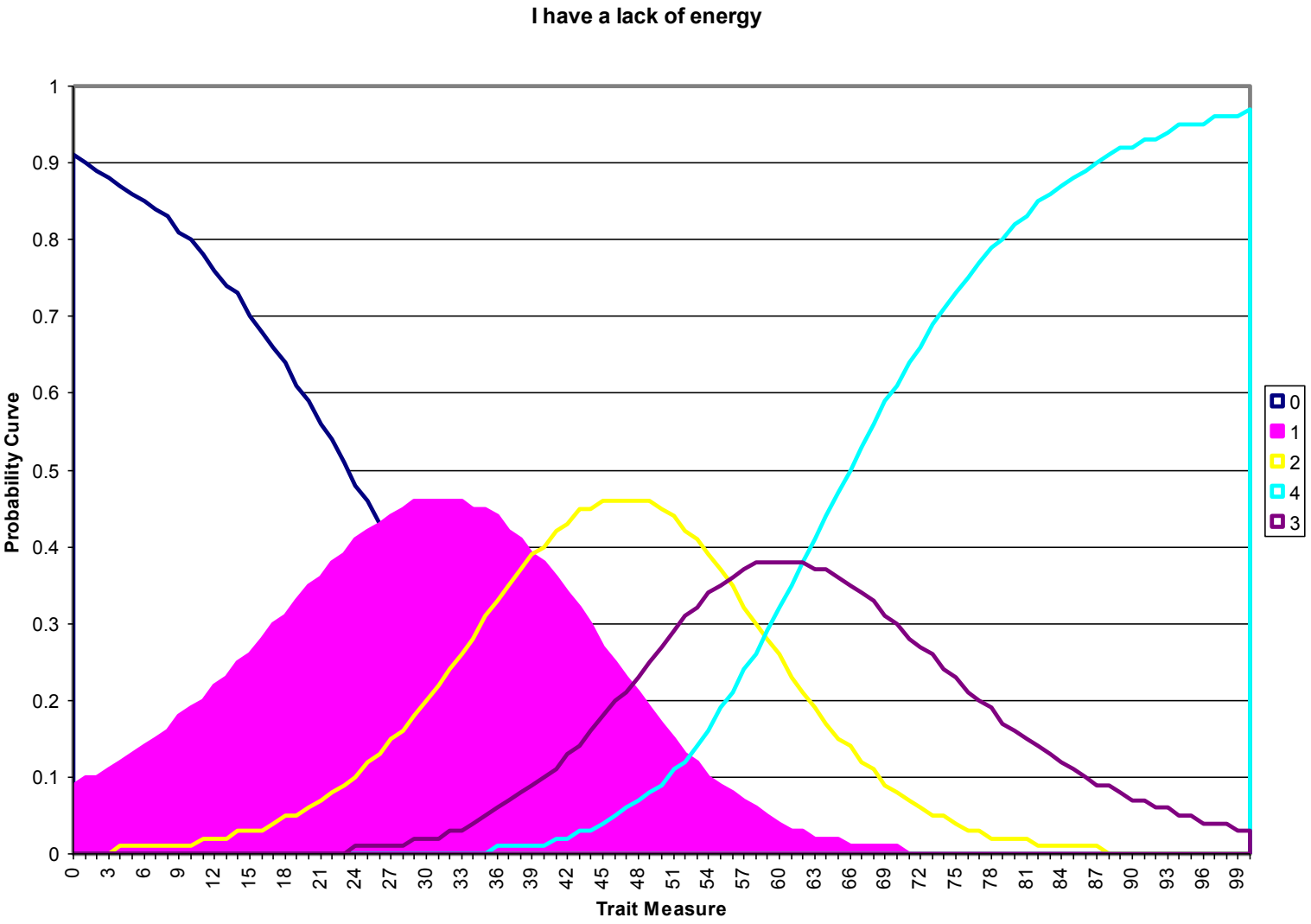
I have a lack of energy



0 = Not at All; 1 = A Little Bit; 2 = Somewhat; 3 = Quite a Bit; 4 = Very Much

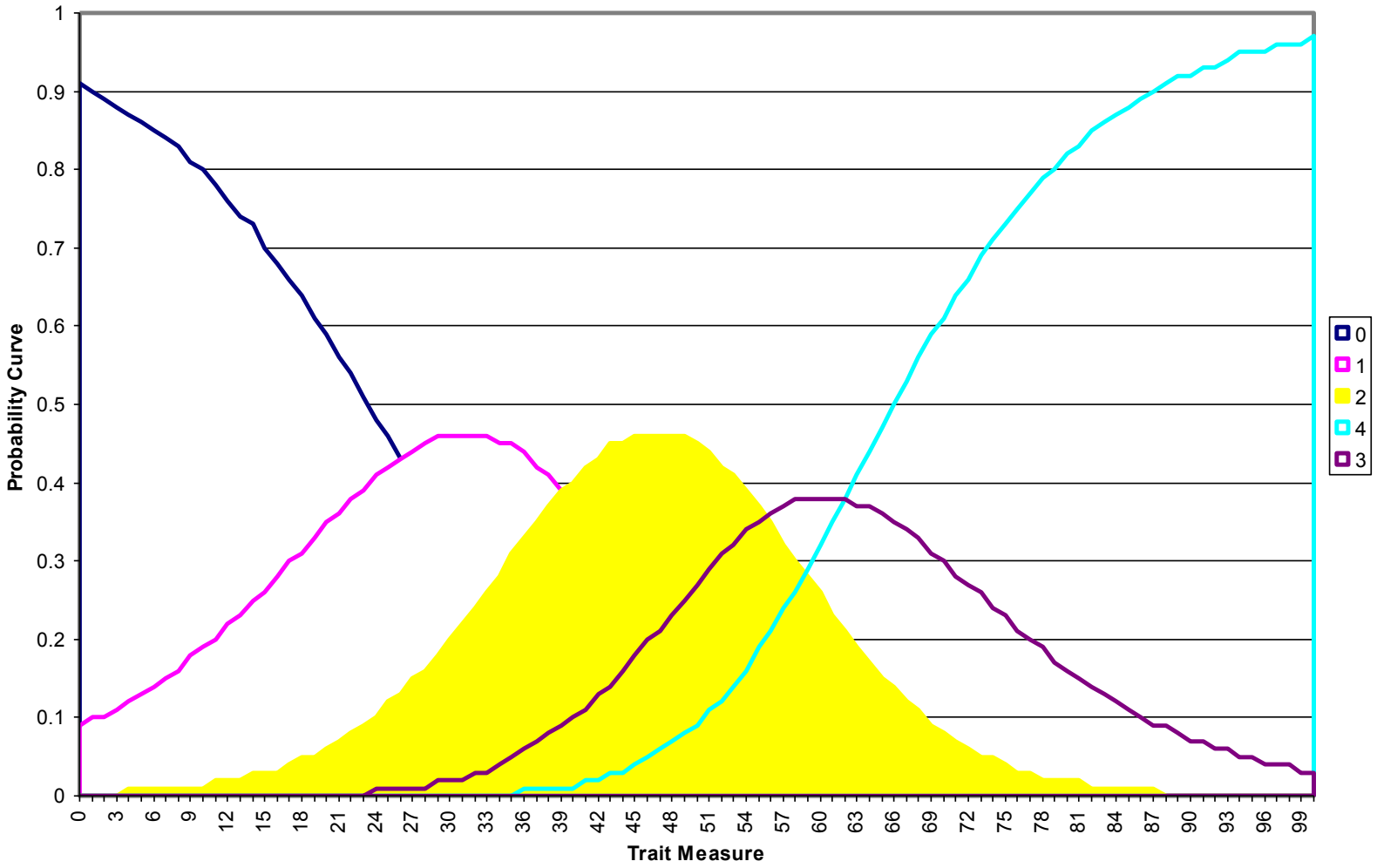


0 = Not at All; 1 = A Little Bit; 2 = Somewhat; 3 = Quite a Bit; 4 = Very Much



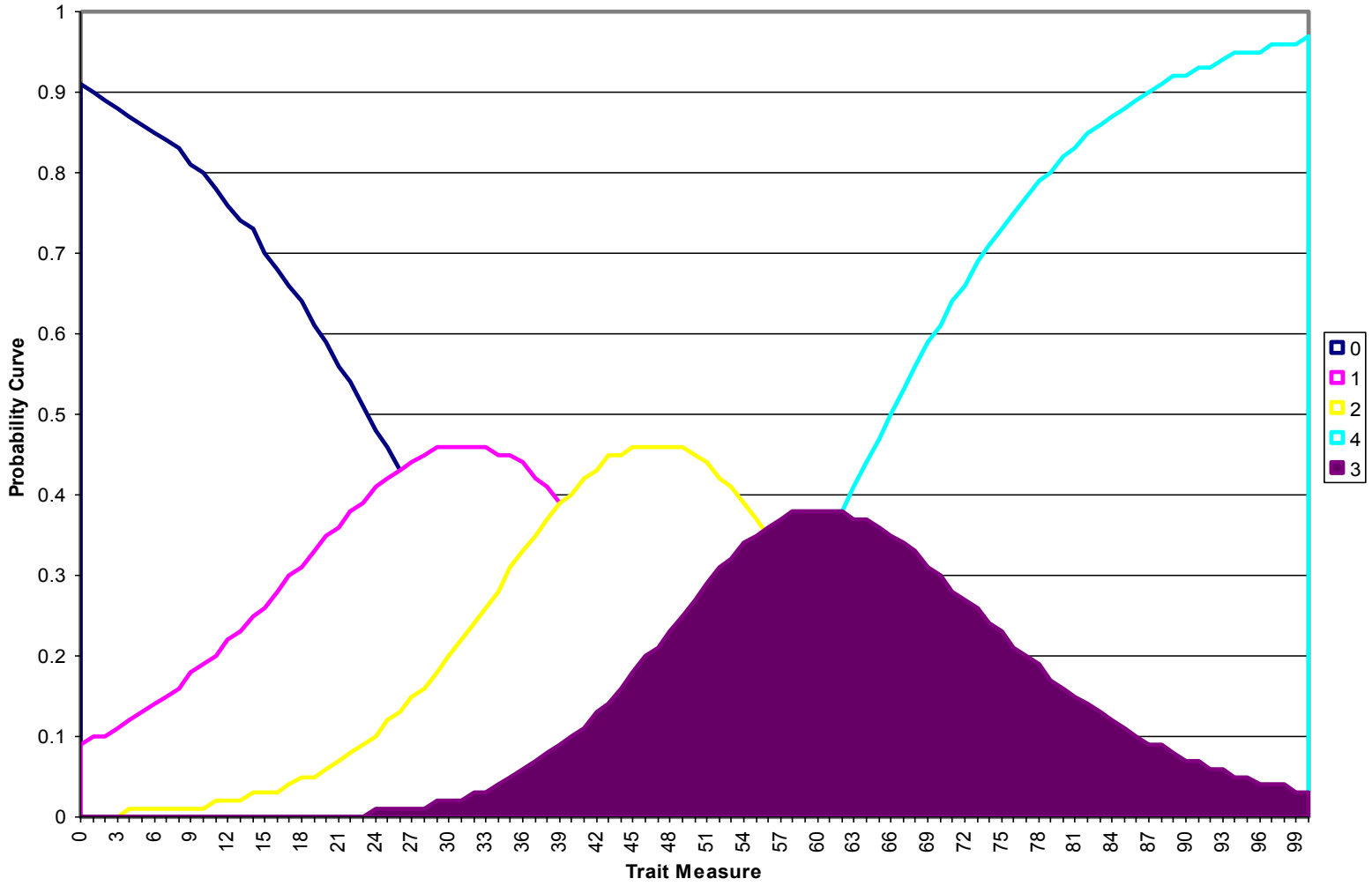
0 = Not at All; 1 = A Little Bit; 2 = Somewhat; 3 = Quite a Bit; 4 = Very Much

I have a lack of energy

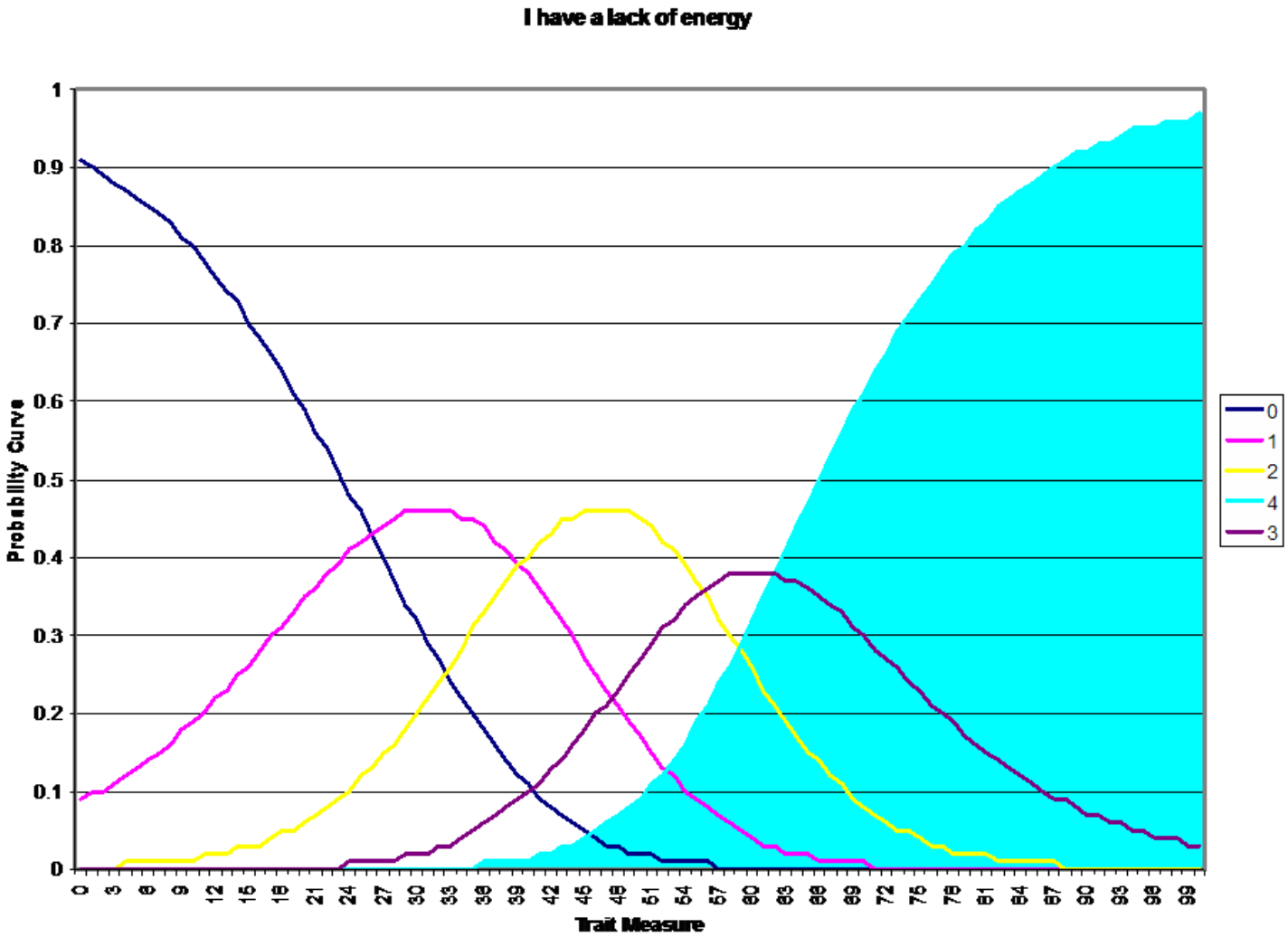


0 = Not at All; 1 = A Little Bit; 2 = Somewhat; 3 = Quite a Bit; 4 = Very Much

I have a lack of energy

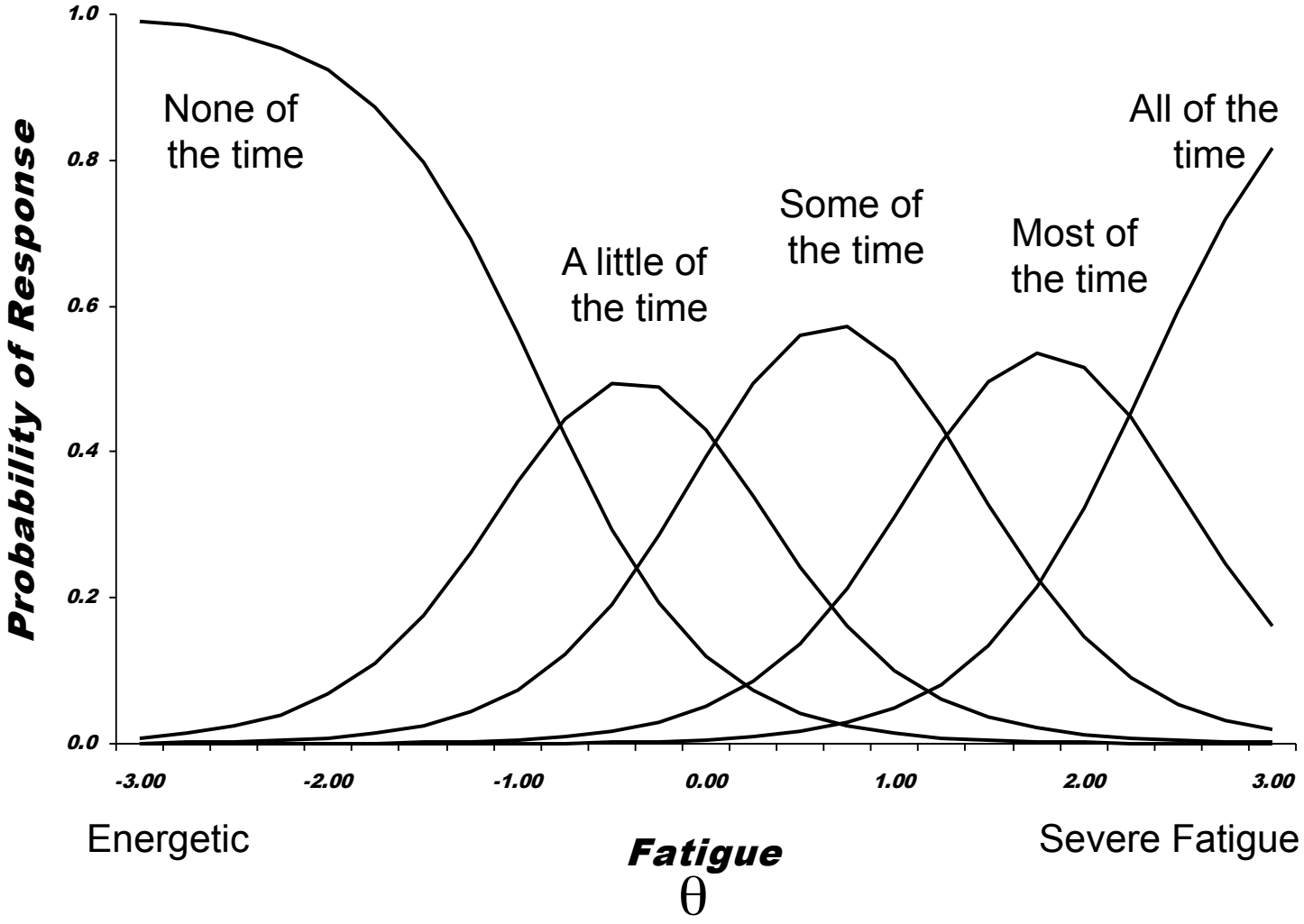


0 = Not at All; 1 = A Little Bit; 2 = Somewhat; 3 = Quite a Bit; 4 = Very Much

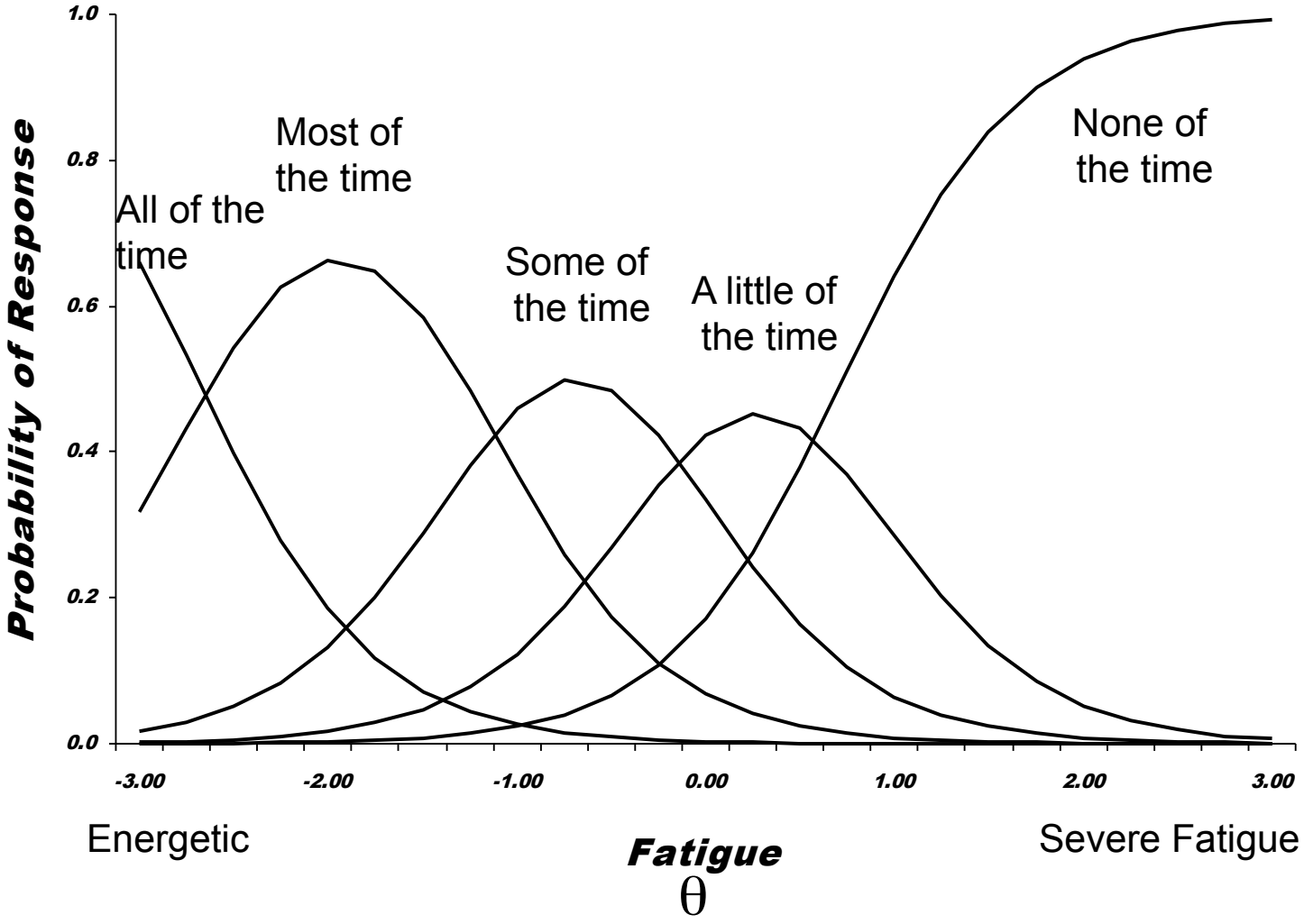


0 = Not at All; 1 = A Little Bit; 2 = Somewhat; 3 = Quite a Bit; 4 = Very Much

I have been too tired to feel happy.



I have felt energetic.



Calibration Sample: n = 21,133

- Age: 18-100 (mean = 53)
- 52% Female
- 9% Latino/Hispanic, 9% black, 2% other
- 3% < high school, 16% high school only
- 59% Married
- 39% Working full-time

Dimensionality

- Item-scale correlations for 10 global items
  - Ranged from 0.53 to 0.80
- Internal consistency reliability = 0.92
- Confirmatory factor analysis (categorical) for one-factor model
  - CFI = 0.927
  - RMSEA = 0.249 (*note: < .06 desirable*)
- PCA eigenvalues: **6.25**, **1.20**, 0.75, …

Two-Factor CFA Loadings

Item	Physical	Mental
3. Rate physical health	0.89+	
6. Carry out phys acti	0.81+	
7. Rate pain	0.64+	
8. Rate fatigue	0.58+	0.18
2. Rate quality of life	0.50	0.46+
4. Rate mental health		0.87+
5. Rate sat with social		0.88+
10. Emot. Problems		0.66+
1. Rate general health	0.88	
9. Usual social act	0.50	0.44

Physical Health 1-factor CFA

- Five items
  - RMSEA = 0.220
- r = 0.29 between two items:
  - In general, how would you rate your health (1)
  - In general, how would you rate your physical health? (3)
  - RMSEA = 0.081
- Dropped general health item (1)

4-item Global Physical Health Scale

- In general, how would you rate your physical health? (3)
- To what extent are you able to carry out your everyday physical activities …? (6)
- How would you rate your pain on average? (7)
- How would you rate your fatigue on average? (8)

Physical Health Item Parameters

Item	A	B1	B2	B3	B4
Global03	2.31	-2.11	-0.89	0.29	1.54
Global06	2.99	-2.80	-1.78	-1.04	-0.40
Global07	1.74	-3.87	-1.81	-0.67	1.00
Global08	1.90	-3.24	-1.88	-0.36	1.17

3. In general, how would you rate your physical health?
6. To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries or moving a chair?
7. How would you rate your pain on average?
8. How would you rate your fatigue on average?

3: Poor; Fair: Good; Very Good: **Excellent**
6: Not at all,; A Little; Moderately; Mostly; **Completely**
7: Worse pain imaginable (10) - **No pain** (0)
8: Very Severe; Severe; Moderate; Mild; **None**

Mental Health 1-factor CFA

- Four items
  - RMSEA = 0.196
- r = 0.16 between two items:
  - In general, how would you rate your mental health? (4)
  - How often have you been bothered by emotional problems? (10)
  - RMSEA = 0.084

4-item Global Mental Health Scale

- In general, would you say your quality of life is …? (2)
- In general, how would you rate your mental health …? (4)
- In general, how would you rate your satisfaction with social activities and relationships? (5)
- How often have you been bothered by emotional problems …? (10)

Mental Health Item Parameters

Item	A	B1	B2	B3	B4
Global02	2.41	-2.45	-1.32	-0.29	1.07
Global04	3.67	-2.31	-1.26	-0.33	0.67
Global05	2.98	-1.78	-0.90	-0.01	1.07
Global10	1.89	-2.82	-1.51	-0.25	0.99

2. In general, would you say your quality of life is …?
4.In general, how would you rate your mental health, including your mood and your ability to think?
5. In general, how would you rate your satisfaction with social activities and relationships?
10. How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?

2, 4, 5: Poor; Fair: Good; Very Good: **Excellent**
10: Always; Often; Sometimes, Rarely; **Never**

Physical and Mental Health: r = 0.63

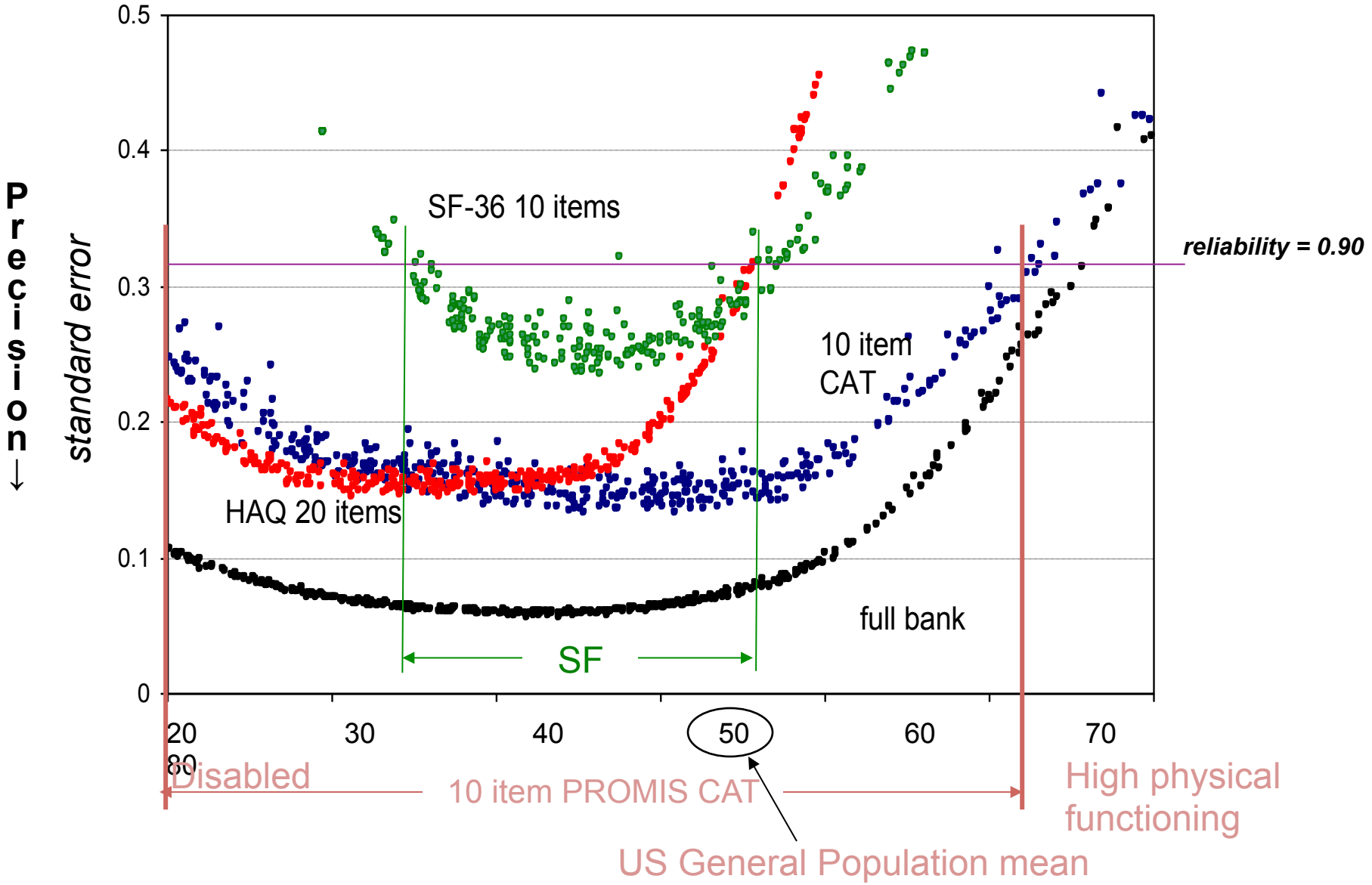
- Physical (α = 0.81)
  - r = -0.75 (pain impact), -0.73 (fatigue), 0.71 (physical functioning), -0.67 (pain behavior)
- Mental (α = 0.86)
  - r = -0.71 (depressive symp.), - 0.65 (anxiety), 0.60 (satisfaction with discretionary social activities)

Reliability and SEM

- For z-scores (mean = 0 and SD = 1):
  - Reliability = $1 - SEM^2 = 0.90$
    - IF SEM = 0.32

- With 0.90 reliability
  - 95% Confidence Interval
    - z-score: - 0.62 → 0.62
    - T-score: 44 → 56

Physical Functioning CAT – Higher Precision



Thank You!

Acknowledgements to the PROMIS Collaborative Group and the National Institutes of Health.

For more information:

drhays@ucla.edu

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

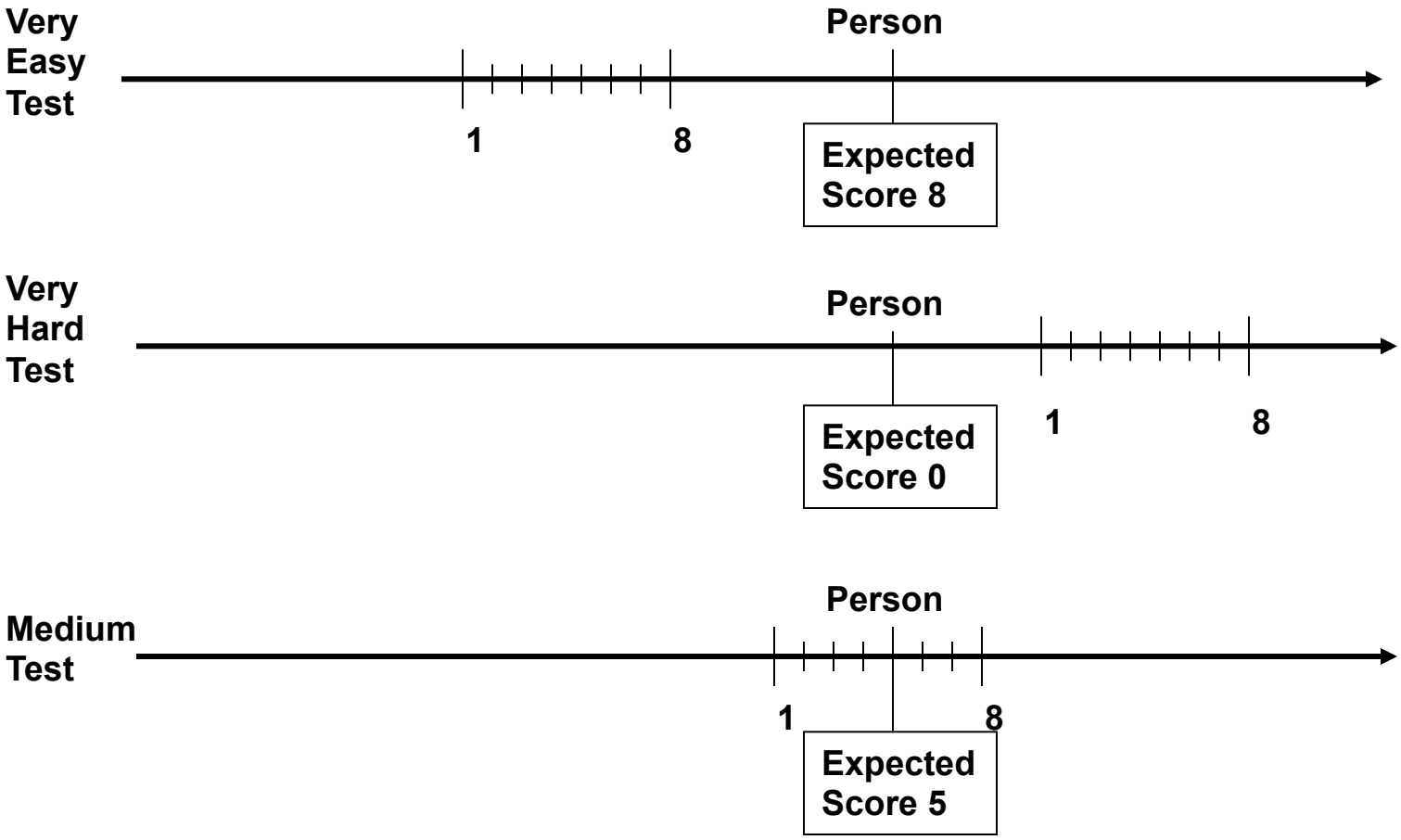
2010 PROMIS Pediatric Banks

Domains	Items in Bank	Items in Short Form
Emotional Distress – Anger	n/a	6
Emotional Distress – Anxiety	15	8
Emotional Distress – Depression	14	8
Fatigue	23	10
Pain – Interference	13	8
Peer Relationships	15	8
Physical Function – Mobility	23	8
Physical Function – Upper Extremity	29	8
Asthma Impairment	17	8

Advantages of Using IRT

- Equal Interval Measure
- Respondents and items are represented on the same scale
- Item calibrations are independent of the respondents used for calibration
- Ability estimates are independent of the particular set of items used for estimation
- Measurement precision is estimated for each person and each item

How Scores Depend on the Difficulty of Items



Reprinted with permission from: Wright, B.D. & Stone, M. (1979) *Best test design,* Chicago: MESA Press, p. 5.

Three Parameter Logistic Model

$$P_{1,0} = c + (1-c)\frac{e^{a\,(ability - b)}}{1 + e^{a\,(ability - b)}}$$

Three parameters

a= Discrimination

b= Item Difficulty

c= Guessing