The National Institutes of Health (NIH) Patient-Reported Outcomes Measurement Information System (PROMIS): a view from the UK

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Main messages

• PROMIS is a robust, precise and efficient system for the measurement of patient reported outcomes
• It provides common metric which facilitates cross-walks with AND between other measures
• Its use is gradually expanding beyond the US with many item banks and short forms available in Spanish, Chinese, German, Dutch and many other languages.
• Increasingly recognized as a gold standard measure (ICHOM)
• The use in the UK remains limited
• Huge potential for outcome measurement in NHS for individual/aggregate use
What is PROMIS®?

Patient-Reported Outcomes Measurement Information System®

- Set of measures of physical, mental, and social health (adult & pediatric)
- Relevant across all conditions
- Developed and evaluated using state-of-the-science psychometric methods
- Scores on one metric

HealthMeasures.net/PROMIS
## Essential Components of PROMIS

<table>
<thead>
<tr>
<th><strong>DOMAIN</strong></th>
<th><strong>ITEM BANK</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>The feeling, function, or perception you wish to measure.</td>
<td></td>
</tr>
<tr>
<td>Cuts across different diseases and settings. E.g., physical function, depressive symptoms.</td>
<td></td>
</tr>
<tr>
<td>Collection of items that each measure the same domain.</td>
<td></td>
</tr>
<tr>
<td>Used to create different measure types, all producing a score on the same metric.</td>
<td></td>
</tr>
</tbody>
</table>

HealthMeasures.net/PROMIS
PROMIS Measures

• Adult Health Measures
  • More than 1,000 individual items (questions)
  • 51 distinct item banks or scales
  • 12-124 items per bank
Domains for Adult Assessment

PROMIS® Adult Self-Reported Health

- **Global Health**
- **Physical Health**
  - Fatigue
  - Pain Intensity
  - Pain Interference
  - Physical Function
  - Sleep Disturbance
- **Mental Health**
  - Anxiety
  - Depression
- **Social Health**
  - Ability to Participate in Social Roles & Activities
  - Companionship
  - Satisfaction with Social Roles & Activities
  - Social Isolation
  - Social Support

PROMIS Profile Domains

PROMIS Additional Domains

Dyspnea
Gastrointestinal Symptoms
Pain Behavior
Pain Quality
Sexual Function
Sleep-related Impairment

Alcohol
Anger
Cognitive Function
Life Satisfaction
Positive Affect
Psychosocial Illness Impact
Self-efficacy for Managing Chronic Conditions
Smoking
Substance Use

HealthMeasures.net/PROMIS
PROMIS Measures

• Adult Health Measures
  • More than 1,000 individual items (questions)
  • 51 distinct item banks or scales
  • 12-124 items per bank

• Pediatric Health Measures
  • More than 150 items (questions)
  • 18 distinct banks or scales
  • 22 more on the way
Domains for Pediatric Assessment

HealthMeasures.net/PROMIS
Items from Instrument A

Items from Instrument B

Items from Instrument C

New Items

Item Library (>8,000)

Content Expert Review

Focus Groups

Cognitive Testing

Secondary Data Analysis
PROMIS Item Bank Development

- Comprehensive collection and review of existing items (legacy items)
- Development of new and modified items (approx. 8000 total items)
- Binning and winnowing of items (1064 items)
- Readability analysis and revisions
- Focus groups
- Cognitive interviews (784 items)
Item Bank

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

Item Bank

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

Short Form Instruments

CAT

Secondary Data Analysis

Cognitive Testing

Focus Groups

Content Expert Review

Item Library (>8,000)

New Items

Items from Instrument A

Items from Instrument B

Items from Instrument C

Questionnaire administered to large representative sample

Information

Probability of Response

Theta

Theta

Theta

Theta
PROMIS Measure Types

**SHORT FORMS**
- Subsets of item banks
- Focused on a single domain
- Off-the-shelf or custom
- Usually 4-10 items

**COMPUTER ADAPTIVE TESTS (CATs)**
- Individually tailored electronic questionnaires
- Focused on a single domain
- Next item administered from item bank depends on previous answers
- Usually 4-12 items

**PROFILES**
- Collection of short forms covering multiple domains (e.g. depression, physical function, pain interference)
- Adult profiles (29, 43, and 57 item versions), Pediatric and Parent-Proxy profiles (25, 37, 49 item versions)

HealthMeasures.net/PROMIS
Understanding PROMIS Scores

- PROMIS measures use a T-score metric
  - 50 is the mean for a relevant reference population (US!)
  - 10 is the standard deviation (SD) of that population

- Meaning of the score is defined by how it compares to the scores of others in a reference population

- High scores equal more of the domain being measured (e.g., more fatigue, more physical function)

HealthMeasures.net/PROMIS
Fatigue Item Bank

Chemotherapy trial

Osteoarthritis trial

Diabetes trial

Epilepsy trial

Heart Failure trial

Same metric, same meaning
PROMIS Fatigue Across Five Clinical Conditions

N = 310

N = 229

N = 114

N = 64

N = 125

Average for General Population
What is Computerized Adaptive Testing (CAT)?

A technique for administering a PRO instrument that

• selects questions on the basis of a person’s response to previously administered questions
  • each question, stored in an “item bank” has been psychometrically and qualitatively reviewed as informative for measuring the health construct

• determines a person’s score with the minimal number of questions and no loss of measurement precision
Computer Adaptive Tests

2. Question

3. Question

Questionnaire with a high precision - AND a wide range
A family of models that describe, in probabilistic terms, the relationship between people’s responses to questions and their position on the continuum of what is being measured (e.g., pain)
How much bodily pain have you had during the past 4 weeks?

IRT assigns properties to each question that provide information on which people a given question is best suited for.
Advantages of adding IRT to Classical Test Theory

• Item Response Theory focuses on the mathematical relationship of items to the latent trait

• Advantages:
  • Scale reduction – potentially more precision with less items
  • Scale flexibility – different items to measure the same trait
  • Equate scores of different scales (crosswalking)
  • Test item equivalence across groups (DIF)
  • Tailored administration (CAT)
Computerized Adaptive Testing (CAT)

- Select questions based on a person’s response to previously administered questions.
- Iteratively estimate a person’s standing on a domain (e.g., depressive symptoms)
- Administer most informative items
- Desired level of precision can be obtained using the minimal possible number of questions.
I felt depressed

1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

T-Score = 52  SE = 4

Next Best Item - I felt like a failure
I felt like a failure
1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

T-Score = 53  SE = 3
I felt worthless

1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

T-Score = 55  SE = 2
I felt that nothing could cheer me up

1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

T-Score = 55  SE = 2
Advantages of CAT Assessments

• Provide an accurate estimate of a person’s score with the minimal number of questions
  • Questions are selected to match the health status of the respondent

• Minimize floor and ceiling effects
  • People near the top or bottom of a scale will receive items that are designed to assess their health status
Advantages of Short-Forms
Developed from Item Banks

• Flexibility in length and content
  • Select items matched to clinical features and severity in the target population
  • Select items known to provide the most information

• Any form selected or created produces scores on a common metric
The PROMIS of a better future...

A publicly available, adaptable and sustainable Internet-based system that will:

1. Administer individually “tailored” questionnaires (using Computer Adaptive Testing (CAT) technology) to measure health status outcomes
2. Collect and analyze responses
3. Provide instant health status reports to users to:
   - Enhance research
   - Improve clinical decision-making
   - Facilitate policy-making by health plan and systems and public programs
PROMIS Assessment Center and Opportunities for Interaction

A publicly available, adaptable and sustainable Internet-based system that:

1. Hosts 11 item banks for precise, valid, and efficient health status assessment via short forms or CAT
2. Collects and analyze patients’ responses
3. Provides instant health status reports to users to:
   - Enable and enhance research
   - Improve clinical decision-making
   - Facilitate policy-making by health plan and systems and public programs
ID: Fatigue
In the past 7 days, how often did you feel run-down?

<table>
<thead>
<tr>
<th>Event Date</th>
<th>Category</th>
<th>Revised</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/01/2006</td>
<td>Expert / Editorial Review</td>
<td>Yes</td>
</tr>
<tr>
<td>05/01/2006</td>
<td>Cognitive / Patient Review</td>
<td>Yes</td>
</tr>
<tr>
<td>03/01/2006</td>
<td>Translatability Review</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Context**
Please rate the following statement about how you felt over the past 7 days.

**Stem**
How often did you feel run-down?

**Comments**
6/7 said easy, 2/6 said response scale hard.
Assessment Center Aims

Assessment Center supports...

- Research and clinical applications
- CAT
- Custom or off-the-shelf short forms
- Non-PROMIS measures welcome
- Study set up, maintenance and storage
- Scoring, reporting and interpretation
Linking Measures

- Converts score from one measure to PROMIS metric
- Enables comparisons when different measures used

- [www.prosettastone.org](http://www.prosettastone.org)
PHO: PROMIS Health Organization

The PROMIS Health Organization (PHO) is an open charitable foundation that welcome members from around the world to bring the "patient's voice" to the forefront of care.

• **Origin:** founded in 2008 by scientists who developed and validated PROMIS.

• **Mission:** to improve health outcomes by developing, maintaining, improving, and encouraging the application of PROMIS in research and clinical practice
  
  PROMIS as a gold-standard outcome metric which integrated as part of routine clinical practice across multiple specialties
PHO: PROMIS Health Organization

To advance the Science of Health Outcomes Assessment
To foster and support a vibrant community of researchers in collecting PRO data for research and for improving PROMIS® through the addition of new domains and items, maintaining consistent growth to support continual improvements.

To disseminate standardized and validated health outcome questionnaires
To encourage widespread adoption of PROMIS by maintaining open access to all interested parties for item banks, software, and findings from research and the provision of reliable, valid, and cost-effective measurements of relevant health outcomes to the greater scientific and clinical research community and to other health care organizations.

To foster the development of new patient-reported health outcomes for diverse populations
To establish a broad inventory of methods for capturing PRO data from diverse population groups (including translations), including both static short forms and dynamic CAT through various secured accessible delivery platforms.

To educate the scientific and clinical communities on the science of patient reported outcomes
To communicate the value of PROMIS to the scientific community, emphasizing its performance compared with legacy instruments; and to increase clinical adoption by organizing and presenting PRO data that are relevant and useful to clinicians, patients, and researchers; and to contribute to the reorientation of clinical research by creating useful endpoints for clinical trials and research studies.
PHO International Committee

Part of the PHO which informs/advises the board on the identification, coordination, and promotion of best practices to develop, translate, validate, and utilize PROMIS instruments across countries.

Scientific activities

• developing standards to assess cultural relevance and cross-cultural validity of PROMIS instruments
  • Working paper (WP) on Minimum requirements for the release of PROMIS instruments after translation and recommendations for further psychometric evaluation
• assisting with translation, cross-cultural validation, and review to determine if country-specific items and norms are needed
  • WP on the DUTCH model for translation, validation, and distribution (ongoing).

Organizational activities

• identifying individuals who will serve as national contact points
• addressing distribution rights: WP on work-flow for supporting international distribution (ongoing)
• collaborating with national contact points to identify local solutions to ensure privacy of data, country-specific data management tools (Assessment Center) and websites
• assisting with fundraising activities
• recruitment of additional international partners
PHO International Committee

General membership. Open to all international scientists and clinicians who are involved in PROMIS-related projects.

National contact points. Up to 2 persons per country hold voting privileges within the International Committee. For the UK: Chris Gibbons (Cambridge) and Jose M Valderas (Cambridge).

Executive Committee: J. Alonso, S. Bartlett, S. Nolte/M. Rose, and C. Terwee. At any point in time at least one member of the Executive Committee is also a full voting member of the PHO board.

Communication
- Executive Committee: monthly teleconference
- All members: quarterly teleconferences for update on current projects and activities and one face-to-face meeting will be held each year adjacent to annual meetings of either the PHO or the International Society for Quality of Life Research (ISOQOL)
- Website
<table>
<thead>
<tr>
<th>PROMIS Domain</th>
<th>Only Short Forms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emotional Distress - Anxiety v1.0</td>
<td>French (4a), Italian (4a), Simplified Chinese (7a)</td>
</tr>
<tr>
<td>Emotional Distress - Depression v1.0</td>
<td>Czech (8b, 4a, 6a), French (8b, 4a, 6a), Hungarian (8b, 4a, 6a), Italian (8b, 4a, 6a), Polish (8b, 4a, 6a), Russian (8b, 4a, 6a), Simplified Chinese (8b, 4a, 6a), Ukrainian (8b, 4a, 6a)</td>
</tr>
<tr>
<td>Fatigue v1.0</td>
<td>Arabic (7a), Afrikaans (4a, 6a, 8a), Bulgarian (4a, 6a, 8a), Croatian (7a), Czech (7a), Danish (7a, 4a, 6a, 8a), Finnish (4a, 6a, 8a), French (7a, 4a, 6a, 8a), German (7a, 4a, 6a, 8a), Greek (4a, 6a, 8a), Hungarian (7a), Italian (7a, 4a, 6a, 8a), Japanese (7a), Korean (7a, 4a), Malay (4a, 6a, 8a), Polish (7a, 4a, 6a, 8a), Portuguese-Br (7a, 4a, 6a, 8a), Romanian (4a, 6a, 8a), Russian (7a, 4a, 6a, 8a), Serbian (4a, 6a, 8a), Simplified Chinese (7a, 4a, 6a, 8a), Swedish (7a), Traditional Chinese (7a, 4a, 6a, 8a), Ukrainian (4a, 6a, 8a)</td>
</tr>
<tr>
<td>Pain Interference v1.1</td>
<td>Czech (6b), Danish (4a, 6b), Finnish (6b), French (4a, 6b), Hungarian (4a), Italian (4a, 6b), Japanese (4a), Korean (4a), Polish (6b), Russian (6b), Norwegian (6b), Swedish (4a), Simplified Chinese (6b), Traditional Chinese (6b)</td>
</tr>
<tr>
<td>Physical Function v1.2</td>
<td>French (4a, 6b, 8b, 10a, 20a), Hungarian (4a, 10a), Italian (4a, 6b, 8b, 10a, 20a), Japanese (4a), Korean (4a), Polish (10a), Russian (10a), Simplified Chinese (4a, 6b, 8b, 10a), Swedish (4a), Traditional Chinese (4a, 6b, 10a), Ukrainian (10a)</td>
</tr>
<tr>
<td>Sleep Disturbance v1.0</td>
<td>Bulgarian (4a, 6a, 8a), Danish (4a, 6a), Finnish (4a, 6a, 8a), French (4a, 6a, 8a), Italian (4a), Polish (4a, 6a, 8a), Romanian (4a, 6a, 8a), Simplified Chinese (8b, 4a)</td>
</tr>
<tr>
<td>Ability to Participate in Social Roles and Activities v2.0</td>
<td>French (4a), German (4a), Italian (4a)</td>
</tr>
<tr>
<td>Cognitive Function v2.0</td>
<td>Simplified Chinese (4a, 6a), Traditional Chinese (4a, 6a)</td>
</tr>
<tr>
<td>Global Health v1.1</td>
<td>Danish, Dutch, German, French, Italian, Portuguese-Br, Spanish, Simplified Chinese</td>
</tr>
<tr>
<td>Language</td>
<td>Adult item banks translated</td>
</tr>
<tr>
<td>-------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Spanish</td>
<td>40</td>
</tr>
<tr>
<td>Dutch-Flemish</td>
<td>17</td>
</tr>
<tr>
<td>German</td>
<td>8</td>
</tr>
<tr>
<td>Portuguese-Br</td>
<td>6</td>
</tr>
<tr>
<td>Traditional Chinese</td>
<td>5</td>
</tr>
<tr>
<td>Danish</td>
<td>2</td>
</tr>
<tr>
<td>Latvian</td>
<td>1</td>
</tr>
<tr>
<td>Swedish</td>
<td>4</td>
</tr>
<tr>
<td>French</td>
<td></td>
</tr>
</tbody>
</table>
PROMIS Int’l: The Netherlands

Website: www.dutchflemihspromis.nl
PROMIS Int’l: Germany

Website: [http://promis-germany.de/](http://promis-germany.de/)
PROMIS Translations

Universal Approach –

create one language version for multiple countries instead of country-specific versions of the same language

• Translators from different regions or dialects contribute to the process from the start

• Avoid colloquial expressions

• Pretest questionnaire with patients from relevant regions

References:


Harmonization across languages –

Harmonization is about determining the range of acceptable variation between the languages, while maintaining the intention of the source.
ICHOM’s mission is to unlock the potential of **value-based health care** by defining global **Standard Sets** of **outcome measures that really matter to patients** for the most relevant medical conditions and by driving **adoption and reporting** of these measures worldwide.
PROMIS in ICHOM

Stroke PROMIS-10
Pregnancy and Childbirth PROMIS-10
National Quality Registries

In 2016: 96 National Quality Registries (NQRs); 12 NQR candidates; all initiated and led by healthcare professionals.

NQRs cover many areas of healthcare, from common to rare conditions, from nursing and primary to tertiary care.

Examples: Stroke; Ischemic heart disease; Heart failure; most forms of cancer; Bipolar disorder; Eating disorders; End-of-life care; Neurology with MS, Parkinson’s etc; Dementia care; HIV-AIDS; Diabetes Mellitus; Orthopedics.
PROMIS® IN ACTION: Clinical and Research Implementations / Implications
Tuesday, October 17, 2017 7:30 AM - 4:30 PM (Eastern Time)

Pittsburgh, Pennsylvania 15213
201 S. Christopher Columbus Blvd
Philadelphia, Pennsylvania 19107
United States

This ONE DAY conference will bring together clinicians, researchers, government officials and industry representatives to advance the use of PROMIS around the world.

There will be a strong emphasis on the practical application of the measures in clinical settings and the latest PROMIS research will be presented to advance health care.

Comments about last year's conference:

I liked the enthusiastic atmosphere and the comprehensiveness of issues presented at the current stage of the PROMIS today. Well done, thank you!

Loads of practical and useful knowledge.
PROMIS in the United Kingdom

- Cambridge/Exeter in collaboration with researchers in France and Germany
- PROMIS Short Form 29: administered to random sample of population in each country (ca. 1500)
- Calibrations NOT different from US calibrations: scores from the English (and French and German PROMIS Profile-29 measures) are directly comparable and suitable for research or clinical use.
- Norms available
- Further research is needed to develop more comparable metrics for the United Kingdom
PROMIS in the United Kingdom

• PROMIS Upper Extremity (Devon, ongoing)
• PROMIS Global Health (Aneuris Bevan Health Board Wales, ongoing)
• PROMIS Depression, Anxiety and Physical function (funding requested)
Research needs

• Establishing cross-cultural validity
• Calibration of item banks
• Development of administration interface (CONCERTO)
IN SUMMARY

• Originally developed in the US using state of the art psychometric techniques
• Use in US expanding significantly
• Efforts to facilitate access and uptake
• Translated to several countries across the world
• Limited use in the UK
• Huge potential for improving clinical care and evaluation of provider performance BUT
• Substantial research needs