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Choosing the right outcome measurement instruments for patients with low back pain

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A B S T R A C T

Choosing the most fit-for-purpose outcome measurement instruments is fundamental because using inappropriate instruments can lead to detection bias and measurement inconsistency. Recent recommendations, consensus procedures and systematic reviews on existing patient-reported outcome measures (PROMs) informed this manuscript, which provides suggestions on which outcome domains and measurement instruments to use in patients with low back pain (LBP). Six domains are identified as highly relevant: (1) physical functioning, (2) pain intensity, (3) health-related quality of life, (4) work, (5) psychological functioning and (6) pain interference. For each domain, one or more PROMs are suggested for clinical research and practice, selecting among those that are most frequently used and recommended, and that have satisfactory measurement properties in patients with LBP. Further research on the measurement properties of these suggested PROMs is needed while also considering other emerging instruments, such as the PROMIS computerised adaptive testing and short forms.

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Measurement in low back pain: a brief introduction

Measurement is at the core of science and essential in clinical practice. In health sciences, this typically corresponds to the measurement of health- and/or disease-related outcome measurement instruments. These can include measures of pathophysiological variables (e.g. radiography, magnetic resonance imaging (MRI) or clinical chemistry measurement in blood samples), physical tests for measuring constructs such as muscle strength or range of motion, and patient-reported outcome measures (PROMs) aiming to measure health-related quality of life (HRQoL). The results of these measurements are often the basis on which the clinical management is (or is not) altered. In addition, decisions about the reimbursement of health care interventions are (at least partly) based on measurements such as the EuroQol-5D (EQ-5D) questionnaire. This means that outcome measurement instruments need to be valid, reliable and responsive, otherwise there is a serious risk of imprecise or biased results. In clinical trials on low back pain (LBP), PROMs are the most frequently used type of measurement instruments [1], and the same is likely in LBP clinical practice. They are efficient and do not require advanced technologies or high costs for administration. In this manuscript, we focus on PROMs, although the fundamental issues also apply to other types of instruments.

The number of available PROMs has dramatically increased over the past few decades; consequently, the choice of which PROM to use is becoming more difficult. There are often multiple instruments available for measuring the same health construct in the same patient population. For example, a systematic review published in 2005 identified 36 PROMs for measuring back-specific functional status in patients with LBP [2]. This means that there is a high risk that poor quality instruments are being used, which can introduce information bias into research or practice.

Given the number of PROMs available, it is not surprising that there is an inconsistency in outcome assessment across clinical trials; this hampers the comparability of results and makes conducting meta-analyses difficult [3]. The lack of large meta-analyses means that estimates of intervention effectiveness are not precise and that research is less informative for clinical practice. Another problem is that researchers tend to selectively report their outcomes, choosing only those for which there were more favourable results [4]. Problems of outcome inconsistency and selective reporting can be addressed by the development of a core outcome set (COS) [5]. A COS is an agreed minimum set of outcomes to be measured and reported in all clinical trials in a specific health condition [6,7]. COSs are usually developed for clinical research, but since they represent the most relevant outcomes, they are often applicable to clinical practice as well [8].

Different stakeholders (e.g. clinicians, researchers, patients, policy makers, health insurance and industry representatives) with relevant expertise should be involved in establishing a COS. The development of a COS is a two-step process: first, determine which outcome domains should be included (i.e. 'what' to measure) and second, select measurement instruments for the core outcome domains (i.e. 'how' to measure) [6,7]. The outcome domain is the construct or aspect of interest to be measured, and it is sometimes represented by a latent variable that cannot be directly observed (e.g. physical functioning, pain interference or fatigue). The measurement instrument is the means used to quantify the construct [6]. A detailed description of the methodology to develop a COS can be found in the recent work summarising the topic [6–8].

How to select an outcome measurement instrument

The first step in selection of an instrument is definition of the outcome domain and the target population [9]. Defining specifically 'what' to measure is crucial because domains with the same name may be defined in different ways [10]. For instance, 'disability' is defined by the World Health Organization as 'problems an individual may experience in functioning, namely impairments, activity limitations and participation restrictions' [11]; however, Garrad and Bennett defined 'disability' as 'limitation of the performance of an individual when compared to a fit person' [12]. The target population also needs to be carefully defined because aspects of the same domain may be differently important in different populations. For example, self-care activities relevant to very disabled patients with LBP may not be very relevant for high-functioning patients, such as long-distance runners who experience LBP only after having run a certain distance.

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