

Discussion

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Patient-Reported Outcomes Measurement Information System
Dynamic Tools to Measure Health Outcomes From the Patient Perspective

Is HRQOL on Trial?

Is HRQOL on Trial?

- Moral high ground
- Today's Decisions
 - Regulator: approve or disapprove?
 - Clinician: use or do not use?
 - Payer: pay or do not pay?
 - Clinical researcher: include or exclude as an endpoint?
- Do these decision-makers care about PROs?
- Do these decision-makers use PRO data?
- Have we (i.e., PRO researchers) paid enough attention to these decision-makers?

Item Banks and NCI Clinical Trials



PROMIS (www.nihpromis.org)

Patient

Reported

Otcomes

Measurement

Information

System



Patient-Reported Outcomes Measurement Information System

Dynamic Tools to Measure Health Outcomes From the Patient Perspective

What **PROMIS** Promises

Precision

Repository

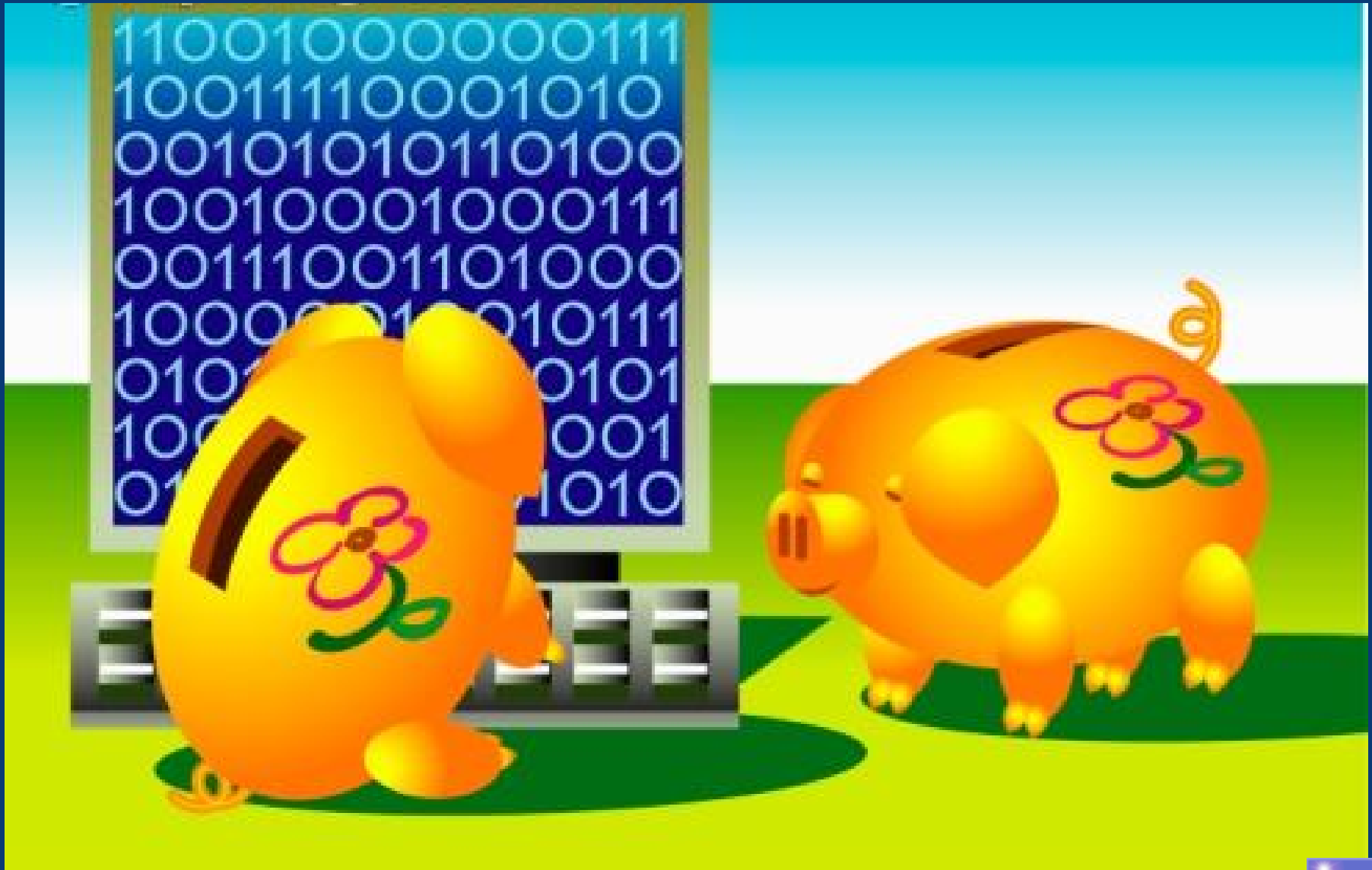
Outcome tools

Methodologies

Interpretability

Software

Item Banking and Computerized Adaptive Testing (CAT)

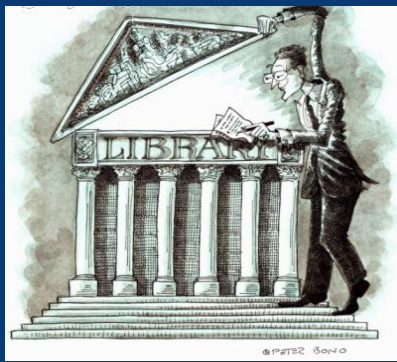


Repository: PROMIS Item Library

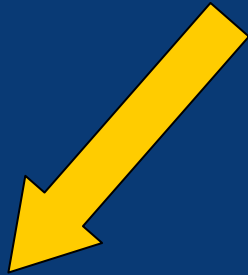
- Central repository for existing PRO items
 - Identified through literature searches in the five PROMIS domains, plus investigator contributions
- Relational database of more than 7,000 items
- Catalog characteristics of items including
 - Context
 - Stem
 - Response options
 - Time frame
 - Instrument of origin (if appl)
 - Intellectual property status
 - Track modifications to items

A pink piggy bank is the central focus, sitting on a dark desk. To its right, a hammer with a black handle and a silver head lies on the desk. In the foreground, a black calculator is partially visible. The background shows a computer keyboard and mouse, suggesting an office or financial setting. The lighting is dramatic, with strong highlights and deep shadows.

Looking Inside an Item Bank



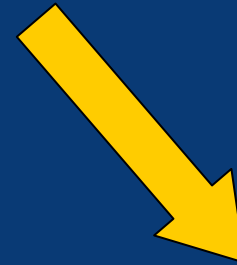
Item Library



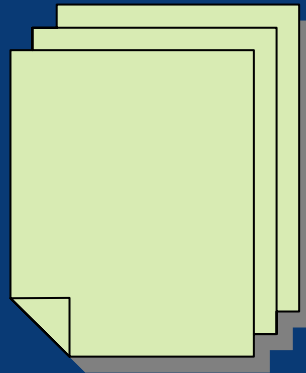
CAT



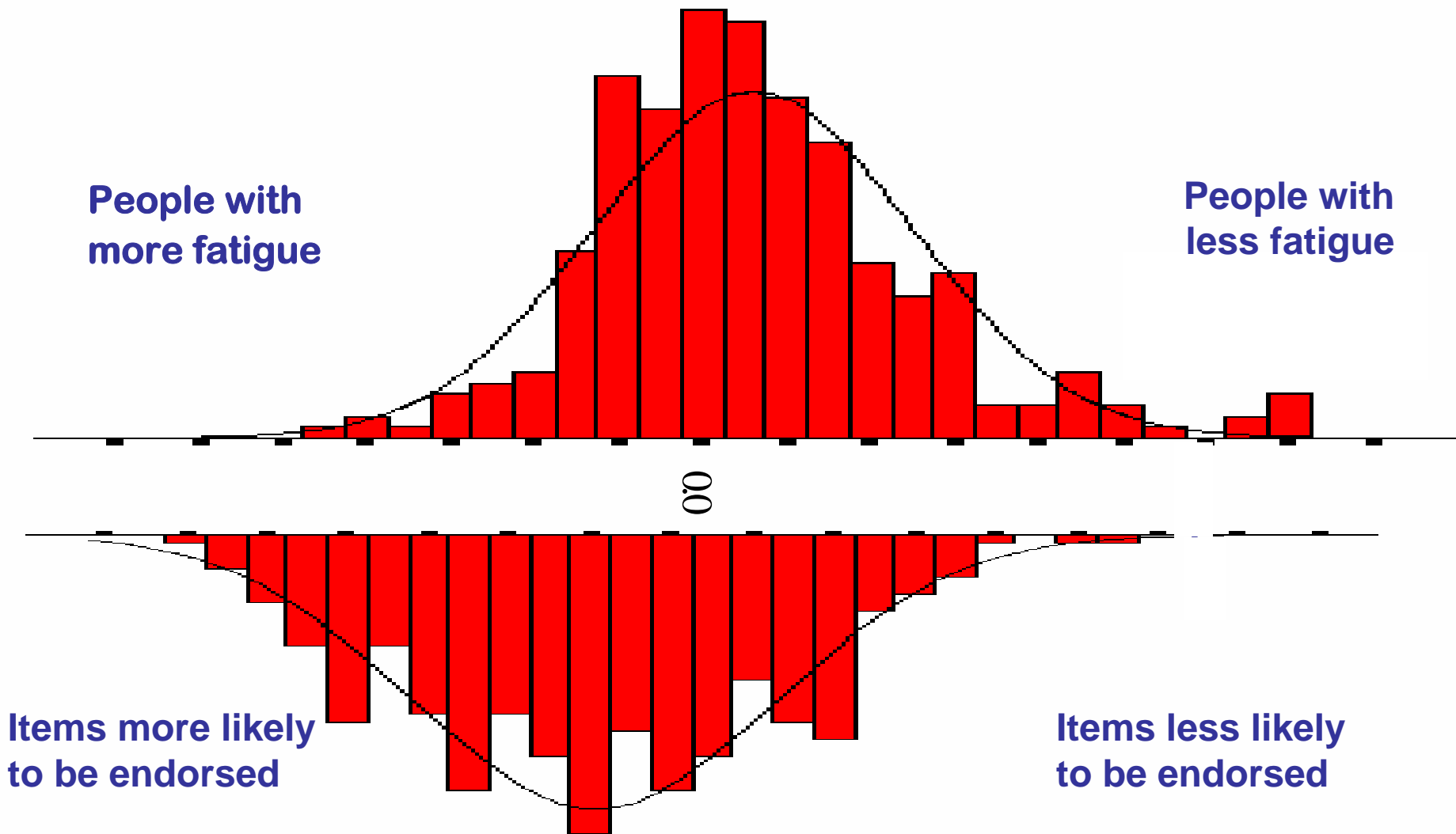
Pick-a-PRO



Build-a-PRO

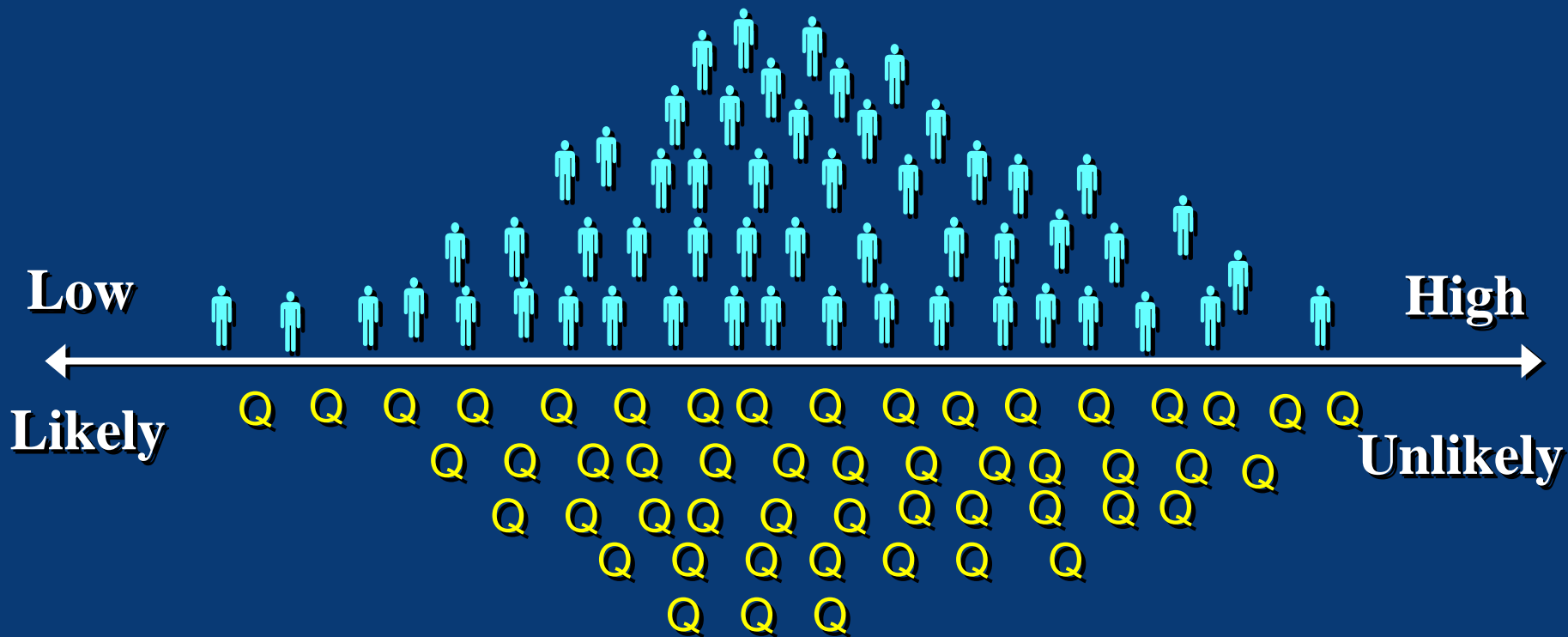


People and Items Distributed on the Same Metric: Fatigue



Interpretation Aids

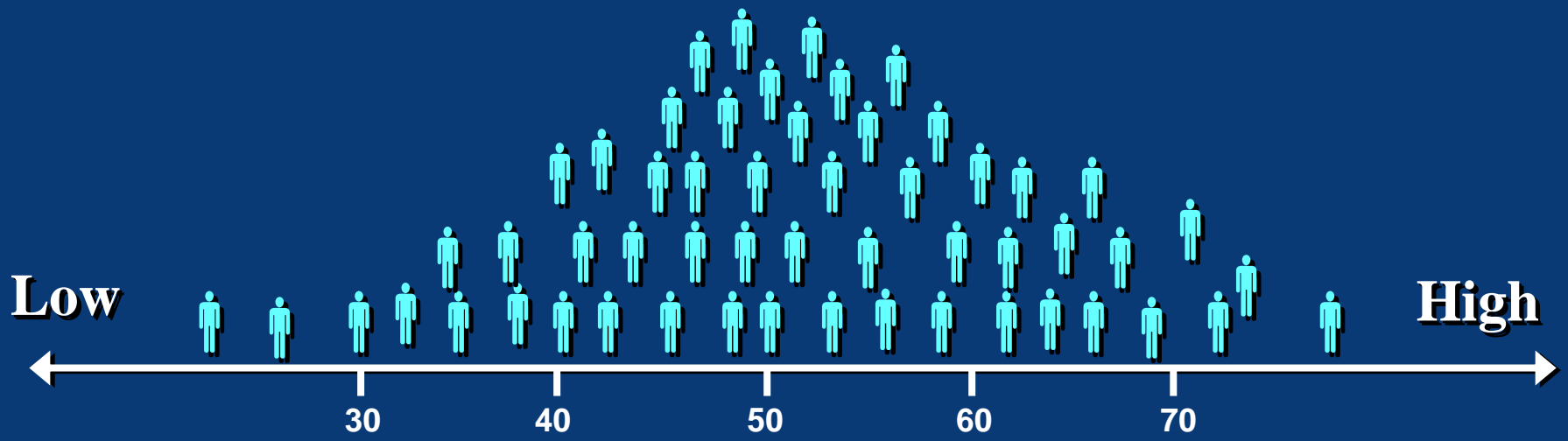
PRO Bank Person Score



Item Location

Interpretation Aids

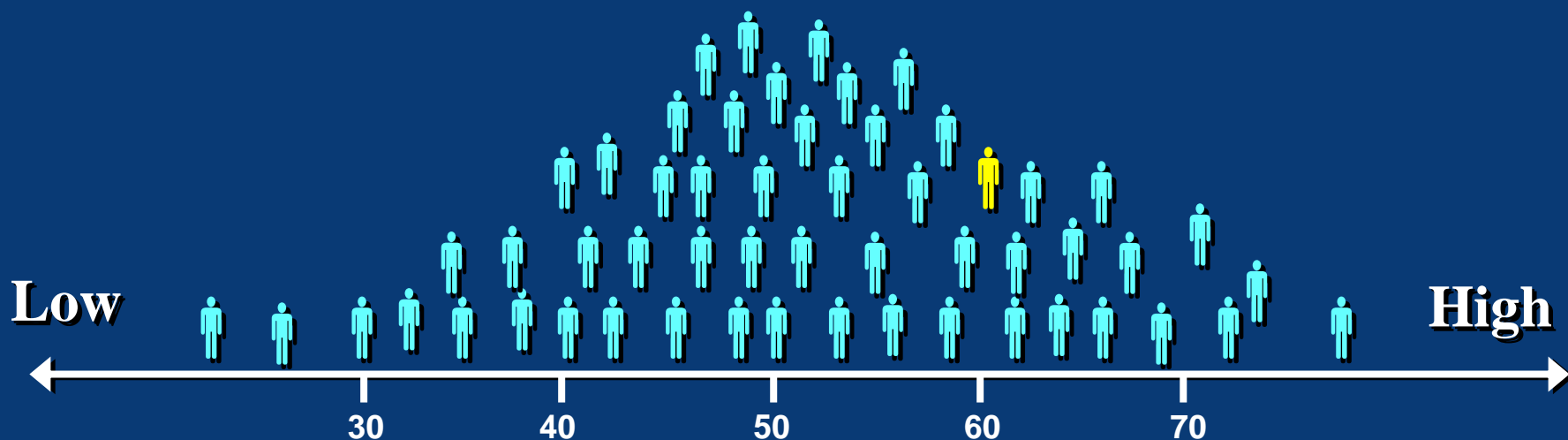
PRO Bank Person Score



M = 50, SD = 10

Interpretation Aids: Cancer example

Fatigue Score=60



This patient's fatigue score is **60**, significantly worse than average (50). Cancer patients who score **60** on fatigue tend to answer questions as follows:

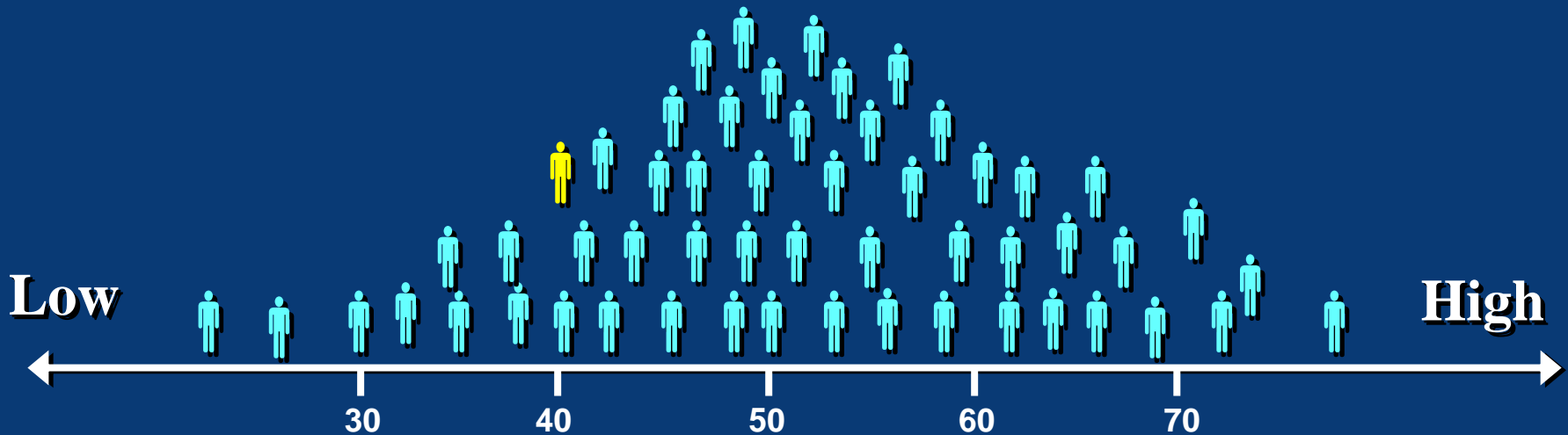
..."I have been too tired to climb one flight of stairs: VERY MUCH

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

[Click here if you would like to see this patient's individual answers](#)

Interpretation Aids: Cancer example

Fatigue Score=40



This patient's fatigue score is **40**, significantly better than average (50). People who score **40** on fatigue tend to answer questions as follows:

..."I have been too tired to climb one flight of stairs: SOMEWHAT


..."I have had enough energy to go out with my family: VERY MUCH

[Click here if you would like to see this patient's individual answers](#)

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Address <http://www.nihpromis.org> Go Links



Patient-Reported Outcomes Measurement Information System

Dynamic Tools to Measure Health Outcomes From the Patient Perspective

Log-In User ID: Password: [Forgot Password](#)

What Is PROMIS? Overview

The Patient-Reported Outcomes Measurement Information System (PROMIS) initiative establishes a collaborative relationship between NIH and individual research teams through a cooperative agreement (U01) mechanism. The broad objectives of the PROMIS network are to:

- Develop and test a large bank of items measuring patient-reported outcomes
- Create a computerized adaptive testing system that allows for efficient, psychometrically robust assessment of patient-reported outcomes in clinical research involving a wide range of chronic diseases
- Create a publicly available system that can be added to and modified periodically and that allows clinical researchers to access a common repository of items and computerized adaptive tests.

The network will collaborate on the collection of self-reported data from diverse populations of individuals with a variety of chronic diseases, using agreed-upon methods, modes, and questionnaires.






Click below for:

[Domain definitions](#) [item content review](#) [item characteristics](#)

or select a box on the right and proceed

[Advanced Search Page](#)

What would you like to measure in your study?

- [pain](#) 
- [fatigue](#) 
- [emotional distress](#) 
- [physical function](#) 
- [social role participation](#) 

Internet

The Decider's Challenge

- Decision-maker must make binary decisions in a complex world
 - They are usually not experts in PRO science
 - and not likely to become converted despite our lofty purpose
 - They tend to WANT to incorporate PROs into their decisions
 - But tend to believe that as people themselves they can make their own assessments without needing formal questionnaires
 - They require easy interpretation on their terms
 - They have things other than what the patient feels on their minds (Believe it or not)

Torrance's Regret → Advice

- Learn more about the decision-makers' needs
- Try to make some decisions of our own based on PRO data
 - Should I approve for marketing a tumor-targeted therapy that makes people feel better without any measurable impact upon the tumor itself or survival?
 - Should I stop treating a patient whose HRQL is declining sharply if she wants to leave no therapeutic stone unturned?
 - Should I authorize Medicare coverage for broad and costly off-label use of a drug that improves HRQL?
 - Should I support the costs of PRO study in my cooperative group?
 - Should I support the necessary R&D for building a PRO claim base based on our limited knowledge of the drug in development and the available FDA guidance?

Advice to CTWG

- Include PRO Expert(s) at the Table
- Demand Consensus on Basic Issues
 - Priorities
 - Measurement
 - Analysis
 - Interpretation