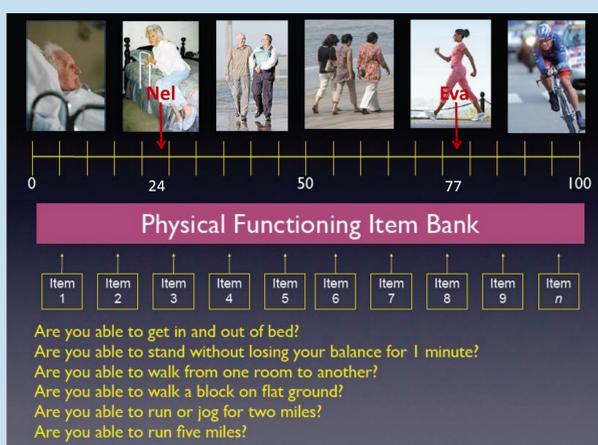


PROMIS: the new gold standard for assessing patient-reported health and quality of life

BACKGROUND

The Patient Reported Outcomes Measurement Information System (PROMIS) is a new, state-of-the-art system for measuring patient-reported health and quality of life of adults and children that is more valid, reliable, and responsive than existing questionnaires. PROMIS consists of a large number of item banks that can be administered in short forms or, more efficiently, through Computerized Adaptive Testing (CAT).



ITEM BANKS AND CAT

An item bank comprises a large collection of questions that measure a common construct (e.g. pain or fatigue). Item banks are calibrated using Item Response Theory (IRT) methods, which model the relationship between a person's score on the construct and the probability of choosing a response on an item. Ordinal items are characterized by two parameters: item discrimination and item difficulty. These parameters are used to estimate a person's score from any subset of items in a bank. Researchers or clinicians can select items that are uniquely targeted to a given group or patient (e.g. select different items for diabetic patients than for arthritis patients). IRT-based item banks also enable Computerized Adaptive Testing (CAT). CAT make it possible to select the most informative items from the item bank for every individual patient according to his or her response to previously administered items. Since items in the bank are calibrated onto the same continuum, the scores obtained from any subset of items are assumed to be comparable to that from the complete bank.



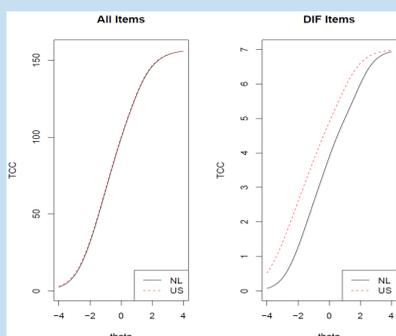
VALIDATION STUDY

METHODS

17 item banks for adults (563 items) and 9 for children (151 items) were translated using standardized methodology. Calibration of three item banks (Pain Behavior, Pain Interference and Physical Functioning) was done in 1046 adults with chronic pain using Item Response Theory analyses. Assumptions were checked and the fit to a Graded Response Model (GRM) was tested. Differential Item Functioning (DIF) was evaluated for age, gender and language. The standard error (SE) of theta (reliability) was evaluated across levels of theta.

RESULTS

Acceptable translations were obtained for all items. Good fit to the GRM model was found for the three item banks. Acceptable information ($SE < 0.3$) for theta was found: -1.9-3.6 for Pain Behavior, -3.3-2.8 for Pain Interference, -1.6-4 for Physical Functioning. Language DIF was found for 19 items, but the impact on total scores was minimal (Figure).

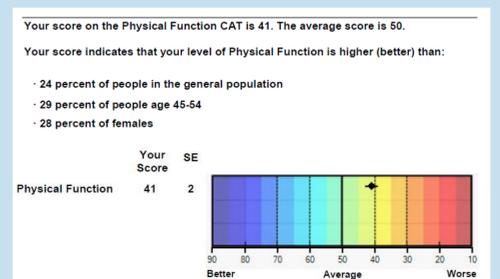


DUTCH PROMIS ITEM BANKS

PROMIS adult item banks	Number of items
Anger	22
Anxiety	29
Depression	28
Fatigue	95
Pain Behavior	39
Pain Interference	40
Physical Function	121
Sleep Disturbance	27
Sleep-related Impairment	16
Ability to Participate in Social Roles and Activities	35
Satisfaction with Social Roles and Activities	44
Companionship	6
Emotional Support	16
Informational Support	10
Instrumental Support	11
Social Isolation	14
Global	10
Total	563

PROMIS pediatric item banks	Number of items
Asthma	17
Anger	5
Anxiety	13
Depressive Symptoms	13
Fatigue	23
Pain Interference	13
Physical Function — Mobility	23
Physical Function — Upper Extremity	29
Peer relationships	15
Total	151

PROMIS REPORT



CONCLUSION

Calibration of the first three item banks was successful. Twelve validation studies are ongoing. It is expected that PROMIS will become the gold standard for assessing patient-reported health and quality of life in all disease populations and will soon replace currently used questionnaire such as SF-36 and EQ-5D.

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