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The Canadian minimum dataset for chronic low back pain research: a cross-cultural adaptation of the National Institutes of Health Task Force Research Standards

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Abstract

Background: To better standardize clinical and epidemiological studies about the prevalence, risk factors, prognosis, impact and treatment of chronic low back pain, a minimum data set was developed by the National Institutes of Health (NIH) Task Force on Research Standards for Chronic Low Back Pain. The aim of the present study was to develop a culturally adapted questionnaire that could be used for chronic low back pain research among French-speaking populations in Canada.

Methods: The adaptation of the French Canadian version of the minimum data set was achieved according to guidelines for the cross-cultural adaptation of self-reported measures (double forward–backward translation, expert committee, pretest among 35 patients with pain in the low back region). Minor cultural adaptations were also incorporated into the English version by the expert committee (e.g., items about race/ethnicity, education level).

Results: This cross-cultural adaptation provides an equivalent French-Canadian version of the minimal data set questionnaire and a culturally adapted English-Canadian version. Modifications made to the original NIH minimum data set were minimized to facilitate comparison between the Canadian and American versions.

Interpretation: The present study is a first step toward the use of a culturally adapted instrument for phenotyping French- and English-speaking low back pain patients in Canada. Clinicians and researchers will recognize the importance of this standardized tool and are encouraged to incorporate it into future research studies on chronic low back pain.

Estimates of lifetime prevalence of low back pain in the adult general population are variable across studies but have been reported to be as high as 84%.[1,2] Although most acute low back pain episodes resolve,[3,4] it can persist, and the incidence of chronic low back pain among patients who have an episode of acute or subacute low back pain ranges from 34% to 59%.[5–10] Chronic low back pain is estimated to affect 4%–25% of the adult general population, depending on the case definition, methodology and study sample.[11] Because low back pain is the leading cause of years lived with disability worldwide,[12] and because chronic low back pain ranks among the highest in terms of physician consultations among people less than 60 years of age in Canada,[13] better recognition, prevention and management of this condition is warranted. Interpretation and comparison of clinical and epidemiologic studies about chronic low back pain frequency, risk factors, prognosis, impact and treatment are, however, impeded by methodologic heterogeneity.

In response to the lack of standardized definitions and measures, the National Institutes of Health (NIH) Task Force on Research Standards for Chronic Low Back Pain developed a minimum data set (self-administered questionnaire) to be used to study factors influencing the onset, natural history and clinical course of chronic low back pain. Their recommenda-

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tions were published in several leading pain and professional journals in 2014 and 2015.[14–22] However, this questionnaire was originally developed for American English-speaking populations and is not necessarily linguistically and culturally adapted for countries such as Canada. The proportion of Canadians who report French as their first official spoken language is 23.2% (85.5% in the province of Quebec).[23] Moreover, some items within the recommended minimum data set do not represent the sociodemographic profile of the Canadian population (e.g., race/ethnicity, education system).

The objective of this study was to perform a cross-cultural adaptation of the NIH task force's minimum data set to provide a culturally adapted questionnaire for both francophone and anglophone populations in Canada that could be used to standardize chronic low back pain research and clinical assessment.

Methods

The NIH task force's minimum data set

Using a thorough process, the NIH Task Force on Research Standards for Chronic Low Back Pain developed and issued several recommendations regarding definitions, a minimum data set, reporting of outcomes and future research.[14–22] A set of specific domains and descriptors was proposed to facilitate comparison and consensus across clinical and epidemiologic studies of chronic low back pain. The minimum data set recommended by the task force contains 40 items, takes about 7 minutes to complete[14–22] and is suggested as a minimum standard for conducting studies about the risk factors and the prognosis of chronic low back pain.

The minimum data set starts with 2 items that together create a standard definition of chronic low back pain — that is, low back pain that is considered to be an ongoing problem for at least 3 months and that has resulted in a problem on at least half of the days in the past 6 months.[14–22] Then, low back pain characteristics such as duration, intensity in the past 7 days (0–10 numerical rating scale) and sciatica are evaluated. Comorbid painful conditions are measured, in addition to a history of low back pain surgical interventions, pain interference (Patient-Reported Outcomes Measurement Information System [PROMIS] SF4a),[24] low back pain treatments, low back pain–related work absenteeism and low back pain–related workers' compensation benefits. Moreover, the questionnaire focuses on physical function (PROMIS SF4a),[24] emotional distress or depression (PROMIS SF4a),[24] sleep disturbance (PROMIS SF4a),[24] kinesiophobia (item from the STarT Back Screening Tool)[25,26] and catastrophizing (item from the STarT Back Screening Tool).[25,26] Finally, other collected variables include low back pain–related lawsuits and legal claims, substance abuse, sociodemographic profile, smoking status and obesity (height, weight).

The PROMIS scales included in the minimum data set enables the computation of a total score for each of the domains that are measured (pain interference, physical function, emotional distress or depression, sleep disturbance).[24] Such scales have been validated in several populations, including in patients suffering from chronic musculoskeletal pain.[27] A combination of low back pain intensity in the past 7 days, physical function and pain interference PROMIS scores allows for the computation of an Impact Score, which has been validated among patients with chronic musculoskeletal pain.[14–22,27]

Cross-cultural adaptation of the minimum data set

The development of the Canadian adaptation of the minimum data set was achieved according to published and recognized guidelines for the cross-cultural adaptation of self-reported measures.[28] Permission to proceed with the adaptation was provided by the corresponding author of the NIH Task Force on Research Standards for Chronic Low Back Pain. The present initiative originally intended to translate and culturally adapt the questionnaire into a French-Canadian version, but after a careful review of the original instrument, minor revisions of a culturally adapted English-Canadian version also appeared to be relevant (e.g., items about race/ethnicity, education level).

Step 1: French translation

Forward translation of all items included in the minimum data set was conducted by 2 independent bilingual people from the province of Quebec (Canada) whose mother tongue was French (i.e., they had the ability to speak both languages with the facility of a native speaker). One was a researcher in the field of chronic pain (A.L.), and the other was a certified French linguist with no biomedical background (no a priori knowledge of the concepts being measured). Each provided a detailed report that included comments about rationale for their choices, challenging sentences and uncertainties.

Step 2: Synthesis meeting

A meeting was subsequently held between the translators and a coordinator (using a web-based screen-sharing system) to discuss the reports produced in step 1, reconcile discrepancies and agree on a common French-Canadian translation.

Step 3: Back translation

Using the common French-Canadian translation created in step 2, 2 independent bilingual people from Canada whose mother tongue was English and who were blinded to the original version of the questionnaire (one with, and one without a biomedical background) translated all items back into English. Following the first 3 steps, a global report was created, including the original version of the instrument, the 2 French-Canadian translations and comments of the translators (step 1), the common French-Canadian translation (step 2), and the 2 English back translations and comments of the translators (step 3).

Step 4: Expert committee

An expert committee was convened to reach consensus on the pre–final French-Canadian version of the minimum data set. The committee involved the aforementioned translators and the coordinator, in addition to chronic pain researchers,

health care practitioners and methodologists with expertise in questionnaire development and validation (n = 8; 2 English-Canadian and 6 French-Canadian members of the Steering Committee of the Low Back Pain Strategic Initiative of the Quebec Pain Research Network). The global report of the preceding steps was sent to committee members in advance. A teleconference (supplemented with web-based screen-sharing system) was then planned to reach 2 main objectives. First, the expert committee reviewed the complete French-Canadian translation report and achieved consensus on the semantic, idiomatic, experiential and conceptual equivalence between the original and new French-Canadian version of the questionnaire. Special attention was given to reviewing the language to ascertain that all items could be understood by patients, irrespective of their educational background. Second, the expert committee agreed on item standardization and minor cultural adaptations that should be made to both the French-Canadian and the original English version of the minimum data set to better reflect the Canadian context. The corresponding author of the minimum data set was contacted to discuss some minor issues (e.g., standardization of "low-back pain" instead of "back pain," answer choices).

Step 5: Pretest

Guidelines for the cross-cultural adaptation of self-reported measures recommend that the pre–final version of a questionnaire should be pretested among 30–40 people from the target setting.[28] Therefore, the French-Canadian version of the minimum data set was pretested among a convenience sample of Quebec residents with low back pain. Aside from being a common set of descriptors for chronic low back pain research, the minimum data set was also designed for the estimation of prevalence and incidence of chronic low back pain.[14–22] For this reason, no specific inclusion criterion was applied at the time of recruitment regarding the duration of low back pain, thus maximizing the chances of recruiting cases of acute, subacute and chronic low back pain. In June 2016, participants with varying socioeconomic status were approached (using a snowball sampling method among the research team's entourage). Participants who reported pain in the low back region received a paper-and-pencil anonymous questionnaire, a prepaid return envelope and a cover letter asking them to complete the questionnaire and to annotate their suggestions regarding the clarity of the items; each item was accompanied by a shaded box asking participants if the question was clear or needed improvement, with the possibility to include comments. Informed consent was established through the return of the completed questionnaire to the research team. Only the French-Canadian version of the minimum data set was pretested as only minor modifications were made to the English version by the expert committee in step 4.

Step 6: Final versions

The pretest allowed the expert committee to agree on minor modifications to the French-Canadian items, weighing the importance of being able to compare results obtained between the Canadian and American versions, the importance of preserving validated measures included in the questionnaire (e.g., PROMIS scales) and the number of participants reporting clarity issues and their comments. Questioning and disagreement between expert committee members were discussed with the corresponding author of the minimum data set (i.e., clarification examples, time frames). Minor improvements made in light of the results of the pretest of the French-Canadian version were also applied to the English-Canadian version. The final versions of the 2 questionnaires are presented in Appendix 1 (available at www.cmajopen.ca/content/5/1/E237/suppl/DC1).

Ethics approval

The study was approved by the Institutional Ethical Review Board of the Université du Québec en Abitibi-Témiscamingue.

Results

An overview of the adaptations made to the original minimum data set and endorsed by the expert committee (steps 1–4) is presented in Table 1. Although most items were translated by our team, some pre-existing French versions of the scales were included (i.e., PROMIS scales[24] and items from the STarT Back Screening Tool[25]). Only minor adaptations were made to the questionnaire; the main modification being to replace the response categories for the race/ethnicity and education level questions by those used in the bilingual Statistics Canada censuses.[30]

For the pretest (step 5), 44 pre–final questionnaires were distributed to participants who had low back pain. A total of 35 participants returned the questionnaire to the research team (return rate: 79.5%); 33 participants completed the questionnaire and provided their judgment on the clarity of the items, while 2 participants made suggestions about the clarity of the items but did not answer the questions. Characteristics of the study sample are presented in Table 2. Participants' ages varied from 24 to 82 years, and 63.6% were women. Participants had various socioeconomic backgrounds in terms of employment status and education level. A total of 48.4% of participants had chronic low back pain based on the NIH Task Force definition.

An overview of the results of the pretest, as well as the slight changes made to produce the final Canadian version of the minimum data set (steps 5 and 6) are presented in Table 3.

Interpretation

To use a patient-reported outcome measure with different language groups or in different cultural settings, an instrument must not only be translated into the new language, but it must also be adapted to the local culture to maintain its content validity.[28] This study reports on the different steps of a Canadian cross-cultural adaptation of the minimum data set developed by the NIH Task Force on Research Standards for Chronic Low Back Pain. Our investigation is in line with the task force recommendations that the minimum

data set should undergo continual refinement and testing.[14–22] Globally, only minor modifications were made to the original minimum data set, which should not impede the validity and comparability of studies conducted in the United States and Canada.

Chronic low back pain is commonly defined as low back pain of 3–6 months' duration, but case definitions are heterogeneous in the medical literature.[11] In our study sample, 90.9% of participants reported low back pain as a problem for at least 3 months' duration, but using the NIH task force recommendations, only 48.4% of participants met the case definition. This substantial difference underlines the challenges faced when comparing or pooling published studies that do not use the same definition and highlights the importance of standardizing chronic low back pain research using a universal definition.

As noted above, the new standards stipulate that only low back pain that has been an ongoing problem for at least 3 months and that has been an ongoing problem on at least half the days in the past 6 months should be defined as chronic.[14–22] However, during the pretest of the French questionnaire, we noticed that the formulation of these 2 questions excluded many patients who self-identify as living with low back pain for several years but for whom low back pain was not a "problem." To maintain the comparability between the American and Canadian versions of the minimum data set, no changes were brought to the questionnaire. However, to circumvent this issue, we propose that inception cohort studies involving patients with acute and subacute low back pain use the recognized Delphi Definitions of Low Back Pain Prevalence as a selection criterion,[31] which screens for low back pain's severity (i.e., low back pain in the past 4 weeks that is bad enough to limit usual activities or change daily routine for more than 1 day).

Limitations

Although we adhered to the guidelines for the cross-cultural adaptation of self-reported measures,[28] and pretesting of the questionnaire was achieved in a heterogeneous sample of patients with low back pain (i.e., various education levels, low back pain duration), there are limitations associated with our study. For example, further validation studies should be conducted to assess the full range of psychometric properties of the Impact Score[14–22,27] using the new French-Canadian version of the questionnaire.

Only the French-Canadian version of the minimum data set was pretested. Although only minor modifications were brought to the English-Canadian version, it could be further refined by future pretest and validation studies.

Additional limitations are inherent to the original minimum data set. The original questionnaire was designed as the best trade-off of appropriate length with a psychometrically sound assessment. Researchers can replace the PROMIS items by lengthier and well-validated instruments.

Finally, the questionnaire is a minimum set of baseline descriptors and is not intended to serve as a set of patient-reported outcomes for clinical trials of the effectiveness of low back pain treatment. Core outcomes for clinical trials involving patients with chronic pain or back pain are already the subject of consensuses.[29,32,33]

Conclusion

The minimum data set developed by the NIH Task Force on Research Standards for Chronic Low Back Pain[14–22] is a promising tool to standardize the identification of cases of chronic low back pain, to describe patient characteristics and to facilitate the comparison of results across clinical and epidemiologic studies. The present study was a first step toward the use of a culturally adapted instrument for phenotyping French- and English-speaking patients with low back pain in Canada. Clinicians and researchers will recognize the importance of this standardized tool and are encouraged to incorporate it into future research studies on low back pain.

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Contributors: Mark Ware and Laura Stone shared responsibility for leading the Low Back Pain Strategic Initiative and provided the original idea. All authors participated in the cross-cultural adaptation of the minimum data set (translation, expert committee). Anaïs Lacasse coordinated the acquisition of data, the data analysis and drafted the manuscript. All authors critically revised the manuscript, approved the final version to be published and agreed to act as guarantors of the work.

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Table 1 (part 1 of 2): Overview of the adaptations made to the original minimum data set and endorsed by the expert committee

Items of the original minimum data set		French translation method	Adaptations made to both French and English versions
Human body drawing to locate low back pain		NA	Addition: Introduction sentence to inform the respondent that the drawing shows the part of the body referred to in the questionnaire
1,2	LBP duration	Double forward–backward translation	Modification (item 1): Answer choices "1–3 months", "3–6 months" and "6 months–1 year" were respectively replaced by "1–2 months", "3–5 months" and "6–11 months" to allow a collectively exhaustive set of answers
3	LBP intensity in the past 7 days	Double forward–backward translation	A typographical error was made by the authors of the minimum data set when presenting the pain intensity scale (1–10 rather than 0–10 numerical rating scale);[14–22] the correction was made because 0–10 scales are considered a standard in pain research[29]
4	Sciatica	Double forward–backward translation	Addition: Human body drawing to reduce uncertainty and missing data Standardization of the item: "low-back pain" instead of "back pain"
5	Comorbid pain conditions	Double forward–backward translation	NA
6, 7, 8	History of LBP surgical interventions	Double forward–backward translation	Modification (items 6–8): "surgery" instead of "operation" Modification (item 7): The second answer choice "More than 6 months, but less than 1 year ago" was replaced by "6 months or more but less than 1 year ago" to allow a collectively exhaustive set of answers Standardization of items: "low-back surgery" instead of "back surgery"
9, 10, 11, 12	Pain interference	French version ordered directly from PROMIS Cooperative Group[24]	NA
13	LBP treatments	Double forward–backward translation	Modification: The list of examples of prescription medications was adjusted according to drugs available in Canada Standardization of items: "low-back pain" instead of "back pain"
14	LBP-related workplace absenteeism	Double forward–backward translation	Modification: The answer choices "Agree" and "Disagree" were replaced by "Yes" and "No"
15	LBP-related workers' compensation benefits	Double forward–backward translation	Modification: The answer choices "Agree" and "Disagree" were replaced by "Yes" and "No"
16, 17, 18, 19	Physical function	French version ordered directly from PROMIS Cooperative Group[24] Addition: We felt that the French version of item 19 ("Are you able to run errands and shop?") used European French wording that is not straightforward for French-Canadians of various socioeconomic statuses; to reduce the risk of losing psychometric validity, the item was not reformulated but a bracketed specification was added to increase clarity	NA

Table 1 (part 2 of 2): Overview of the adaptations made to the original minimum data set and endorsed by the expert committee

Items of the original minimum data set		French translation method	Adaptations made to both French and English versions
20, 21, 22, 23	Emotional distress or depression	French version ordered directly from PROMIS Cooperative Group[24]	NA
24, 25, 26, 27	Sleep disturbance	French version ordered directly from PROMIS Cooperative Group[24]	NA
28	Kinesiophobia	French-European version of the STarT Back Screening Tool[25]	Standardization of the item: "low-back problem" instead of "back problem"
29	Catastrophizing	French-European version of the STarT Back Screening Tool[25]	Standardization of the item: "low-back pain" instead of "back pain"
30	LBP-related lawsuits and legal claims	Double forward–backward translation	Standardization of the item: "low-back problem" instead of "back problem"
31, 32	Substance abuse	Double forward–backward translation	Modification (item 31): We felt that the formulation lacked clarity about the type of substances the questionnaire refers to ("Have you drunk or used drugs more than you meant to?"); the sentence was replaced by "Have you consumed alcohol or used drugs more than you meant to?"
33	Age	Double forward–backward translation	NA
34	Sex	Double forward–backward translation	NA
35, 36	Race and ethnicity	Double forward–backward translation	Modification: Answer choices were replaced by non-mutually exclusive categories used in Statistics Canada Censuses (National Household Survey)[30] that are available in French and English
37	Employment Status	Double forward–backward translation	NA
38	Highest education level attained	Double forward–backward translation	Modification: Answer choices were replaced by mutually exclusive categories used in Statistics Canada Censuses (National Household Survey)[30] that are available in French and English; additional examples were added by our team for some education-level categories
39	Smoking status	Double forward–backward translation	NA
40	Obesity (height and weight)	Double forward–backward translation	The presentation format of the questions was slightly modified to ease data collection and analysis; the specifications regarding whether height and weight were measured or self-reported were replaced by "has just been measured" and "is an estimation", respectively

Note: LBP = low back pain, NA = not applicable, PROMIS = Patient-Reported Outcomes Measurement Information System.

Table 2 (part 1 of 2): Characteristics of the study participants (*n* = 33)

Characteristic	No. (%)*
Age, yr, mean ± SD†	46.5 ± 14.4
Median	41
Minimum	24
Maximum	82
Sex‡	
Female	21 (63.6)
Male	12 (36.4)
Unknown or unspecified	0 (0.0)
Aboriginal persons§ (not mutually exclusive categories)	
Not an Aboriginal person	30 (96.8)
First Nations (North American Indian)	1 (3.2)
Other categories listed (Métis or Inuk)	0 (0.0)
Race/ethnicity¶ (not mutually exclusive categories)	
White	31 (96.9)
Arab	2 (6.3)
Other categories listed	0 (0.0)
Employment status‡ (not mutually exclusive categories)	
Working now (full- or part-time)	22 (66.7)
Retired	7 (21.2)
Disabled due to back pain (permanently or temporarily)	3 (9.1)
Student	1 (3.0)
Looking for work	1 (3.0)
Other categories listed	0 (0.0)

Table 2 (part 2 of 2): Characteristics of the study participants (*n* = 33)

Characteristic	No. (%)*
Highest education level attained‡	
No high school diploma	3 (9.1)
High school diploma or equivalent	4 (12.1)
Registered apprenticeship or other trades certificate or diploma	3 (9.1)
College, CEGEP or other non-university certificate or diploma	6 (18.2)
University certificate or diploma below bachelor's level	0 (0.0)
Bachelor's degree	7 (21.2)
University certificate or diploma above bachelor's level	3 (9.1)
Master's degree	4 (12.1)
Degree in medicine, dentistry, veterinary medicine or optometry	0 (0.0)
Doctorate	3 (9.1)
LBP that persisted at least 3 mo‡	
Yes	30 (90.9)
No	3 (9.1)
LBP that has resulted in pain on at least half the days in the past 6 mo§	
Yes	16 (51.6)
No	15 (48.4)
Presence of CLBP based on the NIH definition§	
Yes	15 (48.4)
No	16 (51.6)
LBP intensity in the past 7 d (0–10), mean ± SD‡	4.8 ± 2.3
Median	5 ± 2.3
Minimum	0
Maximum	9

Note: CLBP = chronic low back pain, LBP = low back pain, SD = standard deviation.
*Unless otherwise specified.
†5 missing data.
‡0 missing data.
§2 missing data.
¶ 1 missing data.

Table 3 (part 1 of 4): Overview of results of the pretest, and changes made to produce the final version of the Canadian minimum data set

Items of the original minimum data set		Proportion of participants reporting the item as completely clear (n = 35), %	Comments and suggestions of participants who reported that the clarity of the item should be improved	Modifications brought to the final version of the French and English questionnaires
Human body drawing to locate low back pain		100.0	NA	NA
1, 2	LBP duration	91.4	Participants reported that they have LBP, but that it is not a problem for them. They suggested clarifying the term "problem" (n = 3).	Considering the small proportion of participants who reported that these items were unclear and the importance of these 2 items for the NIH's standard definition of CLBP cases, no modification was made to these 2 items.
		94.3	They did not understand the relevance of the second question when the first one was already asked (n = 1). The 2 last answer choices of the second item are very similar (n = 1).	
3	LBP intensity in the past 7 days	94.3	It is difficult to report LBP intensity in the past 7 days on average (n = 1). There are too many points on the scale (n = 1).	Because 0–10 numerical rating scales for average pain intensity are standards in pain research,[29] no modification was made.
4	Sciatica	94.3	The question should present a larger time window because 2 weeks is not representative of their condition (n = 2).	Given that comments did not reflect a clarity issue and in order to maximize the comparability of results obtained with the Canadian and American version of the minimum data set, the time frame was not modified.
5	Comorbid pain conditions	91.4	The difference between "widespread pain" and "pain in most of your body" as 2 different concepts was not clear (n = 1). It was not clear if pain in legs and arms could qualify as "pain in most of your body" (n = 1). Other pain conditions were not listed (n = 1).	To reduce confusion, "pain in most of your body" was presented in brackets as a synonym of "widespread pain" rather than a different concept.
6, 7, 8	History of LBP surgical interventions	77.1	The first question should be used as a branching question (screener) for items #7 and #8 that are follow-up questions for patients who answered "yes" to item #6. No instructions are provided (e.g., If no, go to question #9). They do not want to read questions that do not apply to them (n = 8). Just like for item #7, add "If yes" to item 8 (n = 1).	Future users of the minimum data set should number the items and use a skip ahead instruction (paper-and-pencil questionnaire) or use an automatic Question Skip Logic (web-based questionnaire).

Table 3 (part 2 of 4): Overview of results of the pretest, and changes made to produce the final version of the Canadian minimum data set

Items of the original minimum data set		Proportion of participants reporting the item as completely clear (*n* = 35), %	Comments and suggestions of participants who reported that the clarity of the item should be improved	Modifications brought to the final version of the French and English questionnaires
9, 10, 11, 12	Pain interference	77.1	The difference between item 10 about "work around the home" and item 12 about "household chores" is unclear. Examples should be provided (*n* = 8). Gardening can be considered a day-to-day activity (item 9), work around the home (item 10) and a household chore (item 12). Where should we include this activity? (*n* = 1).	The research team was confronted with many comments regarding the PROMIS Pain interference scale but had to keep in mind that items of a validated scale cannot be reformulated without risk of losing psychometric validity. We however felt that giving examples to patients could be a good idea. Examples such as garden work and renovations were added for the "work around the home" item. Examples such as house cleaning and vacuuming were added for the "household chores" item.
13	LBP treatments	77.1	A time window should be presented, e.g., current use of treatments, use of treatments in the past year (*n* = 3). The general format of the question was not clear, i.e., same answer choices for the type of treatment used by the patient and for the current use of opioid painkillers (*n* = 3). The French term "Infiltration" should be added as a synonym of injections (*n* = 1). "Exercise therapy" is not clear. Does this include personal exercise plan that was not prescribed by a physiotherapist? (*n* = 1). It is not clear if injections and provided examples include intramuscular or intravenous methotrexate injections (*n* = 1).	Answer choices for treatment use were modified as follows: "Yes, I am currently using this treatment", "Yes, I have used this treatment in the past but stopped", "No", and "Not sure". The term "Infiltration" was added as a synonym of "Injections".
14	LBP-related workplace absenteeism	94.3	A time window should be presented (*n* = 2).	No modification was made. However, if a distinction between past and recent disability is important, researchers might add a time frame to this item (e.g., past 12 mo).
15	LBP-related workers' compensation benefits	100	NA	NA

Table 3 (part 3 of 4): Overview of results of the pretest, and changes made to produce the final version of the Canadian minimum data set

Items of the original minimum data set		Proportion of participants reporting the item as completely clear (*n* = 35), %	Comments and suggestions of participants who reported that the clarity of the item should be improved	Modifications brought to the final version of the French and English questionnaires
16, 17, 18, 19	Physical function	94.3	A time window should be presented (*n* = 1). It is difficult to answer these questions because physical functioning varies according to pain symptoms during a given week (*n* = 1).	Considering the large proportion of participants who reported that these items were clear, and the importance of keeping the psychometric validity of the PROMIS Physical Function scale, no modification was made.
20, 21, 22, 23	Emotional distress/ depression	94.3	The French term for "helpless" ("désemparé") is not clear (*n* = 1). The difference between the French term for "helpless" ("désemparé") and the French term for hopeless ("désespéré") is not clear (*n* = 1).	Aforementioned rationale. No modification was made.
24, 25, 26, 27	Sleep disturbance	94.3	It was not clear if the questions were about general or LBP-related sleep quality (*n* = 1). It was not clear if questions were about sleep quality with or without sleeping pills (*n* = 1).	Aforementioned rationale. No modification was made.
28	Kinesiophobia	85.7	Questions should not be formulated in a negative way (*n* = 3). The item is not clear. Do you mean that doing exercise will result in my condition getting worse? (*n* = 1). It was unclear according to whom physical activity was considered unsafe. The participant? His physician? Scientific evidence? (*n* = 1).	This item was taken from the French-European version of the STarT Back Screening Tool.[25] No modification was made.
29	Catastrophizing	94.3	There are 2 questions in this statement. It should be divided: LBP is terrible (agree/disagree) and LBP is never going to get any better (agree/disagree) (*n* = 1). This item should have a "not sure option" (*n* = 1).	This item was taken from the French-European version of the STarT Back Screening Tool.[25] No modification was made.
30	LBP-related lawsuits and legal claims	97.1	Examples of agencies where a legal claim can be submitted should be provided (*n* = 1).	Given the large proportion of participants who reported that this item was clear, and the variability of agencies across Canadian provinces, no modification was made.

Table 3 (part 4 of 4): Overview of results of the pretest, and changes made to produce the final version of the Canadian minimum data set

Items of the original minimum data set		Proportion of participants reporting the item as completely clear (*n* = 35), %	Comments and suggestions of participants who reported that the clarity of the item should be improved	Modifications brought to the final version of the French and English questionnaires
31,32	Substance abuse	97.1	It was not clear if "drugs" would include only illicit drugs or also medications. Specifically mentioned about the debate surrounding opioid use (*n* = 1).	Given the large proportion of participants who reported that this item was clear, no modification was made.
33	Age	88.6	The specification "(0-120 yr)" sound weird/not required (*n* = 4).	No modification was made because this aspect should not affect the validity of the answer.
34	Gender	82.9	Added a question/exclamation mark at the side of the "Unknown" and "Unspecified" answer choices (*n* = 2). Both choices ("Unknown" and "Unspecified" answers) are not required. A simple "Other" category should be added (*n* = 4).	No modification was made following the pre-test in order to replicate the answer choices of the original data set.
35	Race and ethnicity	97.1	It was not clear if descendant aboriginal counts as an aboriginal person (*n* = 1).	Because it represented categories used in Statistics Canada Censuses,[30] no modification was made.
36		91.4	It was not clear if "White" meant "Quebecker" (*n* = 1). The "Arab" category should have examples. Is Maghreb included (*n* = 1)? Strange categories (*n* = 2).	Because it represented categories used in Statistics Canada Censuses,[30] no modification was made.
37	Employment status	85.7	The "working now" answer choice should be separated for full- and part-time work (*n* = 2). Added a question mark at the side of the "Unknown" answer choice (*n* = 1). Categories should not be mutually exclusive (*n* = 2).	The statement "mark more than one answer if applicable" was added, and full- versus part-time work are now presented as different options.
38	Highest education level attained	100	NA	NA
39	Smoking status	100	NA	NA
40	Obesity (height and weight)	85.7	The specification on whether height and weight have just been measured is not clear. When? By whom? (*n* = 5). It is strange and not relevant to ask if height and weight have just been measured or are estimations (*n* = 2).	The research team felt that the information about whether height and weight have been measured by the patient, by his physician or is a self-reported estimation was not of great relevance for data analysis and phenotyping of CLBP patients. It was thus removed. However, future users of the minimum data set could keep these specifications if they want to consider this information in their analysis.

Note: CLBP = chronic low back pain, LBP = low back pain, NA = not applicable, NIH = National Institutes of Health, PROMIS = Patient-Reported Outcomes Measurement Information System.