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Permalink

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Journal

Journal of Pain, 24(3)

ISSN

1082-3174

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Publication Date

2023-03-01

DOI

10.1016/j.jpain.2022.10.012

Peer reviewed

Journal Pre-proof

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PII: S1526-5900(22)00438-2
DOI: <https://doi.org/10.1016/j.jpain.2022.10.012>
Reference: YJPAI 4191



To appear in: *Journal of Pain*

Received date: 19 August 2022
Revised date: 14 October 2022
Accepted date: 19 October 2022

Please cite this article as: Patricia M Herman , Nabeel Qureshi , Susan D Arick , Maria O Edelen , Ron D Hays , Anthony Rodriguez , Rebecca L Weir , Ian D Coulter , Definitions of Chronic Low Back Pain from a Scoping Review, and Analyses of Narratives and Self-Reported Health of Adults with Low Back Pain, *Journal of Pain* (2022), doi: <https://doi.org/10.1016/j.jpain.2022.10.012>

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Definitions of Chronic Low Back Pain from a Scoping Review, and Analyses of Narratives and Self-Reported Health of Adults with Low Back Pain

Short running title (45 characters, excluding spaces): Definitions of Chronic Low Back Pain and Their Impact

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Disclosures

Research funding: This work was supported by the National Center for Complementary and Integrative Health (NCCIH). [Grant No. 1R01AT010402-01A1, 2020]. NCCIH had no role in study design; in the collection, analysis, and interpretation of data; in the writing of the report; nor in the decision to submit the article for publication.

Highlights

- Those with chronic (versus nonchronic) low back pain face more suffering and costs.
- However, what defines low back pain as chronic varies widely.

- Most recent randomized controlled trials defined chronic low back pain by duration.
- Most individuals with low back pain define chronicity in terms of frequency.
- Pain management behaviors and outcomes differ across groups meeting each definition.

Conflicts of interest: The authors declare that there are no conflicts of interest.

Journal Pre-proof

Abstract

Among those with low back pain (LBP), individuals with chronic LBP (CLBP) face different treatment recommendations and incur the majority of suffering and costs. However, the way CLBP has been defined varies greatly. This study used a scoping review and qualitative and quantitative analyses of data from LBP patients to explore this variation. CLBP in most recent randomized controlled trials (RCTs) was defined by duration of pain, most commonly ≥ 3 months. However, individuals with LBP most often define CLBP by frequency. CLBP has also been defined using a combination of duration and frequency (16% of RCTs and 20% of individuals), including 6% of recent RCTs that followed the NIH Pain Consortium research task force (RTF) definition. Although not a defining characteristic of CLBP for individuals, almost 15% of recent RCTs required CLBP to have a healthcare provider diagnosis. In our LBP sample moving from ≥ 3 months to the RTF definition reduced the CLBP group size by 25% and resulted in a group that used more pain management options and reported worse health across all outcome measures. A pain duration definition offers ease of application. However, refinements to this definition (e.g., RTF) can identify those who may be better intervention targets.

Perspective [max 50 words; now 50]: This article presents the definitions used for chronic low back pain by researchers and individuals, and the impact of these definitions on pain management and health outcomes. This information may help researchers choose better study inclusion criteria and clinicians to better understand their patients' beliefs about chronic low back pain.

Key words (5): chronic low back pain; scoping review; qualitative analysis; pain management; back pain outcomes

Introduction

Low-back pain (LBP) is common and is considered the leading cause worldwide of years lived with disability.^{13, 16, 22, 44} Various studies indicate that among those with LBP, those with chronic LBP (CLBP) incur the majority of the suffering and costs.^{3, 7, 16} Recommendations for treatment also differ between those with non-chronic (acute or subacute) LBP and those with CLBP.^{1, 10, 30} Therefore, identifying those who have CLBP is important for both diagnosis and treatment. A consistently applied definition of CLBP is also needed for research. Variations in inclusion/exclusion criteria and case definitions used in studies for CLBP make it difficult to compare and pool data and results, replicate and interpret findings, and resolve conflicting conclusions.^{7, 14, 16, 44}

Although the term 'chronic' gets used as a prognostic indicator (i.e., will the pain continue?) most CLBP is defined by duration of pain to date.^{26, 36, 39} Nevertheless, as chronic pain can run a recurrent course or fluctuate from day to day, duration alone does not provide the full picture.^{3, 16, 42} In their 2014 publication, the National Institutes of Health Pain Consortium's research task force (RTF) on research standards for CLBP added symptom frequency to duration for their proposed CLBP definition.⁷ They recommended that CLBP be defined by at least 3 months' duration AND symptoms on at least half the days in the past 6 months. There are also other definitions of CLBP, including that a healthcare provider identify certain LBP as chronic,³ or that patients define their own LBP as chronic.³³ Understanding how often these definitions are used and how the application of different definitions changes the size and characteristics of the CLBP population to be studied is crucial to interpreting research results and choosing the best definition to use.

This study uses three methods to fulfill four objectives. First, we use a scoping review to examine the published literature for recent randomized controlled trials of patients with CLBP to see how CLBP has been defined (Objective 1). Second, we examine the statements made in a recent survey of individuals with LBP about how they define their LBP as chronic (Objective 2). Finally, we use other results from the same survey to examine the frequency and overlap between four chronicity definitions applied to a general LBP sample (Objective 3) and how their demographics, pain management behaviors, and outcomes differ by the definition of CLBP used (Objective 4).

Methods

The three methods used in this study are: a scoping review of the CLBP literature; and a qualitative and a quantitative analysis of individuals' data from a recent survey of respondents with LBP. The study was reviewed and approved by the RAND Human Subjects Protection Committee (2019-0651-AM02).

Scoping Review (Objective 1)

Because we could find no published empirical data on usage of different CLBP definitions, a scoping review (following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for scoping reviews, PRISMA-ScR³⁷) was used to fulfill Objective 1: identify and quantify the frequencies of CLBP definitions used by researchers. The results of this scoping review were used to justify the need for other analyses, our focus on nonspecific LBP, and the CLBP definitions used. Because of the primacy of the randomized controlled trial (RCT) study design in establishing evidence,²⁵ our search captured all published RCTs or RCT protocols for CLBP available in Medline (Ovid), CINAHL and Embase for 2020 and 2021. We restricted the search to human studies published in English. The full search for Medline and the PRISMA-ScR Checklist are shown in the Appendix. For each study, two reviewers (PMH and SDA)

determined eligibility and extracted the inclusion/exclusion criteria, the intervention studied, the country in which the study took place and the year of publication.

Data Used for the Qualitative and Quantitative Analyses

Our data on individuals were gathered between August 21 and November 2, 2021, from 1972 workers on Amazon's Mechanical Turk (MTurk) who identified as having back pain. First, a general health survey was fielded to all high-quality, experienced MTurk workers (approval ratings $\geq 95\%$ and 500+ previously completed tasks) using micro batching (the release of 9 surveys per hour every hour, which reduces time-of-day and day-of-week response bias) over a period of two months. This survey included Patient-Reported Outcomes Measurement Information System (PROMIS®) measures (e.g., global health, PROMIS-29), demographic items, and lists of health conditions one had "been told by a doctor or other health professional that" they had or that they "currently" have. Respondents completing this survey received \$1.50. We received 5,775 valid responses.

Respondents who endorsed current back pain were offered an additional \$2.00 to complete a survey about their back pain. The survey included questions about whether the respondent's back pain was chronic according to four definitions (3-month pain duration, RTF definition, a health provider told you, you believe your back pain is chronic). The back pain survey also included items about whether their back pain was due to a specific medical condition, what they did for pain management, and several back pain outcomes measures: Oswestry Disability Index, version 2,⁸ the 24-item Roland-Morris Disability Questionnaire,³² the Pain, Enjoyment and General Activity (PEG) scale,¹⁸ the STarT Back screening tool,¹² the Graded Chronic Pain Scale,⁴⁰ and a single-item measure of high-impact chronic pain.³⁸ Because LBP that is due to a specific medical condition (e.g., cancer, spinal infections, fractures) is treated by addressing that condition, the diagnosis of CLBP is most important to guide treatment for those with

nonspecific LBP, LBP with no known pathoanatomical cause.^{7,21} Therefore, in our analyses we focus on 1482 individuals with the most common type of LBP, nonspecific LBP.

Qualitative Analysis (Objective 2)

Each back pain participant also was given the chance to respond to an open-ended item: “People have different ideas about what it means for pain to be chronic. What does chronic pain mean to you?” We conducted a content analysis of their responses to understand how individuals define pain as chronic (Objective 2).¹⁹ Topics for coding were created *a priori* based on those generally found to be associated with the description of pain (i.e., mentions of frequency of pain, duration of pain, severity of pain, etc.) and codes were added as new topics emerged. Note that an individual’s response to this open-ended question may touch on more than one topic so that the sum of the number of times topics were addressed across all responses can exceed the number of respondents. One coder (NQ) reviewed the responses and coded topics for analysis. We summarized the prevalence of topics within definitions along with subtopics when there was variation in responses. We also examined the extent to which those who endorsed their LBP as chronic gave different definitions of chronicity from those who did not report their LBP as chronic.

Quantitative Analysis (Objectives 3 and 4)

Finally, we used the survey data to identify individuals who met each of the four definitions of chronicity included in the survey: 3-month duration (response of 3 months or more to “how long has low back pain been an ongoing problem for you?”), RTF (3-month plus response of at least half the days in the past 6 months or more to “how often has your low back pain been an ongoing problem?”), provider identified (“Yes” response to “has a health provider told you that your back pain is chronic?”), and individual identified (“Yes” response to “do you think your back pain is chronic?”). We calculated frequencies and

overlap between the groups (Objective 3) and means and standard deviations for demographics, back pain management options, and self-rated health (Objective 4). Because membership in the four chronic definition groups overlapped (i.e., the groups were not independent), statistical comparisons across groups were difficult. Since the RTF group was a subset of the 3-month group, we created a subgroup of those who met the 3-month criterion but did not qualify for the RTF. This allowed us to use independent group t-tests and chi-square tests to compare those within the 3-month group who did and did not meet RTF definition. We also compared those who met any of the chronicity definitions to those who met none.

Results

Table 1 shows the flow of studies into the scoping review and its results for Objective 1. All articles received full text review and 236 were included as RCTs for CLBP; 22 (9%) of these were protocols. The definitions of CLBP used in each article were identified and the studies requiring a particular duration were separated from those who required both a particular duration and frequency. However, most of the studies requiring a provider diagnosis and the one study requiring patient-identification of CLBP also required a particular duration or frequency and duration. These studies are double-counted in Table 1. Having had LBP for a particular duration was the most common definition used (78% of studies) and most of these (62% of studies) used at least 3 months duration as the definition. Requiring both a particular duration and frequency of pain was the second most common (16% of studies) definition although only 15 articles (6% of studies) used the RTF definition; 11 of these were US-based trials [data not shown]. Needing a doctor's diagnosis of CLBP was the third most common (15% of studies) definition and only one study used patients' self-report of chronicity. It was also common (90%) for the trials to focus on nonspecific CLBP with 172 (73%) explicitly stating this by name or through exclusion of

those with any of a detailed list of specific medical causes of their LBP;²¹ 41 others excluded using fewer specific causes of LBP.

Of the 1972 individuals in the respondent data who endorsed having current back pain and who responded to the back pain survey, 1482 (74%) had nonspecific LBP and almost all of these (1462 or 99%) responded to the open-ended question: "What does chronic pain mean to you?" Table 2 shows the results of our content analysis of those comments for Objective 2. Despite how common duration of pain was as the basis for chronicity in RCTs, it was only mentioned by 34% of individuals as part of their definition of chronic pain. Frequency of pain was mentioned more often, i.e., by half (50%) of respondents with "constant" being the most common (43%) frequency mentioned. Duration and frequency were mentioned together by 20%. No respondent mentioned a provider telling them their pain was chronic, but more than 10% mentioned each of the following: how pain becomes chronic, functional limitations, the severity/intensity of symptoms, and the lack of relief. Compared to those who did not self-identify as having CLBP, the group who did provided relatively more comments related to duration, frequency, and the combination of duration and frequency, and fewer comments related to symptom severity/intensity.

Figure 1 shows the counts and overlap (Objective 3) in our respondent sample between the groups defined using each of four definitions of CLBP: 1) 3 months or greater duration, 2) RTF definition, 3) provider-identified, and 4) individual-identified. Only 243 (16%) individuals out of the 1482 who endorsed having current back pain did not meet any of the four chronicity definitions (i.e., had acute or subacute LBP), 292 (121+8+163 or 20%) met only one of the chronicity definitions, 437 (80+32+5+320 or 29%) met two of the chronicity definitions, 400 (376+18+6 or 27%) met three definitions, and 110 (7%) met all four definitions. The group defined by 3 months or greater duration was the largest (n=1078;

73% of the sample) and captured 87% of the 1239 meeting any chronicity definition. The group defined by a provider was the smallest (n=179; 12% of the sample) and 110 (61%) of that group also met all three of the other chronicity definitions.

Table 3 gives the demographic characteristics of the overall nonspecific LBP sample and for the various chronicity definitions (Objective 4). The group defined as chronic by their health providers were older, and more likely to identify as Hispanic and as White than the other groups. Using an alpha of 0.05, compared to those who only met the 3-month duration definition, those who also met the RTF definition (duration and frequency) were more likely to identify as Hispanic and White and less likely to identify as Asian; were more likely to have annual household income above \$100,000; were more likely to be working full-time and less likely to work part time; were more likely to not be working due to health problems; and were more likely to have open workers' compensation, personal injury, and motor vehicle accident (MVA) claims. Compared to those meeting any of the chronic definitions, those who met none of the definitions (i.e., those with acute or subacute LBP) tended to be younger, better educated and more likely to be working full time.

Table 4 presents strategies respondents reported using to manage their back pain as well as their outcomes for the full nonspecific LBP sample and for those who met the different chronicity definitions (Objective 4). The group defined as chronic by their health providers stands out as being the most likely to use injections, chiropractic, counseling, acupuncture, massage, supplements, prescription medications and narcotics to manage their pain. This group also reported the worst health on average on all measures except the PROMIS-29 physical and mental health summary scores. Compared to those who only met the 3-month duration definition, those who also met the RTF definition (duration and frequency) were less likely to use over-the-counter pain medication and more likely to use every other

pain management option except chiropractic, exercise, and massage. They also reported worse health across all outcome measures. Compared to those meeting any of the chronic definitions, those who met none of the definitions were less likely to use chiropractors, exercise, marijuana products that contain Tetrahydrocannabinol (THC), and medications of all types. They also have better self-rated health by all outcome measures except pain interference, physical function, and the Impact Stratification Score.

Discussion

Although identifying those with CLBP is needed for the diagnosis and treatment of nonspecific LBP, researchers and individuals both use several different definitions of what makes LBP chronic. For researchers these different definitions also make the comparison, pooling, interpretation, and replication of study results difficult. Therefore, the NIH Pain Consortium RTF developed and published what they hoped would become a standard definition of CLBP based on pain frequency and duration. Unfortunately, we found that 7-8 years later only 6% of published trials (26% of US-based trials) used the RTF definition; although an additional 9% were using other definitions that combine duration and frequency. This demonstrates the challenge of obtaining consistent use of a single CLBP definition. Across recent published trials of interventions for CLBP, over three quarters defined chronicity by the duration of pain at baseline, with 3-month duration being the most common. In contrast, when individuals were asked "What does chronic pain mean to you?" duration of pain was mentioned in just over one-third of responses. Frequency of pain was mentioned most often by individuals and almost always as "constant." Individuals also frequently mentioned symptom severity, functional limitations, or lack of effective treatments or cure to characterize chronicity.

Differences Seen Across CLBP Groups

Our descriptive analyses (Objectives 3 and 4) showed that depending on the definition of chronicity used, the number and characteristics of qualifying individuals change. In our sample, the largest group (n=1078) was defined using 3-month duration and the smallest group (n=179) was provider-identified. Moving from a 3-month duration definition to the RTF (frequency and duration) definition reduced the number of individuals with CLBP by 25%, and this shift also eliminated a group of individuals who were quite different. Compared to those meeting the RTF definition, the individuals who only met the 3-month definition were significantly less likely to identify as Hispanic, be working full time, and to have an open workers' compensation, personal injury, or MVA claim. They also had better health and were less likely to have used most of the pain management options. Therefore, the RTF definition can be seen as identifying a more severe/impacted CLBP group than that defined by duration alone. Note that the individual-identified CLBP group was similar in size to the RTF group. These groups overlapped by about two-thirds and also had roughly similar characteristics indicating that whether an individual believes their LBP to be chronic may also identify a more severe/impacted group for intervention.

Provider-Identified CLBP and the new ICD-11

The provider identified CLBP group was the smallest and, according to relative means and frequencies, could be considered as defining an even more severe CLBP group than seen in RTF. According to means and frequencies, this group is most likely to use the majority of pain management options and to have the worst health across almost all back pain-specific measures. Our scoping review showed that 15% of the RCTs used a definition of CLBP that required a provider diagnosis. While individuals reporting a health provider said their back pain was chronic is not always the same as a provider diagnosis, both measures have faced the challenge of the lack of a clearly defined diagnosis code for CLBP in the International Classification of Diseases (ICD).⁴³ There are a number of codes available for back pain, but no specific designation for CLBP. The new ICD 11th Revision (ICD-11) was put in place worldwide January

1, 2022, and it includes codes for specific types of chronic primary (i.e., nonspecific) pain, including MG30.02 chronic primary musculoskeletal pain.²⁸ This new ICD revision may make the identification of those with a provider diagnosis of CLBP easier. Note that this diagnosis requires pain to have persisted for more than 3 months and be “associated with significant emotional distress and/or functional disability.”²⁷ It remains to be seen how these new codes will be applied in practice.

Baseline Indicators Predictive of Chronicity

Earlier it was mentioned that the designation of CLBP often gets used as a prognostic indicator, identifying individuals whose LBP is likely to continue (i.e., be chronic).³⁹ Several studies have shown that duration of pain at baseline is predictive of ongoing pain.^{2, 6, 15} However, it is only one predictor. Other studies have shown that the following factors at baseline also predict chronicity: diagnosed anxiety/depression,^{5, 35} “maladaptive psychosocial factors,”^{5, 6} beliefs that their LBP will persist,^{2, 29} catastrophizing,¹¹ pain intensity,^{2, 11} and disability severity.^{5, 11, 35} These findings support the new ICD 11 diagnosis criteria for CLBP and validate some individuals’ definitions of CLBP as being reasonable prognostic indicators of ongoing pain. However, clinicians should note that addressing and/or changing these indicators may or may not change whether pain persists^{24, 29, 34} and that clinicians’ comments have been shown to be a main source of these prognostic beliefs in individuals.³³

Limitations

Although our study utilized a large set of data it is not without limitations, the most important of which is the representativeness of our data collected using MTurk.^{4, 41, 45} Our general health survey generated 5,775 valid responses. Of those 1,972 (34%) claimed to have current back pain and 1,482 (26%) had nonspecific LBP. This prevalence of back pain is higher than the average point prevalence reported in other national samples (mean of 18%) but within the range seen (1% to 58%).¹³ It is also lower than the

3-month prevalence of 39% seen in a recent US National Health Interview Survey sample.²⁰ We also found that the majority (84%) of our back pain sample met at least one definition of chronicity, and 73% met the most common definition: LBP duration of 3 months or longer. Our 3-month estimate is higher than the 43%-54% of those with LBP seen in three primary care samples who reported pain duration of 3 months or more.^{6,17,23} However, the primary care samples were made up of those with LBP who were seeking care, a group that differs significantly in a number of ways from the more than 40% who do not seek care.⁹ Also, as has been seen in other data gathered using MTurk, the demographic profile of our sample does not match the general US population,^{31,41} which may minimize the generalizability of this study's results to other samples. Nevertheless, we gathered these data using extensive quality checks³¹ and believe them to be valid for comparisons across groups. We limited our scoping review to recent RCTs and protocols to give the RTF definition time to catch on, but a longer review period might have captured more and different definitions of chronicity being used. Our qualitative analysis benefited from almost all (99%) respondents providing comments on what chronic pain means to them. However, one limitation to the provider-identified CLBP group is its dependence on reports by patients who may be unaware of the diagnoses provided by health care providers.

Conclusions

This study documented that there although the NIH RTF attempted to establish a consistent definition of CLBP, 7-8 years later only 26% of US-based trials (6% of published trials) use that definition. Instead, there are many different definitions of CLBP in use in research and perceived by individuals. This inconsistency confounds the appropriate application of treatment recommendations for CLBP and makes it difficult for researchers to compare and pool data and results, replicate and interpret findings, and resolve conflicting conclusions.^{7,14,16,44} Duration of pain is most often used to define CLBP in studies with 3-month duration being the most common. This duration is likely to continue in use both because

of its ease of application and its use in the new ICD-11 diagnosis codes. However, both the RTF definition and the new coding add other criteria to duration in defining CLBP. In the case of the RTF definition the addition of frequency resulted in the identification of a group of individuals more impacted by CLBP, who could serve as a more concise target for intervention. In any case, researchers and the policy makers and clinicians who use their results should be aware of the different pain management behaviors and outcomes seen across the groups who meet each of these definitions.

Acknowledgments

This work was supported by the National Center for Complementary and Integrative Health (NCCIH). [Grant No. 1R01AT010402-01A1, 2020]. The authors would also like to thank Jody Larkin and Orlando Penetrante for their help with the scoping review.

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Figure 1. Overlap of different definitions of chronic low back pain in a population with nonspecific low back pain.

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≥3 Months Duration = Response of at least 3 months or more to “How long has low back pain been an ongoing problem for you?”

RTF = NIH Pain Consortium research task force definition: responses of at least 3 months or more to “How long has low back pain been an ongoing problem for you?” AND at least half the days or every day to “How often has low back pain been an ongoing problem for you in the last 6 months?”

Individual Identified = Response of “Yes” to “Do you think that your back pain is chronic?”

Provider Identified = Response of “Yes” to “Has a health provider told you that your pain is chronic?”

Table 1. Results of the scoping review of definitions of chronic low back pain (CLBP) used in randomized controlled trials

Table 1. Results of the scoping review of definitions of chronic low back pain (CLBP) used in randomized controlled trials

<u>Total number of studies found for 2020 and 2021 in the search</u>	<u>263</u>
<u>Number excluded for reasons below</u>	<u>27</u>
<u> Duplicate</u>	<u>1</u>
<u> Not English language</u>	<u>2</u>
<u> Not a study of chronic low back pain (CLBP)</u>	<u>9</u>
<u> Not a randomized controlled trial</u>	<u>15</u>
<u>Number of studies included in the analysis</u>	<u>236</u>
<u> Percentage (#) of these that were protocols</u>	<u>9.3 (22)</u>
<u> Percentage (#) of studies where chronicity was based on duration¹</u>	<u>78.0 (184)</u>
<u> Minimum duration <3 months</u>	<u>1.3 (3)</u>
<u> >=3 months duration</u>	<u>62.3 (147)</u>
<u> >=6 months duration</u>	<u>13.1 (31)</u>
<u> >=12 months duration</u>	<u>1.3 (3)</u>
<u> Percentage (#) of studies with chronicity based on duration and frequency¹</u>	<u>15.7 (37)</u>
<u> NIH RTF definition</u>	<u>6.4 (15)</u>
<u> Other duration and frequency definitions</u>	<u>9.3 (22)</u>

<u>Percentage (#) of studies requiring provider diagnosis of CLBP²</u>	<u>14.8 (35)</u>
<u>Percentage (#) of studies where chronicity based on patient report³</u>	<u>0.4 (1)</u>
<u>Percentage (#) of studies where chronicity was not defined</u>	<u>2.5 (6)</u>
<u>Percentage (#) of studies that excluded those with specific medical conditions</u>	<u>90.3 (213)</u>
<u>Percentage (#) that excluded based on full list of specific conditions</u>	<u>72.9 (172)</u>

¹There is no overlap between the counts of studies with definitions of CLBP based on duration and those with definitions based on duration and frequency.

²All studies in this category required a diagnosis of CLBP (not just a diagnosis of LBP) and 26 of these studies also required certain duration (17 also required duration of 3 months or more and 6 also required duration of 6 months or more) or duration and frequency (3 studies) criteria to be met in addition to the diagnosis. These 26 studies are each included twice in this table.

³The one study in this category is also included in the >=6 months duration category because both were required.

Table 2. Analysis of responses from those with nonspecific back pain to open-ended item “What does chronic pain mean to you?” by those who did and did not answer “Yes” to “Do you think your back pain is chronic?”

Table 3. Demographic characteristics by chronicity definition for those with low-back pain

Table 4. Pain management behaviors and outcomes by chronicity definition for those with low-back pain

