

SUMMARY REPORT: SYNTHESIS OF PUBLIC COMMENTS SUBMITTED TO PCORI RELATING TO PROMIS

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Background

The NIH Patient Reported Outcomes Measurement Information System (PROMIS) began in 2004 as a time-limited (10-year) initiative of the Common Fund. The objective of the initiative was to develop and evaluate item banks (questions about health status and wellbeing) for clinical research and demographic analysis and to support development of precise and reliable short-form measurement and survey instruments. Initially designed as an inventory, advances in modern measurement theory have made it possible to further develop and maintain item banks, to compare across survey items, and to create computerized adaptive testing that allows item subsets to be tailored to the individual. These new technologies have enabled PROMIS to evolve into a tool that now allows researchers to construct unique and customizable survey instruments for patient reported outcomes. Despite these technological advances, data elicited through existing patient questionnaires are not always aligned with outcomes that are of particular salience to the patient experience.

On January 15, 2014, PCORI published a Request for Information (RFI), *Seeking Input on Future PROMIS Research*, to gather input and ideas from patient groups and other stakeholders (i.e., those who have an interest in the design or use of PROMIS measures and tools) about potential areas for future research related to PROMIS. In broad terms, PCORI sought input on opportunities to support or expand existing PROMIS research areas, and to support new research incorporating PROMIS measures. Specifically, PCORI asked stakeholders to comment upon opportunities to

- Develop new item banks within PROMIS to aid with evaluation of care quality and the patient experience of clinical care;
- Fill research gaps in patient-centered CER for which PROMIS measures could contribute to outcomes assessment;
- Expand use of PROMIS measures in clinical care;
- Evaluate performance of PROMIS item banks across diverse clinical populations and settings;
- Maintain or expand the PROMIS infrastructure with a focus on models for sustainability; and
- Use PROMIS measures in regulatory approval for new drugs, devices, and diagnostics, including opportunities for measure qualification by the Food and Drug Administration.

Methodology

NORC received the comments for analysis from PCORI as an emailed collection of attached responses that had been submitted through the website, via email, and as Word documents or PDFs. A team of NORC researchers divided and read through the responses, categorizing them by respondent type and developing a list of codes that could be used to note themes for each comment entry. The starting point for developing organizational categories was the list of potential stakeholders identified in the PCORI RFI.

Coding

NORC started with the list of issues that PCORI had highlighted in the RFI to identify predefined themes for each response. After initial reads of the responses, the team met to discuss comments that did not fit readily into the initial thematic categories. In such cases, we added thematic categories, typically breaking down a single category into two or more. For example, the single category, “Opportunities to develop new item banks within PROMIS to aid with evaluation of care quality and the patient experience of clinical care” became three new categories, including “new item banks”, “evaluation of care quality”, and “applications in clinical care;” we chose this approach because these comments did not specifically address the original question. We provide a list of themes that were used to organize and code the responses in Appendix A. These themes were used to populate the left column of an Excel spreadsheet, while respondent types were used to populate the top row of the spreadsheet. For each of the 17 responses, we entered representative quotes or summarized key points from the submissions and entered them into the Excel file.

Counting and Summarizing Themes

We tallied the number of comments falling within each of the final twelve thematic categories. These comments are summarized in the following section of this memorandum. Some responses to the RFI presented a single point; others offered more than a dozen distinct observations or recommendations that fell under several categories. In some cases, a single comment appears under two different themes. For example, “Evaluate PROMIS measures in both clinical and research practice settings to support their integration into routine clinical care and clinical research” appears under both “Applications: Research” and “Applications: Clinical.”

Characterization of Respondents

A total of seventeen responses to the PCORI RFI were received. Most responses (12 of 17) were submitted by organizations or individuals who are involved in research activities (i.e., academic research centers, individual researchers, or research collaboratives). The remaining 5 responses originated from various stakeholders, including consumer organizations, a payer/ purchaser, and a data organization. Seven of the

respondents indicated that their comments had been developed in consultation with patients/ stakeholders. Respondent types are listed below.

Types of Respondents		
Research-Affiliated	Academic Research Center	5
	Individual Researcher	4
	Research Collaborative	3
Other Stakeholder Types	Consumer Organization	3
	Payer/Purchaser	1
	Data Organization	1
Total Submissions		17

Analysis of Comments

Theoretical Foundations of PROMIS

One response from a research collaborative recommended the development of a theoretical model of perceived health that explicates uni-dimensional health attributes (concepts measurable with an item bank), and that compares this approach with other models and empirically tests the model.

Applications/Use of PROMIS

Twenty-six specific comments from 12 respondents addressed applications or uses of PROMIS measures. Six comments referred to research applications; 7 to use in clinical care settings; 3 respondents commented on opportunities for use of PROMIS measures in regulatory approval for new drugs, devices and diagnostics including opportunities for measure qualification by the FDA; and one proposed the development of tools based on PROMIS for patient communication.

New Item Banks and Evaluation of Item Banks

Sixteen respondents offered suggestions for new item banks. These are organized into subcategories including pediatric, disease-specific, caregivers, developmental disabilities, women’s health and childbirth, medical devices, and others. Each of these categories had two or three responses, except for applications for medical devices, which had one. Three commenters recommended that item banks and applications be developed for children. Three respondents suggested evaluating or adapting PROMIS measures for specific diseases, including establishing a core set of data elements and use of disease registries. Two respondents noted the need to develop and evaluate caregiver proxy item banks for elders or other cognitively impaired adults, and for a quality of life profile for caregivers of children with rare diseases. Two respondents noted that PROMIS has not been evaluated for developmentally disabled populations. They suggested that research is needed to determine: what skills are required to be able to self-report, to evaluate the psychometrics of self-

report, and to develop measures for early identification of developmental disorders. Two respondents proposed developing item banks for patient-reported outcomes in pregnancy or childbirth, particularly as a mechanism for provider performance evaluation. Four commenters addressed the need to evaluate item banks with respect to specific populations or in collaboration with patients.

Translation/Crosswalks among Indices and Coordination with Existing Instruments Gaps

Seven respondents proposed research or analysis to establish crosswalks between PROMIS domains and instruments with existing multi-attribute indices, or to develop a universal taxonomy of domains, similar to the recommendation for a theoretical model that maps to underlying, one-dimensional health attributes.

Adaptations of PROMIS

Six commenters noted the need for research to adapt PROMIS tools for diverse population and clinical settings, including disadvantaged populations and subpopulations that have not been included in the design of current measures.

Measurement Refinement and CAT/IRT

Eight responders offered suggestions for further statistical or methodological refinements and testing of PROMIS measures, particularly assessing the relative performance of generic and disease-specific instruments. One commenter noted the need for establishing minimum clinically important differences in scores. An additional four comments addressed applications of Computer Adaptive Testing (CAT) or Item Response Theory (IRT) to advance measurement.

Incorporation in Health IT/Electronic Health Record (EHR) Systems

Four commenters suggested employing or integrating PROMIS measures in EHRs or personal (consumer accessible) health records.

Communication and Dissemination

Six respondents had comments relating to communication and dissemination, including communication with patients (2), providers (2), and stakeholders (1), and one comment relating to improving understanding of PROs and the selection and application of specific metrics.

Sustainability of PROMIS

Notably, only one response (from a research collaborative) directly addressed sustainability, and the need to address the “value added” and return on investment. This analysis would include any adverse outcomes to patients using PROMIS. The response also called for research on the infrastructure, education, and training needed to support the use of PROMIS in clinical settings.

Appendix A

The following is a list of themes used to organize and code the responses received by NORC

- Theoretical foundations of PROMIS framework
- Applications/Uses of PROMIS
- New Item Banks
- General Evaluation of Item Banks
- Translation/Crosswalks
- Coordination/Compatibility with Existing Instruments
- Adaptations of PROMIS
- Measurement Refinement
- Computer Adaptive Testing (CAT)/ Item Response Theory (IRT)
- Health IT/ EHR Systems
- Communication/Dissemination
- Sustainability of PROMIS