



# Mixed-methods development of a new patientreported outcome instrument for chronic low back pain: part 1—the Patient Assessment for Low Back Pain - Symptoms (PAL-S)

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#### Abstract

We describe the mixed-methods (qualitative and quantitative) development and preliminary validation of the Patient Assessment for Low Back Plan-Symptoms (PAL-S), a patient-reported outcome measure for use in chronic low back pain (quantitative methods (concept elicitation and cognitive interviews) were used to identify and refine symptom concepts and quantitative methods (dassical test theory and Rasch measurement theory) were used to evaluate him- and scale-level performance of the measure using an terrative approach. Patients with dLBP participated in concept elicitation interviews (N = 43), cognitive interviews (N = 38, and interview based assessment of paper-to-electronic mode equivalence (N = 5). A web-based sample of patients with self-reported cLBP participated in quantitative studies to evaluate preliminary (N = 598) and revised (n = 401) challes and a physician-diagnosed ochort of patients with dLBP (N = 45) participated in preliminary validation of the measure. The PAL-S contained 14 items describing symptoms (overall pain, sharp, pricking, sensitive, tender, radiating shooting, shooting, burning, equesting, musicle spasms, throbbing, admig, and stribest). Item-level performance, scale structure, and scoring seemed to be appropriate. One-week test-west epipodicibility was acceptable (intraciass correlation coefficient 0.8) [95% confidence-interval, 0.61-0.91). Convergent valid by was demonstrated with total score and MOS-38 Bodily Pain (Peason correlation = 0.79), Neuropatric Pain Symptom Inventory (0.73), Reland-Monis Disability Questionaire (0.67), and MOS-38 Physical Functioning (= 0.68), Individual item scores and total score described between numeric string scale tertle groups and pain DETECT categories. Respondent interpretation of paper and electronic administration modes was equivalent. The PAL-S has demonstrated content valid y and is potentially useful to assess treatment benefit in cuBP clinical tities.

Koywords: Patent-reported outcome instrument, Chronic low back pain, Qualitative research

#### 1. Introduction

Lowback pain (LBP), generally described as pain, musde tension, or musde stiffness with or without radiation to the distal lower externity.

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is the second most common cause of disability among adults in the United States. \*\* Athough acute and subscute episodes (those lasting up to 3 months) are the most common presentations of LBP, chronic low back pain (cLBP) is associated with long-term pain and disability.\*\*

Pain has been described as one of the most important domains to be assessed in LBP, along with back-specific function, generor health status, work disability, and patient satisfaction. \*10-10 Pain is one of the best determinants of disability due to cLBP, \*1,000-21 and is predictive of work resumption within the year after related short-term absence. \*10-10 Athough pain and function are interdependent parts of the patient experience, patients often seek care because of pain, and this variable therefore needs to be assessed at baseline and in response to treatment. Because the sewerty of cLBP symptoms is often related to the degree of impairment that patients experience, the assessment of this concept is an essential endpoint for clinical studies. Pain-related function/impairment is an outcome that should also be assessed.

Although various patient-reported outcome (PRC) instruments have been used in dLBP dinical trials, many present pain as a single overall concept, which may not fully capture the pain sensations of cLBP. The use of multidimensional pain assessments that encompass pain-related physical function and psychological factors is recommended to evaluate chronic pain. "" We conducted a review of existing instruments that are currently used to collect patent-reported concepts of pain

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