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The Canadian version of the National Institutes of Health minimum dataset for chronic low back pain research: reference values from the Quebec Low Back Pain Study

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Abstract

The National Institutes of Health (NIH) minimum dataset for chronic low back pain (CLBP) was developed in response to the challenge of standardizing measurements across studies. Although reference values are critical in research on CLBP to identify individuals and communities at risk of poor outcomes such as disability, no reference values have been published for the Quebec (Canada) context. This study was aimed to (1) provide reference values for the Canadian version of the NIH minimum dataset among individuals with CLBP in Quebec, both overall and stratified by gender, age, and pain impact stratification (PIS) subgroups, and (2) assess the internal consistency of the minimum data set domains (pain interference, physical function, emotional distress or depression, sleep disturbance, and PIS score). We included 2847 individuals living with CLBP who completed the baseline web survey of the Quebec Low Back Pain Study (age: 44.0 ± 11.2 years, 48.1% women) and were recruited through social media and healthcare settings. The mean score was 6.1 ± 1.8 for pain intensity. Pain interference, physical function, emotional distress or depression, sleep disturbance, and PIS scores were 12.9 ± 4.1, 14.4 ± 3.9, 9.8 ± 4.4, 13.0 ± 3.6, and 26.4 ± 6.6, respectively. Emotional distress or depression showed floor effects. Good-to-excellent internal consistency was found overall and by language, gender, and age subgroups for all domains (alpha: 0.81-0.93) and poor-to-excellent internal consistency for PIS subgroups (alpha: 0.59-0.91). This study presents reference values and recommendations for using the Canadian version of the NIH minimum dataset for CLBP that can be useful for researchers and clinicians.

Keywords: Minimum dataset, Measurement, Chronic low back pain, Normative data, Self-report, Reference values

1. Introduction

Low back pain (LBP) has been the leading cause of global disability since 1990.[35] According to the National Institutes of Health (NIH) Task Force on Research Standards for chronic LBP (CLBP),[14–18,30,41] CLBP is *"a back pain problem that has persisted at least 3 months and has resulted in pain on at least*

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half the days in the past 6 months." In the general population, lifetime LBP prevalence has been estimated to be up to 80%.[34] Among individuals with new onset, acute, LBP, 2% to 48% will transition to CLBP,[10] and one-fifth of adults will develop disabling CLBP in 1 year.[10] The individual and societal burdens related to CLBP are highly driven by productivity loss and disability claims.[28] Understanding the determinants of the transition from acute to CLBP, identifying factors associated with remission or persistent LBP, and preventing disabling CLBP are necessary to tackle this burden. Thus, the standardization and accuracy of the measurements of individuals' phenotype is a priority.

The NIH minimum dataset for CLBP research was developed to encourage the use of standardized measures to enable comparisons across studies.[14–22] It includes 17 items taken from the Patient-Reported Outcomes Measurement Information System (PROMIS), 2 from the STarT Back Screening Tool,[6,33] and a remaining 21 items are individual categorical variables not subject to psychometric analyses. In 2017, the Quebec Back Pain Consortium[42] cross culturally adapted this questionnaire and put forward the Canadian version of the NIH minimum dataset,[40] following minimal changes from the original English version and the creation of a Francophone version. Although there are reference values in the United States for the PROMIS items among people living with chronic pain,[44] reference values of the NIH minimum dataset among individuals living with CLBP have not been published.

Reference values for patient-reported outcomes (PROs) used among patients living with CLBP are relevant for clinicians, researchers, and stakeholders to identify individuals and communities at risk of "mild" or "severe" CLBP, differentiating those who can function with CLBP from those who develop disabling CLBP.[12,49] Furthermore, reference values can be the basis for comparing variations between countries and could support further studies on how biological, psychological, and sociocultural differences and living conditions may influence the development and persistence of disabling CLBP. Since the NIH minimum dataset,[5,24–26,52] and especially its Canadian version, has been available only recently, reference values are not available for a U.S. or Canadian population with CLBP.

Our objective was to provide, for the first time, community-based sample reference values in Quebec, Canada, for the Canadian version of the NIH minimum dataset, overall and stratified by gender identity, age, and pain impact subgroups. As the Canadian cross cultural adaptation of the minimum dataset did not assess the psychometric properties of its composite scales,[40] a secondary objective was to assess the internal consistency of the main domains of the Canadian minimum dataset by gender, age, pain impact subgroups, and language.

2. Methods

2.1. Study design

This study is a cross-sectional analysis of the baseline evaluation of participants of the Quebec LBP Study (QLBPS), an ongoing longitudinal prospective cohort study launched in Canada in November 2018. The detailed methodology can be found in the QLBPS protocol published previously.[42] The Research Ethics Office (Institutional Review Board) of McGill University, Canada, approved the QLBPS (A06-M22-18A), which has been conducted in conformity with the ethical principles set by the Regulatory Framework in Health Research at the McGill University Health Centre in accordance with the second edition (2018) of the Tri-Council Policy Statement.[8] All participants gave their written informed consent. This article follows the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[55]

2.2. Participants

As of June 16, 2021, 6829 potential participants had accessed the baseline QLBPS questionnaire. Regardless of the LBP duration, all participants could complete the questionnaire if they were fluent in either French or English and had Internet access. We excluded those who did not formally consent to participate, were younger than the age of 18 years, or were living outside Quebec, Canada. We also excluded participants for whom the CLBP status could not be verified because of missing key-question data (LBP duration or frequency). For this study, we analyzed participants with CLBP and complete responses at baseline (n = 2847; see flowchart in **Fig. 1** for details). CLBP was defined as having an ongoing problem for at least 3 months, with pain present for at least half the days in the past 6 months according to NIH recommendations.[14–22]

2.3. Recruitment

In the QLBPS, participants were mostly recruited through web-based study ads. Interested participants were directed to the study websites (painconsortium.ca or the aliases mybackhurts.ca or malaudos.ca). Efforts were made in collaboration with marketing experts, patient representatives, clinicians, and researchers to set up the website, the registration phase, and optimal online strategies for recruitment and retention of individuals with LBP regardless of its duration. The recruitment strategies allowed the inclusion of a community sample of participants from across the province of Quebec, ensuring representation from urban, remote, and rural areas.[42] Among those who consented to participate (n = 6782), 82.5% (n = 5592) had heard about the study through social media, whereas others heard about it through other channels (eg, e-mail, a friend, and posters displayed in public places).

In the registration phase, potential participants received an invitation to a web platform (backpainconsortium.ca/ or aliases mybackhurts.ca or malaudos.ca). The landing page asked the participants about the presence of back pain, postal code, sex at birth, age, and interest in participating in the research. Potential participants confirmed their interest by providing their email address and full name and completing a CAPTCHA (Completely Automated Public Turing Test to Tell Computers and Humans Apart) verification. Only those who provided all the required information and self-identified with LBP received an email inviting them to access the baseline online survey, including the informed consent form. We used the Research Electronic Data Capture (REDCap) to collect data and control the study workflow. Baseline data were used for this study.

2.4. Representativity of the Quebec Low Back Pain Study

For representativity, the percentage of women, participants with postsecondary education, and current smokers, as well as the mean and SD of pain intensity using a 0 to 10 Numerical Rating Scale of participants of the QLBPS have been found to be similar to other large random samples of adults living with CLBP in Canada and elsewhere[2,23,24,29,50,52] (Appendix A, available as supplemental digital content at http://links.lww.com/PAIN/B659). However, our study was found to overrepresent

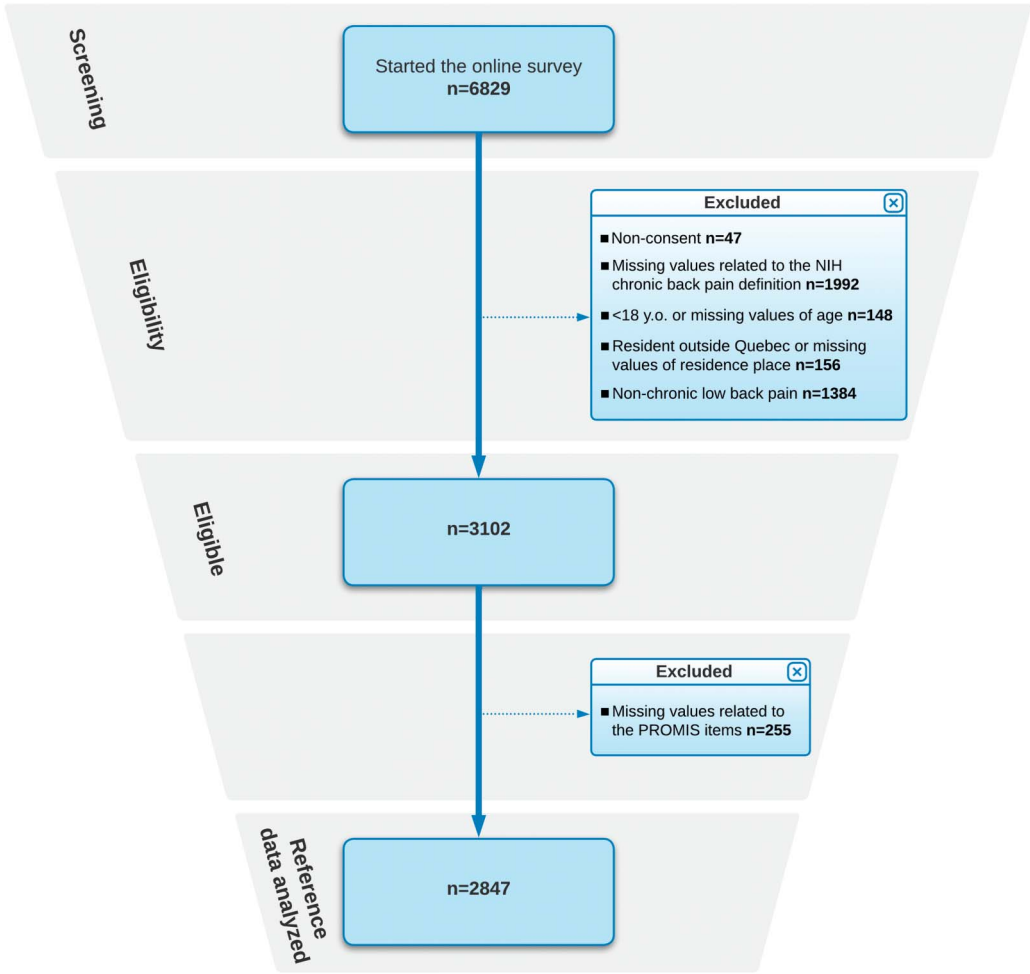

Figure 1. Flowchart of the study.

participants aged 35 to 49 and classified as obese as well as underrepresent participants aged 65 and older, which warrants age-stratified prevalence estimates when using the QLBPS data. The online recruitment strategy and questionnaire administration enabled the research team to reach participants living with CLBP in remote regions of the province of Quebec, an often underrepresented population in many academic research settings. Thus, in our sample, 7.5% (n = 213) lived in a remote region, which is similar to Quebec with 9.9%.[47]

2.5. Variables and questionnaires

The NIH minimum dataset for CLBP[14–22] and its Canadian cross-cultural adaptation[40] include 40 items. The NIH minimum dataset cross-cultural adaptation into a French-Canadian version was made following Beaton et al.'s[3] guidelines. The main cultural modifications were to replace the response categories for the race or ethnicity and education-level questions with those used in the bilingual Statistics Canada censuses. Minor changes following the questionnaire pretest included the following: (1) examples of activities for the pain interference (PI) questions were added; (2) answer choices for treatment use were modified as to read "Yes, I am currently using this treatment," "Yes, I have used this treatment in the past but stopped," "No," and "Not sure"; (3) the statement "Mark more than one answer if applicable" was added into the employment status variable; and 4) whether height and weight have been measured by the patient, by their physician, or as a self-reported estimation was no longer collected. Since the modifications of the original NIH minimum dataset were minimal and both questionnaires allow the collection of the same information, limitations of the Canadian NIH minimum dataset discussed reflect the limitations of the original minimum dataset.

The collected variables are distributed as follows: LBP characteristics (4 questions about LBP duration, intensity, and sciatica); comorbid painful conditions (one question to document stomach pain, pain in other sites, headaches, and widespread pain); history of LBP surgical interventions (3 questions); PI (4 questions on a 5-point Likert scale ranging from 1 (not at all) to 5 (very much)—PROMIS SF4a[45]; LBP treatments (one question to document opioid use, infiltrations or injections, exercise therapy, and psychological counselling); LBP-related workplace absenteeism and compensation benefits (2 questions); physical function (PF) (4 questions on a 5-point Likert scale ranging from 1 [unable to do] to 5 [without any difficulty]—PROMIS SF4a[45]); emotional distress or depression (EDD) (4 questions on a 5-point Likert scale ranging from 1 [never] to 5 [always]—PROMIS SF4a[45]); sleep disturbance (SID) (4 questions as follows: the quality question on a 5-point Likert scale ranging from 1 [very good] to 5 [very poor] and 3 questions ranging from 1 [very much] to 5 [not at all], where the question related to refreshing sleep was reversed—PROMIS SF4a[45]); kinesiophobia (an agree or disagree question with the statement "It's not really safe for a person with my low back problem to be physically active"—an item from the

STarT Back Screening Tool[6,33]); catastrophizing (an agree or disagree question with the statement "I feel that my low back pain is terrible and it's never going to get any better"—an item from the STarT Back Screening Tool[6,33]); LBP-related lawsuits and legal claims (one question); substance abuse (2 questions); socio-demographic profile (6 questions—age, gender identity, indigenous membership, racialized group membership, employment, and education level); smoking status (one question); and obesity (one question). Nine of these items (pain intensity item, 4 PI items, and 4 PF items) were used to create the pain impact stratification (PIS) score.[14–21] The total score on the PIS ranges from 8 (least impact) to 50 (most impact) and is classified by the NIH Research Task Force as mild (8-27 points), moderate (28-34 points), or severe impact (35-50 points).[15]

2.6. Statistical analysis

All statistics were completed using SAS version 9.4 (SAS Institute, Cary, NC). The characteristics of the study population were summarized using descriptive statistics. Age was presented as mean ± SD, median, and interquartile range. Categorical variables were presented as absolute values (n) and percentages.

Reference values and internal consistency were calculated for the following PROMIS domains of the NIH minimum dataset[14–22]: PI, PF, EDD, SID, and PIS score. We followed the PROMIS Scoring Manuals,[46] as per which missing data have to be excluded, and the scores were calculated based on complete data according to the 4-item short form algorithms. The raw score was computed by summing the 4 items and then rescaled into T-scores.[46] The PROMIS Scoring Manuals provide a score conversion table to translate the total raw score into a T-score for each participant.[46] For the PI, PF, EDD, and SID PROMIS measures, the reference population was the 2000 General US Census.[45] High scores are interpreted as having more of what is being measured. The utility of the T-score is an easier interpretation, because T-scores range from 1 to 100, where a score of 50 represents the average of the reference population and 10 is one SD.[45] A T-score of 40 is 1 SD lower than the mean of the reference population.[45] There is no conversion table for the pain intensity (single item) and the pain impact measures. Because the pain intensity measure is a single item, the internal consistency was not evaluated.

Reference values were reported according to the recommendations of Schmidt and Pardo[49] and Streiner et al.[53] We provide the mean, SD, median, 25th percentile, 75th percentile, minimum, and maximum for the whole sample and the mean and SD when the scores were stratified into the age groups, gender identity, and pain impact subgroups. Although sex at birth was measured in the LBPS, only gender identity is asked in the NIH minimum dataset, thus justifying the use of this variable. Furthermore, we reported the floor and ceiling effects, which were calculated by identifying the proportion of participants who either had the lowest or the highest possible scores for the following PROMIS domains of the NIH minimum dataset: pain intensity, PI, PF, EDD, SID, and PIS score. A ceiling or floor effect is usually defined as 15% (or more) of individuals in a sample achieving the highest or lowest level of the score.[54] We then examined the score differences between groups using the Kruskal–Wallis test and the Dwass–Steel–Crichtlow–Fligner test for pairwise comparisons.[37] The Dwass–Steel–Crichtlow–Fligner test uses a specific approach to controlling the familywise error rate, and it is considered the most appropriate test for all pairwise nonparametric comparisons.[37] All tests were 2-sided, and the alpha level was set at 0.05.

To achieve the secondary objective related to internal consistency, Cronbach reliability coefficients and their 95% confidence intervals were calculated for the 5 PROMIS domains of the Canadian NIH minimum dataset. These values were computed for the whole sample and stratified by gender identity, age groups, PIS subgroups, and language of data collection. George and Mallery (2020) suggest interpreting the Cronbach alpha values as follows: ≥0.9—excellent, ≥0.8—good, ≥0.7—acceptable, ≥0.6—questionable, ≥0.5—poor, and ≤0.5—unacceptable.[27]

3. Results

Of the 6829 Canadians screened to participate, 3727 (54.6%) were excluded based on our selection criteria (see Methods and **Fig. 1**). These exclusions left 3102 (45.4%) eligible participants, 2847 (41.7%) of whom had complete data for the 5 PROMIS domains.

The demographic characteristics of the sample are shown in **Table 1**. The participants' (n = 2847) mean age was 44 ± 11.2 years, and 48.1% (n = 1368) were self-identified as women (15.7% (n = 448) did not answer the gender question). Participants were mostly White (84.2%), nonaboriginal (95.2%), full-time workers (51.1%), Francophones (94.5%), and had postsecondary education (69.4%). Most reported CLBP as an ongoing problem for a year or more (86.6%), with a frequency of every day or nearly every day in the past 6 months (60.1%) and reported associated sciatica (58.8%). The most bothersome comorbidity (reported as "bothered a lot") was pain in the arms, legs, or joints (40.3%). Physical exercise therapy (37.1%) was the most common type of treatment currently used, and 5.8% had back surgery. Disability or workers compensation claims were reported by 12.2%. Kinesiophobia and catastrophizing were reported by 26.5% (n = 755) and 55.5% (n = 1579), respectively. Over a third of participants (n = 1058, 37.2%) were classified as obese (body mass index ≥ 30), and 20.3% were current smokers. The reference values for the remaining categorical variables of the Canadian version of the NIH minimum dataset can be found in Appendix B (available as supplemental digital content at http://links.lww.com/PAIN/B659).

The distribution of scores for the whole sample is shown in **Table 2** and **Figures 2A–F**. The mean and SD were 6.1 ± 1.8 for pain intensity, 12.9 ± 4.1 for PI, 14.4 ± 3.9 for PF, 9.8 ± 4.4 for EDD, 13.0 ± 3.6 for SID, and 26.3 ± 6.6 for PIS score.

Table 3 shows the mean and SD for each domain by gender identity, age, pain impact score groups, and language. Men reported significantly better PF ($P < 0.001$) and significantly lower scores in PI ($P < 0.006$), EDD, ($P < 0.001$), SID, ($P < 0.001$), and PIS scores ($P < 0.001$) compared with their counterparts who self-identified as women and those with missing data in the gender variable. Overall, there was a trend of better scores in the younger age with the exception of the EDD score and a trend of better PIS scores as it was decreased.

Since the highest score was greater or equal to 15%, a floor effect was present in men and missing category of the gender variable, all age groups, language groups, and the whole sample (men and women combined). Details of the floor and ceiling effects for the PROMIS domains of the Canadian version of the NIH minimum dataset can be found in the Appendix C (available as supplemental digital content at http://links.lww.com/PAIN/B659).

The internal consistency of the PROMIS domains of the NIH minimum dataset was not significantly different across gender identities, age groups, or languages of data collection (94.5% Francophones, see **Table 4**). However, Cronbach alpha coefficients between 0.50 and 0.70 (representing questionable and acceptable internal consistency levels, respectively) were found in the moderate and severe pain impact groups, particularly in the PI, PF, and PIS score domains, ranging from 0.59 to 0.67. For the whole sample, the internal consistency was good to excellent in

Table 1

Sociodemographic characteristics of the study population (n = 2847).

Variable	Category	Total
Age, yrs	n = 2847, mean ± SD; Median (interquartile range)	44.0 ± 11.2; 43.0 (36.0-51.0)
Variable	**Category**	**n (%)**
Age groups, years	18-34	660 (23.2)
	35-49	1334 (46.9)
	50-64	718 (25.2)
	65-86	135 (4.7)
Gender identity	Missing	448 (15.7)
	Women	1368 (48.1)
	Men	1027 (36.1)
	Nonbinary	4 (0.1)
Aboriginal	No	2709 (95.2)
	Yes	138 (4.8)
Ethnicity	Missing	30 (1.1)
	White	2396 (84.2)
	Latin American	147 (5.2)
	Arab	96 (3.4)
	Black	82 (2.9)
	Others	96 (3.4)
Employment status	Working now full time	1456 (51.1)
	Working now part time	294 (10.3)
	Looking for work, unemployed	176 (6.2)
	Sick leave or maternity leave	151 (5.3)
	Disabled due to back pain, permanently or temporarily	329 (11.6)
	Disabled for reasons other than back pain	155 (5.4)
	Student	195 (6.8)
	Temporarily laid off	52 (1.8)
	Retired	207 (7.3)
	Keeping house	96 (3.4)
Postsecondary education	Missing	64 (2.2)
	No	808 (28.4)
	Yes	1975 (69.4)
Language	English	157 (5.5)
	French	2690 (94.5)

the 5 evaluated domains (0.81-0.92). The Cronbach alpha coefficients evaluating the effect of removal of an item on the questionnaire for the whole sample were also good to excellent (See Appendix D, available as supplemental digital content at http://links.lww.com/PAIN/B659.

4. Discussion

This study presents reference values for the Canadian minimum dataset for CLBP research in the Quebec population, which can be useful for interpreting data. Reference values for the Quebec population were presented for the whole sample and subsets stratified on age, gender, PIS score, and language. There were floor effects in the EDD domain. Results of our study also indicate acceptable internal consistency for 5 domains of the Canadian version of the minimum dataset for CLBP research in the whole sample. However, lower internal consistency was found in the moderate and severe PIS subgroups.

4.1. Reference values

Reference values of the NIH minimum dataset in individuals living with CLBP were lacking. However, the T-scores of our study can be compared with various studies that used PROMIS scales conducted on individuals living with CLBP. Our results on PI, depression, and SID were lower than those obtained in a sample of Thais living with CLBP[39] and similar to pain intensity of Americans living with musculoskeletal pain (5.9 ± 1.8),[22] or chronic pain in general (6.38),[44] and Spaniards living with CLBP (6.0 ± 2.14).[23] However, since there were differences in age and gender, it is recommended to make comparisons separately by age and gender.

When comparing the 6 domains by age groups, we found significantly lower scores in the oldest than youngest categories, except for the EDD domain. Similarly, Pope et al.[44] found significant differences in the PF domains between the < 40 (mean = 38) and 80+ (mean = 34) age groups in individuals with chronic pain.

We found that men differed from the other gender identity categories in 5 of the 6 domains. Men reported a greater PF score and lower PI, EDD, SID, and PIS scores compared with women or the missing category. This finding may be due to differences in sociocultural beliefs about femininity and masculinity and pain coping strategies.[1] These findings support the need to continue implementing sex-based and gender-based analysis in communities living with CLBP.

In our study, the percentage of participants severely affected by pain was 12.7%, with the average PIS score in the whole

Table 2

Reference values: mean and SD of each Patient-Reported Outcomes Measurement Information System domain of the National Institutes of Health minimum dataset in the whole sample (n = 2847).

Domain (possible score)	Mean	SD	Min	P25	Median	P75	Max
Raw scores							
Pain intensity (0 = no pain 10 = worst imaginable pain)	6.1	1.8	0	5	6	7	10
Pain interference (4-20)	12.9	4.1	4	10	13	16	20
Physical function (4-20)	14.4	3.9	4	12	15	18	20
Emotional distress or depression (4-20)	9.8	4.4	4	6	10	13	20
Sleep disturbance (4-20)	13.0	3.6	4	10	13	16	20
Pain Impact Stratification Score (8-50)	26.3	6.6	9	21	26	31	44
T-scores							
Pain interference (41.6-75.6)	62.4	6.6	41.6	58.5	62.5	66.6	75.6
Physical function (22.9-56.9)	40.9	6.8	22.9	36.7	40.4	45.3	56.9
Emotional distress or depression (41.0-79.4)	57.3	9.8	41.0	51.8	58.9	63.9	79.4
Sleep disturbance (32.0-73.3)	56.1	7.6	32.0	50.5	56.1	61.7	73.3

P25, percentile 25; P75, percentile 75; Min, minimum; Max, maximum.

sample being 26.4 ± 6.6. These results are concurrent with the percentage of participants who receive or have applied for disability or workers' compensation benefits (12.2%). Compared with our study, Deyo et al. reported a greater percentage of severely affected participants (36%) with a greater mean score (32.0 ± 8.3) in older adults undergoing epidural steroid injections.[19] Other studies also reported a greater mean PIS score in older adults with chronic musculoskeletal pain (27.2 ± 7.8)[22] and CLBP patients from a healthcare center (34.4 ± 7.4).[25]

4.2. Floor and ceiling effects

Floor and ceiling effects may affect sensitivity to change of an index. Thus, changes in a measure over a specified time frame could be masked because of the limited variability in the scores.[54] When floor and ceiling effects are present, the questionnaire cannot differentiate among those scores at the ends of the spectrum.[54] Detecting negative changes in EDD in all groups, except women, was problematic because of the floor effect. Similar to our findings, Dutmer et al.,[25] Deyo et al.,[22] and Cheng et al.[9] also found the floor effect in the EDD domain, which could be explained by participants spending less time responding to the depression questions.[4,31] It could also be related to the stigma associated with mental illness and, consequently, patients tending to minimize or underreport depressive symptoms.[32] Globally, these floor effects call for caution in interpreting emotional distress and depression results. The depression questions may need modification before the widespread adoption of the NIH minimum dataset.

4.3. Internal consistency

The Cronbach alpha coefficient analysis showed homogeneity in all items and across categories except for the moderate and severe PIS score subgroups. This could be explained by the homogeneity of the sample within the subgroup. Low variability (SD <2.2, see **Table 3**) in the moderate and severe PIS groups could decrease the correlations and, therefore, the estimated alphas.[53] Given that a low number of items typically lead to lower alpha coefficients,[13,53] it is noteworthy that the 5 NIH minimum dataset domains had high levels of internal consistency when the whole sample was considered. Similar to our findings, Deyo et al.[22] found that the SID domain had the lowest Cronbach alpha (0.81).

4.4. Limitations and strengths

Some of this study's limitations are worth noting. Although the sample size was large for this study, the age distribution was not similar to a large random sample of Canadians living with CLBP,[2] with approximately 70% of the sample (n = 2052) falling between 35 and 64 years. The oversampling of participants aged between 35 and 64 years could be explained at least in part by the fact that social media was the primary recruitment strategy. People aged 35 to 64-years could be more exposed to the QLBPS social media advertising and have better computer skills than older groups.[48] Furthermore, since the Internet user rate was low among the more aging population,[48] we also expected less participation from the older adults in our study as it happened. The differences between our sample and other large ones could also be explained by the definition of CLBP and year of study completion.[11]

Moreover, online self-reported data collection may reduce social desirability bias and reduce data entry errors. For example, Burkill et al.[7] found that those who responded to a self-administer web survey reported more sensitive information than those who responded to computer-assisted personal interviews. Selection bias due to the recruitment strategies could occur in our study as web surveys may exclude individuals without Internet access. However, this bias is expected to be minimum because 94% of Canadians had household Internet access in 2020.[51] This percentage is, however, lower in Canadians aged 65 years and older (83%). Since reference values were calculated based on a sample that did not entirely represent the population of individuals living with CLBP, caution should be applied when attempting to use these reference values without age stratification.

Furthermore, as a great number of statistical tests were conducted and we cannot exclude the possibility of a type I error (no correction was applied to reduce the possibility of a type II error[43]), the presence of clinically important differences in scores should always be taken into account when interpreting statistically significant *P*-values. Another limitation was the exclusion of nonbinary participants from the statistical analysis, which is ethically problematic, but was justified on the grounds of statistical validity. Future research should address these limitations by recruiting gender-diverse individuals.

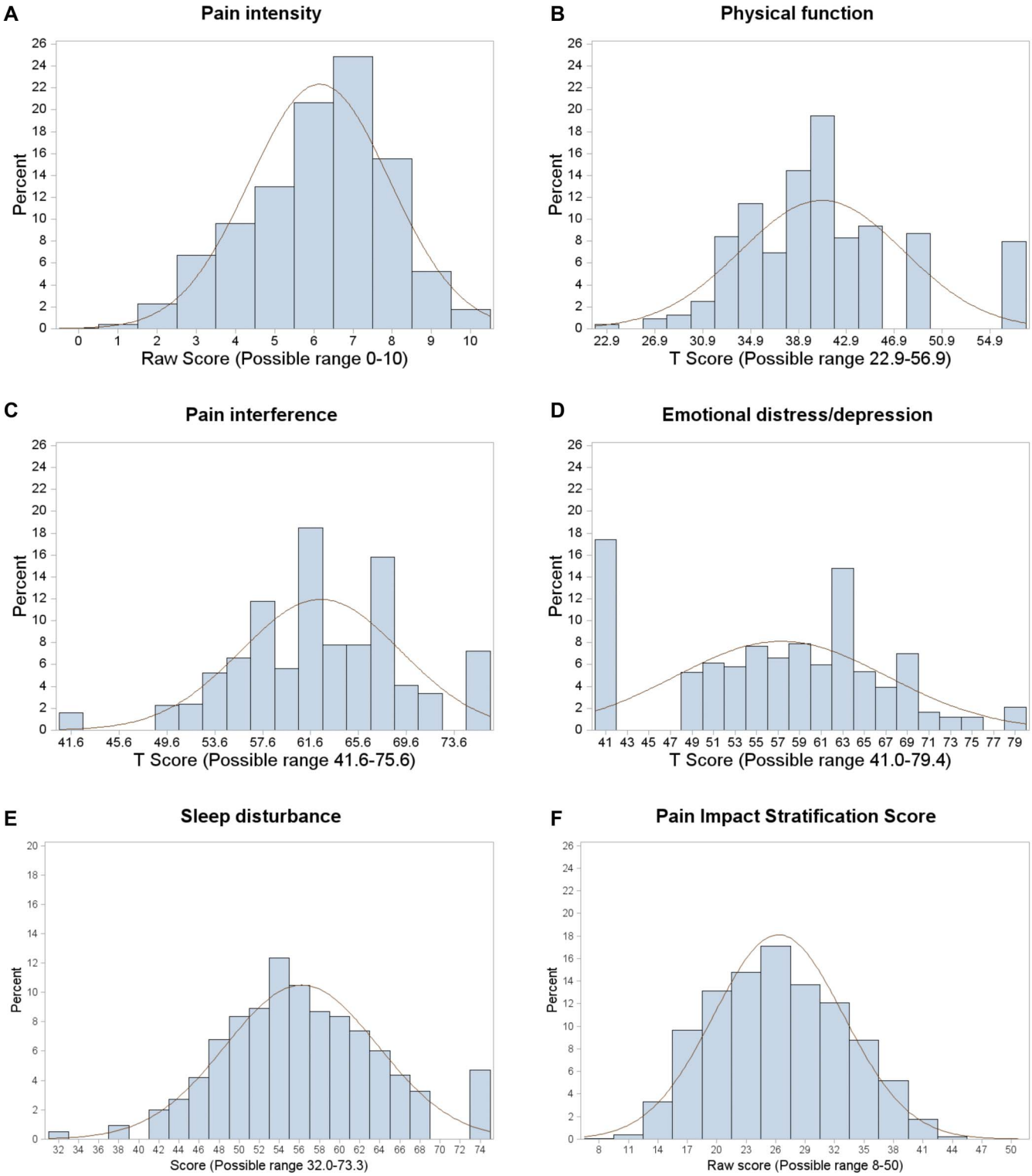

Figure 2. Histograms of each domain of the NIH minimum dataset distributions in all subjects (n = 2847).

To the best of our knowledge, our study is the first of its kind to provide comprehensive reference values for the NIH minimum dataset for CLBP based on data collected in Quebec. Our results are also based on a large sample of individuals living with CLBP. Unlike many previous cohort studies[25,52] that typically enroll patients from a hospital or those who have contact with the healthcare system, the QLBPS is community-based, meaning that this study includes participants from urban, remote, and rural areas, and not necessarily seeking treatment for their LBP.

4.5. Clinical application

Patient-reported outcomes' reference values can be used to make indirect and direct comparisons in clinical settings.[36]

Table 3

Mean and standard deviation scores of each Patient-Reported Outcomes Measurement Information System domain of the NIH minimum dataset by gender identity, age groups, and Pain Impact Stratification Score subgroups (n = 2847).

Variable	n	Pain intensity (mean ± SD)	Pain interference (mean ± SD)		Physical function (mean ± SD)		Emotional distress/depression (mean ± SD)		Sleep disturbance (mean ± SD)		Pain impact stratification score (mean ± SD)
Possible score		Raw score (0-10)	Raw score (4-20)	T-Score (41.6-75.6)	Raw score (4-20)	T-Score (22.9-56.9)	Raw score (4-20)	T-Score (41.0-79.4)	Raw score (4-20)	T-Score (32.0-73.3)	Raw score (8-50)
Gender identity*											
Women	1368	6.1 ± 1.7	13.0 ± 4.1†	62.6 ± 6.6†	14.0 ± 3.9†	40.1 ± 6.5†	10.2 ± 4.3†	58.3 ± 9.2†	13.2 ± 3.6†	56.7 ± 7.5†	26.9 ± 6.7†
Men	1027	6.1 ± 1.8	12.5 ± 4.1†‡	61.8 ± 6.6†‡	15.1 ± 3.7†‡	42.2 ± 7.0†‡	9.2 ± 4.4†‡	55.7 ± 10.3†‡	12.5 ± 3.5†‡	55.1 ± 7.4†‡	25.3 ± 6.4†‡
Missing	448	6.3 ± 1.8	13.3 ± 4.0‡	63.0 ± 6.5‡	14.1 ± 3.9‡	40.5 ± 6.7‡	9.9 ± 4.4‡	57.4 ± 9.8‡	13.3 ± 3.6‡	56.8 ± 7.7‡	26.9 ± 6.6‡
Age groups (yrs)											
18-34	660	5.9 ± 1.7§‖¶	11.8 ± 4.0§‖¶	60.8 ± 6.5§‖¶	15.6 ± 3.4§‖¶	43.0 ± 6.8§‖¶	9.9 ± 4.5	57.5 ± 10.0	13.1 ± 3.7¶	56.4 ± 7.9¶	24.3 ± 6.2§‖¶
35-49	1334	6.1 ± 1.9#	13.0 ± 4.1#	62.6 ± 6.7#	14.5 ± 3.8#‖¶	41.1 ± 6.8#‖¶	9.8 ± 4.4	57.2 ± 9.9	13.0 ± 3.6¶	56.2 ± 7.6¶	26.4 ± 6.6#‖
50-64	718	6.4 ± 1.7#	13.4 ± 4.0#	63.3 ± 6.5#	13.4 ± 4.0#§	39.3 ± 6.4#§	9.8 ± 4.3	57.4 ± 9.5	13.0 ± 3.4¶	56.2 ± 7.1¶	27.7 ± 6.6#§
65-84	135	6.5 ± 1.6#	13.2 ± 3.8#	62.7 ± 6.2#	13.1 ± 4.2#§	38.4 ± 6.3#§	8.9 ± 3.9	55.4 ± 9.0	11.7 ± 3.3#§‖	53.4 ± 7.1#§‖	27.6 ± 6.5#
Pain Impact Stratification Score groups											
Mild (8-27)	1660**††	5.7 ± 1.7**††	10.3 ± 3.0**††	58.5 ± 5.0**††	16.9 ± 2.2**††	44.9 ± 5.7**††	8.1 ± 3.7**††	53.6 ± 8.9**††	12.1 ± 3.4**††	54.4 ± 7.2**††	21.7 ± 3.8**††
Moderate (28-34)	832††‡‡	6.5 ± 1.7††,‡‡	15.5 ± 2.1††‡‡	66.1 ± 3.3††‡‡	12.1 ± 2.2††‡‡	36.9 ± 2.7††‡‡	11.5 ± 4.1††‡‡	60.9 ± 8.4††‡‡	14.0 ± 3.4‡‡	58.3 ± 7.2‡‡	30.8 ± 2.0††‡‡
Severe (35-50)	355**‡‡	7.2 ± 1.6**‡‡	18.7 ± 1.6**‡‡	72.0 ± 3.6**‡‡	8.1 ± 2.0**‡‡	31.9 ± 2.9**‡‡	13.8 ± 4.0**‡‡	65.6 ± 8.1**‡‡	14.5 ± 3.6‡‡	59.3 ± 7.7‡‡	37.3 ± 2.0**‡‡
Language of data collection											
English	157	6.1 ± 1.8	13.3 ± 4.2	63.2 ± 6.5	15.0 ± 3.8	41.7 ± 6.6	9.0 ± 4.2	55.7 ± 9.5	13.1 ± 3.8	56.2 ± 8.4	26.2 ± 6.4
French	2690	6.1 ± 1.8	12.8 ± 4.1	62.3 ± 6.6	14.4 ± 3.9	40.9 ± 6.8	9.8 ± 4.4	57.3 ± 9.8	13.0 ± 3.6	56.1 ± 7.5	26.3 ± 6.6

* Nonbinary gender was excluded from the stratified analyses (n = 4).
†Significant difference between male and female.
‡ Significant difference between male and missing.
§ Significant difference against the 35 to 49 age group.
‖ Significant difference against the 50 to 64 age group.
Significant difference against the 18 to 34 age group.
¶ Significant difference against the 65 to 84 age group.
** Significant difference against the moderate group.
†† Significant difference against the severe group.
‡‡ Significant difference against the mild group.

Table 4

Internal consistency of the Patient-Reported Outcomes Measurement Information System domains of the NIH minimum dataset by gender, age groups, pain impact stratification score groups, and language of the questionnaire (n = 2847).

Variable	n	Pain interference	Physical function	Emotional distress or depression	Sleep disturbance	Pain impact stratification score
		Alpha (95% CI)	Alpha (95% CI)	Alpha (95% CI)	Alpha (95% CI)	Alpha (95% CI)
Gender identity*						
Women	1368	0.91 (0.91-0.92)	0.89 (0.88-0.90)	0.92 (0.91-0.92)	0.80 (0.79-0.82)	0.91 (0.91-0.92)
Men	1027	0.91 (0.91-0.92)	0.88 (0.87-0.89)	0.93 (0.92-0.94)	0.80 (0.78-0.83)	0.91 (0.90-0.91)
Missing	448	0.92 (0.90-0.93)	0.89 (0.87-0.91)	0.93 (0.91-0.94)	0.81 (0.78-0.84)	0.92 (0.90-0.93)
Age groups (yrs)						
18-34	660	0.90 (0.88-0.91)	0.87 (0.85-0.87)	0.92 (0.91-0.94)	0.83 (0.81-0.87)	0.89 (0.88. 0.91)
35-49	1334	0.92 (0.91-0.93)	0.89 (0.88-0,90)	0.93 (0.92-0.94)	0.80 (0.79-0.82)	0.91 (0.90-0.92)
50-64	718	0.92 (0.91-0.93)	0.89 (0.88-0.90)	0.92 (0.91-0.93)	0.79 (0.76-0.82)	0.92 (0.91-0.93)
65-86	135	0.89 (0.86-0.92)	0.89 (0.86-0.92)	0.90 (0.87-0,93)	0.78 (0.72-0.85)	0.91 (0.89-0.94)
Pain Impact Stratification Score groups						
Mild (8-27)	1660	0.83 (0.81-0.84)	0.70 (0.68-0.73)	0.90 (0.89-0.91)	0.80 (0.79-0.82)	0.79 (0.78-0.80)
Moderate (28-34)	832	**0.66 (0.61-0.71)**	**0.59 (0.54-0.63)**	0.91 (0.90-0.92)	0.78 (0.75-0.81)	**0.60 (0.56-0.63)**
Severe (35-50)	355	0.72 (0.66-0.77)	**0.62 (0.55-0.69)**	0.90 (0.89-0.92)	0.77 (0.72-0.81)	**0.67 (0.63-0.71)**
Language						
English	157	0.91 (0.89-0.94)	0.88 (0.84-0.91)	0.92 (0.89-0.95)	0.81 (0.75-0.87)	0.91 (0.88-0.93)
French	2690	0.91 (0.91-0.92)	0.89 (0.88-0.90)	0.92 (0.92-0.93)	0.81 (0.79-0.82)	0.91 (0.91-0.92)
Whole sample	2847	0.91 (0.91-0.92)	0.89 (0.88-0.90)	0.92 (0.92-0.93)	0.81 (0.79-0.82)	0.91 (0.91-0.92)

Bold text is used to highlight Cronbach alpha coefficients below 0.75.
* Nonbinary gender was excluded from the stratified analyses (n = 4).
95% CI, 95% confidence interval.

Indirect comparisons are made when PRO reference values are used to create action thresholds for healthcare providers without PRO scores being reported to providers or patients. Direct comparisons of PRO reference values are made by communicating to the users how their score compares with others within a CLBP reference population. For example, in a first-time visit to a pain clinic in Quebec, a woman could report a PI T-score of 70. Since our reference values for PI T-score in women is 62.6 ± 6.6, and the recommended clinical cut-off corresponds to 1 SD,[38] this woman has a PI greater than the average women living with CLBP in Quebec. The clinician and patient can thus use this information to better understand a given treatment's expectations and inform treatment decisions. Furthermore, PRO reference values make it easier to understand treatment access needs and impacts of a disease in a given population, which is helpful for resource allocation. In addition, reference values make comparing results across studies and countries easier.

5. Conclusions

This study provides reference values stratified by age, gender identity, PIS score, and language for the Canadian version of the NIH minimum dataset for CLBP that will help future users interpret their data in the context of Quebec. Owing to floor effects, EDD scores should be considered with caution. Although the 5 evaluated domains showed good-to-excellent internal consistency in the whole sample, lower internal consistency for PF and PIS scores among those classified as having moderate and severe pain impact was found. This Canadian version of the NIH minimum dataset for CLBP should be used, but future efforts to refine it are warranted.

Conflict of interest statement

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Data availability. The data that support the findings of this study are available from the corresponding author, A. Lacasse, on reasonable request and conditionally to a proper ethical approval for a secondary data analysis. The data are not publicly available because participants did not initially provide consent to open data.
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Appendix A. Supplemental digital content

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