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### Authors

Edelen, Maria Orlando

Hays, Ron D

Herman, Patricia M

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## Introducing the PROMIS-16 profile 1.0

Maria Orlando Edelen<sup>1,2</sup> · Ron D. Hays<sup>3</sup> · Patricia M. Herman<sup>4</sup>

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This special section introduces the Patient-Reported Outcomes Measurement Information System (PROMIS®) [1] 16-item Profile (PROMIS-16). The motivation for its development was to provide a brief multiple-scale option suitable for assessing patients in clinical care and for researchers needing a parsimonious health-related quality of life (HRQoL) measure. Many researchers and clinicians want to include PROMIS measures in their battery of assessments but have limited bandwidth for additional items. This has led to uptake of the 10-item PROMIS Global-10 [2], a measure that yields global mental and physical HRQoL summary scores, but no domain-level information, which limits its usefulness. In contrast, the PROMIS-16 assesses eight HRQoL domains: physical function, cognitive function, ability to participate in social roles, pain interference, fatigue, sleep disturbance, depression, and anxiety. Like other PROMIS Profile measures, one can also estimate the physical and mental HRQoL summary scores from the PROMIS-16. Its inclusion of the cognitive function domain makes it possible to calculate the PROPr preference-based score for use in economic evaluations [3].

The development of the PROMIS-16, described in the first paper in this section, included rigorous empirical analyses of a 50-item candidate set using data from a large online panel, extensive discussion and feedback from a 13-member stakeholder group, and input from a small sample of adults. The remaining four papers in this section evaluate

the performance of the PROMIS-16 domain, summary, and PROPr scores relative to comparable scores from the PROMIS-29+2 [4] scores, and sensitivity to change in domain scores over time. Three of these papers used data independent of the development sample from members of a large nationally representative online panel.

The PROMIS-16 is an ideal screening tool for clinical care that can help clinicians quickly identify distinct areas of concern for further assessment and follow-up. In addition, it allows researchers to assess multiple HRQoL domains in their studies with minimal burden. Because the scores are in the T-score metric used across PROMIS (mean = 50, SD = 10), users can consult the health measures website for score interpretation (<https://www.healthmeasures.net/score-and-interpret/interpret-scores/promis/promis-score-cut-points>), including suggested cut scores signifying within normal limits, mild, moderate and severe scores relative to the general adult population.

The team of developers is aligned with the stakeholder panel in recognizing the importance of being transparent about the limitations of measuring constructs with only two items. While the initial results indicate strong psychometric performance of the PROMIS-16 scores, the advantages of a shorter instrument with fewer items per domain come at some cost to precision. Regardless of how it is deployed in routine clinical care, users should be mindful that, with two items per domain, the PROMIS-16 domain scores are just the first step in gaining insight into a patient's standing on a given domain. Any concerning scores should be followed up with further inquiry. To that end, it is recommended that PROMIS-16 domain scores be used for screening and monitoring purposes in clinical care. For example, a screening program using the PROMIS-16 could trigger the administration of domain-specific follow-up questions for patients with scores in the moderate to severe range on a given domain. Similarly, when used for research purposes, the PROMIS-16 domain scores are ideal for supporting the validation of other measures or providing information about respondents' physical and mental HRQoL when those are not the primary focus for the study.

✉ Maria Orlando Edelen  
orlando@rand.org

<sup>1</sup> RAND Corporation, Behavioral and Policy Sciences, 20 Park Plaza #920, Boston, MA, USA

<sup>2</sup> Patient Reported Outcomes, Value and Experience (PROVE) Center, Department of Surgery, Brigham and Women's Hospital, Boston, MA, USA

<sup>3</sup> Division of General Internal Medicine and Health Services Research, UCLA Department of Medicine, Los Angeles, CA, USA

<sup>4</sup> RAND Corporation, Behavioral and Policy Sciences, 1776 Main Street, Santa Monica, CA, USA

In both clinical care and research, the physical and mental health summary scores and PROPr scores are comparable to those generated from the PROMIS-29+2, thus representing a highly efficient option for ongoing population surveillance. In addition, physical and mental health summary scores can be used to estimate the widely used PROMIS Global-10 summary scores. However, users need to consider whether a more robust instrument would be preferable for situations in which mental or physical HRQoL and/or HRQoL economic evaluation are the focus of the study.

The overarching goal of the PROMIS-16 effort was to increase the accessibility of domain-level HRQoL measurement in clinical care and research. The study team started with state-of-the-science elements, conducted robust empirical analyses, included extensive input from nationally recognized stakeholders, and considered the patient perspective in selecting the final items. Although further research is needed to evaluate the performance of the PROMIS-16 in distinct clinical and research applications, the initial reliability and validity evidence presented in the papers in this section provides strong support for the usefulness of the PROMIS-16. Interested users can access the PROMIS-16 at <https://www.healthmeasures.net/>, and questions about its performance can be directed to Maria Orlando Edelen ([orlando@rand.org](mailto:orlando@rand.org)).

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