Outcomes Measurement Information System (PROMIS): An NIH Roadmap Initiative

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On behalf of the PROMIS network
What Is PROMIS?

- **An NIH Roadmap Initiative: Re-Engineering the Clinical Research Enterprise**

- **Goal:** To improve assessment of self-reported symptoms and other health-related quality of life domains across many chronic diseases
  - Core domains include pain, fatigue, emotional distress, physical function, and social well-being

- **Structure:** 25+ Million, 5-Year cooperative agreement between NIH and extramural investigators
  - Statistical coordinating center
  - 6 primary research and data collection sites
Themes of the NIH Roadmap

- **New Pathways to Discovery**
- **Research Teams of the Future**
- **Re-engineering the Clinical Research Enterprise**
  - Implement new paradigms in how clinical research information is collected, used, and reported.
  - Incorporate advances in information technology, psychometrics, and qualitative, cognitive, and health survey research.
  - Develop new partnerships of research with organized patient communities, community-based health care providers, industry, and academic researchers.
Broad Objectives of PROMIS
RFA-RM-04-011

- Develop and test a large item bank measuring patient-reported outcomes (PROs)
- Create a computerized adaptive testing system that will allow for efficient, psychometrically robust assessment of patient-reported outcomes for a wide range of chronic disease outcome research
- Create a publicly available system that can be added to and modified periodically and that will allow clinical researchers access to a common item repository and to computerized adaptive testing
PROMIS Grantees

- David Cella, Ph.D.  
  Northwestern U.

- Dagmar Amtmann, Ph.D.  
  U. of Washington

- Jim Fries, M.D.  
  Stanford University

- Darren DeWalt, Ph.D.  
  U. of North Carolina

- Paul Pilkonis, Ph.D.  
  U. of Pittsburgh

- Arthur Stone, Ph.D.  
  Stony Brook University

- Kevin Weinfurt, Ph.D.  
  Duke University

- Westat
- Medtap
- UCLA

- Health Assessment Lab
- Texas A & M
- Scott & White Mem Hosp
- Assessment Systems
- Boston U.
- U. of Michigan
PROMIS Domain Framework

Health
- Physical Health
  - Physical Function
  - Symptoms
    - Pain
    - Fatigue
    - Other
  - Upper Extremities: grip, buttons, etc (dexterity)
  - Lower Extremities: walking, arising, etc (mobility)
  - Central: neck and back (twisting, bending, etc)
  - Activities: IADL (e.g. errands)
- Mental Health
  - Emotional Distress
    - Anxiety
    - Depression
    - Anger/Aggression
    - Subjective Well-Being (positive effect)
    - Meaning and Coherence (spirituality)
    - Mastery and Control (self-efficacy)
    - Positive Impacts of Illness
  - Perceived Cognitive Functioning
  - Positive Psychological Functioning
  - Substance Abuse (alcohol)
  - Negative Impacts of illness
- Social Health
  - Social Function
    - Ability to Participate
  - Social Support
    - Experience
    - Impact
  - Satisfaction
- Satisfaction
PROMIS Integrates Cognitive, Qualitative, and Survey Research Methods

- Conceptualize and operationalize the domains and issues affecting patients

- Build PRO assessment tools that are applicable for a broad range of respondents of various races, cultures, ages, education level, disease groups, and disease severity.

- Ensure content valid and meaningful results for researchers, clinicians, and patients
What is a Computerized Adaptive Testing (CAT)?

- CAT integrates the advances in measurement theory and the power of computer technology to administer a PRO instrument that selects questions on the basis of a patient’s response to previously administered questions.

- Highly informative questions are carefully selected so that we may determine a person’s standing on a domain (e.g., physical functioning, depression) with the minimal number of questions without a loss in measurement precision.
The “Promise” of PROMIS: Developing Instruments for Use in Clinical Research and Practice that:

- Reduce response burden.

- Improve measurement precision.

- Provide the ability to compare or combine results from multiple studies.

- Simplify administration via computer-based administration, scoring, and reporting.
PROMIS Item Bank
Development

- Extant review of existing items (legacy items)
- Development of new and modified items (approx. 8000 total new and derived items)
- Binning and winnowing of items (1064 items)
- Revisions for readability, consistency, and translation
- Patient focus groups
- Cognitive interviews (784 items)
Psycho-metric Testing

Item Bank
(IRT-calibrated items reviewed for reliability, validity, and sensitivity)

Short Form Instruments

CAT

Item Pool

Content Expert Review

Focus Groups

Cognitive Testing

Secondary Data Analysis

Questionnaire administered to large representative sample

Psychometric Testing

Items from Instrument A

Items from Instrument B

Items from Instrument C

New Items

Probability of Response

Theta

Information

Theta
Additional Domain Development

- **Independent and Supplement Project Domains**
  - Pediatric Core Domains (Physical, Emotional, Social, School/Cognitive)
  - Pediatric Asthma
  - Sleep/Wake Functioning
  - Sexual Functioning
  - Perceived Cognitive Functioning

- **Supplementary projects**
  - Modified item banks for patients using wheelchairs and assistive devices
  - Parent-proxy item banks that parallel the pediatric item banks
  - Validation studies in patients with COPD, CHF

- **Collaborations with Other Federally Funded Initiatives**
  - DBDR/NHLBI AscQ-me project
  - NCI PROMIS supplement (Cancer-relevant domains)
  - NINDS NeuroQOL
  - NIH Toolbox (Sensory, Motor, Cognitive, Emotional)
  - CMS Post-Acute Care Demonstration Project

Collaborations with Test Developers and End Users
PROMIS Independent Projects and PIs

- **Duke University**
  - Kevin Weinfurt, PhD
  
  *Challenges for Using IRT-Based Assessments in Multi-center Clinical Trials*

- **Univ. of North Carolina, Chapel Hill**
  - Darren DeWalt, MD, MPH
  
  *Pediatric Reported Outcomes Assessment Using CAT ("Kitty")*
PROMIS Independent Projects and PIs

- University of Pittsburgh
  - Paul A. Pilkonis, PhD
  
  *Measuring Patient-Reported Sleep and Emotional Distress*

- Stanford University
  - James F. Fries, MD
  
  *Improved Outcome Assessment in Arthritis and Aging*
PROMIS Independent Projects and PIs

- **Stony Brook University**
  - Arthur A. Stone, PhD
  
  *Ecological Validity in Patient-Reported Chronic Disease Outcomes*

- **University of Washington**
  - Dagmar Amtmann, PhD
  
  *Improving Measurement of Pain and Fatigue and Increasing the Scientific Understanding of Pain and Fatigue in Children and Adults with Disabilities*
Disease-Specific Validation Efforts

- Current PROMIS Network Validation Projects
  - Construct Validity and Sensitivity to Change in:
    - COPD
    - Depression
    - Back Pain
    - Congestive Heart Failure
    - Arthritis
  - Mode of Administration Testing
- PROMIS item banks released specifically to encourage others to validate in their patient populations
Collaborations

- Currently, there are 114 collaborative projects
  - Translation & validation studies in non-US populations (Brazil, China)
  - Use of PROMIS measures in different clinical care settings (Cleveland Clinic, hospices & palliative care)
  - Development & use of PROMIS tools in a range of diseases & conditions
    - NCI PROMIS supplement (Cancer-relevant domains)
    - NINDS NeuroQOL
    - NIH Toolbox (Sensory, Motor, Cognitive, Emotional)
    - NHLBI ASCQ-me project (Sickle Cell Disease)
Adult Sickle Cell Quality of Life Measurement Information System (ASCQ-Me)

- Primary Purpose: To develop, validate, and disseminate a health-related quality of life (HRQOL) measurement information system for Sickle Cell Disease (SCD) patients

- Secondary Purpose: To identify core data elements for a short form to be used as a paper-and-pencil questionnaire
PROMIS II

- NIH Roadmap committed to an additional network funding through 2013
- PROMIS II to begin August 2009
- PROMIS II goals include:
  - Development and testing of additional item banks
  - Further validation of existing and new domains
  - Further improvements to Assessment Center
  - Development of a public-private partnership to sustain PROMIS post Roadmap funding.
The PROMIS Potential

- Standardize the measures used in clinical research to enhance our ability to evaluate the effectiveness of interventions and treatments in clinical research and trials.

- The ability to link databases (e.g., EMR) with systems like PROMIS would strengthen our national capacity to monitor progress against the burden of disease and to support a wide range of studies on the determinants of health care utilization and outcomes*.

WEBSITES

PROMIS: www.nihPROMIS.org

Roadmap: www.nihroadmap.nih.gov