

ORIGINAL RESEARCH

Nonadherence to Clinical Practice Guidelines for Opioid Prescribing in Patients with Chronic Low Back Pain: A Pain Research Registry–Based Study

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Introduction: This study measured the prevalence and impact of nonadherence to clinical practice guidelines (CPGs) that recommend using nonpharmacological and nonopioid treatments such as nonsteroidal anti-inflammatory drugs (NSAIDs) before considering opioids in patients with chronic low back pain.

Methods: Participants within the PRECISION Pain Research Registry provided data during the period from April 2016 through October 2021. The prevalence of nonadherence to CPGs was based on current or prior use of 6 common nonpharmacological treatments, NSAIDs, and opioids for low back pain. The primary outcome measures were low back pain intensity, back-related disability, and pain impact on health-related quality of life.

Results: The prevalence of nonadherence to CPGs was 68 (18.0%) participants among the 378 participants currently using opioids. Participants having some post–high school education (OR, 0.41; 95% CI, 0.22–0.74) or at least a college education (OR, 0.26; 95% CI, 0.12–0.56) were at decreased risk of treatment that was nonadherent to CPGs in a multivariate analysis. Participants whose treatment was nonadherent to CPGs reported significantly worse clinical outcomes across all 3 measures ($P \leq .001$; Cohen's d range, 0.41 to 0.62).

Conclusion: Up to one-fifth of patients with chronic low back pain may be prescribed opioids in a manner that is not adherent to CPGs, thereby placing them at risk for poor outcomes. (J Am Board Fam Med 2022;35:724–732.)

Keywords: Health Care Outcome Assessment, Health Literacy, Low Back Pain, Multivariate Analysis, Opioids, Prevalence, Quality of Life, Registries

Introduction

Low back pain is a problem that affects more than 600 million persons and is the leading cause of disability worldwide.¹ The clinical practice guidelines (CPGs) developed to address this issue often promote a biopsychosocial approach to pain management, including patient self-management, nonpharmacological treatments, and avoiding

opioids as first-line pharmacological treatment. Nevertheless, a substantial gap exists between evidence-based guidelines and clinical practice.² Two major guidelines in the United States address the treatment of chronic pain, including low back pain. The Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain, which addresses chronic, noncancer pain, recommends that both nonpharmacological and nonopioid treatments be initiated before using opioids.³ The American College of Physicians Clinical Practice Guideline, which addresses low back pain, also recommends nonpharmacological treatments and nonsteroidal anti-inflammatory drugs (NSAIDs) before considering opioids in patients with chronic low back pain.⁴ We aimed to primarily measure the prevalence and impact of nonadherence to these CPGs for opioid prescribing in patients with chronic low back pain in the United States, and to secondarily

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identify patient and physician factors associated with CPG nonadherence.

Methods

Pain Registry for Epidemiologic, Clinical, and Interventional Studies and Innovation (PRECISION Pain Research Registry)

Adults with chronic low back pain within the 48 contiguous states and the District of Columbia are recruited for the PRECISION Pain Research Registry using a screening questionnaire that is promoted through social media. To be eligible for registry enrollment, participants must be from 21 to 79 years of age and meet the diagnostic criteria established by the National Institutes of Health Task Force on Research Standards for Chronic Low Back Pain.⁵ These require participant reporting of a low back pain duration of at least 3 to 6 months and a pain frequency of at least 1-half of the days in the past 6 months. Participants are also required to have a physician who regularly treats their low back pain. Case report forms are available only in English and they are disseminated and collected using a digital research platform. Participants with limited English language proficiency may seek assistance from registry staff, including the option of an interview for those with limited reading or writing abilities. Pregnant women and persons living at institutional facilities are excluded from the registry. This research is approved by the North Texas Regional Institutional Review Board and all participants provide informed consent before enrollment. The registry routinely conducts quarterly follow-up of participants for 12 months after enrollment. A current description of the PRECISION Pain Research Registry (NCT04853732) and its data collection is available at ClinicalTrials.gov.⁶

Study Design and Data Collection

All registry participants who met the inclusion criteria described above during the period from April 2016 to October 2021 were included in the present study. These participants provided comprehensive data on a series of validated or recommended research instruments that are relevant to chronic low back pain, its treatment, and outcomes at the time of registry enrollment. No additional data were collected for this study. Among these data were sociodemographic, psychological, and clinical

characteristics, including aspects of the physician interaction in treating low back pain. Clinical data included the current or prior use of 6 common non-pharmacological treatments (exercise therapy, yoga, massage therapy, spinal manipulation, acupuncture, and cognitive-behavioral therapy), NSAIDs, and opioids for low back pain. The prevalence of nonadherence to CPGs was measured as the percentage of participants who reported currently using opioids for low back pain without prior use of any of the 6 nonpharmacological treatments or NSAIDs at the time of registry enrollment.

Physician Interactions

Physician interactions that may have impacted the treatment of chronic low back pain and adherence to CPGs were studied using 3 participant-reported measures that were routinely collected at the time of registry enrollment using its digital research platform. The Communication Behavior Questionnaire is a 23-item instrument that was developed, validated, and further assessed in patients with chronic low back pain.^{7,8} Its 4 scales measure patient participation and patient orientation, effective and open communication, emotionally supportive communication, and communication about personal circumstances. Scores on each scale may range from 0 to 100, with higher scores representing better physician communication behavior. The Consultation and Relational Empathy Measure is a 10-item instrument that measures physician empathy in primary care or other consultational settings,^{9,10} such as those commonly involved in the treatment of chronic low back pain. Scores may range from 10 to 50, with higher scores representing greater physician empathy. The Patient Satisfaction Questionnaire with 18 items includes 7 scales that measure satisfaction with various aspects of a clinical encounter.¹¹ The 4 scales used herein were those that focused primarily on the physician interaction, including technical quality, interpersonal manner, communications, and time spent with the patient. Scores on each scale may range from 1 to 5, with higher scores representing greater patient satisfaction. The analyses for physician interactions included only those participants whose low back pain onset occurred during the time period in which they were being treated by their current physician.

Outcome Measures

Three primary outcomes were measured in the study using participant-reported data provided within the digital research platform at the time of registry enrollment. A numeric rating scale from 0 to 10 was used to measure the average low back pain intensity over the past 7 days. The Roland-Morris Disability Questionnaire (RMDQ) is a 24-item instrument that was used to measure back-related functioning.¹² Scores on the RMDQ may range from 0 to 24, with higher scores representing greater back-related disability. A pain impact score was measured using the National Institutes of Health Minimum Dataset for Chronic Low Back Pain.⁵ The 9 items on this measure include the numeric rating scale for low back pain intensity and 4 items on each of the physical function and pain interference scales of the Patient-Reported Outcomes Measurement Information System.¹³ Pain impact scores may range from 8 to 50, with higher scores indicating that low back pain has a greater adverse impact on health-related quality of life.

Statistical Analysis

Participant characteristics were summarized using the number (%) for categorical variables and the mean (SD) for continuous variables. Differences in these variables between participants whose treatment was adherent versus nonadherent to CPGs were assessed using contingency table methods and the Student's *t* test, respectively. Multiple logistic regression was used to compute ORs and 95% CIs for sociodemographic, psychological, and clinical predictors of nonadherence to CPGs. Physician interactions and primary outcomes were also assessed with the Student's *t* test. Primary outcomes were further classified with Cohen's *d*-statistic to determine the effect sizes and their clinical importance. Effect sizes ≥ 0.20 were considered to be clinically important and were classified as follows: small effect, $0.20 \leq d \leq 0.49$; medium effect, $0.50 \leq d \leq 0.79$; or large effect, $d \geq 0.80$.¹⁴ All analyses were performed with the IBM SPSS Statistics software package (Version 28). Hypotheses were assessed at the 0.05 level of statistical significance using 2-sided tests.

Results

There were 1119 participants in the study. Their mean (SD) age was 53.2 years (13.2 years), 840

(75.1%) were female, and 378 (33.8%) currently used opioids for low back pain at the initial registry encounter. A total of 778 (69.5%) participants reported having low back pain for more than 5 years. The prevalence of nonadherence to CPGs was 68 (18.0%) participants among the 378 participants currently using opioids. These included 45 (11.9%) participants who had never used any non-pharmacological treatment, 32 (8.5%) participants who had never used NSAIDs, and 9 (2.4%) participants who had never used nonpharmacological treatments or NSAIDs before using opioids for low back pain.

Participants whose treatment was not adherent to CPGs were older and more likely to be male than those whose treatment was CPG-adherent (Table 1). Other significant differences between participants based on CPG adherence status were also observed. Most notably, participants whose treatment was not adherent to CPGs reported lower levels of education, more bothersomeness of widespread pain, greater pain catastrophizing, and lesser pain self-efficacy. However, in the multiple logistic regression analysis, educational level clearly emerged as the strongest predictor of CPG nonadherence (Table 2). Participants with some post-high school education (OR, 0.41; 95% CI, 0.22-0.74) and those with at least a college education (OR, 0.26; 95% CI, 0.12-0.56) were less likely to receive treatment that was not adherent to CPGs. Other participant factors that were associated with CPG nonadherence in this multivariate analysis were being 60 years of age or older, male, or bothered a lot by widespread pain.

A total of 947 (84.6%) participants reported that their current physician had treated their low back pain since its onset. Physician communication behavior relating to patient participation and patient orientation was rated higher by participants whose treatment was nonadherent to CPGs (mean, 75.3; 95% CI, 69.3 to 81.3) than by those whose treatment was CPG-adherent (mean, 68.7; 95% CI, 66.9 to 70.4) (Table 3). There was no other significant difference based on CPG adherence status in any other variable involving physician communication behavior, physician empathy, or patient satisfaction with the physician interaction.

There were significant differences in all primary outcomes between participants whose treatment was nonadherent to CPGs and those whose treatment was CPG-adherent (Table 4). All group

Table 1. Participant Characteristics According to CPG Adherence Status*

Characteristic	Adherent to CPGs (n = 1051)		Non-Adherent to CPGs (n = 68)		P
	No.	%	No.	%	
Age, yr (mean ± SD)	52.9 ± 13.2		57.5 ± 11.4		0.002
Sex					0.01
Female	798	75.9	42	61.8	
Male	253	24.1	26	38.2	
Race					0.15
Black	181	17.2	18	26.5	
Other	27	2.6	2	2.9	
White	843	80.2	48	70.6	
Ethnicity					0.25
Hispanic	88	8.4	3	4.4	
Non-Hispanic	963	91.6	65	95.6	
Educational level					<0.001
High school or lower	171	16.3	28	41.2	
Some post-high school	448	42.6	27	39.7	
College degree or higher	432	41.1	13	19.1	
Cigarette smoking status					0.03
Never or former smoker	882	83.9	50	73.5	
Current smoker	169	16.1	18	26.5	
Body mass index (mean ± SD)	32.4 ± 8.2		35.3 ± 11.0		0.04
Duration of low back pain					0.46
<5 years	323	30.7	18	26.5	
≥5 years	728	69.3	50	73.5	
Bothersomeness of widespread pain					<0.001
Not at all	375	35.7	13	19.1	
A little bit	404	38.4	22	32.4	
A lot	272	25.9	33	48.5	
Pain catastrophizing (mean ± SD)	19.1 ± 13.1		25.4 ± 14.4		<0.001
Pain self-efficacy (mean ± SD)	33.6 ± 14.9		26.4 ± 14.3		<0.001
No. of comorbidities (mean ± SD)	1.8 ± 0.8		1.8 ± 0.7		0.62
Herniated disc					0.02
No	659	62.7	33	48.5	
Yes	392	37.3	35	51.5	
Sciatica					0.95
No	530	50.4	34	50.0	
Yes	521	49.6	34	50.0	
Osteoarthritis					0.34
No	572	54.4	33	48.5	
Yes	479	45.6	35	51.5	
Osteoporosis					0.02
No	907	86.3	52	76.5	
Yes	144	13.7	16	23.5	
Heart disease					0.05
No	944	89.8	56	82.4	
Yes	107	10.2	12	17.6	

Continued

Table 1. Continued

Characteristic	Adherent to CPGs (n = 1051)		Non-Adherent to CPGs (n = 68)		P
	No.	%	No.	%	
Hypertension					0.003
No	612	58.2	27	39.7	
Yes	439	41.8	41	60.3	
Diabetes Mellitus					0.21
No	853	81.2	51	75.0	
Yes	198	18.8	17	25.0	
Asthma					0.11
No	773	73.5	44	64.7	
Yes	278	26.5	24	35.3	
Depression					0.31
No	453	43.1	25	36.8	
Yes	598	56.9	43	63.2	

*Table entries are No. and % unless otherwise indicated. The Pain Catastrophizing Scale and the Pain Self-Efficacy Questionnaire were each used to measure the respective characteristics. CPG denotes clinical practice guideline.

Abbreviation: SD, standard deviation.

differences met the criterion for a clinically important effect based on Cohen's *d* statistic (range, 0.41 to 0.62). Moreover, the results for back-related disability and pain impact on health-related quality of life surpassed the threshold for a medium effect size.

Discussion

Almost one-fifth of participants who were prescribed opioids for low back pain did not receive them in a manner that was adherent to CPGs in the United States. Such participants used neither non-pharmacological treatments nor NSAIDs before using opioids for treatment of their chronic low back pain, contrary to recommendations from the Centers for Disease Control and Prevention³ and the American College of Physicians.⁴ These participants experienced worse clinical outcomes than their counterparts who used opioids in accord with CPGs, as manifested by greater low back pain intensity, back-related disability, and pain impact on health-related quality of life. The 2 latter findings surpassed the threshold for a medium effect size (Cohen's $d \geq 0.5$). Thus, the study findings suggest that important health benefits may derive from adherence to major clinical practice guidelines for chronic low back pain in the United States.^{3,4} Although several sociodemographic, psychological,

and clinical characteristics were associated with nonadherence to CPGs in univariate analyses, only having a low educational level or being 60 years of age or older, male, or bothered a lot by widespread pain remained significantly associated with nonadherence to CPGs in the multivariate analysis.

Most importantly, having intermediate or higher levels of education were strongly and inversely associated with nonadherence to CPGs in this study. Alternatively, having no more than a high school education was an important risk factor for nonadherence to CPGs. Over the past 2 decades, several organizations in the United States have highlighted that only a small proportion of the population is sufficiently proficient in health literacy to understand opioid contracts or such related items as patient educational materials and informed consent documents.¹⁵ The National Pain Strategy now envisions that patients with low literacy or communications disabilities would have access to information that they can understand about the benefits and risks of treatment options, including opioids.¹⁶ Correspondingly, the Federal Pain Research Strategy endorses public health strategies to educate patients on managing pain, including health literacy.¹⁷ Although the association between low literacy and opioid use may be potentially confounded by other variables not controlled in our study, the findings generally support greater efforts to

Table 2. Factors Associated with CPG Nonadherence (n = 1119)*

Characteristic	OR	95% CI	P
Age (yr)			
21 to 49	1
50 to 59	1.38	0.68 to 2.83	0.38
≥60	2.28	1.15 to 4.52	0.02
Sex			
Female	1
Male	1.81	1.05 to 3.12	0.03
Race			
White	1
Black	1.24	0.66 to 2.34	0.50
Other	1.65	0.35 to 7.70	0.53
Ethnicity			
Non-Hispanic	1
Hispanic	0.53	0.15 to 1.82	0.31
Educational level			
High school or lower	1
Some post-high school education	0.41	0.22 to 0.74	0.003
College degree or higher	0.26	0.12 to 0.56	<0.001
Cigarette smoking status			
Never or former smoker	1
Current smoker	1.12	0.59 to 2.14	0.72
Body mass index			
<30	1
≥30	1.40	0.80 to 2.45	0.24
Duration of low back pain (yr)			
<5	1
≥5	0.98	0.54 to 1.79	0.95
Bothersomeness of widespread pain			
Not at all	1
A little bit	1.24	0.59 to 2.57	0.57
A lot	2.19	1.06 to 4.52	0.03
Pain catastrophizing			
Low (<12)	1
Medium (12 to 24)	0.61	0.27 to 1.35	0.22
High (≥25)	1.04	0.47 to 2.28	0.93
Pain self-efficacy			
Low (<27)	1
Medium (27 to 41)	0.77	0.41 to 1.42	0.40
High (≥42)	0.53	0.22 to 1.27	0.15
No. of comorbidities			
<2	1
2 to 3	1.01	0.43 to 2.34	0.99
≥4	1.24	0.52 to 2.94	0.62

*Odds ratios were adjusted for each other variable in the table. The Pain Catastrophizing Scale and the Pain Self-Efficacy Questionnaire were each used to classify participants according to tercile cutpoints on each instrument. CPG denotes clinical practice guideline. Abbreviations: OR, odds ratio; CI, confidence interval.

mitigate the impact of opioid use that is not adherent to CPGs among patients with low educational levels.

It is interesting to note that most aspects of the participant interaction with their physician, including satisfaction with the technical quality of the physician, were not associated with CPG adherence status. Only the patient participation and patient orientation scale of the Communication Behavior Questionnaire demonstrated a marginally significant statistical association with nonadherence to CPGs. Participants who received care for chronic low back pain that was nonadherent to CPGs rated their physicians more highly on this scale. This may simply represent a type I error attributable to the multiple physician interactions studied herein. However, several items on the patient participation and patient orientation scale focus on the degree to which the physician discusses and explains treatment options, involving the patient in a collaborative manner. It remains unclear if such patient involvement facilitates physician deviation from CPGs. Recent research has shown that patients on long-term opioid therapy for chronic noncancer pain report significantly lower satisfaction with their pain treatment when opioids are discontinued.¹⁸

Our study findings are consistent with the belief that reducing pain intensity through opioid prescribing should not be the ultimate goal of chronic pain management. Opioid prescribing that was not adherent to CPGs may have represented failed efforts to eliminate or minimize chronic pain among the participants in our study. Such opioid prescribing may have adversely selected for patients who were least likely to benefit and most likely to be harmed by opioids.¹⁹ Patient functioning and health-related quality of life may be more appropriate clinical endpoints in the management of chronic low back pain.

There were several strengths of our study. It was conducted within a pain research registry using a digital platform that enhanced and facilitated participation, particularly since the onset of the COVID-19 pandemic in March 2020. This digital research platform also precluded missing data in any of the research instruments used by the registry.⁶ The registry used methods recommended by the National Institutes of Health Task Force on Research Standards for Chronic Low Back Pain.⁵ These included the diagnostic criteria for chronic low back pain, use of the RMDQ as a legacy

Table 3. Physician Interactions According to CPG Adherence Status*

Physician Interaction	Adherent to CPGs (n = 891)		Non-Adherent to CPGs (n = 56)		P
	Mean	95% CI	Mean	95% CI	
Physician communication behavior					
Patient participation and patient orientation	68.7	66.9 to 70.4	75.3	69.3 to 81.3	0.04
Effective and open communication	69.7	68.0 to 71.4	75.7	69.7 to 81.8	0.09
Emotionally supportive communication	74.0	72.4 to 75.6	77.1	72.4 to 81.9	0.21
Communication about personal circumstances	58.1	56.2 to 59.9	59.5	51.4 to 67.6	0.71
Physician empathy	38.7	38.0 to 39.5	39.0	36.1 to 41.9	0.86
Satisfaction with physician characteristics					
Technical quality	3.8	3.7 to 3.8	3.8	3.6 to 4.0	0.66
Interpersonal manner	4.1	4.1 to 4.2	4.1	3.9 to 4.3	0.80
Communications	4.0	3.9 to 4.1	3.9	3.7 to 4.1	0.65
Time spent with patient	3.6	3.6 to 3.7	3.5	3.2 to 3.8	0.28

*Interactions were self-reported by participants using the Communication Behavior Questionnaire, Consultation and Relational Empathy Measure, and Patient Satisfaction Questionnaire with 18 items, respectively. Analysis includes only those participants whose low back pain onset occurred during the time period in which they were treated by their current physician. Higher scores represent better physician interaction. CPG denotes clinical practice guideline.

Abbreviations: CI, confidence interval.

measure of back-related functioning, and quantifying the impact of low back pain on health-related quality of life. The study was conducted after the Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain was published.³ Although there is often a lag time between guideline publication, dissemination, and implementation, it is important to note that substantial efforts were undertaken during 2016 to address the “opioid crisis” and hasten implementation of the Centers for Disease Control and Prevention guideline. For the first time in the 145-year history of the Office of the Surgeon General, a letter was mailed specifically to medical professionals (including 2.3

million doctors, nurses, dentists, and other clinicians) calling them to action in ending the opioid epidemic through the Turn The Tide Rx program.²⁰ The letter included a pocket card for prescribing opioids for chronic pain as part of the program. Thus, physicians should have been well aware of opioid prescribing guidelines during the entire study period.

There were also limitations that should be noted because this was a cross-sectional study using only participant-reported data collected at the initial registry encounter to measure the prevalence of nonadherence to CPGs. It is possible that some participants may not have recalled use of nonpharmacological treatments or NSAIDs

Table 4. Primary Outcomes According to CPG Adherence Status*

Outcome	Adherent to CPGs (n = 1051)		Non-Adherent to CPGs (n = 68)		P	Cohen's d	95% CI
	Mean	95% CI	Mean	95% CI			
Pain intensity	6.0	5.9.0 to 6.1	6.8	6.3 to 7.2	0.001	0.41	0.16.0 to 0.65
Back-related disability	14.3	14.0 to 14.6	17.6	16.4 to 18.9	<0.001	0.59	0.34.0 to 0.84
Pain impact on health-related quality of life	30.8	30.3 to 31.4	36.3	34.4 to 38.1	<0.001	0.62	0.38.0 to 0.87

*Outcomes were measured using a numerical rating scale for low back pain intensity, the Roland-Morris Disability Questionnaire, and the National Institutes of Health pain impact measure, respectively. Higher scores represent worse outcomes. CPG denotes clinical practice guideline.

Abbreviations: CI, confidence interval.

before using opioids for low back pain. It was not possible to assemble a sufficiently large cohort of opioid-naïve participants for meaningful longitudinal follow-up over 12 months of registry observation. Thus, the temporal relationships among measures were not always clear. For example, we may have underestimated nonadherence to CPGs by identifying only prevalent cases at the initial registry encounter. Incident cases of nonadherence to CPGs that occurred before registry enrollment would have been left-censored if the participant subsequently initiated use of a non-pharmacological treatment or NSAID after using opioids, but before enrollment. Alternatively, we may have overestimated nonadherence to CPGs because we collected data on only 6 common non-pharmacological treatments for low back pain. It is possible that participants may have used other less common nonpharmacological treatments, including those not shown to be effective,^{4,21} before initiating opioids.

In summary, our study findings suggest that up to 1/5th of patients with chronic low back pain in the United States may be prescribed opioids in a manner that is not adherent to CPGs, thereby placing them at risk for poor outcomes involving low back pain intensity, back-related disability, and pain impact on health-related quality of life. Patients with low educational levels, older persons, males, and those with bothersome widespread pain are at greatest risk of receiving opioids that are not prescribed according to CPGs. Physician characteristics, such as communications with their patients and empathy, and patient satisfaction with physician interactions are generally not associated with CPG adherence status.

To see this article online, please go to: <http://jabfm.org/content/35/4/724.full>.

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