HSMP 660, Readings and Discussion for 10/18/17
Meghan Mayhew

Hello,

Thank you for reviewing the readings and draft. I would appreciate if you could complete the readings first since my background is still very "drafty" and has some holes which the readings will fill in. I have arranged this packet in the order that would be best for you to read. I look forward to your input!

Meghan

Readings

- Gore M, et al. The burden of chronic low back pain: clinical comorbidities, treatment patterns, and health care costs in usual care settings. *Spine.* 2012 May 15;37(11): E668-77.
- Pages 1-2 of the Evidence-based Practice Center Systematic Review Protocol for the Project Title: Noninvasive, Nonpharmacological Treatment for Chronic Pain
- Oregon Health Authority "Back Policy Changes Fact Sheet"

Spine

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HEALTH SERVICES RESEARCH

The Burden of Chronic Low Back Pain

Clinical Comorbidities, Treatment Patterns, and Health Care Costs in Usual Care Settings

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Study Design. Retrospective analysis of an insurance claims database.

Objective. To examine the comorbidities, treatment patterns, health care resource utilization, and direct medical costs of patients with chronic low back pain (CLBP) in clinical practice.

Summary of Background Data. Although the socioeconomic impact of CLBP is substantial, characterization of comorbidities, pain-related pharmacotherapy, and health care resource use/costs of patients with CLBP relative to non-CLBP controls have been infrequently documented.

Methods. Using the LifeLink Health Plan Claims Database (IMS Health Inc., Watertown, MA), patients with CLBP, defined using the *International Classification of Diseases, Ninth Revision, Clinical Modification*, were identified and matched (age, sex, and region) with non-CLBP individuals. Comorbidities, pain-related pharmacotherapy, and health care service use/costs (pharmacy, outpatient, inpatient, total) were compared for the 2 groups during 2008.

Results. A total of 101,294 patients with CLBP and controls were identified (55% women; mean age was 47.2 ± 11.6 years). Relative to controls, patients with CLBP had a greater comorbidity burden including a significantly higher ($P < 0.0001$) frequency of musculoskeletal and neuropathic pain conditions and common sequelae of pain such as depression (13.0% *vs.* 6.1%), anxiety (8.0% *vs.* 3.4%), and sleep disorders (10.0% *vs.* 3.4%). Pain-related pharmacotherapy was significantly greater ($P < 0.0001$) among patients with CLBP including opioids (37.0% *vs.* 14.8%; $P < 0.0001$), nonsteroidal anti-inflammatory drugs (26.2% *vs.* 9.6%; $P < 0.0001$), and tramadol (8.2% *vs.* 1.2%; $P < 0.0001$). Prescribing of "adjunctive" medications for treating conditions associated with pain (*i.e.*, depression, anxiety, and insomnia) was also significantly greater ($P < 0.0001$) among patients with CLBP; 36.3% of patients received combination therapy. Health care costs were significantly higher in the CLBP cohort ($P < 0.0001$), reflecting greater resource utilization. Total direct medical costs were estimated at $8386 ± $17,507 in the CLBP group and $3607 ± $10,845 in the control group; $P < 0.0001$).

Conclusion. Patients with CLBP are characterized by greater comorbidity and economic burdens compared with those without CLBP. This economic burden can be attributed to greater prescribing of pain-related medications and increased health resource utilization.

Key words: chronic low back pain, disease burden, comorbidity, pharmacotherapy, health care costs. **Spine 2012;37:E668–E677**

Low back pain (LBP) is one of the most prevalent and costly musculoskeletal conditions.[1,2] An epidemiologic review reported that more than a quarter of adults in the United States have had LBP "in the past 3 months," increasing to 55% when the duration of report was extended to the past year.[3] LBP is equally common among men and women and has a substantial impact on functioning.[3]

Recent estimates of the economic burden of LBP in the United States, encompassing both direct and indirect costs, range from $84.1 billion to $624.8 billion.[2] Lost work productivity is the primary driver of this economic burden, resulting in indirect costs of $7.4 billion to $28 billion.[2] However, LBP also results in substantial direct medical costs associated with the use of health care resources, including physician visits; LBP is the second most common reason for visits to physicians in the United States.[4,5] In addition, pharmacologic, nonpharmacologic, and invasive therapies contributed to the $26 billion in incremental health care expenditures that were attributable to LBP for the year 1998, the most recent year for which comprehensive data are available.[6]

Although most cases of LBP resolve within 8 to 12 weeks, it may become chronic (≥3 months) in up to 15% of patients, resulting in periods of intense pain, significant physical limitations, and activity impairment.[7–11] Despite the low proportion of cases, chronic LBP (CLBP) accounts for a majority of the disability and costs associated with LBP.[7,11,12]

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Recommendations for CLBP management include a multidisciplinary approach that may consist of patient education, pharmacotherapy, psychosocial interventions, physical therapy, massage therapy, acupuncture, spinal manipulation, and alternative treatments; surgical interventions are generally reserved for subsets of patients (*e.g.*, those with progressive neurological deficit).[13–15] Among pharmacotherapeutic options, acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), opioids, tramadol, and antidepressants are used, although no 1 drug has been identified as conveying an advantage, and suboptimal efficacy or side effects complicate their use.[16] Opioids have limited long-term data to support their use, present issues of tolerability, and are associated with potential misuse/abuse.[17–21] There are inadequate data supporting the analgesic effects of acetaminophen, particularly in severe pain.[22] Although NSAIDs also have limited efficacy in severe pain, their cardiovascular, renal, and gastrointestinal side effects are of significant concern, especially in the elderly.[23–25] Nevertheless, a recent review of pharmacologic recommendations reinforces acetaminophen and NSAIDs as first-line options regardless of symptom duration, and skeletal muscle relaxants and benzodiazepines are suggested as adjunctive medications with the caveat that these drugs have a high incidence of sedation.[26]

The burden of CLBP is diffuse and has not been fully characterized. Burden of illness studies has explored the socioeconomic impact of CLBP (reviewed by Dagenais *et al*[2]), yet the characterization of comorbidities compared with non-CLBP individuals has been infrequently documented.[27,28] Although a series of studies has evaluated psychiatric comorbidity in patients with chronic disabling occupational spinal disorders,[29–31] it is not clear how this broader category of disabilities/disorders overlaps with CLBP, nor is the proportion of patients with CLBP reported in the observed populations. In addition, to our knowledge, comparisons of patients with CLBP with non-CLBP individuals has not been combined with an evaluation of pain-related pharmacotherapy and other health resource utilization in clinical practice. Therefore, the purpose of this study was to determine the comorbidity prevalence in patients with CLBP and to evaluate pain-related treatment patterns and costs among these patients in usual care settings relative to individuals without CLBP.

MATERIALS AND METHODS

Data Source

Data for the study were obtained from the LifeLink Health Plan Claims Database (IMS Health Inc., Watertown, MA). The LifeLink database comprises adjudicated medical and pharmaceutical claims data from a systematic sample of more than 98 commercially managed care health plans throughout the United States (Midwest 34%, Northeast 22%, South 29%, West 15%), covering more than 62 million individuals and more than 4 billion claims. The data are nationally representative, quality controlled, and HIPAA (Health Insurance Portability and Accountability Act of 1996) compliant. The database includes patient demographic and enrollment information, inpatient and outpatient diagnoses, surgeries, procedures, and retail and mail order prescription records. All records for each patient can be linked with a unique encrypted patient identifier to create a longitudinal record of the individual's medical and pharmacy claims during the period of evaluation.

Sample Selection

All patients with 2 or more health care encounters with an associated diagnosis of CLBP (*International Classification of Diseases, Ninth Revision, Clinical Modification* codes 720, 720.1, 720.2, 721.3, 721.42, 722.1, 722.32, 722.5, 722.73, 722.83, 722.93, 724, 724.02, 724.2, 724.3, 724.4, 724.5, 724.6, 724.7, 724.71, 724.79, 738.4, 739.3, 739.4, 756.11, 756.12, 805.4, 805.6, 846, 846.1, 846.2, 846.3, 846.8, 846.9, 847.2, 847.3, 847.4) during each of calendar years (CY) 2007 and 2008, with the 2 diagnoses records being at least 90 days apart, in each of the 2 years, were identified. Patients with CLBP who were continuously enrolled during CY 2008 were then selected. Patients were excluded if they were younger than 18 years, had missing data for age or sex, or were 65 years or older and not enrolled in a Medicare risk plan, because claims histories of these patients may be incomplete. An age-, sex-, and region-matched comparison group of persons with no diagnosis of CLBP during their entire tenure in the database was also identified. All other sample inclusion and exclusion criteria (continuous enrollment during CY 2008, 18 years or older, no missing data for age and sex, and 65 years or older and not enrolled in a Medicare risk plan) were also applied to the control group.

Measures and Analyses

Demographic and Clinical Characteristics

Demographic and clinical characteristics of patients with CLBP and controls were examined, including age, sex and coprevalence of selected musculoskeletal pain conditions, neuropathic pain conditions, and common sequelae of pain including depression, anxiety, and sleep disorders. The prevalence of comorbidities was determined on the basis of the presence of 1 or more health care encounters with an associated diagnosis code (see the Appendix, Supplemental Digital Content 1, http://links.lww.com/BRS/A654) for the specific comorbidity during the study period.

Pain-Related Treatment Patterns

Pain-related medication exposure was determined in terms of proportions of subjects who received 1 or more prescriptions for the various medication classes and the average number of prescriptions for each of the medication classes used to treat CLBP and sequelae of chronic pain, such as anxiety/depression and sleep disorders. The medication classes examined in this study included opioids, nonselective NSAIDs, cyclooxygenase-2 (COX-2) inhibitors, salicylates, tramadol, acetaminophen, muscle relaxants, selective serotonin reuptake inhibitors, serotonin-norepinephrine reuptake inhibitors, tricyclic antidepressants, tetracyclic and

miscellaneous antidepressants, benzodiazepines, sedatives and hypnotics, antiepileptics, miscellaneous agents, topical agents, and intramuscular onabotulinumtoxinA (Botox).

Health Care Resource Utilization and Direct Medical Costs

Use of health care resources and direct medical costs were examined for the CLBP and control groups, including CLBP-related surgeries (lumbar and sacral laminectomy and discectomy, and lumbar fusion) and procedures (epidural, transforaminal, or intravertebral injections), physician office visits by specialty type, emergency department (ED) visits, hospitalizations, and use of other outpatient services (*e.g.*, labs, radiology, imaging). Direct costs included amounts reimbursed by payers as well as patient co-pays.

Statistical Analyses

Descriptive statistics (numbers and percentages for categorical variables; means with standard deviations and medians with interquartile ranges [IQR] for continuous variables) were used to evaluate the different variables as appropriate. Conditional logistic regression models conditioning for matching group were used to evaluate the differences between patients with CLBP and controls in the prevalence of comorbidities and percentage of exposure to pain-related medications. Proportional odds models adjusting for correlated observations within matching group (using GEE, or generalized estimating equations) were used to examine the association between CLBP/control group membership and quartiles of prescription medications and health care resource use (*e.g.*, physician office visits, ED visits, hospitalization) variables. Age, sex, and region were used as covariates in the models. Odds ratios with 95% confidence intervals (CIs) provided an estimate of effect size. Because cost data are highly skewed, the nonparametric Wilcoxon signed-rank test (which does not assume a normal population) was used to compare cost differences between the CLBP and control groups. $P < 0.05$ was considered statistically significant. All analyses were performed using the SAS software system, PC version 8.0 (SAS Institute Inc., Cary, NC).

RESULTS

Demographic and Clinical Characteristics

A total of 101,294 patients with CLBP satisfied the study entry criteria and were included in the analyses. The control group comprised a 1:1 age, sex, and region match of the CLBP group. Both cohorts comprised 54.8% women, with a mean age of 47.2 ± 11.6 years.

The prevalence of all examined comorbidities was significantly higher ($P < 0.0001$ for all comorbidities except phantom limb pain) for patients with CLBP than for controls (Table 1). Back pain and neck pain other than LBP, musculoskeletal (43.1%), as well as neuropathic (34.2%), were the most prevalent pain conditions in the CLBP group. Nearly a third (30.6%) of patients with CLBP also had neuropathic LBP, pain radiating into the buttock and leg and considered to result from sciatica or disc herniation. The prevalence rates of common sequelae of chronic pain including depression (13.0%), anxiety (8.0%), and sleep disorders (10.0%) were 2.3-, 2.5-, and 3.2-fold higher, respectively, among patients with CLBP than among controls.

Pain-Related Treatment Patterns

Exposure to pain-related treatments among patients with CLBP and controls is described in Table 2. Relative to controls, except for intramuscular onabotulinumtoxinA (P = NS), a significantly higher proportion of patients with CLBP ($P < 0.0001$) received all the evaluated pain-related medications, including any opioids (37.0% *vs.* 14.8%), any NSAIDs (26.2% *vs.* 9.6%), tramadol (8.2% *vs.* 1.1%), muscle relaxants (21.2% *vs.* 2.6%), and antiepileptics (9.7% *vs.* 2.3%).

In addition, many patients with CLBP were prescribed "adjunctive" medications often used to treat conditions associated with pain such as depression, anxiety, and insomnia. Combination therapy was consistently higher in the CLBP group than in the controls ($P < 0.05$), with more than a third (36.3%) of patients in the CLBP group receiving combinations of drugs, compared with only 10.5% of individuals in the control group. The most frequent combinations in the CLBP group were NSAIDS + opioids and opioids + muscle relaxants, with 16.3% of patients with CLBP receiving each of these combinations.

Except for intramuscular onabotulinumtoxinA, patients with CLBP also received a significantly higher ($P < 0.0001$) number of prescriptions (median [IQR]) for a majority of the evaluated medications during the study period than controls including (Table 3) any opioids (3.0 [1.0–10.0] *vs.* 1.0 [1.0–2.0]); any NSAIDs (2.0 [1.0–4.0] *vs.* 1.0 [1.0–2.0]); tramadol (2.0 [1.0–4.0] *vs.* 1.0 [1.0–3.0]); muscle relaxants (2.0 [1.0–4.0] *vs.* 1.0 [1.0–2.0]); benzodiazepines (3.0 [1.0–8.0] *vs.* 2.0 [1.0–6.0]); and sedatives and hypnotics (3.0 [1.0–8.0] *vs.* 3.0 [1.0–7.0]).

Health Care Resource Utilization and Direct Medical Costs

Less than 10% of patients with CLBP received epidural, transforaminal, or intravertebral injections during the study period; 1.5% underwent lumbar or sacral laminectomy/discectomy; 0.7% had lumbar fusion; and 1.6% received acupuncture. The use of epidural injections and acupuncture was significantly higher ($P < 0.0001$) in the CLBP group than in the controls, and as would be expected, no patients in the control group had any surgeries for LBP. Among patients with CLBP who received acupuncture during the study period, the average number of sessions, mean 6.5 ± 6.6 and median 4.0 (IQR, 2.0–9.0), was not significantly different relative to controls, mean 7.2 ± 6.5 and median 6.0 (IQR, 2.0–10.0). However, the number of epidural injections during the study period was significantly higher among patients with CLBP (mean 2.0 ± 1.2, median 2.0 [IQR, 1.0–3.0]) than among controls (1.1 ± 0.2, median 1.0 [IQR, 1.0–1.0]; $P < 0.0001$).

Health care resource utilization is described in Table 4 and direct medical costs are described in Table 5. Both the proportions of patients with CLBP who used health care services ($P < 0.0001$) and the magnitude of service use

TABLE 1. Prevalence of Specific Chronic Comorbidities in Patients With Chronic Low Back Pain and Controls

Comorbid Diagnosis*	n (%)		Odds Ratio (95% CI)	P†
	CLBP Patients (n = 101,294)	Controls (n = 101,294)		
Musculoskeletal pain conditions				
Back and neck pain, other than low back pain	43,606 (43.0)	3504 (3.5)	21.34 (20.59–22.12)	<0.0001
Rheumatism, excluding the back	40,787 (40.3)	12,098 (11.9)	5.08 (4.96–5.20)	<0.0001
Arthritis and other arthropathies	34,807 (34.4)	11,016 (10.9)	4.40 (4.30–4.51)	<0.0001
Osteoarthritis	14,364 (14.2)	3845 (3.8)	4.53 (4.36–4.70)	<0.0001
Rheumatoid arthritis	1698 (1.7)	544 (0.5)	3.18 (2.88–3.50)	<0.0001
Diffuse diseases of connective tissue	314 (0.3)	97 (0.1)	3.24 (2.58–4.07)	<0.0001
Other musculoskeletal pain conditions	41,748 (41.2)	6949 (6.9)	10.23 (9.95–10.52)	<0.0001
Neuropathic pain conditions				
Back and neck pain with neuropathic involvement (except low back)	34,622 (34.2)	600 (0.6)	91.71 (84.54–99.49)	<0.0001
Neuropathic low back pain	30,970 (30.6)	…	…	…
Other polyneuropathies	3968 (3.9)	713 (0.7)	5.77 (5.33–6.25)	<0.0001
Carpal tunnel syndrome	3131 (3.1)	832 (0.8)	3.87 (3.58–4.18)	<0.0001
Causalgias	1391 (1.4)	240 (0.2)	5.88 (5.12–6.74)	<0.0001
Diabetic neuropathy	408 (0.4)	102 (0.1)	4.02 (3.24–5.00)	<0.0001
Atypical facial pain	167 (0.2)	59 (0.1)	2.83 (2.10–3.81)	<0.0001
Autonomic neuropathies	153 (0.2)	34 (0.0)	4.51 (3.11–6.54)	<0.0001
Trigeminal neuralgia	141 (0.1)	62 (0.1)	2.28 (1.69–3.07)	<0.0001
Postherpetic neuralgia	126 (0.1)	36 (0.0)	3.49 (2.41–5.05)	<0.0001
Phantom limb pain	11 (0.0)	1 (0.0)	10.89 (1.42–83.55)	0.0217
Depression	13,148 (13.0)	6203 (6.1)	2.31 (2.24–2.38)	<0.0001
Anxiety	8081 (8.0)	3459 (3.4)	2.47 (2.37–2.57)	<0.0001
Insomnia/sleep disorders	10,087 (10.0)	3419 (3.4)	3.18 (3.06–3.31)	<0.0001

**Comorbidities defined as ≥1 claim for each comorbidity during the study period.*

†Conditional logistic regression models.

CLBP indicates chronic low back pain; CI, confidence interval.

among users ($P < 0.0001$) were significantly higher in the CLBP group than in the controls. For example, all patients in the CLBP group *versus* 85.4% of controls had at least 1 outpatient visit and 9.2% of patients with CLBP *versus* 4.9% of controls had at least 1 hospitalization during the study period. Among the users of these services, the number of physician office visits during the study period among patients with CLBP were median 10.0 (IQR, 6.0–17.0) compared with median 3.0 (IQR, 2.0–6.0) among controls and the number of hospitalizations among patients with CLBP were median 3.0 (IQR, 2.0–5.0) compared with median 2.0 (IQR, 1.0–4.0) among controls.

Total medication costs for the CLBP group ($1572 ± $4451, median $323; IQR, $13–$1506) were significantly higher ($P < 0.0001$) than for the control group ($909 ± $4171, median $104, IQR $0–$733). The direct costs of physician office visits ($1110 ± $1216 *vs.* $453 ± $696), ED visits ($331 ± 1414 *vs.* $78 ± $376), hospitalizations ($1892 ± $11,559 *vs.* $870 ± $6911), and total direct medical costs ($8386 ± $17,507 *vs.* $3607 ± $10,845) were each significantly higher ($P < 0.0001$) in the CLBP group than in the controls.

Among patients with CLBP who had low back surgical procedures, the costs were lumbar and sacral laminectomy/discectomy ($28,286 ± $28,798, median $19,590; IQR,

TABLE 2. Proportions of Patients With Chronic Low Back Pain and Controls Using Various Pain-Related Medications

Medications	n (%)		Odds Ratio (95% CI)	*P**
	CLBP Patients (n = 101,294)	Controls (n = 101,294)		
Long-acting opioids	3830 (3.8)	276 (0.3)	14.42 (12.75–16.29)	<0.0001
Short-acting opioids	37,013 (36.5)	14,927 (14.7)	3.38 (3.31–3.45)	<0.0001
Strong opioids	15,604 (15.4)	4348 (4.3)	4.10 (3.96–4.25)	<0.0001
Weak opioids	31,040 (30.6)	12,359 (12.2)	3.22 (3.15–3.30)	<0.0001
Any opioids	37,435 (37.0)	14,959 (14.8)	3.43 (3.36–3.51)	<0.0001
Cox-2 inhibitors	3440 (3.4)	908 (0.9)	3.94 (3.66–4.24)	<0.0001
Nonselective NSAIDs	24,398 (24.1)	9024 (8.9)	3.28 (3.20–3.37)	<0.0001
Any NSAIDs	26,566 (26.2)	9724 (9.6)	3.40 (3.31–3.49)	<0.0001
Salicylates	534 (0.5)	250 (0.2)	2.14 (1.84–2.49)	<0.0001
Tramadol	8288 (8.2)	1162 (1.1)	7.73 (7.27–8.23)	<0.0001
Acetaminophen	1531 (1.5)	605 (0.6)	2.57 (2.34–2.82)	<0.0001
Muscle relaxants	21,494 (21.2)	2674 (2.6)	10.15 (9.74–10.58)	<0.0001
SSRIs	12,606 (12.4)	9307 (9.2)	1.41 (1.37–1.45)	<0.0001
SNRIs	5244 (5.2)	2019 (2.0)	2.71 (2.57–2.85)	<0.0001
Tricyclic antidepressants	3432 (3.4)	1255 (1.2)	2.81 (2.63–3.00)	<0.0001
Tetracyclic and miscellaneous antidepressants	5902 (5.8)	3550 (3.5)	1.71 (1.64–1.78)	<0.0001
Benzodiazepines	15,023 (14.8)	6622 (6.5)	2.53 (2.45–2.61)	<0.0001
Sedative and hypnotics	8459 (8.3)	3737 (3.7)	2.40 (2.31–2.50)	<0.0001
Anticonvulsants	9780 (9.7)	2307 (2.3)	4.64 (4.43–4.86)	<0.0001
Miscellaneous agents	2096 (2.1)	1049 (1.0)	2.02 (1.88–2.18)	<0.0001
Intramuscular onabotulinumtoxinA (Botox)	17 (0.0)	7 (0.0)	2.43 (1.01–5.85)	0.0483

**Conditional logistic regression models.*

CLBP indicates chronic low back pain; CI, confidence interval; Cox, cyclooxygenase; NSAIDs, nonsteroidal anti-inflammatory drugs; SSRIs, selective serotonin reuptake inhibitors; SNRIs, serotonin-norepinephrine reuptake inhibitors.

$10,250–$36,491) and lumbar fusion ($47,205 ± $39,212, median $37,417; IQR, $27,653–$55,102).

DISCUSSION

This study, using data from a large and geographically diverse US population, demonstrates that patients with CLBP have a significantly higher prevalence of comorbid conditions and are characterized by a substantial medication burden compared with matched controls. As expected, comorbid musculoskeletal pain conditions were significantly more prevalent among patients with CLBP than among controls. However, the magnitude of the prevalence of conditions, such as arthritis and other arthropathies (34%) and rheumatism excluding the back (40%), was surprising considering the young demographic of this population (mean age, 47.2 ± 11.6 yr; 97.3% <65 yr).

Although the cause-and-effect relationship between CLBP and comorbidities is unclear, it has been suggested that LBP may be part of an overall health pattern characterized by disease clusters in certain individuals. Despite the uncertain causality, the prevalence of conditions associated with chronic pain, including depression and anxiety, was higher among patients with CLBP, and increased sleep disturbances were also more likely in patients with CLBP. The higher prevalence of such conditions may derive in part from a reciprocal relationship between these outcomes and pain.[32–37]

The presence of any comorbidity in patients with CLBP may be associated with a significantly longer duration of work disability,[38,39] and it has also been reported that health care costs for other conditions, especially those prescribed psychiatric medications, are higher after LBP onset.[40] In this regard, as previously noted, the likelihood of depression or

TABLE 3. Number of Prescriptions for Various Pain-Related Medications Among Users of These Medications

Medications	CLBP Patients (n = 101,294) Median (IQR)	Controls (n = 101,294) Median (IQR)	Odds Ratio (95% CI)	*P**
Long-acting opioids	7.0 (2.0–12.0)	2.0 (1.0–8.5)	67.37 (55.46–81.84)	<0.0001
Short-acting opioids	3.0 (1.0–9.0)	1.0 (1.0–2.0)	9.76 (9.41–10.12)	<0.0001
Strong opioids	2.0 (1.0–7.0)	1.0 (1.0–2.0)	14.29 (13.33–15.32)	<0.0001
Weak opioids	2.0 (1.0–7.0)	1.0 (1.0–2.0)	9.52 (9.14–9.91)	<0.0001
Any opioids	3.0 (1.0–10.0)	1.0 (1.0–2.0)	10.09 (9.73–10.46)	<0.0001
Cox-2 inhibitors	2.0 (1.0–4.0)	2.0 (1.0–4.0)	6.71 (5.90–7.63)	<0.0001
Nonselective NSAIDs	2.0 (1.0–3.0)	1.0 (1.0–2.0)	6.28 (6.00–6.58)	<0.0001
Any NSAIDs	2.0 (1.0–4.0)	1.0 (1.0–2.0)	6.53 (6.25–6.83)	<0.0001
Salicylates	2.0 (1.0–4.0)	2.0 (1.0–5.0)	3.60 (2.73–4.74)	<0.0001
Tramadol	2.0 (1.0–4.0)	1.0 (1.0–3.0)	18.21 (16.24–20.41)	<0.0001
Acetaminophen	1.0 (1.0–4.0)	1.0 (1.0–3.0)	5.57 (4.67–6.64)	<0.0001
Muscle relaxants	2.0 (1.0–4.0)	1.0 (1.0–2.0)	27.59 (25.53–29.81)	<0.0001
SSRIs	5.0 (2.0–9.0)	5.0 (3.0–9.0)	1.62 (1.55–1.70)	<0.0001
SNRIs	5.0 (2.0–10.0)	6.0 (3.0–10.0)	5.18 (4.72–5.69)	<0.0001
Tricyclic antidepressants	3.0 (1.0–6.0)	4.0 (1.0–9.0)	5.60 (4.97–6.30)	<0.0001
Tetracyclic and miscellaneous antidepressants	4.0 (2.0–8.0)	4.0 (2.0–9.0)	2.40 (2.23–2.59)	<0.0001
Benzodiazepines	3.0 (1.0–8.0)	2.0 (1.0–6.0)	4.95 (4.70–5.22)	<0.0001
Sedatives and hypnotics	3.0 (1.0–8.0)	3.0 (1.0–7.0)	4.58 (4.27–4.91)	<0.0001
Anticonvulsants	4.0 (1.0–8.0)	5.0 (2.0–10.0)	7.16 (6.65–7.71)	<0.0001
Miscellaneous agents	1.0 (1.0–2.0)	1.0 (1.0–2.0)	3.78 (3.29–4.34)	<0.0001
Topical agents	1.0 (1.0–2.0)	1.00 (1.0–1.0)	42.77 (29.50–62.00)	<0.0001
Intramuscular onabotulinumtoxinA (Botox)	1.0 (1.0–3.0)	2.0 (1.0–3.0)	4.53 (0.80–25.75)	0.0887

**Proportional odds models.*

CLBP indicates chronic low back pain; IQR, interquartile range; CI, confidence interval; Cox, cyclooxygenase; NSAIDs, nonsteroidal anti-inflammatory drugs; SSRIs, selective serotonin reuptake inhibitors; SNRIs, serotonin-norepinephrine reuptake inhibitors.

anxiety was higher in patients with CLBP, odds ratios of 2.3 and 2.5, respectively, than in controls.

Regardless of causality, the increased presence of comorbid conditions among patients with CLBP increases the complexity of management, as manifested by the overall significantly higher medication burden observed among patients with CLBP. Importantly, there was substantial polypharmacy, including concomitant use of different pain medication classes, and pain medications combined with adjunctive medications for the treatment of insomnia and mood. It should be noted that the total medication burden is likely to be underestimated because our estimates included only prescription pain-related medications; we did not consider medications for many of the comorbidities. Furthermore, because the database provides information only on prescription medications, we could not evaluate the potential utilization of over-the-counter medications for CLBP or other pain-related conditions.

Opioids and opioid combinations were most frequently prescribed, exceeding NSAIDs in proportion of patients and number of prescriptions. Because of the limited evidence for efficacy and the potential for side effects, opioids are recommended for the treatment of CLBP in patients who have severe, disabling pain that is not controlled with acetaminophen and NSAIDs.[14,16,26] Although acetaminophen and NSAIDs are generally considered first-line, we could not ascertain whether opioids were prescribed as first-line, as a result of prior treatment failure, or as rescue medication. Thus, we cannot be

TABLE 4. Use of Health Care Services Among Patients With Chronic Low Back Pain and Controls

	CLBP Patients (n = 101,294)		Controls (n = 101,294)			
	Number of Visits†		Number of visits†			
Resource Use Category	n (%)	Median (IQR)	n (%)	Median (IQR)	Odds Ratio (95% CI)	*P**
Physician office visits						
GP/FP	55,208 (54.5)	3.0 (1.0–5.0)	36,117 (35.7)	2.0 (1.0–3.0)	2.34 (2.29–2.39)	<0.0001
Internal medicine	29,288 (28.9)	3.0 (1.0–5.0)	27,289 (26.9)	2.0 (1.0–3.0)	1.03 (1.01–1.07)	0.0196
Orthopedists	18,784 (18.5)	2.0 (1.0–3.0)	5979 (5.9)	1.0 (1.0–2.0)	7.31 (6.94–7.70)	<0.0001
Chiropractor	50,681 (50.0)	5.0 (3.0–9.0)	2516 (2.5)	4.0 (2.0–9.0)	103.54 (97.54–109.91)	<0.0001
Rheumatologist	5074 (5.0)	2.0 (1.0–4.0)	1216 (1.2)	2.0 (1.0–3.0)	10.39 (9.29–11.62)	<0.0001
Neurologist	10,608 (10.5)	2.0 (1.0–3.0)	2514 (2.5)	1.0 (1.0–2.0)	10.79 (9.99–11.66)	<0.0001
Anesthesiologists	3445 (3.4)	2.0 (1.0–3.0)	62 (0.1)	1.0 (1.0–2.0)	375.64 (263.01–536.51)	<0.0001
PT/OT/Phys Med	14,911 (14.7)	4.0 (2.0–9.0)	2860 (2.8)	5.0 (2.0–11.0)	13.86 (12.93–14.85)	<0.0001
Any physician office visit	101,020 (99.7)	10.0 (6.0–17.0)	81,839 (80.8)	3.0 (2.0–6.0)	1.57 (1.56–1.58)	<0.0001
Emergency department visits	23,170 (22.9)	1.0 (1.0–2.0)	9265 (9.1)	1.0 (1.0–1.0)	5.56 (5.32–5.81)	<0.0001
Other outpatient visits	93,842 (92.6)	6.0 (3.0–11.0)	79,868 (78.8)	3.0 (2.0–6.0)	1.40 (1.38–1.41)	<0.0001
Total outpatient visits	101,294(100.0)	14.0 (8.0–24.0)	86,477 (85.4)	5.0 (2.0–10.0)	1.41 (1.40–1.42)	<0.0001
Hospitalizations	9281 (9.2)	3.0 (2.0–5.0)	4946 (4.9)	2.0 (1.0–4.0)	3.04 (2.85–3.23)	<0.0001

**Proportional odds models.*

†Visits represent unique days of office visits.

CLBP indicates chronic low back pain; IQR, interquartile range; CI, confidence interval; GP/FP, general practice/family practice; PT/OT/Phys Med, physical therapy/occupational therapy/physical medicine and rehabilitation.

TABLE 5. Direct Medical Costs of Health Care Services Among Patients With Chronic Low Back Pain and Controls

	Costs ($)				
	CLBP Patients (n = 101,294)		Controls (n = 101,294)		
Cost Category	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	*P**
Medications	1572.03 (4450.61)	322.50 (12.60–1505.70)	908.97 (4170.82)	104.05 (0.0–733.10)	<0.0001
Physician office visits	1110.15 (1215.96)	770.44 (429.70–1365.50)	452.85 (696.28)	260.66 (88.50–554.40)	<0.0001
Emergency department visits	330.60 (1413.64)	0 (0)	77.63 (376.29)	0 (0)	<0.0001
Other outpatient visits	3481.65 (8529.21)	1188.23 (260.60–3734.40)	1297.47 (4084.69)	281.42 (30.00–1109.70)	<0.0001
Total outpatient visits	4922.40 (9264.52)	2413.88 (948.60–5697.80)	1827.96 (4464.23)	663.43 (176.20–1873.70)	<0.0001
Hospitalizations	1891.55 (11,558.88)	0 (0)	869.70 (6910.82)	0 (0)	<0.0001
Total medical costs	8385.97 (17,507.11)	3622.97 (1383.60–8784.20)	3606.63 (10,844.50)	1120.10 (285.50–3193.60)	<0.0001

**Wilcoxon signed rank test.*

CLBP indicates chronic low back pain; SD, standard deviation; IQR, interquartile range.

certain to what extent current recommendations for pharmacologic therapy were followed.

Short-acting opioids are frequently used as rescue mediation or on an "as needed" basis, and the high prescribing of these medications (36.5%) may support this type of use. Although the frequency of use of long-acting opioids was low (3.8%), the median (7.0) number of prescriptions were higher than for any other medication. A similarly high rate of opioid prescribing (37.7%) for CLBP was previously reported,[41] but these rates are substantially lower than the 60% recently suggested on the basis of patient self-report for a population of patients with CLBP in a regional study.[42] Although Ritzwoller *et al*[39] observed an overall lower rate of opioid use (28.5%), they reported that use increased with increasing number of LBP episodes, an observation we could not confirm because of database limitations. Opioids continue to be recommended and used, despite evidence of a negative association with outcomes in CLBP, including function and productivity,[21,43,44] and an increased likelihood of substance use disorders.[45]

Prescribing of pain-related medications in the CLBP cohort was paralleled by mean costs for these medications that were nearly twice that of controls and median costs that were slightly more than 3-fold higher. We also observed significantly greater resource utilization compared with controls across all other resource categories, resulting in costs approximately 2- to 3-fold higher across categories and total costs more than 2-fold higher among patients with CLBP. The primary cost driver was outpatient visits, accounting for 59% of total medical costs. This high utilization of outpatient services may be indicative of less than optimal efficacy of therapeutic regimens, because there was still a substantial need for these services despite prescribing of pain-related medications. However, it could not be determined to what extent these services were specifically for CLBP, and the possibility exists that at least some of these visits were related to comorbidities.

Although acupuncture and chiropractic services are among the nonpharmacologic therapies that are recommended,[14,46] they are often not reimbursed by health insurance plans, and the extent to which these services were covered in the study database is not known. Therefore, it is likely that our assessment of these resources represents an underestimate.

Limitations associated with such retrospective database analyses include errors in coding and recording, which could potentially result in misdiagnosis in a proportion of patients. Because we required at least 2 claims in each of 2 consecutive years (at least 4 claims during a 2-yr period) with a diagnosis code for CLBP to select patients in the CLBP cohort, we do not think that coding errors could have affected our identification of patients with CLBP. However, the comorbidity burden might be overestimated in our study, because the presence of comorbidities was identified on the basis of 1 or more claims for each comorbidity during the study period. Although this might be a potential limitation, any overestimation is likely to be random and unlikely to differentially affect either group, thus maintaining the validity of the reported differences in the comorbidity profiles between the 2 groups.

Another limitation of claims databases is an inability to link the condition of interest, CLBP, with the prescribing of a particular pain or adjunctive medication. This limitation may be especially relevant to populations characterized by multiple comorbidities, including those with neuropathic involvement for which many of the same medications are also recommended.[47] Nevertheless, the data indicate that regardless of the reasons, patients with CLBP were prescribed significantly more pain-related medications than controls. A similar limitation is that such a database precludes ascertainment of patient compliance, with the corollary that prescribing particular medications does not necessarily imply that the patient filled the prescriptions or used the medications. Finally, because information on pain severity is not available in the database, we recognize that it is not possible to know the basis for medication prescribing, nor the effect on pain-related outcomes.

Despite the limitations, this study extends our knowledge of the CLBP burden by characterizing this population with respect to comorbidities and resource utilization. These analyses demonstrate the presence of significantly greater comorbid conditions and emphasize increased use of analgesic and adjunctive medications as well as overall resource utilization in patients with CLBP relative to non-CLBP individuals. Such data may help inform clinical decisions regarding appropriate management strategies for patients with CLBP. Although a comparison of the burden of CLBP with other musculoskeletal disorders was not a goal of this study, such comparisons are warranted, and the results reported here can provide a useful baseline for further research.

➢ Key Points

- ❑ Relative to controls, patients with CLBP had a significantly higher ($P < 0.0001$) prevalence of musculoskeletal and neuropathic pain conditions and common sequelae of pain including depression, anxiety, and sleep disorders.
- ❑ Pain-related pharmacotherapy was significantly greater ($P < 0.0001$) among patients with CLBP including opioids, NSAIDs, and tramadol.
- ❑ Prescribing of "adjunctive" medications (for depression, anxiety, and insomnia) was also significantly greater ($P < 0.0001$) among patients with CLBP.
- ❑ Health care costs were significantly higher ($P < 0.0001$) in the CLBP cohort, reflecting the greater resource utilization among these individuals.
- ❑ Total direct medical costs were estimated at \$8386 ± \$17,507 in the CLBP group and \$3607 ± \$10,845 in the control group; $P < 0.0001$.

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Evidence-based Practice Center Systematic Review Protocol

Project Title: Noninvasive, Nonpharmacological Treatment for Chronic Pain

I. Background and Objectives for the Systematic Review

Nature and Burden of Chronic Pain

Chronic pain, defined as pain lasting 12 weeks or longer or persisting past the normal time for tissue healing,[1,2] is a monumental public health challenge. It affects millions of adults in the United States, with a conservative annual cost estimated at $560 billion to $635 billion.[2] In addition to personal and health system expenditures, chronic pain substantially impacts physical and mental functioning, productivity, and quality of life, as well as relationships with family; it is the leading cause of disability and is often refractory to treatment.[3,4] Nervous system changes that occur with chronic pain, combined with its psychological and cognitive impacts, have led to conceptualization of chronic pain as a distinct disease entity.[2] This multifaceted disease is influenced by multiple factors (e.g., genetic, central nervous system, psychological, and environmental factors), with complex interactions, making assessment and management a challenge. A number of characteristics influence the development of and response to chronic pain, including sex, age, presence of comorbidities, and psychosocial factors. For example, women report chronic pain more frequently than do men, are at higher risk for some conditions such as fibromyalgia,[2] and may respond differently than men. Older adults are more likely to have comorbidities and are more susceptible to polypharmacy, impacting choices and consequences of therapies. Pain is greatly influenced by psychosocial factors, which may predict who will develop chronic disabling pain as well as treatment response. Therefore, chronic pain is best understood from a biopsychosocial perspective. This means that consideration of psychological and social factors as well as underlying biological mechanisms and physical manifestations of chronic pain is necessary for effective management. Musculoskeletal pain, particularly related to joints and the back, is the most common single type of chronic pain.[2] While there are many different underlying causes for chronic pain, this comparative effectiveness review focuses on five common chronic pain conditions: low back pain, neck pain, osteoarthritis, fibromyalgia, and headache. Although many of the same treatments may be employed for each of these conditions, treatment effectiveness may vary across them.

Management of Chronic Pain

The overarching goal of chronic pain management is to relieve pain and improve function. The National Pain Strategy (NPS) report recommends that management be integrated, multimodal, interdisciplinary, evidence-based, and tailored to individual patient needs.[5] In addition to addressing biological factors when known, it is thought that optimal management of chronic pain also addresses psychosocial contributors to pain,

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while taking into account individual susceptibility and treatment responses. Self-care is an important part of chronic pain management. At the same time, the NPS points to the "dual crises" of chronic pain and opioid dependence, overdose, and death as providing important context for consideration and implementation of chronic pain management strategies. A vast array of pharmacologic and nonpharmacological treatments is available for management of chronic pain. An overview of these interventions is briefly presented below.

Pharmacological Treatment

Pharmacological treatments for chronic pain include nonsteroidal anti-inflammatory drugs (NSAIDs), acetaminophen, opioids, muscle relaxants, antiseizure medications, antidepressants, and corticosteroids. These may be used alone or in combination. Each has potential side effects and contraindications. Nationally, a concern regarding appropriate use, misuse, and diversion of opioids for treatment of chronic pain has been the subject of numerous scientific and news reports. Opioid prescriptions for chronic pain have increased substantially in the past 20 years, but evidence shows only modest short-term benefits.[6-8] Lack of evidence on long-term effectiveness[9] and serious safety concerns[10] speak to the need to consider alternative treatments to opioids. The 2016 *CDC Guidelines for Prescribing Opioids for Chronic Pain* recommend that non-opioid therapy is preferred for the treatment of chronic pain.[11]

Noninvasive, Nonpharmacological Treatment

Noninvasive methods considered for this report will include exercise and physical therapy, mind-body practices (Yoga, Tai Chi, Qigong), psychological therapies (cognitive-behavioral therapy, biofeedback, relaxation techniques, acceptance, and commitment therapy), interdisciplinary rehabilitation, mindfulness practices (meditation, mindfulness-based stress reduction practices), osteopathic and spinal manipulation, acupuncture, and physical modalities (traction, ultrasound, transcutaneous electrical nerve stimulation [TENS], low level laser therapy, interferential therapy, superficial heat or cold, bracing for knee, back or neck, electro-muscular stimulation, and magnets), acupuncture, and functional restoration training. Across many chronic pain conditions, exercise is commonly recommended.

One primary challenge for this review is its breadth; it encompasses five diverse conditions for which over a dozen different interventions will be considered. Across the conditions and interventions, the literature base is large and complex, which poses another challenge to this review. These challenges speak to the need for focusing the review in order to provide meaningful and useful evidence synthesis. Other challenges related to the evidence and its synthesis include: (1) the most appropriate outcomes to assess, their diversity, and the need to consider multiple outcomes related to pain, function, and quality of life, (2) understanding the clinical meaningfulness of observed effects, (3) heterogeneity within the conditions and generalizability of evidence across subpopulations, (4) optimal methods for administering noninvasive therapies (e.g., the number, duration, or intensity of treatment sessions and adherence), and (5) difficulty in effectively blinding for some nonpharmacological therapies.

Back Policy Changes Fact Sheet

Implementation delay:

This document enumerates changes to the Prioritized List of Health Services, which were implemented July 1, 2016. (Implementation had previously been temporarily delayed from the original January 1, 2016 implementation date.)

What changes to OHP's coverage for treatment of back conditions are coming?

The HERC based its decisions on new evidence, including a bio-psycho-social model designed to help people with back problems resume normal activities. This model will help people manage their pain with less reliance on medication and fewer costly surgeries.

Until now, the OHP has limited treatment to patients who have muscle weakness or other signs of nerve damage. Beginning in 2016, treatments will be available for all back conditions. Before treatment begins, providers will assess patients to determine their level of risk for chronic back pain, and whether they meet criteria for a surgical consultation. Based on the results, one or more of the following covered treatments may be appropriate:

- Acupuncture
- Chiropractic manipulation
- Cognitive behavioral therapy (a form of talk therapy)
- Medications (including short-term opiate drugs, but not long-term prescriptions)
- Office visits
- Osteopathic manipulation
- Physical and occupational therapy
- Surgery (only for a limited number of conditions where evidence shows surgery is more effective than other treatment options)

In addition, yoga, intensive rehabilitation, massage, and/or supervised exercise therapy are recommended to be included in the comprehensive treatment plans. These services, which also have evidence of effectiveness, will be provided where available as determined by each Coordinated Care Organization (CCO).

HERC based its decision on the recommendations of the Back Lines Reorganization Task Force, a special workgroup consisting of a neurosurgeon, a chiropractor, an acupuncturist, an orthopedic surgeon, a primary care physician, a physiatrist, physical therapists, specialists in mental health and addiction, a health plan medical director, pain specialists, and a national expert in the evidence on treatments for back pain. This Task Force reviewed a large body of evidence about the effectiveness of various treatments and the potential harms of certain therapies.

Back Policy Changes Fact Sheet

Why did HERC undertake this process?

Back pain and other back conditions are very common for OHP members. In 2013, about 8 percent of OHP recipients saw a provider for back conditions, and over half of those individuals received narcotic medications, often for many months. OHP has spent a great deal of public money on treatments such as surgery and medications, without good evidence that they improve patient's lives. At the same time, narcotics also carry risks of dependency, misuse and overdose.

In recent years, the HERC has conducted reviews which found evidence that various therapies help back pain and other back conditions. These therapies could not, however, be added to the prioritized list because of the way back conditions were ranked. As a part of its biennial review, the HERC created a task force to find a way to reorganize the Prioritized List to reflect the new evidence. The task force created recommendations which prioritize therapies such as acupuncture, chiropractic, and physical therapy over surgery and narcotics for most back conditions, recognizing the effectiveness of these treatments in improving people's health and reducing suffering.

What is the history of OHP coverage of treatments for back conditions?

1. OHP historically has covered only the back conditions with radiating symptoms of weakness or numbness due to nerve damage, for a full range of services such as physical therapy, chiropractic, acupuncture and surgery.
2. People with back pain without nerve symptoms were limited to primary care visits and medications such as narcotics.

What was the process for HERC's decision?

1. The HERC adopted coverage guidances regarding diagnostic testing and effective treatments for low back pain and neck pain in 2013 and 2014.
2. The HERC created a Task Force to reorganize the Prioritized List lines dealing with back pain to allow coverage of evidence-based, effective therapies.
3. The Back Line Reorganization Task Force was created in the fall of 2014, and met monthly through February 2015
4. At its January, 2015, meeting, the Value-based Benefits Subcommittee (VbBS) and the HERC heard a draft proposal from the Task Force
5. At its March, 2015 meeting, VbBS and HERC heard the final proposal from the Task Force, made revisions, and approved the revised prioritization of back treatments resulting in the new coverage package
6. In August, 2015, the HERC decided to revise guideline note 56 to allow patients scoring as medium risk on the validated assessment tool to receive more intensive interventions.

7. In January, 2016, the HERC decided to remove coverage for epidural steroid injections for back pain and revise the guideline note on diagnostic imaging for back pain.
8. In May 19, 2016 the HERC approved several additional changes, including changing the requirements for patients already on opioid therapy who would need to work with their provider to establish a plan to transition to other pain management strategies, including nonpharmacologic treatments, by January 1, 2018.

How can I participate or get updates on HERC's activities?

You can subscribe at the HERC website at www.oregon.gov/OHA/OHPR/Pages/HERC/ to receive notifications of future meetings and look at materials being discussed. You can attend the meetings, which are open to the public, and speak during time set aside for public comment.

Background

Back pain is the most common type of pain and a leading reason that patients seek medical care.[1,2] At least a quarter of adults in the United States report having had back pain in the past 3 months and it is the most common cause of lost productivity.[3,4] Chronic back pain (pain persisting for 3 months or more) is associated with significant impairments in physical and psychosocial functioning, and more than half of adults with chronic back pain report difficulties with movement, cognition, and self-care.[1] Further, chronic back pain disproportionally impacts vulnerable populations, including those of lower socioeconomic status and racial/ ethnic minority groups.[7] Given its high prevalence and associated scope of suffering, a recent Institute of Medicine (IOM) report identified effective chronic pain management as a "moral imperative" arguing that chronic pain should be considered a disease with a distinct pathology and called for non-pharmacotherapy treatment approaches, including those that avoid overuse of opioid drugs.[1]

There has been an alarming escalation in opioid use for treating chronic pain over the past two decades.[8-12] Widely described as an "opioid epidemic,"[13,14] this is driven by the rising identification and prevalence of chronic pain sufferers, liberalization of laws governing the use of opioids, aggressive pharmaceutical marketing, acceptance of opioids as standard pain treatment, and mounting pressure on physicians to avoid undertreating pain.[15,16] There is a growing recognition of the significant risks of opioid use in treating chronic pain[17-20] and concerns about the efficacy of opioids for the management of chronic pain.[21-23] Further, a large percentage of patients (30-80%) report unwanted side effects from the use of opioids for pain management.[24-28]

Current initiatives encourage a shift toward treatment approaches that focus on improving patients' functioning rather than prioritizing pain reduction.[38] This shift poses a major challenge for primary care providers who are largely overseeing and coordinating the care of patients with chronic pain. While providers are aware of the risks and limitations of prescribing opioids as a monotherapy for pain, they often lack support for the provision of non-pharmacological back pain treatment services or readily available evidence-based treatment options due to limited coverage of these treatments by health care payors.

An exciting and innovative initiative is underway with Oregon's Medicaid program that offers an opportunity to assess the effectiveness of a state-wide payor strategy to prevent opioid prescribing for back pain and enable access to evidence-based non-pharmacological treatments. The Oregon Health Evidence Review Commission (HERC) issued coverage guidance for those receiving Medicaid-insured services for back pain. The guidance is intended to discourage use of treatments with limited demonstrated efficacy and / or with patient safety risks and facilitate access to non-pharmacotherapeutic services for back pain. While attention is being paid nationally to decreasing opioid prescribing for chronic pain, Oregon is the only state to implement explicit incentives to make a range of evidence-based and patient-centered care options available.

Hello again, At this point it is important to clarify that PCORI has funded a large study to evaluate the impact of the new guidelines on: opioid prescribing, patient utilization of pain-related health care services, and patients' pain, functional outcomes and satisfaction with care. The study uses California as the comparison. However, the study does not assess impact on costs of care or costs for patients. Therefore, my proposed study will focus on understanding the impact these guidelines may have on health care expenditures and patient costs.

Problem Statement:

Back pain is a prevalent and costly condition that requires a biopsychosocial treatment approach, however most patients are not offered or able to access the evidence-based nonpharmacological treatments which are

recommended. This is due to many factors but a significant one is the lack of payor coverage for these treatments. Information is needed to enable payors to understand the overall cost-benefit of covering these services for back pain treatment.