

# REVIEW Focused Evidence Review: Psychometric Properties of Patient-Reported Outcome Measures for Chronic Musculoskeletal Pain

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**BACKGROUND:** Developing successful interventions for chronic musculoskeletal pain requires valid, responsive, and reliable outcome measures. The Minneapolis VA Evidence-based Synthesis Program completed a focused evidence review on key psychometric properties of 17 selfreport measures of pain severity and pain-related functional impairment suitable for clinical research on chronic musculoskeletal pain.

**METHODS:** Pain experts of the VA Pain Measurement Outcomes Workgroup identified 17 pain measures to undergo systematic review. In addition to a MEDLINE search on these 17 measures (1/2000–1/2017), we handsearched (without publication date limits) the reference lists of all included studies, prior systematic reviews, and—when available—Web sites dedicated to each measure (PROSPERO registration CRD42017056610). Our primary outcome was the measure's minimal important difference (MID). Secondary outcomes included responsiveness, validity, and test-retest reliability. Outcomes were synthesized through evidence mapping and qualitative comparison.

**RESULTS:** Of 1635 abstracts identified, 331 articles underwent full-text review, and 43 met inclusion criteria. Five measures (Oswestry Disability Index (ODI), Roland-Morris Disability Questionnaire (RMDQ), SF-36 Bodily Pain Scale (SF-36 BPS), Numeric Rating Scale (NRS), and Visual Analog Scale (VAS)) had data reported on MID, responsiveness, validity, and test-retest reliability. Seven measures had data reported on three of the four psychometric outcomes. Eight measures had reported MIDs, though estimation methods differed substantially and often were not clinically anchored.

**CONCLUSIONS:** In this focused evidence review, the most evidence on key psychometric properties in chronic musculoskeletal pain populations was found for the ODI, RMDQ, SF-36 BPS, NRS, and VAS. Key limitations in the field include substantial variation in methods of estimating psychometric properties, defining chronic musculoskeletal pain, and reporting patient demographics.

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# INTRODUCTION

Chronic musculoskeletal pain is a major source of disability and morbidity in the USA,<sup>1</sup> and affects approximately 60% of Veterans with chronic health conditions in Veterans Health Administration (VHA) primary care.<sup>2</sup> Management remains challenging, and groups ranging from pain expert coalitions to the National Institutes of Health and the Institute of Medicine have called for more focused and strategic pain therapy research.<sup>3</sup> As these groups note, successful development and testing of interventions to improve chronic musculoskeletal pain depends on the use of valid, reliable, and responsive measures of pain domains.

Existing pain outcome measures often span multiple physical, emotional, and social domains. To guide development and use of these measures, experts and stakeholders have formed such initiatives as Outcome Measures in Rheumatology (OMERACT), the Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) public-private partnership with the US Food and Drug Administration (FDA), the associated Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT), and the NIH Task Force on Research Standards for Chronic Low Back Pain. These groups have published several reviews and compiled recommendations suggesting that pain outcome studies measure multiple domains via multiple modes of assessment.<sup>4-9</sup> These groups have identified both pain intensity or severity (hereafter "severity") and pain-related impairment of physical function (hereafter "functional impairment") as key domains for study, as these reflect both pain symptoms and pain's impact on

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people's daily lives.<sup>4,8</sup> Functional impairment has been identified as a priority concern for patients<sup>10</sup> and is an increasingly common primary outcome domain alongside pain severity. Self-report measures remain the gold standard mode of assessing core pain outcomes, as they reflect subjective pain experience, and as existing observer- and laboratory-based pain measures do not consistently reflect clinically meaningful changes in key pain domains.<sup>4,6,11</sup>

The Department of Veterans Affairs 2016 State of the Art (SOTA) Conference on non-pharmacological approaches to chronic musculoskeletal pain management recognized the value of adopting a consistent core set of outcome measures for future chronic pain research. For example, such a core could facilitate cross-study comparisons of intervention effectiveness and other findings. To inform their choice of key measures, the VA Pain Measurement Outcomes Workgroup requested an evidence review focused on describing existing research on key psychometric properties of 17 commonly used self-report measures of pain severity and pain-related functional impairment. Research on such psychometric properties would not provide the only criterion for selecting core measures,<sup>12</sup> but can be seen as a basic requirement of candidates for wide implementation. Our review addressed the following key question: Which of the 17 self-report pain measures nominated by the VA Pain Measurement Outcomes Workgroup had sufficient psychometric evidence to consider their adoption for use as core outcome measures in future clinical research? The findings in this manuscript are based on a VA Evidence-based Synthesis Program report available online.<sup>13</sup>

#### **METHODS**

In conjunction with the topic nominators' expert input, we developed a protocol for this review (registered in the PROSPERO database: CRD42017056610) and identified the populations of interest, study inclusion and exclusion criteria (Table 1), and our primary and secondary psychometric outcomes. The topic nominators requested a focus on chronic, non-traumatic musculoskeletal pain, which was defined as musculoskeletal pain of at least a 3month duration. There was a particular interest in measures that had been used in Veteran populations and in multidimensional measures that assessed both pain severity and pain-related functional impairments, such as activity limitations and interference with physical function.

Our primary outcome was whether a minimal important difference (MID) had been established for each measure, with a focus on minimal clinically important difference vs. statistically detectable difference. Secondary outcomes related to measures' psychometric properties of responsiveness to change, validity, and retest reliability. The 17 pain measures assessed in this review were selected by pain experts in the SOTA workgroup and are outlined in more detail in Table 2.

#### Table 1 Inclusion and Exclusion Criteria

Inclusion criteria

(1) Studies of adults with chronic musculoskeletal pain of at least a 3-month duration (or described as "chronic" by the study authors); if the study included multiple types of pain, at least 75% of the population must have had chronic musculoskeletal pain unless results were reported separately for the chronic musculoskeletal pain group (2) Reporting on self-reported measures of pain intensity or pain-related functioning, limited to the following: Brief Pain Inventory (BPI) Defense and Veterans Pain Rating Scale (DVPRS) Graded Chronic Pain Scale (GCPS) Hip Osteoarthritis Outcomes Scale (HOOS) Knee Osteoarthritis Outcomes Scale (KOOS) McGill Pain Questionnaire (MPQ) Multidimensional Pain Inventory (MPI, WHYMPI) Numeric Rating Scale (NRS) Oswestry Disability Index (ODI) Patient Global Impression of Change (PGIC) PEG (assesses [P] pain intensity, [E] enjoyment of life, and [G] general activity) Patient-Reported Outcomes Measurement Information System - Pain Interference (PROMIS-PI) Roland-Morris Disability Questionnaire (RMDQ) SF-36 Bodily Pain Scale (SF-36 BPS) Visual Analogue Scale (VAS) Western Ontario and McMaster Universities Arthritis Index (WOMAC) Wong Faces Scale (3) Reporting any or all outcomes of interest: minimal important difference (primary outcome), responsiveness, validity (concurrent and/or discriminant), test-retest reliability Exclusion criteria (1) Studies of patients with conditions often associated with chronic musculoskeletal pain unless the study specified that the patients had chronic musculoskeletal pain (e.g., radiologically defined osteoarthritis) (2) Studies reporting on non-English language versions of the pain measures (3) Trials of interventions for pain unless assessment of psychometric properties was noted in the abstract (4) Studies of patients with rheumatoid arthritis, orofacial pain, or headache

## Search Strategy

We followed a multi-pronged search strategy. First, we searched MEDLINE (Ovid) from January 2000 to January 2017 for English language publications. Our search strategy, developed with input from a medical librarian, included Medical Subject Heading (MeSH) terms for Pain Measurement and specific locations/types of pain (e.g., Low Back) along with title and abstract words. The search was designed to include all study designs, including systematic reviews. The full search strategy is presented in Supplemental Content Table 1. At the request of reviewers of the full evidence report, we repeated the search with MeSH and title/abstract terms for fibromyalgia. Second, we used Google Scholar, the National Center for Biotechnology Information (NCBI), and PubMed to identify articles not found through the MEDLINE search. Third, we searched for Web sites associated with each pain measure and hand-reviewed all Web references, including those that predated 2000. We also searched for original development and validation papers associated with each measure, regardless of publication date. Fourth, we hand-reviewed the reference lists of all included studies and the reference lists of relevant systematic reviews identified through MEDLINE. Fifth, we invited the SOTA experts to identify additional key articles for review. Sixth, the draft evidence report underwent peer review

Scale	Development pain type				Pain Domain	Length		
	General	LBP	Knee/ hip	Other	Severity/ intensity	Function/ interference	Number of items	
BPI (Cleeland 1994) <sup>14</sup>				1	1	1	17	
DVPRS (Buckenmaier 2012) <sup>15</sup>	$\checkmark$				$\checkmark$	$\checkmark$	5	
GCPS (von Korff 1992) <sup>16</sup>	$\checkmark$				$\checkmark$	$\checkmark$	7	
HOOS (Klassbo 2003) <sup>17</sup>			$\checkmark$		$\checkmark$	$\checkmark$	40	
KOOS (Roos 2003) <sup>18</sup>			$\checkmark$		$\checkmark$	$\checkmark$	42	
MPQ (McCaffery 1989) <sup>19</sup>	$\checkmark$				$\checkmark$	$\checkmark$	78	
MPI/WHYMPI	$\checkmark$	$\checkmark$			$\checkmark$	$\checkmark$	52	
(Kerns 1985) <sup>20</sup>								
NRS (McCaffery 1989) <sup>19</sup>	$\checkmark$				$\checkmark$		1	
ODI (Smeets $2011)^{21}$		$\checkmark$			$\checkmark$	$\checkmark$	10	
PGIC (Farrar 2001) <sup>22</sup>	?				?	?	1	
PEG (Krebs 2009) <sup>23</sup>	$\checkmark$				$\checkmark$	$\checkmark$	3	
PROMIS-PI (PRÓMIS Web site) <sup>24</sup>	$\checkmark$					$\checkmark$	41	
RMDQ (Roland 1983) <sup>25</sup>		$\checkmark$				$\checkmark$	24	
SF-36 BPS (Ware 1998) <sup>26</sup>	$\checkmark$				$\checkmark$	$\checkmark$	2	
VAS (Wewers 1990) <sup>27</sup>				$\checkmark$	$\checkmark$	$\checkmark$	1	
WOMAC (Am Coll Rheum) <sup>28</sup>			$\checkmark$		$\checkmark$	$\checkmark$	24	
Wong Faces Scale (Wong-Baker Web	$\checkmark$			$\checkmark$	$\checkmark$		1	
site) <sup>29</sup>								

 Table 2 Overview of Pain Measures

SAQ self-administered questionnaire, ? not identified

(including SOTA experts), and peer reviewers were asked to identify any potentially eligible references. All identified references were assessed for eligibility. We set no date limitations on publications identified through hand reviews of reference lists, Web sites, or expert nomination.

#### **Study Selection**

Eligibility criteria are presented in Table 1. Abstracts of studies identified in our MEDLINE search were reviewed by trained staff. The full text of potentially eligible articles from abstract review, and of all articles identified from reference list searching or online sources, was reviewed independently by two researchers. Disagreements were resolved by consensus.

#### Data Abstraction and Quality Assessment

From each eligible study, trained staff abstracted (1) study/population characteristics: location of study, funding source, measurement scales evaluated, time period of assessment (e.g., reporting pain over past week, past month), mode of administration, setting, chronic pain condition, study inclusion/exclusion criteria, baseline pain characteristics, sample size, age, gender, and race/ethnicity, and (2) our psychometric outcomes of interest. For the primary outcome, we noted whether the minimal important difference was clinically anchored (e.g., based on the smallest difference at which participants felt better or worse) or based solely on statistical parameters (e.g., standard error of the measurement). Data were abstracted onto standardized forms piloted by research staff. All data abstraction was completed by one reviewer and verified by another. The psychometric properties represent quality measures; no further quality assessment was done.

## **Data Synthesis**

We summarized included studies to provide an overview of the populations and pain conditions for which the psychometric properties of measures have been evaluated. We present frequency of estimation of each psychometric outcome for each measure in the form of a heat map and provide a tabular summary of primary outcome results.

### RESULTS

## Literature Flow

The literature flow diagram (Fig. 1) illustrates the process of study review and selection. Using our various search strategies, we identified 1635 abstracts, of which 331 proceeded to full-text review. Over half of the articles excluded after full-text review did not report the psychometric properties of interest; over one-third did not assess a pain measure of interest and/or did not study a population documented to have chronic musculoskeletal pain.

#### **Overview of Study Characteristics**

Table 3 summarizes the characteristics of the pain measurement studies included in the review. We included 43 studies: 23 from the USA,  $^{20,23,30,31,36,38,39,43,45,46,48-52,56,59,62,64-67,70}$  3 from Canada,  $^{32,57,60}$  one from South America,  $^{41}$  5 from A u s t r a l i a,  $^{34}$ ,  $^{35}$ ,  $^{47}$ ,  $^{54}$ ,  $^{63}$  and 11 from E u-rope.  $^{33,37,40,42,44,53,55,58,61,68,69}$  Of the US studies, four enrolled exclusively military Veterans  $^{20,48,52,65}$  and two enrolled both Veterans and non-Veterans.  $^{23,50}$  Study enrollments ranged from  $30^{53}$  to  $998^{64}$  with 29 enrolling more than 100 and 3 enrolling more than  $500.^{36,46,64}$  The most common chronic musculoskeletal pain condition was low back pain (LBP), with 16 studies enrolling only LBP

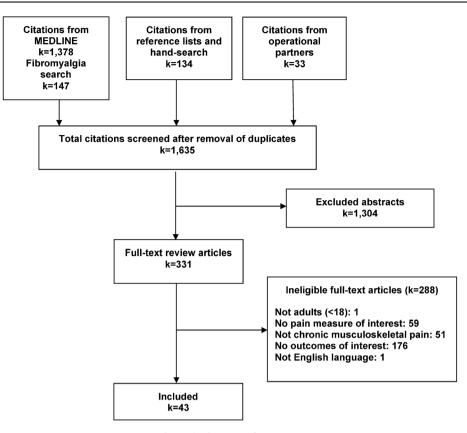


Figure 1 Literature flow chart.

patients.<sup>31,33,34,36,37,40,44–46,49,52,54,55,59,66,68</sup> Thirteen studies included patients with any chronic musculoskeletal pain.<sup>20,30,35,38,41,48,51,53,57,61,64,65,70</sup> Mean age, reported in 40 studies, ranged from 32 years<sup>69</sup> to 80 years<sup>45</sup>: less than 50 years in 18 studies, 50 to 59 years in 15 studies, and 60 years and older in 7 studies. The percentage of women ranged from 8 to 19% in the studies that enrolled exclusively US military Veterans. Five of the remaining studies enrolled fewer than 50% women,<sup>34,43,53,58,62</sup> 29 enrolled 50% or more, and 5 did not report the percentage of women enrolled. Race/ ethnicity was reported in 18 of the studies, all but one from the USA. The percentage of white enrollees was 75% or higher for 11 of the 18 studies. Additional study characteristics are reported in Supplemental Table 2 (available online).

#### Heat Map

Figure 2 presents a heat map summarizing findings for the 17 pain measures on four psychometric outcomes of interest: MID, responsiveness, validity (concurrent and/or discriminant), and test-retest reliability. As the heat map shows, 14 measures had data reported on both responsiveness and concurrent validity, 5 measures had data reported on discriminant validity, and 10 measures had data reported on test-retest reliability. Data on all four main psychometric outcomes of interest were reported for five measures: Numeric Rating Scale (NRS), Oswestry Disability Index (ODI), Roland-Morris Disability Questionnaire (RMDQ), SF-36 Bodily Pain Scale (SF-36 BPS), and Visual Analog Scale (VAS). The highest numbers of relevant studies were also found on these five measures. Data on MID, responsiveness, and validity were reported for Brief Pain Inventory (BPI), Graded Chronic Pain Scale (GCPS), and Pain intensity, Enjoyment of life, and General activity (PEG). Data on responsiveness, validity, and test-retest reliability were reported for Multidimensional Pain Inventory (MPI)/ West Haven-Yale Multidimensional Pain Inventory (WHYMPI), McGill Pain Questionnaire (MPQ), Patient-Reported Outcomes Measurement Information System -Pain Interference (PROMIS-PI), and Western Ontario and McMaster Universities Arthritis Index (WOMAC). We found no studies meeting eligibility criteria for the DVPRS or the KOOS. Screened studies of the Defense and Veterans Pain Rating Scale (DVPRS) were not specific to chronic musculoskeletal pain, and studies of the KOOS did not administer the measure and/or report findings in English. Supplemental Table 3 (in electronic appendices) identifies specific reviewed studies within this evidence map configuration, and Supplemental Table 4 contains more details on reported quantitative indicators of psychometric properties and relevant study design features.

#### Primary Psychometric Outcome

Table 4 reports findings on the primary psychometric outcome, minimal important difference (MID). The VAS is

Author year	Scales evaluated	Study characteristics							
		Sample Pain		Mean	Women	Race/ethnicity (%)			
		Size	condition	age (years)	(%)	White	Black	Hispanic	Other
Anagnostis	ODI	230	CDMD	43	53	60	29	11	0.1
2004 <sup>30</sup> Askew 2016 <sup>31</sup>	PROMIS-PI	218	LBP	N/D	56	84	4	1	11
Burhnam 2012 <sup>32</sup>	MPQ, ODI	60	Spine	60	67	N/D			
Changulani 2009 <sup>33</sup>	ODI, VAS	107	LBP	58	58	N/D			
Chansirinukor	RMDQ	143	LBP	38	26	N/D			
2005 <sup>34</sup> Chien 2013 <sup>35</sup>	BPI	254	General MSP	51	50	N/D			
Cook 2008 <sup>36</sup>	RMDQ	875	LBP	47	N/D	85	9	3	Asian, 2; other, 1
de Vet $2007^{37}$	NRS	438	LBP Commit MSD	N/D	N/D	N/D		4	4
Deyo 2016 <sup>38</sup> Driban 2015 <sup>39</sup>	PROMIS-PI-SF PROMIS-PI, SF-36	198 204	General MSP Knee (OA)	67 60	62 70	92 53	N/D 36	4 N/D	4 12
	BPS, WOMAC				70	55	50	10.0	12
Fisher 1997 <sup>40</sup>	MPQ, ODI	54	LBP	41	63	N/D			
Gallasch 2007 <sup>41</sup>	Wong Faces, NRS, VAS	32	General MSP	51	N/D	N/D			
Gentelle-	VAS, WOMAC	80	Knee (OA)	62	70	N/D			
Bonnassies									
2000 <sup>42</sup> Godil 2015 <sup>43</sup>	NRS	88	Neck and arm	52	44	N/D			
Gronblad 1993 <sup>44</sup>	ODQ, VAS	94	LBP	43	51	N/D			
Hicks 200945	ODI, SF-36 BPS	107	LBP	80	72	100	N/D	N/D	N/D
Jensen 2012 <sup>46</sup>	VAS	639	LBP	52	62	90	5	N/D	Asian, 1; other, 4
Kamper 2015 <sup>47</sup>	NRS, SF-36 BPS	280	Whiplash	44	65	N/D	4.0		
Kean 2016 <sup>48</sup> *	BPI, PEG, PROMIS-PI-SF, SF- 36 BPS	244	MSP	55	17	77	19	N/D	4
Keller 2004 <sup>49</sup>	BPI, GCPS, SF-36	131	LBP	46	N/D	N/D			
Kerns 1985 <sup>20</sup> *	BPS, RMDQ MPI (WHYMPI),	120	Chronic MSP	51	19	N/D			
Krebs 2010 <sup>50†</sup>	MPQ BPI, GCPS, PEG,	427	Back, hip,	59	53	58	38	N/D	4
Krebs 2009 <sup>23†</sup>	RMDQ, SF-36 BPS BPI, GCPS, PEG,	500	knee Back, hip,	59	52	58	38	N/D	4
Kicos 2009	PGIC, RMDQ, SF- 36 BPS	500	knee	59	52	50	50	IN/D	7
Krebs 2007 <sup>51</sup>	NRS	275	General MSP	59	59	70	24	N/D	6
Lovejoy 2012 <sup>52</sup> *	MPI, MPQ-2-SF,	186	LBP, neck,	54	8	75	N/D	N/D	15
Lund 2005 <sup>53</sup>	MPQ	30	joint MSP	12	12	N/D			
Macedo 2011 <sup>54</sup>	VAS RMDQ	30 461	LBP	43 53	43 61	N/D N/D			
Maughan 2010 <sup>55</sup>	NRS, ODI, RMDQ	48	LBP	52	67	N/D			
Merriwether	PROMIS-PI	106	Fibromyalgia	49	100	96	N/D	N/D	4
2016 <sup>56</sup> Mikail 1993 <sup>57</sup>		215	Comanal MCD	4.4	53	N/D			
Nilsdotter 2003 <sup>58</sup>	MPI, ODI HOOS, WOMAC, SF-36 BPS	315 62	General MSP Hip (OA)	44 73	33 45	N/D N/D			
Parker 2012 <sup>59</sup>	ODI, VAS	47	LBP	55	64	N/D			
Pinsker 2015 <sup>60</sup>	NRS, WOMAC	142	Ankle	61	54	N/D			
Scott 2015 <sup>61</sup>	PGIC	476	Not specified	46	67	72	17	N/D	Asian, 7; other, 4
Sindhu 2011 <sup>62</sup>	NRS, VAS	33	Elbow, forearm, hand	39	48	N/D			
Stewart 2007 <sup>63</sup>	NRS, SF-36 BPS	132	Whiplash	43	67	N/D			
Stroud 2004 <sup>64</sup>	RMDQ	998	Not specified	44	57	84	3	4	Asian, 2; Native American, 4;
Tan 2004 <sup>65</sup> *	BPI, RMDO	440	Not specified	55	8	72	21	N/D	other, 3 7
Tong 2006 <sup>66</sup>	VAS	440 52	LBP	33 41	8 62	88	21 3	N/D N/D	Asian, 3;
	110	54		11	02	00	5		other, 6
Trudeau 2015 <sup>67</sup> van der Roer	WOMAC, NRS NRS	47 138	Knee (OA) LBP	N/D 44	N/D 59	N/D N/D			, -
2006 <sup>68</sup> van Grootel	VAS	118	TMD	32	93	N/D			
$2007^{69}$	MDI ODI OD M	07	Characterist	17	67	70		NI/D	21
Wittink 2004 <sup>70</sup>	MPI, ODI, SF-36 BPS	87	Chronic pain	47	67	79	N/D	N/D	21

#### Table 3 Overview of Included Studies

CDMD chronic disabling musculoskeletal disorders, LBP low back pain, MSP musculoskeletal pain, N/D not determined, OA osteoarthritis, TMD temporomandibular disorder

\*Enrolled exclusively US Veterans

†Enrolled US Veterans and non-Veterans; results not stratified by Veteran status

	Minimally Important Difference	Responsiveness	Concurrent Validity	Discriminant Validity	Test-retest Reliability
Brief Pain Inventory (BPI)	1	6	3	0	0
Defense and Veterans Pain Rating Scale (DVPRS)	0	0	0	0	0
Graded Chronic Pain Scale (GCPS)	1	3	2	0	0
Hip Osteoarthritis Outcomes Scale (HOOS)	0	1	1	0	0
Knee Osteoarthritis Outcomes Scale (KOOS)	0	0	0	0	0
McGill Pain Questionnaire (MPQ)	0	1	2	1	1
Multidimensional Pain Inventory (MPI/WHYMPI)	0	1	3	1	1
Numerical Rating Scale (NRS)	3	5	4	1	3
Oswestry Disability Index (ODI)	3	5		1	3
Patient Global Impression of Change (PGIC)	0	2	1	0	0
PEG	1	3	1	0	0
Patient-reported Outcomes Measurement Information System-Pain Interference (PROMIS-PI)	0	3	1	0	1
Roland-Morris Disability Questionnaire (RMDQ)	3	7	5	0	1
SF-36 Bodily Pain Scale (SF-36 BPS)	1	7		1	1
Visual Analogue Scale (VAS)	2	3	3	0	4
Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)	0	3	3	0	1
Wong Faces Scale/ Wong-Baker Face Scale	0	0	0	0	1

Figure 2 Number of studies reporting psychometric properties.

reported twice in this table because the scoring range differed 10-fold across the two studies. Table 4 demonstrates the variety of statistical approaches used to estimate MID. Four studies calculated measure-specific minimal clinically important differences (MCIDs) using a clinically anchored approach,<sup>37,55,59,68</sup> and one study used two different populations to calculate statistically detectable differences that were then compared to global ratings of change via kappa statistics.<sup>50</sup> Three studies used distribution-based statistical estimations only.<sup>34,45,69</sup>

#### DISCUSSION

This focused evidence review evaluated published research on psychometric properties of 17 key patient-reported pain outcome measures assessed in chronic musculoskeletal pain populations. Of the five scales with reported data on all four psychometric outcomes (ODI, RMDQ, SF-36 BPS, NRS, and VAS), three (the ODI, RMDQ, and SF-36 BPS) measure multiple pain domains. The NRS and VAS varied among studies with respect to key construct (pain severity or painrelated functional impairment), phrasing, recall periods, and score ranges, making this overview more a cataloging of different numeric rating scales and visual analog scales than a review of two clearly defined pain measures. Seven additional scales (BPI, GCPS, MPI/WHYMPI, MPQ, PEG, PROMIS-PI, and WOMAC) also had evidence for three key psychometric properties. Findings are consistent with pain outcome measurement reviews focused on specific painrelated diagnoses: a review focused on responsiveness of patient-reported health outcome measures for LBP found the ODI and RMDQ to be the most comprehensively validated,<sup>71</sup> and a previous review of back-specific functional status questionnaires for LBP found the ODI and RMDQ to have been most frequently studied, with good measurement properties in their original form as retested in multiple settings.<sup>72</sup>

The range of MID assessment methods identified in this review reflects variation in current MID-related research. Assessments of minimal clinically important difference (MCID) for a patient-reported outcome measure involve anchoring the measure to an indicator of meaningful patient-reported change in a clinical outcome.<sup>73–75</sup> While some MID estimates reported here constitute MCIDs anchored to patient-reported clinical improvement via adaptations of the Patient Global Impression of Change (PGIC),<sup>37,55,59,68</sup> others are purely estimates of statistical minimum detectable change (MDC) based on study population distribution characteristics<sup>34,45,69</sup> without reference to clinical import of that change. Comparing anchor-based MCID findings with distribution-based MDC findings can be useful in MID estimation, as this allows researchers to consider both an external benchmark of clinical change and a measure of change detectable despite variation.<sup>37,73,74</sup> Reviewed studies, however, contained relatively few estimates via any method. Estimation methods also differed substantially, resulting in large discrepancies both within and across measures, and precluding comparison and generalization of measure-specific MIDs. The widespread

Measure	Range	Number of studies	N per study (ref)	Minimal important difference (MID)								
				Estimated	l using a c	linical anchor	Estimated using statistical approaches					
				ROC/ optimal cutoff	95% limit cutoff	Average change among responders	Change difference, responders vs. non- responders	Minimal detectable change	Smallest detectable difference	SEM*		
Oswestry Disability Index	0–100	3	$47^{59}_{63^{55}}_{107^{45}}$	4.0 7.5		8.2	8.3	$2.0^{\dagger}$ 16.7 <sup>‡</sup> 10.7 <sup>§</sup>				
Visual Analog Scale	0–10 mm	1	47 <sup>59</sup>	3.0		3.2	2.0	$2.2^{\dagger}$				
Visual Analog Scale	0–100 mm	1	118 <sup>69</sup>						49#			
Bodily Pain Index	0–10	2	$205^{50}_{222^{50}}$							0.6 0.7		
PEG	0–10	2	$205^{50}$ $222^{50}$							1.8 1.9		
Chronic Pain Grade-intensity	0–100	2	$205^{50}$ $222^{50}$							9.0 9.9		
Chronic Pain Grade- disability	0–100	2	$205^{50}$ $222^{50}$							8.7 10.3		
Roland Morris Disability	0–24	4	$63^{55}$ $205^{50}$	3.5				4.9 <sup>‡</sup>		1.0		
Questionnaire			$222^{50}$ $143^{34}$					7.5 <sup>‡</sup>		1.2		
SF-36 Bodily Pain Scale	0–100	2	$205^{50}$ $222^{50}$					+		9.8 11.8		
Numeric Rating Scale	0–10	3	$63^{55}$ $135^{37}$	4.0 3.5	4.7			2.4 <sup>‡</sup>				
-			138 <sup>68</sup>	2.5		3.7		4.5 <sup>‡</sup>				

Table 4 Summary of Results: Minimal Important Difference (MID)

\*Standard error of measurement

 $\dagger$ Estimated by the upper value of the 95% confidence interval for average change score seen in the cohort defined by anchor to be non-responders  $\ddagger$ Estimated by 1.96 × square root of 2 × SEM test-retest

<sup>§</sup>SEM determined from participants classified as stable. The SEM was then used to calculate the 90% CI and then multiplied by the square root of 2 <sup>#</sup>Estimated by the standard deviation of the difference values  $\times$  1.96

application of interpreting a 30% change from baseline as an MID—originally assessed using an NRS for pain severity<sup>22</sup> and ultimately recommended for a range of patient-reported pain outcome measures—<sup>78</sup> may have discouraged measure-specific MID development. Further research should explore whether this approach is empirically generalizable. Consensus is needed on optimal approaches to developing and reporting MID for patientreported measures in chronic musculoskeletal pain.

There is no gold standard comparator for assessment of pain measure validity in the domains assessed. Included studies' methods of assessing concurrent/criterion validity involved finding correlations between a measure of interest and another measure or subscale of interest. Other assessments arguably relevant to construct validity, such as relationships of selfreported pain-related functioning measures to objective physical performance measures, were less commonly identified, consistent with the state of current physical function research in pain.<sup>8</sup> Perhaps unsurprisingly, therefore, our review identified a self-referential network of patient-reported outcome measures validated against one another, making validity estimates difficult to compare within or across measures. Future research could further investigate the network of validity comparisons to clarify underlying assumptions and identify gaps requiring conceptual research. Responsiveness findings in reviewed studies were also challenging to compare both within and across measures. Some methods of comparing pain measure changes within clinical trials of pain interventions cannot separate an intervention's estimated effectiveness (either true differences or chance findings of difference) from the responsiveness of the pain measure used to assess it. Few methods recognize the inherent challenge that short-term fluctuations in pain, which commonly occur in chronic musculoskeletal pain conditions, pose to the capacity of pre-post assessments to track pain trajectory over time. Interpreting test-retest reliability estimates has similar conceptual challenges: separating undesirable measurement variability from variability that reflects actual fluctuations in pain can be difficult. Thus, short-term fluctuations in a measure may not indicate a lack of test/retest reliability, and may instead be evidence of true responsiveness. Researchers interested in comparing measures' responsiveness and test-retest reliability should consider available psychometric evidence in the context of their own work, including the recall period of interest, the expected amount and time frame of change in the pain domains they plan to assess, and their desired study design (e.g., pre-post assessment vs. longitudinal repeated-measures assessment).

Chronic musculoskeletal pain definition and reporting varied widely across reviewed studies. The required duration for pain to be considered "chronic" was inconsistent and was not always reported. Pain type (e.g., musculoskeletal), primary diagnostic cause (e.g., osteoarthritis), and primary bodily site(s) (e.g., low back) were inconsistently reported, as were relevant characteristics such as pain duration and levels at baseline, treatment use, and co-existing physical or mental health conditions. Such differences reflect active discussion in current pain research: when and how duration, causal diagnoses, and bodily site affect key pain qualities, and when and how intermittent pain differs meaningfully from chronic continuous pain.<sup>11,79</sup> Research is needed to define target populations and reporting standards for pain-relevant characteristics in psychometric research on chronic musculoskeletal pain.

The majority of studies were conducted in populations with over 50% women and mean ages 40-59. Most studies did not report race or ethnicity; of those that did, all included more than 50% white participants, and most included more than 75% white participants. No studies reported outcomes stratified by sex or gender, age range, or race/ethnicity. Generalizability of psychometric findings is thus limited by both demographic underreporting and population homogeneity. Given substantial evidence of the influence of age and psychosocial factors on individuals' experiences and reporting of both pain-related functional impairment and pain severity,<sup>76,77,80,81</sup> there is a need for consensus on key study population demographic and clinical characteristics, more consistent reporting of these population characteristics within studies, and further research on how measures' psychometric properties generalize or change across age ranges and psychosocial categories.

Our review was limited to studies that published results in English. We also excluded studies that evaluated non-English language versions of eligible scales. This decision was supported by evidence on the limited generalizability of self-report measures' psychometric properties across languages and highlights the need for linguistic and cultural validation of pain measures.<sup>80,82</sup> With respect to search strategy, our primary abstract search was limited to 2000 onward. We complemented this, however, by applying no date limits to hand-searches of included studies' reference lists, other reviews, and expert/peer reviewer suggestions. Finally, our criteria may have excluded some studies of psychometric properties of measures developed and validated prior to the popularization of specifying chronicity and duration of pain. Researchers considering such pain measures will need to consider the relevance of past psychometric work in the context of current conceptual pain research, and of their planned studies' objectives and target populations.

This focused evidence review had key elements of an evidence mapping approach: systematically surveying the psychometric literature on expert-identified pain measures, summarizing quantities of studies on key psychometric outcomes, and identifying research gaps and relevant challenges to data synthesis.<sup>83</sup> We developed this approach to illuminate the research gaps and data synthesis challenges that became evident through systematic review. Ultimately, we found that primary psychometric research on these measures within chronic musculoskeletal pain populations was limited, with the most evidence on reviewed psychometric properties found for the ODI, RMDQ, SF-36 BPS, NRS, and VAS. Key challenges in current musculoskeletal pain measurement research include substantial variation in methods of estimating psychometric properties, defining chronic musculoskeletal pain, and reporting patient demographics. Findings indicate that further methods research is needed to validate patient-reported pain outcome measures in populations with chronic musculoskeletal pain.

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#### Compliance with Ethical Standards:

**Disclaimer:** The views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs or the US Government.

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