

# A systematic review highlights the need to investigate the content validity of patient-reported outcome measures for physical functioning in patients with low back pain

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## Abstract

**Objectives:** To summarize the evidence on content and structural validity of 17 patient-reported outcome measures (PROMs) to measure physical functioning in patients with low back pain (LBP).

**Study Design and Setting:** MEDLINE, EMBASE, CINAHL, PsycINFO, SportDiscus, and Google Scholar were searched (February 2017). Records on development and studies assessing content validity or unidimensionality in patients with LBP were included. Two reviewers defined eligible studies and assessed their methodological quality with updated Consensus-based Standards for the Selection of Health Measurement Instruments standards. Evidence was synthesized for three separate aspects of content validity: relevance, comprehensiveness, and comprehensibility, and for unidimensionality, a modified GRADE approach was applied to evidence synthesis.

**Results:** High-quality evidence showed that 24-item Roland Morris Disability Questionnaire (RMDQ-24) is a comprehensible but not comprehensive PROM. Low to very low quality evidence underpinned the content validity of the other PROMs. Unidimensionality was: sufficient for Brief Pain Inventory pain interference subscale (moderate quality evidence); inconsistent for RMDQ-23, Oswestry Disability Index 2.1a (ODI 2.1a), and Quebec Back Pain Disability Scale (moderate quality); insufficient for RMDQ-24, ODI 1.0, and RMDQ-18 (high quality) and Short Form 36 physical functioning subscale (SF36-PF, moderate quality).

**Conclusion:** The content validity of PROMs to measure physical functioning in patients with LBP is understudied. Structural validity of several widely used PROMs is problematic. © 2017 Elsevier Inc. All rights reserved.

**Keywords:** Patient-reported outcome measures; Physical functioning; Low back pain; Content validity; Unidimensionality; COSMIN

## 1. Introduction

Low back pain (LBP) is a burdensome and costly health condition that affects many individuals and health care systems [1,2]. Thus, measurement of its impact on patients is

important in clinical research and practice [3]. Physical functioning is considered by researchers, clinicians and patients to be the most important outcome domain to measure in LBP clinical trials [4]. Most frequently, patient-reported outcome measures (PROMs) are used to measure this domain, especially the Oswestry Disability Index (ODI) and the Roland Morris Disability Questionnaire (RMDQ) [5,6]; these two measurement instruments have also been recommended by international standardization initiatives [7–11].

The choice of an adequate instrument is strongly determined by its validity, that is, the extent to which it accurately measures what is supposed to measure [12]. The Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) taxonomy distinguished five subdomains of validity [13], among which content validity is the first one to be considered when

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### What is new?

#### Key findings

- The quality of evidence on content validity of most patient-reported outcome measures (PROMs) to measure physical functioning in patients with low back pain (LBP) is insufficient to draw any firm conclusion about this measurement property.
- High quality evidence suggests that RMDQ-24, RMDQ-18, and ODI 1.0 are not unidimensional tools. Less robust evidence suggests BPI-PI is unidimensional and SF36-PF is not; for RMDQ-23, ODI 2.1a, MPI-PI, and QBPDS results are inconsistent.

#### What this adds to what is known?

- This is the first systematic review to thoroughly assess the content validity of these widely used PROMs.
- Our findings do not support the use of total scores of RMDQ-24, ODI 1.0, RMDQ-18, and SF36-PF and cast serious doubt on the use of the total scores of RMDQ-23, ODI 2.1a, MPI-PI, and QBPDS.

#### What is the implication and what should change now?

- All included PROMs urgently require thorough assessment of content validity through qualitative research with patients to explore their relevance, comprehensiveness, and comprehensibility for measuring physical functioning in patients with LBP. Head-to-head comparisons of different PROMs would be useful.
- Unidimensionality of various PROMs needs to be better investigated, and the impact of multidimensionality can be documented with bifactor analysis or multidimensional item response theory to determine the most appropriate dimensional structure.

selecting a PROM [14]. Content validity refers to “the degree to which the content of an instrument is an adequate reflection of the construct to be measured” [13]; it deals with the relevance, comprehensiveness, and comprehensibility of a PROM with respect to construct, target population, and context of use of interest [15–17]. Content validity influences all other measurement properties. For example, irrelevant items can lead to poor internal consistency, unidimensionality, and interpretability of a PROM, and a lack of comprehensiveness (i.e., absence of key aspects in an instrument) can reduce responsiveness (Terwee et al., 2017, unpublished data).

Next in importance is structural validity, which refers to “the degree to which the scores of an instrument are an adequate reflection of the dimensionality of the construct to be measured” [14]. Physical functioning is usually considered to be a broad but unidimensional domain. For example, in the Patient-Reported Outcomes Measurement Information System (PROMIS) conceptual framework, it was defined as “one’s ability to carry out various activities that require physical capability, ranging from self-care to more vigorous activities” [18]. In research and practice, the total score of ODI and RMDQ is routinely used, under the implicit assumption that these instruments measure one single domain [19]. Therefore, a PROM selected to measure physical functioning in patients with LBP is expected, first, to have good content validity and, second, to be unidimensional.

Two recent systematic reviews found limited evidence for good content validity and moderate evidence for unidimensionality of the Quebec Back Pain Disability Scale (QBPDS), another well-known and used PROM in LBP [20], and a lack of head-to-head comparisons of content and structural validity between the ODI (version) 2.1a vs. the 24-item RMDQ (RMDQ-24) in patients with LBP [21]. No systematic reviews are available on content and structural validity of ODI, RMDQ, or of other PROMs recommended to measure physical functioning in patients with LBP, such as the PROMIS Physical Function 4-item short form (PROMIS-PF-4) recommended by the National Institutes of Health (NIH) Task Force for research standards in chronic LBP [22].

Any systematic review of PROM content validity should not only include content validity studies but also the original PROM development study and the content of the instrument itself. The COSMIN initiative has recently developed methodological guidance for this type of reviews, with criteria to determine what constitutes sufficient content validity, and a method to integrate methodological quality and results into an evidence synthesis rating system (Terwee et al., 2017, unpublished data). The COSMIN checklist and review methods for other measurement properties (including structural validity) have also been updated (Mokkink et al., 2017 and Prinsen et al., 2017, unpublished data).

The present study applies this COSMIN methodology to systematically review content and structural validity of a set of PROMs to measure physical functioning in patients with LBP [5–7,9–11,22]. This review is embedded within an international multidisciplinary collaboration to develop a core outcome measurement set [23,24] for clinical trials in patients with nonspecific LBP (nsLBP) [4].

## 2. Methods

This systematic review was conducted and reported according to the Preferred Reporting Items for Systematic

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