

# The Patient-Reported Outcome Measurement Information System (PROMIS®): International Update

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The Patient-Reported Outcomes Measurement Information System (PROMIS®) seeks to provide a common language for describing lived health and the effectiveness of health interventions—a system that can be embraced universally. PROMIS is designed as a *health-focus concept rather than disease-focused* measurement system which includes, for example, measures of emotional distress, social functioning, pain and many other aspects of health. To be clear, PROMIS is appropriate for use in studies of a single disease and single therapy; in addition, the health-domain focus enables description of the impact of multiple comorbidities and polytherapy, which is appropriate to the experience of most patients and an aging population.

Begun in 2004, and sponsored by the US National Institutes of Health (NIH) Common Fund (<http://commonfund.nih.gov/promis/>),<sup>1</sup> PROMIS' item banks for each health concept are scored according to Item Response Theory (IRT) to enable administration via Computer Adaptive Testing (CAT) technology for ease of use and reduction of respondent burden.<sup>2</sup> The objective is to standardize the metric of the health domain, even though patients are asked questions customized to their level of health.<sup>3</sup> Studies to date demonstrate the success of this method in maintaining precision while reducing the number of questions asked of the respondent.<sup>4</sup> The PROMIS network is in its second funding cycle and has expanded to include 13 primary research sites supported by three centers of excellence (for more information, see: <http://nihpromis.org>).

Since the last publication about PROMIS in this newsletter five years ago,<sup>5</sup> the PROMIS system of five item banks has expanded to include IRT calibrated assessment of 21 health concepts for adults, and nine for children, with many

more item banks under development (see first column of the table below for a list of calibrated item banks). A multi-cultural perspective was incorporated into PROMIS item-bank development at the outset by requiring each item to undergo a systematic evaluation protocol called “translatability and cultural harmonization review.”<sup>6</sup> This assessment identifies potential conceptual or linguistic difficulties inherent in the proposed item design which may be addressed through item revisions or, in rare cases, may require that the item not be used because it is highly specific to a particular culture.

The translation method used by the PROMIS network is a systematic, multistage process of forward and backward translations and multiple reviews that are characteristic of the most effective multinational translation protocols.<sup>7</sup> A universal approach to translation has been adopted, seeking to produce one language version for multiple countries instead of country-specific versions of the same language.<sup>8</sup> The initial focus of this approach is to identify the commonalities rather than the differences, ensuring that the translation does not contain wording that is offensive or inappropriate to a particular subgroup. Pre-testing with cognitive debriefing in the target country/countries confirms the appropriateness of the translation or results in modifications.

Nearly all PROMIS banks have been translated into Spanish and a few are also available in German. Currently, almost all calibrated adult item banks as well as the pediatric item banks are being translated into Dutch, Portuguese, and Mandarin Chinese. The Emotional Distress adult and pediatric item banks are also being translated into Hebrew. Groups of researchers in Canada and Japan have initiated collaborative arrangements to seek funding and coordinate item bank

## KEYWORDS

COMPUTER ADAPTIVE TESTING (CAT) TECHNOLOGY, ITEM BANK, ITEM RESPONSE THEORY (IRT), PATIENT-REPORTED OUTCOMES, TRANSLATION

translations into French and Japanese respectively. PROMIS translation activities are coordinated by the PROMIS Statistical Center (PSC) which seeks to ensure uniform quality across these efforts and harmonization between languages. While the PSC is involved in most of the measure translations, it grants permission to other organizations to conduct translations and/or collaborates in translation projects initiated by other investigators or organizations.

The table below summarizes the status of PROMIS adult and child item-bank translations. PROMIS also includes fixed-format assessments for most item banks in a variety of lengths. The fixed-format assessments encompass fewer items than the item-bank assessments and so many more language translations are either available or in process for those including Italian, Danish, Norwegian, Swedish, Korean, Afrikaans, many Slavic languages (e.g., Bulgarian, Hungarian, Lithuanian, Latvian, Polish, Russian, Romanian), and many Indian languages (Bengali, Gujarati, Hindi, Kannada, Marathi, Malayalam, Punjabi, Tamil, and Telugu). As might be expected, the most translated item banks are those that were developed first: anger, anxiety, depression, fatigue, pain behavior, pain interference, physical and social functioning: each of these has four or more translations complete or in process.

During this second funding cycle, the PROMIS network of investigators is engaging with investigators from other countries to promote the development of PROMIS internationally. Investigators in Germany have received funding from the German government to clinically validate the PROMIS pediatric item banks when translated versions are available. The 18<sup>th</sup> Annual Conference of the International Society of Quality of Life Research (Denver, Colorado, USA, October 2011) was the occasion of an informational exchange and brainstorming session among PRO investigators from Australia, Canada, France, Germany, Spain and the UK, many of whom had been involved in the IQOLA and Who-QOL projects.

This meeting gave rise to a partnership including the six countries and associated institutions.

This collaboration is applying to the European Union for funding to adapt and integrate PROMIS for use in comparative effectiveness research in countries belonging to the EU. Other international collaborations are in the planning stages. These include the integration of PROMIS Sexual Functioning item banks with EORTC measures to develop a culturally harmonized sexual functioning item bank, and the development of a standard multicultural PROMIS short form by a team of investigators from 10 different countries, planned for the coming year. An important consideration for multinational collaborations will be the investigation of Differential Item Function (DIF) across cultures. Statistical evaluation of the validity of cultural adaptations of PRO health assessments is not new;<sup>9</sup> however, standard procedures for investigating DIF cross-culturally require further research and development. The conduct and interpretation of such analysis is complicated by differences among comparator groups in addition to language and culture which must also be evaluated in selecting anchor items.<sup>10</sup> Also under consideration by the NIH are country-specific PROMIS websites. Details to enable this possibility are currently being resolved.

In these efforts and others to expand the development of PROMIS, we want to emphasize the importance of coordination, collaboration, and communication. Measurement is enhanced by standardization, which requires working together to protect the integrity of the measures. Contact information for the PROMIS effort is available at [www.nihpromis.org](http://www.nihpromis.org).

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Table 1.

Patient-Reported Outcomes Measurement Information System: Summary of Translations √=translation completed; \*=translation in process

ITEM BANKS	Spanish	German	Dutch	Mandarin Chinese	Portuguese	Hebrew
<b>Adult</b>						
Anger	√		*	*		*
Anxiety	√	*	*	*	*	*
Depression	√	√	*	*	*	*
Fatigue	√		*	*	*	
Pain Behavior	√		*	*	*	
Pain Interference	√	√	*	*	*	
Pain Intensity	√					
Physical Functioning	√		*	*	*	
Sleep Disturbance	√		*	*	*	
Sleep-Related Impairment	√		*	*	*	
Satisfaction with Participation in Discretionary Social Activities (v1.0)	√	√	*	*	*	
Satisfaction with Participation in Social Roles (v1.0)	√	√	*	*	*	
Satisfaction with Social Roles and Activities (v2.0)	√		*			
Ability to Participate in Social Roles and Activities	√		*			
Emotional Support	√		*			
Informational Support	√		*			
Instrumental Support	√		*			
Companionship	√		*			
Social Isolation	√		*			
Applied Cognition Abilities	√					
Applied Cognition Concerns	√					
Positive Illness Impact						
Negative Illness Impact						
<b>Pediatric</b>						
Asthma Impact	√		*		*	
Anger	√		*	*	*	*
Anxiety	√		*	*	*	*
Depressive Symptoms	√		*	*	*	*
Fatigue	√		*	*	*	
Pain Interference	√		*	*	*	
Peer Relationships	√		*	*	*	
Physical Functioning-Mobility	√		*	*	*	
Physical Functioning-Upper Extremity	√		*	*	*	

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