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Measures for the Assessment of Pain in Adults

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INTRODUCTION

An overview is provided regarding some of the most commonly used measures to assess pain in adults. These measures are appropriate for both general and rheumatologic pain populations. Most measures are easy to use in clinical settings and all are validated for use in research. A number of well-known measures such as the Visual Analog Scale, Numeric Rating Scale, McGill Pain Questionnaire and the Short Form-36 Bodily Pain subscale were described in a previous issue.[1] Pain is complex and thus it is important to conduct a comprehensive assessment. Here we discuss several other measures that are helpful for assessing the severity, location, and quality of pain, as well as pain-related interference in functioning. Further, knowing whether the pain is focal (i.e., isolated to one area of the body) or more widespread can indicate the degree to which the pain is more centralized in nature[2-5] and thus inform the treatment approach to the care of rheumatology patients.

Yet, the assessment of pain (location, severity and quality) and its impact on functioning cannot possibly tell the full story. Pain is a biopsychosocial phenomenon where thoughts, emotions and behavior contribute significantly to pain perception and pain outcomes. While it is beyond the scope of this review to discuss all the possible contributing and potentially ameliorating factors and their measurement, a comprehensive assessment of pain for

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interdisciplinary treatment could also include an assessment of underlying pain mechanisms, the perceived meaning of the pain, level of pain acceptance, pain coping strategies, pain-related behavioral avoidance and/or fear (i.e., kinesiophobia), and even resilience factors such as high levels of positive affect, strong social support, internal locus of control and sense of purpose in life.

Questionnaires presented here include the pain severity and pain interference subscales from the Brief Pain Inventory, the Defense and Veterans Pain Rating Scale, the Michigan Body Map, the painDETECT, the Patient-Reported Outcomes Measurement Information System (PROMIS) measure for pain interference, and the ambulatory assessment of pain intensity including the use of Ecological Momentary Assessment (EMA) and daily pain diaries. The description of ambulatory assessments deviates from that of the other measures given this methodology diverges from the standard PRO format. This form of pain measurement, however, is becoming the gold standard and, as such, is critical for clinicians and researchers to understand. The importance of considering other co-occurring symptoms such as sleep, mood, and fatigue will be described briefly although their measurement will be covered in other sections of this special edition (see: xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx). More comprehensive measures of functional status such as the XXXXXXXXXXXXXXXXXXXXXXX and the YYYYYYYYYYYYYYYYY are described in the XXXXXXXXXXXXXXXXXXX and the YYYYYYYYYYYYYYYYY sections, respectively.

BRIEF PAIN INVENTORY (BPI)

Description

Purpose. The BPI is used to assess pain intensity and pain interference. It was originally developed for use in cancer populations[6] but has since been validated for use in many non-cancer pain populations.[7,8] There is both a long and short version of this measure - the latter being used most often in clinical trials. The short version will be reviewed here.

Content or domains. The BPI assesses for the presence of pain, pain intensity (worst, least, average, and current), pain location (body map), and the impact of pain interference on: a) general activity, b) mood, c) walking ability, d) normal work, e) relationships with others, f) sleep, and g) life enjoyment. It also assists in documenting the types of pain medications being used and the amount of relief provided by those medications and other pain treatments.

Number of items. The BPI has a total of 15 items.

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Response options/scale. The BPI uses a mixture of response sets. Item 1 asks about the presence of pain (Yes/No). Item 2 is a body map and asks the respondent to shade all areas of pain and to then place an "x" on the area that hurts the most. Items 3-6 (pain intensity items: worst, least, average, current) utilize an 11-point rating scale ranging from 0 (no pain) to 10 (pain as bad as you can imagine). Item 7 is an open-ended response field for listing pain medications. Item 8 (percentage of pain relief from medications or pain treatments) uses a 0% (no relief) to 100% (complete relief) response scale. Item 9 has 7 parts representing different aspects of pain interference (see above) (a-g). The response set for pain interference ranges between 0 (does not interfere) to 10 (completely interferes).

Recall period for items. The time frame for the BPI is typically "the past week" but some versions also utilize the "past 24 hours."

Cost to use. Licensing fees and $100 processing fees may be applied to use. Contact MD Anderson Cancer Center to inquire about fees for specific uses.

How to obtain. The BPI is copyrighted and validated intellectual property. If interested, contact information is below.

Department of Symptom Research
Attn: Assessment Tools
The University of Texas MD Anderson Cancer Center
1515 Holcombe Boulevard, Unit 1450
Houston, Texas 77030
symptomresearch@mdanderson.org

Practical Application

Method of administration. The BPI can be administered either as paper/pencil, computerized form, or as an interview.

Scoring. Some of the items represent single item values and do not require scoring (e.g., pain relief). The Pain Severity score is obtained by calculating the mean of the four pain severity items. The Pain Interference score is obtained by calculating the mean of the seven Pain Interference items. The BPI is easily scored by hand.

Score interpretation. The Pain Severity score ranges between 0-10 with larger values representing greater pain severity. The Pain Interference score similarly has a range of 0-10 with larger values being indicative of greater pain interference.

Respondent time to complete. It takes approximately 5 minutes to complete the BPI.

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Administrative burden. Administrative burden is minimal unless an interview format is used. Typically, the form is simply handed to the participant to complete. Scoring involves calculating two means and can be accomplished in under 5 minutes.

Translations/adaptations. The BPI has been translated into over 50 languages. A complete listing of translations is available through the MD Anderson Cancer Center website: https://www.mdanderson.org/research/departments-labs-institutes/departments-divisions/symptom-research/symptom-assessment-tools/brief-pain-inventory.html

Psychometric Information

Floor ceiling effects. Floor and ceiling effects are not often reported for the BPI, but assumed to be adequate. However, at least one study from the cardiac surgery literature suggested substantial floor effects both prior to and following surgery, but minimal ceiling effects were noted.[9]

Reliability. Internal consistency for the Pain Severity score has been reported as being 0.85 and the Pain Interference score has been reported as being 0.88 in non-cancer pain populations.[8] Test-retest reliability for daily administration up to 1 week ranges between 0.83-0.88 for pain severity and ranges between 0.83-0.93 for pain interference.[10]

Validity. Thirty-six studies of the BPI in both cancer and non-cancer populations across multiple languages, support a 2-factor structure for the BPI (i.e., pain severity and pain interference).[11] Construct validity has been supported for the generic use of the BPI with chronic pain in over 72 studies[7] and it has been used to assess pain in over 400 studies with a wide variety of painful conditions. For example, in patients with arthritis, the BPI Pain Severity score correlated r=0.74 with the bodily pain scale of the SF36 (a generic index of pain severity). Similarly, the BPI Pain Interference score correlated r=0.81 with the Chronic Pain Grade disability index, and r=-0.69 with the Health Assessment Questionnaire Disability Index, (a disease-specific measure of functional interference).[7]

Responsiveness. The BPI has demonstrated responsiveness to change in both pharmacological and non-pharmacological treatments.[7,8,11]

Minimally important differences. In chronic pain states a 2- to 3-point change or 30% improvement in pain severity is considered meaningful. In a pharmacological study of fibromyalgia, data were pooled across 12-week treatment periods from 4 randomized controlled trials and anchored against the patient's Global Impressions of Improvement scale. For the BPI Pain Severity score, a 2.2-point change corresponded with a 34% reduction from baseline scores.[12] Few studies have estimated the MID for BPI Pain Interference. One study of bone metastases that did, however, suggest an effect size of .05 SD.[13]

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Generalizability. As stated, the BPI has been validated for use in multiple chronic pain conditions both clinically and for research purposes. The constructs of pain severity and pain interference do not appear to be unique to any one form of pain and therefore the items of this instrument appear to be relevant to chronic pain generally.

Use in clinical trials. Pain severity and pain interference as constructs are recommended as core domains of assessment for clinical trials involving pain interventions. The BPI Pain Severity score and the BPI Pain Interference score are suggested indices for capturing these domains in clinical trials.[14]

Critical Appraisal of Overall Value to the Rheumatology Community

Strengths. The BPI was designed to be a monitoring tool for change in pain and its impact over time. Numerous studies support its valid use in this capacity.

Caveats and cautions. The BPI is considered an industry standard for the assessment of pain and its impact. It possesses strong psychometric properties for its Pain Severity score and its Pain Interference score. Far less is known about the other features of this instrument (e.g., body map, medications, pain relief) and these other features are rarely reported.

Clinical usability. The BPI is recommended for use in clinical settings to monitor pain severity and pain interference.

Research usability. The BPI is also recommended for use in research as it is easily administered, and possesses low patient burden.

Summary/Recommendations

The BPI is a psychometrically sound measure of pain severity and pain interference (i.e., impact). It has been recommended as a potential measure of these constructs in clinical trials and in the construction of core minimum datasets of pain conditions. It is administered either electronically or in traditional paper-pencil formats, as well as by interview. The BPI possesses strong psychometric properties of reliability, validity and responsiveness to change supporting its use.

DEFENSE & VETERANS PAIN RATING SCALE

Description

Purpose. The Defense and Veterans Pain Rating Scale (DVPRS) was developed to standardize assessment of pain across Department of Defense (DoD) and Veterans Health Administration (VHA) health systems.[15,16] Its first iteration incorporated the Faces Rating Scale – Revised, for which The International Association for the Study of Pain (IASP) holds the

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copyright. To avoid copyright infringement, an alternative facial expressions scale was developed for a second version of the instrument (DVPRS v 2.0).

Content or domains. The DVPRS consists of a pain intensity item and four supplemental items. The supplemental items ask about how pain is interfering with usual activity, sleep, mood, and stress during the past 24 hours.

Number of items. The DVPRS consists of five items: a pain intensity item and four supplemental items.

Response options/scales. The pain intensity item comprises an 11-point numeric rating scale (NRS 0–10) that incorporates: i) descriptions for each integer on the scale (e.g., 0 = No pain; 1 = Hardly notice pain; 5 = Interrupts some activities; 10 = As bad as it could be, nothing else matters); ii) a traffic light coding system that groups pain intensity into mild (green, 1–4), moderate (yellow, 5–6), and severe (red, 7–10); and iii) a facial expressions scale. Four supplemental items are accompanied by an 11-point NRS, where 0 is anchored as 'Does not interfere', and 10 as 'Completely interferes'.

Recall period for items. The recall period for the pain intensity item of the DVPRS is the current time. The recall period for pain interference items is the past 24 hours.

Cost to use. The DVPRS is free for clinicians and researchers to use, with the proviso that the instrument remains unaltered.

How to obtain. The DVPRS can be downloaded from the Defense & Veterans Center for Integrative Pain Management website (Webpage: https://www.dvcipm.org/clinical-resources/defense-veterans-pain-rating-scale-dvprs/).

Practical Applications

Method of administration. A paper-based version of the DVPRS can be completed by the patient independently. Alternatively, responses can be obtained through an interview of the patient by the clinician.

Scoring. Separate scores are recorded for pain intensity and each of the supplemental items (interference with activity, sleep, mood, and stress over the past 24 hours). Each item has a possible range of 0–10.

Score interpretation. Higher scores on DVPRS items indicate greater pain intensity or greater pain interference.

Respondent time to complete. The DVPRS takes approximately 3 minutes to complete.[17]

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Administrative burden. Given its ease of access, minimal time required for completion, and the small number of items, the DVPRS presents a low administrative burden.

Translations / adaptations. Spanish and Vietnamese versions of the scale are available. (Webpage: https://www.dvcipm.org/clinical-resources/defense-veterans-pain-rating-scale-dvprs/).

Psychometric Information

A systematic literature search of manuscripts written in English up to January 2017 restricted to adults with chronic (≥ 3 months) musculoskeletal pain was unable to identify studies of the reliability, validity, responsiveness to change or minimally important difference for the DVPRS.[18] However, studies using the instrument, including its post-development preliminary evaluation, have examined its psychometric properties in less restrictive patient cohorts.

Floor and ceiling effects. Floor and ceiling effects of the DVPRS are yet to be investigated.

Reliability. Evaluation of the preliminary version of the DVPRS (v 1.0) using data from inpatients and outpatients with predominantly chronic non-cancer pain or acute postoperative pain demonstrated a high level of internal consistency reliability (Cronbach's alpha for the five items: 0.90).[16] Subsequent examination of DVPRS v 2.0 using data from active duty military personnel and veterans also demonstrated acceptable internal consistency reliability (Cronbach's alpha 0.87).[15] Acceptable test-retest reliability for the pain intensity item (Pearson's r 0.64, $p<0.001$) and the supplemental items (Pearson's r all >0.70, $p<0.001$) has also been reported.[15]

Validity. Evaluation of the construct validity of the preliminary version of the DVPRS (v 1.0) using principal component factor analysis found that one factor accounted for 72% of the variance in the measure (factor loadings for all five items >0.82).[16] Subsequent examination of DPRS v 2.0 using data from active duty military personnel and veterans supported a single-factor structure, explaining 66% of the variance in the measure (factor loadings for all five items ≥0.53).[15] However, in this study a two-factor solution was supported when factor extraction was fixed, indicating the need for further evaluation and confirmatory factor analysis.

Preliminary evaluation of the content validity of the word descriptions integrated alongside the 11-point NRS demonstrated excellent agreement (Intraclass Correlation Coefficient [ICC] 0.94).[16]

Evidence supports the concurrent validity of the pain interference items of the DVPRS.[19] The mean of the four DVPRS pain interference item scores has been shown to correlate with scores on the Pain Disability Questionnaire (PDQ) (Spearman's Rho 0.69, $p<0.001$), and the

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Veterans RAND 36-item Health Survey Bodily Pain subscale (Spearman's Rho -0.65, p<0.001), physical component subscale (Spearman's Rho -0.37, p<0.001), and mental component subscale (Spearman's Rho -0.46, p<0.001).[19] When examined individually, the DVPRS pain interference on activity item correlated with the PDQ functional status component (Spearman's Rho 0.64, p<0.001); DVPRS pain interference on mood and stress items correlated with scores on the PDQ psychosocial status component and Beck Depression Inventory II scores; and the DVPRS pain interference on sleep item correlated with scores on the Insomnia Severity Index (Spearman's Rho 0.57, p<0.001).

Responsiveness. The responsiveness to change of the DVPRS is yet to be investigated.

Minimally important differences. Minimal clinically important differences of the DVPRS items have not been empirically determined.

Generalizability. Given the context within which the DVPRS has been evaluated, generalizability is limited to active-duty military personnel and veterans.

Use in clinical trials. A search of ClinicalTrials.gov with the term 'DVPRS' in January 2020 returned a list of 32 registered trials. As might be expected, the vast majority were conducted, or planned to be conducted, in military contexts or with veteran participants.

Critical Appraisal of Overall Value to the Rheumatology Community

In the absence of comprehensive psychometric evaluation data specific to rheumatic and musculoskeletal disorders, the value of the DVPRS to the rheumatology community is arguably restricted to use in military contexts.

Summary / Recommendations

The DVPRS was developed and has been evaluated within military and veteran populations. It can help track changes in pain intensity and pain interference and may be particularly useful to monitor within-patient symptom change in the context of potentially high levels of transitions between different military healthcare providers.

MICHIGAN BODY MAP (MBM)

Description

Purpose. The Michigan Body Map (MBM) was developed to address a critical need: the availability of a body map that provides a quantifiable score and would be easy to use in clinical

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and research settings.[20,21] The MBM has since been used in a wide range of studies in rheumatologic populations to assess the presence and location of chronic pain in 35 body areas.[22-31]

Content or domains. The MBM consists of a graphic manikin that depicts the front and back sides of an androgynous figure. Check boxes appear over 35 areas commonly reported as being painful (e.g., lower back, neck, knees, wrists, hips, head).

Number of items. The MBM consists of one activity, indicating areas of the body affected by chronic pain.

Response options/scale. Respondents are directed as follows: *"On the image below, CHECK ALL areas of your body where you have felt persistent or recurrent pain present for the last 3 months or longer (chronic pain)."* Up two 35 body areas can be checked to indicate the location(s) of chronic pain.

Recall period for items. Respondents report persistent pain present over the last three months.

Cost to use. The MBM is free for both clinicians and researchers to use, with the understanding that the measure remains unaltered and properly cited in publications.

How to obtain. The MBM and links to original publications and scoring syntax can be obtained here: *https://medicine.umich.edu/dept/pain-research/clinical-research/michigan-body-map-mbm*

Practical Application

Method of administration. The MBM is a self-report measure and can be administered using either a pen and paper form or an electronic version of the MBM (eMBM).[32] The respondent is asked to check every box that indicates an area where they have experienced chronic pain.

Scoring. While the MBM is predominantly used to indicated areas of chronic pain, a score can be derived by totaling the number of body areas impacted.

Score interpretation. In addition to providing information about the location of a patient's chronic pain, it is thought to be most useful for showing the degree to which a patient's pain is widespread. The endorsement of numerous body areas and/or the endorsement of locations across several body zones (e.g., right upper quadrant, right lower quadrant, left upper quadrant, left lower quadrant, head) suggest the presence of a more centralized pain state (i.e., fibromyalgia).[33]

Respondent time to complete. The MBM takes less than one minute to complete.[21]

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Administrative burden. There is little burden associated with this measure. It is readily available in paper and electronic forms, is easy to understand, takes only a few minutes for respondents to complete, and requires no specific training to score and interpret.

Translations/adaptations. The MBM has been translated into German, Chinese, Portuguese, and Yiddish although none have undergone formal validation.

Psychometric Information

Floor and ceiling effects. Floor and ceiling effects have yet to be investigated in the MBM or eMBM.

Reliability. In a study evaluating test-retest reliability, patients completed the MBM, then returned to the clinic for a retest 1–2 weeks later. Wilcoxon signed-rank test and dependent samples t-test were used to assess the test-retest reliability of the MBM. Half of respondents had 0 or 1 discrepant body area between the two administrations. Percentage agreement for each body part from first administration to second ranged from 85% to 100%. The correlation between total number of body areas checked at each administration was positive and statistically significant. The time to complete the MBM was similar between the initial and follow up administrations 1–2 weeks later.[21]

Validity. In a study of convergent and discriminant validity, patients with pain (n=237) completed the MBM and the following commonly used measures of pain outcomes: Brief Pain Inventory (pain severity and pain interference subscales), the painDETECT, Oswestry Disability Index (ODI), the Catastrophizing Subscale from the Coping Strategies Questionnaire (CSQ), and the Hospital Anxiety and Depression Scale (HADS). The correlations between the MBM and each of the pain-related constructs were positive. Correlations of this magnitude suggest that less than 17% of the variance in each of these other scales overlaps with the MBM measure. Thus, in assessing the degree to which pain is pain widespread, the MBM is assessing a somewhat unique construct that has positive associations with other metrics of pain.[21]

Responsiveness. The MBM is typically used as a method of assessing pain location and commonly used as a predictor variable where it is thought that the number of painful sites endorsed could be informative.

Minimally important differences. Not applicable.

Generalizability. The MBM has been translated into several languages and is used in a broad array of settings including in different countries, for non-inflammatory and inflammatory pain conditions and in surgical settings. Such wide use supports the generalizability of the MBM.

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Use in clinical trials. The MBM has been or is being used as an assessment measure in a number of prospective cohort studies and clinical trials for patients with both acute and chronic pain.

Critical appraisal of overall value to the rheumatology community

Strengths. The MBM was designed to address a need in pain location assessment – provide a validated body map that yields a quantifiable measure of the spread of pain across the body.

Caveats and cautions. The MBM is still relatively new and more validation work in diverse patient populations is needed.

Clinical usability. The MBM is recommended for use in clinical settings to assess and monitor the location of pain and changes in location over time.

Research usability. The MBM is recommended for use in research because it provides a score 0-35 that can easily be used to assess whether a patient's pain is focal or widespread. Further, the MBM can also be used for the assessment of the Fibromyalgia Survey Criteria.[33,34] Of the 35 body areas denoted in the MBM, 19 correspond with those in the Widespread Pain Index, which is one of two components of the Fibromyalgia Survey Criteria.[34] This latter feature has made the body map a particularly helpful tool for the assessment of fibromyalgia-like or centralized pain in many populations.[22,24-26,30,31,35,36] The presence of pain that is more widespread, as opposed to localized, has implications for treatment.

Summary / Recommendations

The MBM was originally developed for use in the surgical setting and has since been widely used to assess chronic pain in many populations including rheumatic patients (e.g., osteoarthritis, rheumatoid arthritis, systemic lupus erythematosus, fibromyalgia, low back pain). The MBM is easy for patients to understand, takes only a few minutes to complete and yields important information about the location and spread of pain. The MBM is available in paper or electronic forms at no cost. Initial analysis of psychometric properties support its use in clinical and research settings.

painDETECT

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Description

Purpose. The painDETECT questionnaire (PD-Q) was developed as a screening tool to determine the likelihood of the presence of pain of neuropathic origin.[37]

Content or domains. The PD-Q includes three questions about pain intensity (current, the strongest pain during the past 4 weeks, and how strong the pain was during the past 4 weeks on average). A body manikin is used to collect information about the main area of pain. Seven items enquire about the presence and quality of neuropathic pain symptoms (e.g. burning sensation, tingling/prickling sensations). One item asks about the course of pain over time, and one item asks whether pain radiates to other regions of the body.

Number of items. The PD-Q includes 13 items. Responses to nine of these items are summed to derive a total PD-Q score.

Response options/scales. The three questions about pain intensity are accompanied by 11-point numeric rating scales (0–10). Respondents are asked to mark their main area of pain on a body manikin. The items that ask about the presence and quality of neuropathic pain symptoms (e.g. burning sensation) have Likert response options ranging from 0 (never) to 5 (very strongly). The item that asks about the course of pain over time has four response options, each accompanied by a representative illustration (persistent pain with slight fluctuations; persistent pain with pain attacks; pain attacks without pain between them; pain attacks with pain between them). The item that asks whether pain radiates to other regions of the body also asks respondents to mark the direction in which the pain radiates on the body manikin.

Recall period for items. The recall period for the PD-Q is the current time or over the last four weeks.[38]

Cost to use. The PD-Q is free for clinicians and researchers to use with the understanding that no alterations are made to the measure.

How to obtain. An English language version of the PD-Q can be downloaded at: https://www.pain-detect.de/fileadmin/pain-detect.de/media/painDETECT-Q_English.pdf

Practical Application

Method of administration. The PD-Q can be completed by the patient independently using paper and pencil.

Scoring. Responses to nine of the 13 items are used to create a summary score, with a possible range of -1 to 38. Summed items include: the seven items that ask about the presence and quality of neuropathic pain symptoms (possible range 0 (never) to 5 (very strongly) for each item); responses to the item about the course of pain (0=persistent pain with slight fluctuations; -

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1=persistent pain with pain attacks; +1=pain attacks without pain between them; +1 pain attacks with pain between them); and the item that asks about radiating pain (+2 if yes, 0 if no).

Score interpretation. The sum of the nine scored items of the PD-Q are used to determine the likelihood of the presence of neuropathic pain. Scores of 12 or less indicate that a neuropathic component of pain is unlikely, scores from 13 to 18 are ambiguous; scores of 19 or more indicate that a neuropathic component of pain is likely.

Respondent time to complete. The PD-Q takes approximately 5 minutes to complete.[38]

Administrative burden. Given its ease of access and completion and the relatively small number of items, the PD-Q presents a low administrative burden.

Translations / adaptations. The PD-Q was originally developed in German. It has been extensively translated and cross-culturally adapted and is available in more than 23 languages.[39]

Psychometric Information

Floor and ceiling effects. In a study of inflammatory arthritides (rheumatoid arthritis, psoriatic arthritis and spondyloarthritis), no ceiling effect was observed for the PD-Q.[40]

Reliability. A systematic critical appraisal of the measurement properties of the PD-Q determined that there was evidence for satisfactory internal consistency reliability, although the level of evidence was judged as being very low.[41] Internal consistency reliability for chronic low back pain specifically has been estimated as Cronbach's alpha 0.76.[42]

Test-retest reliability of the English version of the PD-Q using pre- and post-consultation data indicated almost perfect agreement (ICC 0.91, 95% CI 0.88-0.94).[39] In the same study, there was substantial agreement between pre-consultation scores and scores collected one week later (ICC of 0.79, 95% CI 0.70-0.88). Classification by neuropathic pain status performed similarly well when comparing pre- and post-consultation scores (weighted kappa 0.77, 95%CI 0.68-0.86), and when comparing pre-consultation scores and scores collected one week later (weighted kappa 0.69, 95%CI 0.55-0.83).[39]

In a study of inflammatory arthritides (rheumatoid arthritis, psoriatic arthritis and spondyloarthritis), Rasch analysis indicated acceptable psychometric properties. Principal component analysis supported a one-item structure, test-retest reliability demonstrated strong agreement (ICC 0.94, 95% CI 0.84-0.98), and classification consistency was strong (80%).[40] Rasch analysis has also supported the acceptability of the psychometric properties of the instrument when applied to a sample of patients with osteoarthritis.[43]

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Validity. A systematic critical evaluation of the measurement properties of the PD-Q determined that the instrument has satisfactory criterion validity but unsatisfactory content validity, although the level of evidence for both was very low.[41]

The original German version of the PD-Q had a sensitivity of 85% and specificity of 80% in identifying neuropathic pain among adults with chronic low back pain.[37] Sensitivity and specificity was less satisfactory for a sample with neck/upper limb conditions who completed an English version of the instrument (64% and 62% respectively).[44]

Construct validity of a form of the PD-Q modified for use with people with knee osteoarthritis has been reported as satisfactory, although evidence level was judged as low.[41,45]

Responsiveness. The responsiveness to change of the PD-Q is yet to be investigated.

Minimally important differences. Not applicable.

Generalizability. The PD-Q has been translated, cross-culturally adapted and tested in different countries, languages and for non-inflammatory and inflammatory pain conditions. This breadth of research supports the generalizability of the instrument.

Use in clinical trials. The PD-Q has been or is being used as an outcome measure in clinical trials of pharmacological and non-pharmacological interventions for neuropathic pain.

Critical Appraisal of Overall Value to the Rheumatology Community

Psychometric properties of the PD-Q indicate that it may be useful to detect pain of neuropathic origin in patients with chronic low back pain, inflammatory arthritides or osteoarthritis, but less useful for patients with neck or upper limb conditions.

Summary / Recommendations

The PD-Q was originally developed and tested with people with chronic low back pain. Scores derived from the instrument can be quickly summed to categorize pain into a neuropathic component of pain being likely, unlikely, or ambiguous. Analysis of the instrument's psychometric properties generally support its use as a brief screening tool.

PROMIS PAIN INTERFERENCE SCALES

Description

Purpose. The National Institutes of Health (NIH) Common Fund initiative known as the Patient Reported Outcomes Measurement Information System (PROMIS®)[46,47] developed a

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collection of psychometrically rigorous outcomes measures across multiple domains. One of these domains is pain interference, a construct that broadly assesses the consequences of pain on physical, mental and social activities.

Content. The PROMIS Pain Interference (PROMIS-PI) item banks assess the construct of pain interference - which is the extent to which pain impacts engagement in social, cognitive, emotional, physical, and recreational activities. It also includes elements of sleep and life enjoyment.

Number of items. The entire PROMIS-PI item bank is defined by 41 items, however, there are several short forms with strong relationships to the entire item bank that contain 4, 6, and 8 items. PROMIS-PI can also be assessed using computer adaptive testing (CAT).

Response options/scale. The PROMIS-PI item bank utilized 3 different response sets. Each type of interference is evaluated on a scale of "Not at all," "A little bit," "Somewhat," "Quite a bit", and "Very much." (Response set A); or "Never," "Rarely," "Sometimes," "Often," "Always" (Response B); or "Never," "Once a week or less", "Once every few days," "Once a day," "Every few hours" (Response set C).

Recall period for items. All items use a 7-day recall.

Cost to use. PROMIS-PI is free for individual and academic use. There can be fees associated with study-related services and administration for longitudinal uses.

How to obtain. HealthMeasures distributes many of the PROMIS measures. http://www.healthmeasures.net/index.php

Practical Application

Method of administration. Administration of short-form versions can be by paper and pencil or computer/tablet/smartphone. Administration of the PROMIS PI CAT requires a computer/tablet/smartphone.

Scoring. PROMIS instruments use item-level calibrations. While there are tables that can convert raw scores into standardized T-scores, you must have complete data for this method to be valid (i.e., no missing data). The most accurate method of scoring is to use a data collection tool that automatically calculates scores (e.g., REDCap auto-score) or the Health Measures Scoring Service (https://www.assessmentcenter.net/ac_scoringservice.

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Score interpretation. Raw scores are converted to population T-scores with a mean of 50 and a standard deviation (SD) of 10. For example, a score of 60 is 1 SD above the population mean. Higher scores are indicative of more of the construct being measured; thus in this example, 1 SD more pain interference than the population mean. Cut points for PROMIS-PI T-scores include the following: Normal 0-54, Mild 55-59, Moderate 60-79, Severe 70-80+. Normal and mild Pain Interference accounts for about 80% of the general population whereas moderate to severe pain interference accounts for the remaining 20%.[48]

Respondent time to complete. It takes between 45 seconds and 1.6 minutes to complete this assessment depending upon the version being used.

Administrative burden. Administrative burden is minimal as PROMIS-PI can be administered electronically or via paper and pencil. Scoring can be done by hand, by computer, or completed by a service.

Translations/adaptations. PROMIS-PI has been translated into many different languages. A complete listing is available on the HealthMeasures website. http://www.healthmeasures.net/explore-measurement-systems/promis/intro-to-promis/available-translations.

Psychometric Information

The PROMIS measures were developed using Item-Response Theory (IRT) methodology as opposed to Classical Test Construction Theory (CTT). An item pool for Pain Interference was developed to represent the construct. Different assessment forms using different combinations of items (e.g., 4, 6, 8 or CAT) can be used to index the overall pool of items. The PROMIS-PI item bank has an overall Cronbach's alpha of 0.99, is factor analytically unidimensional, can be reliably administered to reflect the construct with short forms of minimal burden (e.g., 4, 6, 8) or with CAT, and experiences minimal Differential item functioning with varying respondent demographics.[49]

Floor ceiling effects. None. Endorsement of "No pain interference" is adequately scaled along with high ranges of pain interference without reaching scaling obstacles.

Reliability. The PROMIS-PI item bank retains highest information between a T-score of 40 (i.e., 1 SD below the population mean) through 80.4 (i.e., 3 SD above the population mean). The majority of the validation sample responses fell within this range which is equivalent to

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reliability of 0.96-0.99 across this range. In the validation sample, no individual scores fell below a T-score of 40 and only 5 individuals (i.e., 1%) scored above 80. The degree of information/precision increased with greater numbers of items (i.e., 4, 6, 8) but all had reliability above 0.95 for scores ranging between 40-80.[49] In a rheumatologic sample, test-re-test reliability of the CAT (i.e., smallest number of items (e.g., 3), was 0.88 for a 2-day interval.[50]

Validity. Construct validity of PROMIS-PI is supported by strong correlations with legacy measures of the same construct (rho=0.90), similar pain constructs (rho=0.84) and lesser associations with differing constructs such as mental health (r=0.33), depression (r=0.35) and anxiety (0.35).[49] Similar support for convergent and divergent validity was found for rheumatic conditions.[50]

Responsiveness. PROMIS-PI showed a dose response relationship with rheumatic disease severity; with responsiveness being identified even at the low end of symptoms and in individuals with minimal disease activity.[50,51]

Minimally important differences. In a study with low back pain, the MID for PROMIS Pain Interference was estimated at between 3.5-5.5 points.[52]

Use in clinical trials. Pain Interference is increasingly recognized as a core outcome in clinical trials for chronic pain.[14]

Critical appraisal of overall value to the rheumatology community

Strengths. The IRT methodology utilized to develop and validate PROMIS Pain Interference makes it psychometrically superior to most legacy measures of the same construct both in terms of precision and minimal patient burden. Legacy measures are static and often require all items to be completed to be valid even if the additional items add no new information – PROMIS measures do not share this weakness.[49]

Caveats and cautions. The psychometric evaluation of an IRT-based instrument is different from one developed using CCT. Many potential users or funders don't understand how different versions of the same item bank using a short form or CAT can be equally reliable and valid indices of the same construct.

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Clinical usability. When multiple domains of assessment are needed, the CAT version of the PROMIS item banks can be the most efficient. Domains can be compared with each other and interpreted easily as they all use the same T-score metric.

Research usability. The static short forms are more commonly used in the research setting where access to CAT scoring algorithms may be more limited.

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Summary/Recommendations

The PROMIS Pain Interference measure is a psychometrically sound instrument for the assessment of this core outcome domain from many required minimum datasets for clinical trials in pain. It comes in both CAT and static short forms of varying lengths each possessing strong psychometric properties of reliability, validity and responsiveness to change supporting is use.

AMBULATORY ASSESSMENT OF PAIN INTESITY

Description

Other measures covered in this chapter rely on respondent's retrospective recollection of their pain experience over a specified time frame, such as pain in the past week or month. In contrast, ambulatory assessment methods of measuring pain involve repeatedly assessing pain experiences in a person's natural environment, in real-time (i.e., report on current experience) or for proximal recall time frames (e.g., since last pain assessment, in the last day). Here the term *ambulatory assessment* refers to self-report methodologies otherwise commonly known as *ecological momentary assessment*, *experience sampling*, or *daily diaries*.

Purpose. Pain intensity is a highly variable symptom, even over short time-frames, and ambulatory assessment of pain is uniquely able to assess pain with high precision and reliability. Use of repeated ambulatory assessments of pain provides a number of significant advantages compared to one-time recall surveys. Ambulatory assessment of pain allows for the examination of the dynamics of pain fluctuations in daily life[53]. Unlike pain ratings collected in the clinic or lab, ambulatory assessment approaches have good ecological validity because it reflects the experience of pain in a person's natural environment[54,55]. Furthermore, this approach does not rely on memory of past pain experiences and is therefore less subject to recall biases, including peak and recency effects on pain ratings[56-58].

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Number of items/assessments. There is some inconsistency in terms of precisely how many ambulatory assessments are needed for a reliable assay of pain in clinical trials research[59-61], with one study finding that a single 24-hour rating of pain had high validity and reliability for detecting treatment effects[62], and others showing that a single momentary assessment is not adequately reliable as a trial outcome[61], and that a composite of at least five days of 24-hour pain ratings are necessary to reach adequate measurement reliability[63]. However, ambulatory assessments are regarded as the most reliable means of assessing pain intensity[64] and this approach is consistent with the most recent US FDA guidelines for the development of analgesic treatments requirements that clinical trial endpoints assess recent pain experience, with recall time frame no longer than the past 24 hours[65].

Practical Application

Although respondent burden is often a concern amongst those considering using ambulatory assessment of pain intensity, available data suggest that these methods are feasible for use in chronic pain populations. Although there are unusual examples of studies with data collection protocol compliance <50%[66,67], average completion rates typically fall in the range of 85%-90%[68,69] and completion rates are high even in populations where chronic pain is secondary to a primary, disabling condition[70-72]. Another common concern in pain assessment is about reactivity to the ambulatory assessment methods; that is, concern that repeatedly asking for pain ratings in real-life settings will alter the respondent's perceptions and ratings of pain. However, a set of studies in diverse populations has found no evidence for reactivity to repeated ambulatory assessment of pain[64,72-75].

Despite the benefits of ambulatory assessment of pain intensity, one major limitation is that methods are currently not standardized and there is tremendous heterogeneity in ambulatory methods used across published studies[68].There is variability across studies in terms of wording of the pain item stem, response scale, data input modality, duration of assessment, frequency of assessment, and assessment schedule. There is no standard wording for pain items in ambulatory assessment and researchers have either replicated wording they find in published research, created a new item stem, or adapted wording from existing recall measures[72,76]. In terms of response scale, prior studies have most commonly used a numerical rating scale (NRS), though visual analog scales (VAS) and verbal ratings scales (VRS) have also been popular[77]. Of these three options, data on patient preference, ease of administration, responsiveness to change, and overall psychometric quality suggest that the NRS is the best

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overall for assessing pain intensity[69,78-84]. The range of response scales also varies widely across studies, though the most common practice is to use a 0-10 NRS, which is consistent with common procedures in clinical care and with the current pain intensity outcome measurement recommendations from the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials[14].

Method of administration. Ambulatory pain data has been collected via paper logs/diaries[85-87], palmtop computers[88], wearable devices (i.e., watches)[70,89-91], and smart phone applications[92,93]. With growing ubiquity of wearable technology and smartphones, use of these devices to collect ambulatory pain data in research has grown tremendously, particularly since 2010[68]. Although pain studies have collected data for various lengths of time, ranging from 1 day to over 1 year, the most common data collection periods are 1 week or 2 continuous weeks of assessment[68]. Similarly, frequency or intensity of data collection is also highly variable, though on average studies assess pain 5X/day[68]. There is also variability in the sampling schedule used across pain studies, though most studies use a time-based fixed or random sampling schedule[68]. It is likely that some flexibility in ambulatory assessment methods is needed to address different types of research questions and to meet different clinical and study needs. However, there is a clear need for more rigorous psychometric evaluation and the development of clear standards for ambulatory assessment methods.

Critical Appraisal of Overall Value to the Rheumatology Community

Strengths. Ambulatory assessment of pain intensity is uniquely capable of capturing the daily fluctuations in pain severity common in people with rheumatologic conditions. Because pain ratings are given in real time or require recall of proximal time frames, ambulatory assessment does not suffer from recall bias and provides an optimally reliable assay of pain when collected over a series of days. Because pain intensity is collected “in the wild” as respondents go about their daily lives, it is considered to have better ecological validity than pain ratings collected in the research lab or clinic. A repeated pain assessment with a maximum of 24-hour recall period for pain intensity is consistent with current FDA guidelines for the assessment of pain.

Caveats and cautions. Currently, there are no standardized ambulatory assessment methods for measuring pain intensity. There is also limited psychometric data regarding the various pain assessment methods that have been developed and employed.

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Clinical usability. Logistic challenges to collecting data outside of the clinic are likely to be primary barriers to using ambulatory assessment of pain intensity clinically. This combined with a lack of normative data and clinical cut-points currently limit the potential usefulness of this approach for clinical application.

Research usability. Ambulatory assessment of pain has been used for decades in the research realm and its popularity has grown tremendously with advances in technology that facilitate data collection. The ubiquity of ambulatory assessment of pain in research continues to grow, as does the need for development and psychometric evaluation of measurement

Summary / Recommendations

Despite the lack of standardized methods and psychometric data, informal best practices are being established, as is ongoing work to examine psychometric qualities of these measures. Given the numerous benefits of this methodology and the growing use of ambulatory assessment in research, researchers should not be discouraged from employing these methods, following best practices as outlined in this section. The challenges are greater for clinical use of ambulatory assessment of pain; norms, clinical cut-points, and solutions to logistical challenges of collecting data outside of the clinic are needed before this approach can be effectively employed in the clinical setting.

DISCUSSION

There are many useful measures for the assessment of pain in adult patients seen in rheumatologic settings. Using validated measures that help elucidate key features of the pain experienced by a patient including pain severity/intensity, location, and quality are important. Of particular interest, and useful to measure, is the degree to which pain interferes with functioning. Described above are some of the most commonly used measures to address those domains. Yet, no measure is perfect and most measures have decided strengths and weaknesses. The Brief Pain Inventory (BPI) is a psychometrically sound measure recommended for use in clinical settings to monitor pain severity and its impact on functioning. It is easy to administer and score, although there can be costs associated with its use. Some aspects of the BPI are rarely reported (e.g., body map, medications, pain relief), but could be considered clinically useful in the care of rheumatology patients. Another commonly used measure of pain intensity and interference is the Defense and Veterans Pain Rating Scale (DVPRS). The DVPRS was developed for and has been used in primarily in military and veteran populations. It was created

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to help track changes in pain intensity and interference and is considered particularly useful for monitoring within-patient symptom changes that commonly occur during transitions between different military healthcare providers. As such, the DVPRS would be most useful in military personnel with rheumatic conditions. Also, the PROMIS Pain Interference measure is an easy to use and psychometrically sound measure for the evaluation of pain interference. Although this measure does not include an assessment of pain severity like the BPI and DVPRS, it is available at no cost and can be administered using as few as 4 items. This measure is available in both CAT and static short forms of various lengths all with strong data supportive of its reliability, validity and responsiveness to change.

In addition to pain severity and interference, the location of pain is crucial to understand. The Michigan Body Map (MBM) consists of a manikin with 35 body areas that can be endorsed to indicate areas of pain. The MBM has been used to assess pain in many rheumatic populations including osteoarthritis, rheumatoid arthritis, systemic lupus erythematosus, fibromyalgia, and low back pain. The body map is available in paper or electronic forms at no cost and is easy for patients to understand, can be completed in a few minutes and provides information about the location and spread of pain. In addition, the number of painful body areas can be summed providing a score that can be used to help assess the degree to which pain is more centralized (fibromyalgia-like).[2,22,33] One limitation is that the MBM areas of bodily pain are finite and thus not all possible areas of pain are options for patients to endorse. As for assessing pain quality, the painDETECT Questionnaire (PD-Q) is thought to be useful for the detection of neuropathic pain in patients with chronic low back pain, inflammatory arthritis or osteoarthritis. Other data suggest that it is less useful for patients with neck or upper limb conditions. Analysis of the instrument's psychometric properties generally support its use as a brief screening tool. Moreover, it is easy for patients to complete, straightforward to score and has been extensively translated and cross-culturally validated. Lastly, ambulatory assessment of pain intensity is increasingly ubiquitous in research and holds tremendous potential for clinical applications. Detecting fluctuations in pain as they occur in real-time provides unprecedented opportunities for researchers and clinicians to better understand the characteristics and underlying mechanism that influence pain; these insights are essential for developing individualized approaches to pain treatment. Coupled with this incredible potential is a current lack of scientific evidence supporting a standard approach to ambulatory assessment. Establishment of standard methods, population norms, and clinical cut-points are necessary before ambulatory assessment can be truly useful in clinical practice. Still, ambulatory assessment of pain can

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provide useful insights and optimally reliable outcome measures in research regardless of the current psychometric unknowns.

Although pain assessment in the clinic typically focuses on pain itself (i.e., intensity, location and quality), pain perception is dependent not only upon *nociception*, but also other mental and physical parameters. Thus, there is value in assessing symptom clusters associated with pain. These symptom clusters allow clinicians to know what other factors are contributing to un-wellness/disability, but also can provide additional clinical targets for treatment given these symptoms are often correlated with both worsening and improvement in pain.[94] One such symptom cluster that is gaining attention in both adult and pediatric chronic pain is remembered by the acronym S.P.A.C.E. (sleep, pain, affect, cognitive dysfunction, energy/fatigue).[94,95] S.P.A.C.E can be efficiently assessed using a combination of PROMIS short-form measures (e.g., Sleep-related impairment, pain intensity, anxiety and depression, cognition, and fatigue scales) or by using one of the PROMIS Profiles such as the PROMIS 29+2 (PROPr)[96] which contains scales assessing each of the elements within S.P.A.C.E. This symptom cluster can also be assessed using a combination of legacy measures for each symptom which have reviewed elsewhere[94] (e.g., the Pittsburg Sleep Quality Index (PSQI), the Michigan Body Map and the PainDetect (reviewed above), the Hospital Depression and Anxiety Scale (HADS), the Multi-dimensional Inventory of Subjective Cognitive Impairment (MISCI), and the Multidimensional Fatigue Inventory (MFI). When such comorbid symptoms are identified, addressing these, especially sleep and mood, can have an appreciable impact on pain and functioning.[97,98]

Pain is complex – no single measure can adequately account for the experience and toll of living with chronic pain. The measures described here and those from past similar publications,[1] can be used to form the substrate for clinical pain assessment. Yet, other symptoms that commonly co-occur with chronic pain are also critical to assess (e.g., S.P.A.C.E. symptoms). A comprehensive understanding of an individual's pain experience through the use of validated measures can help personalize treatment with the goal of achieving optimum outcomes.

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Table 1. Practical applications

Measure	Number of Items	Content/ Domains	Method of administration	Recall period	Response Format	Range of Scores	Score Interpretation	Availability of normative data	Cross-cultural validation
BPI	15	Pain severity Pain Interference	Paper-pencil Computer CAT	24hr and days	11-point Likert with verbal anchors	Pain Severity (0-10) Pain Interference (0-10)	Higher scores indicative of greater pain severity or interference	Has been used in over 400 pain studies	Validation studies in 24 languages
DVPRS	5	Pain intensity Pain interference (usual activity, sleep, mood, and stress)	Paper-pencil	Pain intensity: current Pain interference: past 24 hours	11-point numeric rating scales	Pain intensity (0-10) Pain Interference items (0-10)	Higher scores indicative of greater pain intensity or interference	Not available	Spanish and Vietnamese versions are available*
MBM	1 (up to 35 areas of pain can be indicated)	Pain location	Paper-pencil Computer	Pain that has persisted for greater than 3 months	35 check boxes	Number of painful body areas (0-35)	Higher scores indicative of more areas of the body with chronic pain	Not available	Chinese, German, Portuguese, and Yiddish

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painDETECT	13 (responses to 9 items used to derive summary score)	Pain intensity Pain location and whether pain radiates Pain course Pain quality	Paper-pencil	Currently and over the past 4 weeks	3 x 11-point numeric rating scales, 1 x illustrated question with best choice option for course of pain; 1 x body map with accompanying question about whether pain radiates; 7 x 6-point Likert scales for pain quality	-1 to 38 (0 to 38 displayed on screening scale included in instrument)	≤12: neuropathic pain component unlikely 13-18: Ambiguous. Neuropathic pain component cannot be ruled out ≥19: Neuropathic pain component likely	Not available	Extensively cross-culturally adapted and available in more than 23 languages
PROMIS-PI	41, 4,6,8	Pain Interference	Paper-pencil Computer	7 days	5-point numeric rating scale with verbal anchors	T-scores 0-100	Higher scores indicative of greater pain interference.	T-score tied to population mean. 1SD is 10 points	PROMIS-PI has been translated and has validation studies in numerous languages

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Ambulatory Assessment (e.g., EMA, daily diary)	1	Pain intensity	Paper-pencil, computer, tablet, smart phone, wearables, short message service (text), interactive voice response	Current, since last assessment (variable, but < 24 hours), or past day/24 hours.	numeric rating scale/visual analog scale' or verbal response scale	Most common: 0-10 or 0-100	Higher scores indicate more intense pain	Not available	Not available

*Available at: https://www.dvcipm.org/clinical-resources/defense-veterans-pain-rating-scale-dvprs/

Table 2. Psychometrics

Measure	Floor, ceiling effects	Reliability	Validity	Responsiveness	Minimally important differences	Generalizability	Used in RCTs
BPI	Floor: some Ceiling: minimal	Good IC -Severity: 0.85 -Interference:	Good BPI scores highly correlate with other	Excellent Sensitive to treatment changes.	MID of 2.2 points in severity and 0.50 SD in interference considered meaningful.	Considered a generic assessment of pain severity and interference	Used in many RCTs of varying pain conditions. Recommended measure for core minimum datasets of clinical trials

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		0.88 Test-retest -Severity: 0.83-0.88 -Interference: 0.83-0.93	measures of severity and interference/disability (range: 0.69-0.81)				
DVPRS	No data available	Good IC: 0.87 Acceptable test-retest - Intensity: Pearson's r 0.64 - Interference items: Pearson's r all >0.7	Good construct and content validity -Excellent agreement between 11-point pain numeric rating scale and word descriptions (ICC 0.94). -Concurrent validity of pain interference items demonstrated against	No data available	No data available	Developed and predominantly tested in military/veteran contexts	Used in RCTs with military and veteran populations

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			established instruments				
MBM	No data available	Test-retest reliability: 0.84	Good convergent and discriminant validity.	No data available	No data available	Used in a broad array of settings including in different countries, for non-inflammatory and inflammatory pain conditions and in surgical settings	Used in prospective cohort studies and clinical trials for both acute and chronic pain patients
painDETECT	No ceiling effects observed when tested with people with inflammatory arthritides	Low Back Pain IC: 0.76 Test-retest reliability: almost perfect agreement (ICC: 0.91)	Validity of English version yet to be formally investigated.	No data available	No data available	Can be used to detect neuropathic components of pain in inflammatory and non-inflammatory conditions	Used in RCTs of pharmacological and non-pharmacological interventions for neuropathic pain
PROMIS-PI	None	Excellent IC 0.96-.99	Excellent PROMIS-PI scores	Good Sensitive to treatment	MID of 3.5-5.5 points considered meaningful.	Developed specifically to be a generic	Recommended measure for core minimum datasets of pain studies

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		Test-retest reliability 0.88	correlate with other measures of interference (range 0.84-0.90)	changes.		measure of pain interference	including clinical trials.

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