This Webinar Will

- Explain what patient-reported outcome measures are and why you would want to use them
- Describe the goal of PROMIS
- Describe how PROMIS measures are made and tested
- Show you how to access & use PROMIS measures
Examples of Patient Outcome Measures

• 6-minute walk test
• Observer Rating - Functional Impact Measure
• Patient Report (e.g. 0-to-10 pain scale)
Why PRO’s have become important health data

- Survival not a sufficient measure of health
- Sky-rocketing health care costs require focus on outcomes
- Some health outcome data can only come from patient reports
- Some health outcome data not practical to collect by other means
- Some health outcome data less burdensome to collect through PRO’s
PROMIS asks patients to report on their...

- Social Activity
- Physical Activities
- Activities of Daily Living
- Cognitive Functioning
- Emotions
For example, PROMIS® *Pain Behavior* item

**In the past 7 days**

**When I was in pain I walked with a limp or distorted gait**

- Had no pain
- Never
- Rarely
- Sometimes
- Often
- Always

Source: PROMIS Network
Why are PROs Necessary?

Reported Change in Overall Patient Quality of Life

(Jachuck et al., 1982)
Percent of patients who lost job within 1 year at each level of self-reported health

- < 35: 40%
- 35-44: 25%
- 45-54: 15%
- > 55: 5%
Percent of patients who died within 5 years at each level of self-reported health

Scores on Self-Reported Physical Health - From Poor to Good Health
Translational Research

- T1 -- Clinical Trials
- T2 -- Comparative effectiveness
- T3 – Quality improvement
- T4 – Personalized care

Population Sciences

- Registries
- National surveys
- Health and social policy evaluations
Same Number, Different Measure, Different Meaning
Dramatic Example of the Problem

Respondents, But Different Questions = Different Meanings

Source: Brazier et al., 1992
## Major Barrier to PRO Measurement

Lack of standardization in PRO measurement

<table>
<thead>
<tr>
<th>CONTENT</th>
<th>PDQ-39</th>
<th>PDQL</th>
<th>PIMS</th>
<th>PLQ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking</td>
<td>2</td>
<td>2</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Self-Care</td>
<td>5</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Speech</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cognition</td>
<td>2</td>
<td>2</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Tremor</td>
<td></td>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Pain</td>
<td>2</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Sleep</td>
<td></td>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Depression</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Anxiety</td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Close Relationships</td>
<td>3</td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Work</td>
<td></td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Leisure Activities</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**TIME FRAME**
- 1 Month
- 3 months
- Unspec.
- 1 Week

**RATING**
- Freq
- Freq
- Impact
- Varies
How did this Happen?

• Different *levels* of health require different questions
• Different *types* of health require different questions
• Different health conditions require different questions
• Cannot practically ask all of these questions of everyone
• No centralized, coordinated, adequately funded/staffed initiative to create standard measures
Clinical Outcomes Assessment: PROMIS

Overview

As part of the NIH Roadmap for Medical Research, the PROMIS (Patient-Reported Outcomes Measurement Information System) initiative is developing new ways to measure patient-reported outcomes (PROs), such as pain, fatigue, physical functioning, emotional distress, and social role participation that have a major impact on quality-of-life across a variety of chronic diseases. Clinical measures of health outcomes, such as x-rays and lab tests, may have minimal relevance to the day-to-day functioning of patients with chronic diseases. Often, the best way patients can judge the effectiveness of treatment is by changes in symptoms. The goal of PROMIS is to improve the reporting and quantification of changes in PROs.

This initiative applies to a wide range of disorders including cancer, congestive heart failure, depression, arthritis, and multiple sclerosis, as well as chronic pain conditions. PROMIS is creating new paradigms for how clinical research information is collected, used, and reported. The PROMIS initiative has been funded in the clinical research community for a rigorously tested PRO measurement tool that utilizes recent advances in information technology, psychometrics, and qualitative, cognitive, and health survey research.

The PROMIS program is developing a computerized adaptive testing (CAT) system, based on item response theory (IRT), to administer these items. In addition, it is developing a web-based system to give clinical researchers access to the item banks and the CAT system. Whether administered through an iterative CAT system, that allows research flexibility, or by paper version short forms, PROMIS has already demonstrated improved efficiency and sensitivity in comparison with existing PROs. Long-term trials are planned to address issues of validity and sensitivity to change in clinical populations. The increased efficiency, flexibility, and sensitivity of PROMIS holds potential to become a widely accepted, standardized PRO measurement tool that will allow greater comparison among PRO studies with reduced burden on patients.

As the PROMIS initiative moves into a second phase of research, it will continue to advance the field of patient self-reporting in clinical research and practice, by...
PROMIS Covers Many Aspects of Health

PROMIS Adult Self-Reported Health

**Physical Health**
- Physical Function
- Pain Intensity
- Pain Interference
- Fatigue
- Sleep Disturbance

**Mental Health**
- Depression
- Anxiety

**Social Health**
- Ability to Participate in Social Roles & Activities

PROMIS Profile Domains

PROMIS Additional Domains
- Pain Behavior
- Pain Quality
- Sleep-related Impairment
- Sexual Function
- Gastro-Intestinal Symptoms
- Dyspnea

- Anger
- Cognitive Function
- Alcohol Use, Consequences, & Expectancies
- Psychosocial Illness Impact
- Self-efficacy
- Smoking

- Satisfaction with Social Roles & Activities
- Social Support
- Social Isolation
- Companionship

03/28/2014
Adaptive Assessments

Source: PROMIS Network
P = 0.50

"Easy" item

Probability of specified response

Amount of Trait

less          more

P = 0.50

"Hard" item

Probability of specified response
Items Positioned Along a Continuum Based on Analysis of Patient Responses

1. Are you able to eat?
2. Are you able to get in and out of bed?
3. Are you able to stand without losing your balance for 1 minute?
4. Are you able to walk from one room to another?
5. Are you able to walk a block on flat ground?
6. Are you able to run or jog for two miles?
7. Are you able to run five miles?

Source: PROMIS Network
1. Begin with initial score estimate

2. Select & present optimal scale item

3. Score response

4. Re-estimate health score and confidence interval

5. Is stopping rule satisfied

6. End scale assessment

7. End of battery?

8. Administer next scale

9. Stop

Source: Adapted from Wainer et al. (1990)
Estimate of Person’s “Place” on the health concept continuum gets more precise with every question.

Standard Error of Measurement decreases with each question.

Q1:
Q2:
Q3:
Q4:
Q5:

Source: PROMIS Network
CAT versus Short Forms

• Short Forms
  – 4, 6, or 8 items targeted at clinical range

• CAT
  – Standard error cutoff = .3
  – Minimum Test Length = 4
  – Maximum Test Length = 12
  – Items calibrated using IRT
CAT versus Short Forms

- 4-item SF36/Vitality
- 4-item CAT
- 13-item FACIT-Fatigue
- 13-item CAT

US General Population mean
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
Domain Frameworks
PROMIS Adult Self-Reported Health

Global Health | Physical Health | Mental Health | Social Health

PROMIS Adult Self-Reported Health

Physical Health
- Physical Function
- Pain Intensity
- Pain Interference
- Fatigue
- Sleep Disturbance

Mental Health
- Depression
- Anxiety

Social Health
- Ability to Participate in Social Roles & Activities

PROMIS Profile Domains
- Pain Behavior
- Pain Quality
- Sleep-related Impairment
- Sexual Function
- Gastro-Intestinal Symptoms
- Dyspnea

PROMIS Additional Domains
- Anger
- Cognitive Function
- Alcohol Use, Consequences, & Expectancies
- Psychosocial Illness Impact
- Self-efficacy
- Smoking

Satisfaction with Social Roles & Activities
- Social Support
- Social Isolation
- Companionship

03/28/2014
Physical Health
Under development.

Physical Health—PROMIS Profile Domains

Fatigue
The PROMIS Fatigue item bank assesses fatigue from mild subjective feelings of tiredness to an overwhelming, debilitating, and sustained state of exhaustion that is likely to decrease one’s ability to carry out daily activities, including the ability to work effectively and to function at one’s usual level in family or social roles. Fatigue is divided conceptually into the experience of fatigue (such as its frequency, duration, and intensity), and the impact of fatigue upon physical, mental and social activities.

Pain Intensity
The PROMIS Pain Intensity item pool assesses how much a person hurts. Patients are usually able to provide quantitative pain intensity estimates relatively quickly, and most measures of pain intensity tend to be closely related to one another. This suggests that pain intensity is a fairly homogeneous dimension, and one that is relatively easy for adults to identify and gauge.

Pain Interference
The PROMIS Pain Interference item bank (adult and child banks) assesses the consequences of pain on relevant aspects of persons’ lives and may include the impact of pain on social, cognitive, emotional, physical, and recreational activities as well as sleep and enjoyment in life (Note that the adult Pain Interference bank includes only one sleep item).

Physical Function
The PROMIS Physical Function item bank assesses one’s ability to carry out activities that require physical actions, ranging from self-care (activities of daily living) to more complex activities that require a combination of skills, often within a social context. “Physical Function” is inclusive of the term “disability” and includes the full spectrum of physical functioning from severe impairment to exceptional physical abilities. The PROMIS Physical Function items assess capability to perform a variety of physical activities, and often begin with the stem “Are you able to ...” Items assessing performance of these activities (the frequency with which physical activities were performed within a specified timeframe), may have great utility for some purposes, but are not included in the physical function item bank. Performance requires not only capability but also opportunity and motivation. The use of capability stems in the PROMIS Physical Function item bank also excludes satisfaction items (e.g., “How satisfied are you with your current level of functioning?”). Such questions address subjective appraisals of oneself that incorporate concepts such as coping or coping.
Fatigue

These published studies involve the domain of Fatigue


Information about What’s Included

Physical Health
Under development.

Physical Health—PROMIS Profile Domains

Fatigue

The PROMIS Fatigue item bank assesses fatigue from mild subjective feelings of tiredness to an overwhelming, debilitating, and sustained sense of exhaustion that is likely to decrease one’s ability to carry out daily activities, including the ability to work effectively and to function at one’s usual level in family or social roles. Fatigue is divided conceptually into the experience of fatigue (such as its frequency, duration, and intensity), and the impact of fatigue upon physical, mental and social activities.

Pain Intensity

The PROMIS Pain Intensity item pool assesses how much a person hurts. Patients are usually able to provide quantitative pain intensity estimates relatively quickly, and most measures of pain intensity tend to be closely related to one another. This suggests that pain intensity is a fairly homogeneous dimension, and one that is relatively easy for adults to identify and gauge.

Pain Interference

The PROMIS Pain Interference item bank (adult and child banks) assesses the consequences of pain on relevant aspects of persons’ lives and may include the impact of pain on social, cognitive, emotional, physical, and recreational activities as well as sleep and enjoyment in life (Note that the adult Pain Interference bank includes only one sleep item).

Physical Function

The PROMIS Physical Function item bank assesses one’s ability to carry out activities that require physical actions, ranging from self-care (activities of daily living) to more complex activities that require a combination of skills, often within a social context. “Physical Function” is inclusive of the term “disability” and includes the full spectrum of physical functioning from severe impairment to exceptional physical abilities. The PROMIS Physical Function items assess capability to perform a variety of physical activities, and often begin with the stem “Are you able to . . .” Items assessing performance of these activities (the frequency with which physical activities were performed within a specified timeframe), may have great utility for some purposes, but are not included in the physical function item bank. Performance requires not only capability but also opportunity and motivation. The use of capability stems in the PROMIS Physical Function item bank also excludes satisfaction items (e.g., “How satisfied are you with your current level of functioning?”). Such questions address subjective appraisals of oneself that incorporate concepts such as coping or
FATIGUE
A brief guide to the PROMIS Fatigue instruments:

<table>
<thead>
<tr>
<th>ADULT</th>
<th>ADULT CANCER</th>
<th>PEDIATRIC</th>
<th>PARENT proxy</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROMIS Item Bank v1.0 – Fatigue</td>
<td>PROMIS – Ca Bank v1.0 Fatigue</td>
<td>PROMIS Pediatric Bank v1.0 – Fatigue</td>
<td>PROMIS Parent Proxy Bank v1.0 – Fatigue</td>
</tr>
<tr>
<td>PROMIS Short Form v1.0 – Fatigue 4a</td>
<td></td>
<td>PROMIS Pediatric Short Form v1.0 – Fatigue 10a</td>
<td>PROMIS Parent Proxy Short Form v1.0 – Fatigue 10a</td>
</tr>
<tr>
<td>PROMIS Short Form v1.0 – Fatigue 6a</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PROMIS Short Form v1.0 – Fatigue 7a</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PROMIS Short Form v1.0 – Fatigue 8a</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ABOUT FATIGUE

The PROMIS Fatigue instruments evaluate a range of self-reported symptoms, from mild subjective feelings of tiredness to an overwhelming, debilitating, and sustained sense of exhaustion that likely decreases one’s ability to execute daily activities and function normally in family or social roles. Fatigue is divided into the experience of fatigue (frequency, duration, and intensity) and the impact of fatigue on physical, mental, and social activities.