ELSEVIER

Journal of Clinical Epidemiology ■ (2015) ■

Journal of Clinical Epidemiology

REVIEW ARTICLE

Pragmatic characteristics of patient-reported outcome measures are important for use in clinical practice

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Accepted 14 March 2015; Published online xxxx

Abstract

Objectives: Measures for assessing patient-reported outcomes (PROs) that may have initially been developed for research are increasingly being recommended for use in clinical practice as well. Although psychometric rigor is essential, this article focuses on pragmatic characteristics of PROs that may enhance uptake into clinical practice.

Study Design and Setting: Three sources were drawn on in identifying pragmatic criteria for PROs: (1) selected literature review including recommendations by other expert groups; (2) key features of several model public domain PROs; and (3) the authors' experience in developing practical PROs.

Results: Eight characteristics of a practical PRO include: (1) actionability (i.e., scores guide diagnostic or therapeutic actions/decision making); (2) appropriateness for the relevant clinical setting; (3) universality (i.e., for screening, severity assessment, and monitoring across multiple conditions); (4) self-administration; (5) item features (number of items and bundling issues); (6) response options (option number and dimensions, uniform vs. varying options, time frame, intervals between options); (7) scoring (simplicity and interpretability); and (8) accessibility (nonproprietary, downloadable, available in different languages and for vulnerable groups, and incorporated into electronic health records).

Conclusion: Balancing psychometric and pragmatic factors in the development of PROs is important for accelerating the incorporation of PROs into clinical practice. Published by Elsevier Inc.

Keywords: Patient-reported outcomes; Psychometrics; Utility; Measures; Scales; Quality of life

Introduction

Measurement is a vital aspect of patient care, necessary for diagnosis, grading of disease severity, estimating prognosis, and monitoring and adjusting treatment. However, not all relevant outcomes can be assessed with a device, a laboratory test, a physical finding, or some other data gathered independent of the patient's perceptions and voice. Symptoms, health-related quality of life, and certain other domains rely exclusively or predominantly on patient-articulated feelings and experiences and therefore depend on reliable and valid patient-reported outcome (PRO) measures. Indeed, the National Institutes of Health has recognized the importance of PROs by investing heavily in the development of the Patient-Reported Outcome Measurement Information Systems (PROMIS) scales [1] freely available at www.promis.org.

In this article, we propose several factors to consider when developing a practical PRO measure. By practical, we mean those features that will enhance a measure's adoption and use in clinical practice. William James [2], a founder of the pragmatic school of American philosophy,

Conflict of interest: None.

Funding: This work was supported by a Department of Veterans Affairs Health Services Research and Development Merit Review award to K.K. (IIR 07-119), VA Career Development Award to J. K. (CDA IK2RX000879), and National Institute of Aging R01 award to P.O.M. (R01 AG043465). The sponsor had no role in study design; in the collection, analysis, and interpretation of data; in the writing of the report; or in the decision to submit the article for publication. The views expressed in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs.

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http://dx.doi.org/10.1016/j.jclinepi.2015.03.023
0895-4356/Published by Elsevier Inc.

What is new?

Key points

- Clinical uptake of patient-reported outcome (PRO) measures requires pragmatic and psychometric considerations.
- Eight pragmatic characteristics include actionability, setting appropriateness, universality, self-administration, item features, response options, scoring, and accessibility.
- Examples from the literature and public domain PROs such as the Patient Health Questionnaire and Patient-Reported Outcomes Measurement Information System scales as well as other PROs exemplify these pragmatic considerations.

defined truth as that ''which works'' or has ''cash value.'' The ''cash value'' of a PRO is its relevance to patient care.

The practical characteristics outlined in Table 1 do not include the classical psychometric requirements of a scale, such as reliability or validity, nor do they speak to the many basic and advanced procedures for scale development (e.g., item selection, cognitive testing, differential item functioning, item response theory). Psychometric standards are a given and well described in consensus reports on PROs [3,4]. Indeed, most PROs gravitate from research into practice, and practical considerations should not override the necessity for psychometric rigor in scale development. Table 2 compares our pragmatic recommendations with those of several other groups [5–7], although the latter groups may sometimes use alternative terms or raise different issues related to the eight characteristics and suggest other practical considerations.

Scale development is often a low priority for sponsors that support biomedical research, thereby constraining the funding available for evaluating every psychometric nuance of a PRO. This is especially true when a measure is developed and ''second-generation'' questions arise, such as: (1) differences between modes of administration (e.g., self-report vs. interview; patient vs. proxy; in-person vs. telephone); (2) standards for translating into different languages; (3) abbreviating or modifying versions of the original measure. Therefore, we advocate a balance between psychometric and pragmatic values in all stages of PRO development and validation.

The OMERACT guidelines exemplify a similar balance even for outcome measures used in clinical trials by not only recommending truth and discrimination as psychometric criteria but also feasibility (e.g., can the measure be applied easily, given constraints of time, money, and interpretability?) as a pragmatic criterion [8].

1. Actionability

The utility of a PRO in clinical practice is enhanced when providers know how to translate scores into concrete actions, such as further diagnostic evaluation or testing, treatment initiation or adjustment, or subspecialty referrals [5,9]. Simply providing more data to busy practitioners who already have enormous competing demands for their time in a clinical encounter often limited to 15 minutes or less can be more frustrating than empowering [10,11]. On the other hand, data that efficiently inform specific actions will be embraced. For example, a high depression score prompting an increase in the antidepressant dose can be as useful as an increased serum cholesterol that leads to modifying lipid-lowering therapy. A useful preference-based question asks patients if they desire treatment for their symptoms [12,13]. This provides a patient-centered criterion for interpreting PRO scores in the individual person because different patients may desire (or alternatively refrain from) treatment at different symptom thresholds.

What factors might make a PRO not actionable in a particular clinical setting?

a) The target of the PRO may be outside the purview of a particular clinician who in turn lacks referral options. For example, social functioning is a domain many physicians neither have the skills nor resources to address. Thus, unless a social work referral or community resource is readily available, knowledge of impaired social functioning in the absence of explicit actions to efficiently address these impairments can be demoralizing for the clinician and offer false hope to the patient.

b) The target may be within the purview of the clinician but resource contingent, such that in the absence of these resources, use of the PRO will not benefit patient outcomes. For example, multiple trials have shown that depression screening alone does not enhance outcomes [14], but depression screening combined with other systems enhancements does [15]. This has led the US Preventive Services Task Force to recommend use of a depression screening measure only if systems are in place to adequately optimize depression outcomes [16].

c) The domain assessed by the PRO may be excessively bundled, in which case a particular score cannot inform a targeted action without efforts by the clinician to conduct a differential diagnosis of what may be leading to an increased score and then determine what is and is not actionable. For example, a physical function or role function score may be abnormal due to numerous medical and nonmedical factors. However, there is no discrete ''physical function'' or ''role function'' pill, procedure, or other specific therapy. Still, such summary scores might be useful at a higher level (e.g., assessing quality of care or system-based interventions provided to patient panels or populations).