

# Mixed-methods development of a new patient-reported outcome instrument for chronic low back pain: part 2—The Patient Assessment for Low Back Pain–Impacts (PAL-I)

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## Abstract

We describe qualitative and quantitative development and preliminary validation of the Patient Assessment for Low Back Pain–Impacts (PAL-I), a patient-reported outcome measure for use in chronic low back pain (cLBP) clinical trials. Concept elicitation and cognitive interviews (qualitative methods) were used to identify and refine symptom concepts. Classical test theory and Rasch measurement theory (quantitative methods) were used to evaluate item-level and scale-level performance of the PAL-I using an iterative approach between qualitative and quantitative methods. Patients with cLBP participated in concept elicitation interviews (N = 43), cognitive interviews (N = 38), and assessment of paper-to-electronic format equivalence (N = 8). A web-based sample of self-reported patients with cLBP participated in quantitative studies to evaluate preliminary (N = 598) and revised (n = 401) drafts and patients with physician-diagnosed cLBP (N = 45) participated in preliminary validation of the PAL-I. The instrument contained 9 items describing cLBP impacts (walking, sitting, standing, lifting, sleep, social activities, travelling, climbing, and body movements). Item-level performance, scale structure, and scoring seemed to be appropriate. One-week test-retest reproducibility was acceptable (intraclass correlation coefficient 0.88 [95% confidence interval, 0.78–0.94]). Convergent validity was demonstrated with PAL-I total score and Roland-Morris Disability Questionnaire (Pearson correlation 0.82), MOS-36 Physical Functioning (−0.71), and MOS-36 Bodily Pain (−0.71). Individual item scores and total score discriminated between numeric rating scale tertile groups and painDETECT categories. Interpretation of paper and electronic administration modes was equivalent. The PAL-I demonstrated content validity and is potentially useful to assess treatment benefit in clinical trials of cLBP therapies.

**Keywords:** Low back pain, Patient-reported outcomes, Qualitative research

## 1. Introduction

Low back pain (LBP) is described as “pain, muscle tension, or stiffness localized below the costal margin and above the gluteal folds, with or without leg pain.”<sup>a1,b,20</sup> Low back pain is a common

and painful condition that has been reported to have a global prevalence up to 84% depending on the case definition.<sup>2</sup> The prevalence of chronic LBP (cLBP), defined as LBP with duration >12 weeks,<sup>21</sup> is estimated to be ~23%.<sup>2</sup> Low back pain causes more global disability than any other condition<sup>10</sup> and is frequently work-related. Treatments for cLBP include nonsteroidal anti-inflammatory drugs, acetaminophen, muscle relaxants, opioid pain medications, and physical therapy, which are effective for most patients.<sup>11</sup> For moderate-to-severe pain, epidural steroid injections, facet injections, and radiofrequency ablations are used.<sup>11</sup> Several promising new therapies are in phase 2/3 clinical trials for the treatment of cLBP, including ethanol gel for use in chemonucleolysis protocols (a process of injecting proteolytic enzymes into the intervertebral disk), platelet-rich plasma, stem-cell therapy for disk regeneration, tanezumab (an anti-nerve growth factor antibody) for nociceptor modulation, artemin (a neurotrophic growth factor) for neuronal regrowth,<sup>11</sup> and cefranopadol, a nociceptin/orphanin FQ peptide and opioid peptide receptor agonist.<sup>6</sup>

Patient-reported outcome (PRO) measures are used to evaluate patient perspective in clinical trials. Patient-reported outcome measures capture the health experience of patients and can be used to document treatment benefit and support labeling claims.<sup>17,19</sup> Many PRO measures/instruments are currently used in clinical trials of cLBP, including the Neuropathic Pain Symptom Inventory (NPSI), painDETECT, Roland-Morris Disability Questionnaire (RMDQ), Pain

Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

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PAIN 159 (2018) 2066–2075

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# Pal Video Patient Assessment

**Katherine Seaton, Birgit Loch, Elizabeth  
Lugosi**



## **Pal Video Patient Assessment:**

**Transesophageal Echocardiography of Congenital Heart Diseases** Poonam Malhotra Kapoor, Sarvesh Pal Singh, 2014-09-30 A transoesophageal echocardiography TEE test is an alternative way to perform an echocardiogram An ultrasound transducer positioned on an endoscope is guided down the patient's throat into the oesophagus The test provides a close look at the heart's valves and chambers without interference from the ribs or lungs TEE is often used when the results from standard echo tests are not sufficient or when your doctor wants a closer look at the heart Cleveland Clinic This book is a practical guide to the use of TEE in the diagnosis of congenital heart disease CHD Beginning with an introduction to TEE for CHD the following chapters describe procedures to be used for different cardiac conditions 3D TEE allowing multi dimensional perspectives is also covered This highly illustrated guide helps clinicians perform better TEE examination and understand structural defects and the relationships between intra cardiac structures A DVD demonstrating the latest techniques in TEE is included Key points Practical guide to transesophageal echocardiography TEE of congenital heart disease Covers 3D TEE Highly illustrated with more than 400 images and tables Includes DVD demonstrating latest techniques **Bowker's Complete Video Directory**, 2000 *ICT for assessment and rehabilitation in Alzheimer's disease and related disorders* Philippe Robert, Sophia Antipolis, Iracema Leroi, Valeria Manera, 2016-06-21 Information and Communication Technologies ICT are no longer objects gathering dust on a shelf instead they have become intrinsic in our everyday lives They are now even taking on an indispensable role in many clinical and rehabilitation settings In the past decade there has been a surge of interest in using ICT with elderly people both with and without dementia in various clinical and research settings On the one hand ICT can supplement the assessment of functional ability by more precisely evaluating the nature and extent of functional impairment on the other hand ICT can be used to support elderly people in their everyday activities as well as to ameliorate symptoms and improve quality of life through stimulation and rehabilitation This is the intention driving the development of Serious Games SG which are digital applications often based on Virtual Reality specifically adapted for purposes other than entertaining including rehabilitation training and education Finally ICT can also play a key role in the development of interactive educational programs to support caregivers of people living with dementia A handful of interesting studies have started to investigate the effectiveness of employing ICT in people with different types of dementia such as Alzheimer's disease AD It is therefore timely to attempt to scope this newly emerging field as well as to foster a dialogue among the different professionals including academics clinicians and computer engineers working in the area With this in mind the Research Topic ICT for assessment and rehabilitation in Alzheimer's disease and related disorders aims to provide new and interesting insights into the current use of ICT in healthy and pathological aging The intent is also to identify challenges and new perspectives in the field gather recommendations for the application of ICT in AD and related disorders in clinical practice and to showcase cutting edge clinical research The articles included in this Frontier Research

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Quality Engineering Sebastian Möller, 2023-04-21 Der Begriff der Qualität und der Gebrauchstauglichkeit hat in der Informations und Kommunikationstechnik sowie der Informatik eine herausragende Bedeutung Der Autor führt in diese Thematik ein indem er zunächst die Fachbegriffe und die Grundlagen der Psychophysik und Psychometrie erläutert Darauf aufbauend wird der Kreislauf einer menschenorientierten Systementwicklung vorgestellt Die Messung und Vorhersage von Qualität und Gebrauchstauglichkeit wird anhand von Beispielen veranschaulicht und für Sprach und multimodale Dialogsysteme

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*Evidence-Based Physical Examination* Kate Gawlik,Bernadette Mazurek Melnyk,Alice Teall,2024-03-26 The assessment text of today and the future This unique text is the first to combine scientific and holistic approaches to health assessment while being the first book to also take the health and well being of the clinician into account This valuable resource utilizes the best evidence and clinical relevance underpinning advanced history taking and assessment techniques incorporating the most current guidelines from reliable sources such as the U S Preventative Services Task Force the Choosing Wisely initiative and the NAM s Core Competencies for Health Care Clinicians The updated second edition offers more in depth recognition of population health concepts and as a result includes greater use of inclusive language social determinants of health assessments identification of health inequities and racial ethnic gender and age considerations within advanced assessment This edition delivers increased coverage of documentation abundant new content addressing therapeutic communication and changing practice environments and unique chapters focused on the assessment of a growing cohort of older patients the LGBTQ population telehealth abuse and clinician wellness Chapters have a consistent structure and include anatomy and physiology key history questions and considerations physical exam lab and imaging considerations evidence based practice recommendations and differential diagnoses for both normal and abnormal findings Case studies clinical pearls and key takeaways aid retention while abundant illustrations photographic images and videos demonstrate history taking and assessment techniques Instructor resources include PowerPoint slides a test bank with multiple choice and essay questions additional case studies with short answer questions an image bank and a course

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Handbook of the Laboratory Diagnosis and Treatment of Infertility Brooks A. Keel,Bobby W. Webster,1990-06-22 This book provides comprehensive detailed and step by step descriptions of materials and methods currently used in laboratory procedures within the infertility clinic It addresses the numerous highly sophisticated procedures resulting from research in the area of laboratory diagnosis and treatment of infertility Among those procedures covered are

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biomechanical and motor control principles and provides examples that address combining the principles of kinesiology with clinical occupational therapy practice The text also has case studies and laboratory exercises specifically designed for occupational therapy students The focus is on the concepts of kinesiology and excludes some of the mathematics that is used by biomechanists Written by a kinesiologist who is also an occupational therapist the text is tailored to the needs of the undergraduate and the practicing occupational therapist Principles of kinesiology are combined with clinical practice Includes case studies and laboratory exercises that have been specifically designed for occupational therapists Focuses on concepts used in day to day practice Discusses environments in which therapists work including balance training ergonomics and leisure **Scientific and Technical Aerospace Reports** ,1986 **Takeaways from Teaching through a**

**Pandemic** Katherine Seaton,Birgit Loch,Elizabeth Lugosi,2024-02-01 In this insightful volume more than 50 educators from 4 continents outline thoughtful and intentional innovations of lasting value made in their teaching of tertiary mathematics and statistics in response to COVID 19 pandemic related campus closures The examples given in 20 practical chapters fall into three themes utilization of relevant technologies discipline appropriate assessment alternatives and support for learning and engagement The first theme explored is the utilization of the affordances of communications technology and mathematical software and online tools to create learning resources and activities for virtual classrooms The second theme is the design of sound assessment alternatives together with the associated issue of maintaining academic integrity in disciplines accustomed to established question styles and face to face exams Finally a range of activities to encourage engagement and support learning and teaching both online and as campuses re opened is described Due to their ongoing relevance and benefits for tertiary mathematics education be that of pre service teachers engineers or mathematics majors the examples found in these 20 practical chapters are takeaways or keepers This book was originally published as a special issue of International Journal of Mathematical Education in Science and Technology Facial Palsy Chieh-Han John Tzou,Andrés Rodríguez-Lorenzo,2021-05-27 This book offers a comprehensive overview of the surgical techniques available in reconstruction of the paralyzed face It is divided into six parts The first part introduces the topic of facial palsy and the following parts provide detailed information on facial nerve reconstruction techniques management of eye closure and smile reanimation The book highlights symmetrization techniques and synkinesis and presents innovations and new frontiers in facial palsy Written by an international group of experts who are committed to maintaining high standards and service in treating this condition and improving outcomes it is a valuable source of information for clinicians and practitioners in plastic and reconstructive surgery neurosurgeons and oral and maxillofacial surgeons but also useful for researchers in this field

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