

Final Report

Investigator-Initiated Study –Pfizer

Title: Opioid Misuse Mitigation and Practice Quality Improvement in Primary Care

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BACKGROUND

Pain is a serious public health problem and has a significant social and economic impact. Chronic pain can affect all aspects of life, interfering with sleep, employment, social life, and daily activities and places a devastating toll on overall quality of life. Persons who have chronic pain account for 21 percent of emergency department visits and 25 percent of annual missed work days,^{1,2} and, when direct and indirect costs are considered, imposes a greater economic burden than any other disease, with estimates of annual costs of up to \$630 billion for medical expenses and lost productivity.³ Persistent back pain in particular is one of the principal drivers of these costs, both in the U.S.⁴ and internationally,⁵ with indirect costs (e.g., lost or reduced work productivity) accounting for more than half of this economic burden. In fact, compared with health care expenditures of adults without pain, expenses of patients with severe pain are three times higher.⁶ Within primary care, patients with chronic pain tend to be seen more often than those without pain and require more encounters with specialty care. Mental health conditions such as anxiety and depression as well as history of substance abuse also contribute to greater healthcare utilization.⁷ Overall, chronic pain has remained an expensive, stubborn, debilitating problem for untold millions of individuals who continue to suffer due to poor response to therapy.³

Opioids are the most effective way to treat pain and the usefulness of opioids in the treatment of acute and cancer-related pain has been confirmed by several studies.⁸ Yet some physicians and other health care professionals are reluctant to support the use of opioid medication for patients with chronic noncancer pain because of concerns regarding adverse effects, lack of efficacy, tolerance, and addiction.⁹⁻¹¹ Within the past

ten years the prescription of opioids for the treatment of chronic pain has increased exponentially, primarily for noncancer pain,¹² and the abuse of such medications is receiving increasing notice.¹³ Unfortunately, many physicians prescribing pain medication have little training in this area and may prescribe opioids without any assessment of early signs of risk of medication misuse. The literature suggests that physicians are able to better provide suitable treatment and care of patients with chronic pain when they receive adequate training and necessary assessment information.¹⁴ It has also been shown that risk of misuse behaviors of prescribed opioid medication can be mitigated by assessment and treatment protocols.¹⁵ These protocols help to identify patients who are at risk for opioid misuse and can provide clinicians with patient's background and behavior to help make informed treatment decisions. Although it is well known that misuse is prominent in the chronic pain population and is a clear risk factor for the development of addiction, it is also known that patients with signs of substance misuse may be inadequately treated for pain due, in part, to a reluctance of some physicians to address the risks of opioid abuse.¹⁵⁻¹⁷

Assessment of Opioid Compliance and Misuse Risk

Determining an individual's adherence with opioids is important in the evaluation and management of a patient with chronic pain.¹⁶⁻²¹ Many providers who prescribe opioids for pain use an opioid therapy agreement that identifies patients' responsibilities when taking opioids for pain.²²⁻²³ These responsibilities have included 1) taking opioids as prescribed, 2) using one pharmacy, 3) receiving opioids from only one provider, 4) not running out of opioids early, 5) not missing scheduled medical appointments, 6) not borrowing opioid medication from others, 7) not using illicit substances, 8) taking

precautions not to lose prescription medication, 9) not driving when first starting to take an opioid, 10) agreeing to frequent monitoring and periodic urine screens, and 11) participating fully in the treatment plan and in other rehabilitation activities. Providers hope that the patient taking opioids would be completely honest about using the medication in a responsible manner, although this is not always the case. To make the patients fully aware of their responsibilities, they are frequently asked to sign an opioid agreement and to keep a signed copy in their medical record. For some, a violation of this agreement would mean tapering and eventually discontinuing prescription opioids. Unfortunately, violations of this agreement can go unreported and often the treating physician has difficulty in tracking and verifying adherence.

Chabal²⁹ first developed a prescription abuse checklist of five criteria to document potential noncompliance with opioids. These criteria included 1) overwhelming focus on opiate issues, 2) pattern of early refills, 3) multiple telephone calls or unscheduled visits, 4) episodes of lost or stolen prescriptions, and 5) evidence of supplemental sources of opioids. Patients who met three of the five criteria were considered to be opiate abusers. Similarly, Compton and colleagues³⁰ developed an interview-screening tool for assessment of opioid noncompliance in patients with chronic pain and “problematic” substance use. The Prescription Drug Use Questionnaire (PDUQ) was created to categorize chronic pain patients who are likely to be nonaddicted, substance-abusing, or substance-dependent. Responses of “problematic” patients differed significantly from those of nonproblematic patients on multiple screening items, with the two groups easily differentiated by total questionnaire score. Although useful, these instruments were not directly based on the content of

opioid therapy agreements that are commonly used among patients prescribed long-term opioid therapy.

The Opioid Compliance Checklist (OCC) was recently developed at our center to directly monitor ongoing opioid adherence among chronic pain patients who have been on opioids.³¹ We developed and validated this brief self-administered compliance checklist for chronic pain patients on long-term opioid therapy. The nature of items included in the OCC are based on the components of opioid therapy agreements used in the context of responsible-use long-term opioid therapy for patients with chronic pain.

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Our group has also helped to develop and validate screening tools to identify patients who are at risk for opioid misuse. The first is the Screener and Opioid Assessment for Patients with Pain - Revised, SOAPP-R,³²⁻³⁴ which is a 24-item cross-validated, self-administered screening instrument revised from the original SOAPP v.1,³² used to help determine risk potential for aberrant drug-related behavior. This is a trait measure of factors that predict future opioid misuse. Items are rated from 0=never to 4=very often, and their sum is the total SOAPP-R score. The SOAPP-R has been shown to have good predictive validity, test-retest and internal reliability, and adequate sensitivity and specificity in predicting future opioid misuse. We also actively collaborated in developing the Current Opioid Misuse Measure (COMM),³⁵ which is a 17-item self-reported questionnaire designed to track current aberrant medication-related behaviors during opioid treatment. All items in the COMM are also rated from 0=never to 4=very often, with a total maximum score of 68. Construct validity, test-retest reliability, and the overall accuracy of predicting current aberrant drug-related behavior

was high with suitable sensitivity and specificity. Both of these measures correlate with future opioid misuse.

Universal precautions and abuse mitigation strategies

Gourlay and colleagues were first to promote the notion of universal precautions as a rational approach to opioid therapy for the treatment of chronic pain.³⁶ This concept is similar to the infectious disease paradigms. This approach includes a means of identifying and monitoring patients who may be at risk for misusing prescription opioids. In order to properly assess if patients should be considered for long-term opioid therapy, they suggest the following assessment procedures and treatment steps: (1) diagnosis with the appropriate differential; (2) psychological assessment, including risk potential for substance misuse; (3) informed consent and opioid treatment agreement; (4) pain and function assessment; (5) an opioid therapy trial; (6) periodic re-assessment of pain, function, and behavior (e.g. analgesia, activities of daily living, adverse events); (7) a minimum of once yearly urine screens; (8) regular review of diagnosis and comorbidities; and (9) detailed documentation of progress. They encouraged careful coordination among providers in order to have the best chance of identifying and managing persons with chronic pain who have risk factors for misuse of opioids. This is especially important within primary care. A comprehensive pain management center may provide additional interdisciplinary assessment and treatment recommendations for patients who are treated within primary care. Some pain management specialists have found it useful to offer a trilateral agreement with the patient's primary care physician.³⁷ After being evaluated and treated at a pain center and once it is determined that the patient has been compliant and stable with their opioids, they can be referred back to

their primary care provider for management of their pain. This multidisciplinary team approach could provide a periodic re-evaluation of the patients if necessary.

Unfortunately, chronic pain patients who show aberrant drug-related behavior frequently are discontinued from treatment when they are noncompliant with their use of opioids for pain. A randomized trial was conducted at our center among patients prescribed opioids for noncancer back pain who showed risk for opioid misuse to determine if close monitoring and cognitive behavioral substance misuse counseling could increase overall compliance with opioids.¹⁵ Forty two patients determined to be high risk for opioid misuse were randomized to either standard control (High-Risk Control; N=21) or experimental compliance treatment consisting of monthly urine screens, compliance checklists, and individual and group motivational counseling (High-Risk Experimental; N=21). Twenty patients who met criteria of low potential for misuse were recruited to a low-risk control group (Low-Risk Control). All patients were followed for six months and completed pre- and post-study questionnaires and monthly electronic diaries. The primary study outcome consisted of the percent with a positive Drug Misuse Index (DMI), which was a composite score of self-reported drug misuse (Prescription Drug Use Questionnaire, PDUQ), physician-reported abuse behavior (Addiction Behavior Checklist, ABC), and abnormal urine toxicology results. Significant differences were found between groups after six months with 73.7 % of the High-Risk Control patients demonstrating positive scores on the DMI compared with 26.3% from the High-Risk Experimental group and 25.0% from the Low-Risk Controls ($p < 0.05$). The results demonstrated support for the benefits of a brief behavioral intervention in the management of opioid compliance among chronic back pain patients at high-risk for

prescription opioid misuse. None of the subjects was dismissed from the clinic at post-treatment due to aberrant drug behavior, which was likely an effect of the attention from being in a study and completing monthly electronic diaries. Overall, this study demonstrated improved opioid compliance among those patients at high risk for misuse of opioids as a result of very careful monitoring and motivational counseling. It also demonstrated that these techniques could be incorporated in a clinic to help improve compliance with opioids and to reduce the number of those individuals who are discharged from treatment because of aberrant drug-related behavior. This trial demonstrated that substantial improvement in compliance with prescription opioids for many high-risk pain patients is possible.

Management of Chronic Pain Patients within Primary Care

Management of chronic pain patients within primary care centers is seen as problematic. In a longitudinal study of 61 primary care physicians (PCPs) who managed medically ill patients and who prescribed opioids for pain, most reported low confidence and lower satisfaction in managing chronic pain patients.³⁸ In a mailed survey of 414 PCPs in another study,³⁹ 69.1% reported a reluctance to prescribe strong opioids for chronic noncancer pain. Although most in this survey felt that opioids were effective for chronic noncancer pain, they worried about addiction, adverse effects, and the long-term commitments needed in managing challenging pain patients. In another study of 81 general practitioners, education about opioid guidelines and psychological flexibility training was shown to improve knowledge of opioid prescribing for chronic pain and contributed to decreases in concerns about opioids, but no changes were observed in prescribing behavior.⁴⁰ In a recent survey among 122 clinicians only 50.8% reported any

previous training in pain management, very few followed structured protocols for assessing pain, and the percentage of correct answers on a knowledge of pain test was a little more than half correct (63.2%).⁴¹ The authors of these studies pointed out the need for greater continuing education in pain and the development of protocols for optimizing analgesic therapy.

In a climate with concerns over regulatory scrutiny and opioid misuse, prescribing attitudes of primary care physicians seem to be changing. There is less willingness to manage noncancer pain patients with long-term opioids and the changes in attitudes of primary care physicians about the management of patients with noncancer pain can contribute to poorer long-term outcomes in the care of these patients. Additional studies are needed to assess knowledge and attitudes about prescription opioids among primary care providers who manage patients with chronic pain and to determine how strategies such as careful monitoring and feedback about opioid compliance might improve the confidence of these providers in managing challenging chronic pain patients. The following are the preliminary results of a controlled trial among primary care providers and chronic pain patients on opioid therapy supported in part by Pfizer.

STUDY OVERVIEW

This study was designed to help determine whether careful patient monitoring and incorporation of a structured opioid therapy protocol (risk assessment, periodic urine screens, and compliance checklists) would improve patient compliance with prescription opioids, reduce opioid misuse and reduce healthcare utilization within primary care. We also intended to determine the clinical benefit of increased communication strategies between pain specialists and primary care physicians and use of practice guidelines to improve provider confidence in managing challenging

chronic pain patients within a busy primary care center. We incorporated within the study protocol reliable and validated screening questionnaires and tools to accurately identify opioid medication misuse (SOAPP-R, COMM, OCC) and measures to assess changes in quality of life of patients within primary care centers.

Specific Aims

This 2-year prospective matched-controlled trial was designed to determine the benefit of interventions to improve opioid prescribing practices among PCPs. The study aimed to assess how improved care coordination and provider education and support would serve to advance the quality of care of patients with chronic pain. We identified two types of primary care centers, Specialists (experimental) and Generalists (control), and compared the outcome of different interventions.

Aim 1: To implement the use of an electronic medical record (EMR) system to assess and track patients with chronic pain who are treated at primary care clinics and compare the outcomes in the Specialist centers who have access to this EMR system in helping to facilitate coordinated care of these patients to those in the matched Generalist centers who do not have access to EMR notes.

Aim 2: To developed monthly pain assessment summary reports for all patients prescribed opioids for their pain and make these reports available to PCPs at the Specialist sites compared to Generalist centers where the patients are tracked but providers do not have access to summary reports.

Aim 3: To provide direct support to identified PCPs in the Specialist treatment centers by offering education sessions and access to a pharmacist, addiction specialist, pain

specialty nurse practitioner and other pain medicine staff who would be available to assess patients and review medication strategies for pain management.

The initially proposed study design included recruitment of 100 patients and 20 PCPs. We were able to successfully recruit and follow many more patients and providers than proposed (See Study Schema below). All patients who agreed to participate were to be followed for six months. Patient outcomes and provider ratings were compared between those in the Specialist treatment arm and the Generalist treatment arm. Those providers in the Specialist Centers received periodic updated information about their patients including electronic assessments emailed as an attachment to each provider with a brief patient summary and posted on the electronic medical record system. These monthly reports consisted of assessments of pain, mood, activity level, current medications, side effects, and healthcare utilization, and included the number of clinic and emergency room visits, and hospitalizations over the past month. Also posted were the results of the 8-item Opioid Compliance Checklist (OCC). Those patients determined to be high-risk for opioid misuse were offered evaluations at the Brigham and Women's Hospital Pain Clinic and were closely monitored including periodic urine screens as well as individual motivational counseling.

Chronic pain patients in the Generalist treatment arm who were considered for or were prescribed opioids for pain were identified and asked to participate in the study by their primary providers. These patients received standard of care, which consists of risk assessment using paper versions of the SOAPP-R, opioid prescribing by the primary care provider, and monthly patient monitoring without feedback to the providers or support from pain specialists. The intent for the Generalist condition was to carefully

track those patients who were prescribed opioids for their pain without monthly feedback to the providers about their patients' progress. All centers were offered opioid risk assessment feedback for the participating patients at the initiation of their trial. The centers were independent of each other and at different locations. There was no interaction or overlap between primary care providers in the Specialist and Generalist centers.

METHODS

This study was approved by the institutional review boards (IRBs) of each of the participating healthcare organizations and centers and informed consent was obtained by all the participants. Primary care providers were recruited from centers around the Boston metropolitan area. Those centers designated as Specialist centers were all within the Partners Healthcare System, which consists of the main hospitals of Massachusetts General Hospital and Brigham and Women's Hospital and other health centers and hospitals around Boston. Primary care centers under Partners Healthcare all use the same electronic medical record and clinical messaging system and patient identifiers. Those primary care centers identified as Generalists were outside of the Partners Healthcare network and were either stand-alone centers, part of an HMO, or were under another independent healthcare system.

Each of the heads of the primary care centers was contacted and meetings were arranged with the providers, often scheduled during staff meetings, in order to describe the study. They were informed that the study was aimed at obtaining information about attitudes and concerns about prescription opioids for chronic pain and aimed at helping to manage challenging chronic pain patients. Some providers in the Specialist centers

were identified through the Pain Management Center at Brigham and Women's Hospital because their patients had been referred for an assessment. Primary care physicians, nurse practitioners, and physician assistants were invited to participate and packets of questionnaires were given to them to complete and mail to the research assistant. Providers were offered \$200 for their time to complete the questionnaires. Most PCPs who were asked elected to participate. Reasons given not to participate included 1) limited time, 2) not prescribing opioids for pain, and 3) not currently managing chronic pain patients.

Enrolled providers were sent a follow-up packet of questionnaires after they had been in the study for one year. The packets consisted of a cover letter, the Opioid Therapy Survey, the Concerns About Analgesic Prescriptions questionnaire, and each provider was asked to complete an Addiction Behavior Checklist (ABC) for each of their patients enrolled in the study (e.g., if the provider had 3 patients enrolled in the study they would be asked to complete 3 ABCs). Included with the questionnaires was also a self-addressed stamped envelope. The providers were again paid \$200 once their follow-up packet was received.

Study Measures

Primary Care Provider Measures

The following measures were administered to each of the primary care participants:

1. Background and Prescribing Practices Questionnaire.⁴⁰ This 19-item questionnaire adapted for this study requests information about demographic data (age, gender, race/ethnicity), work experience and current working conditions, information regarding general and work-related levels of stress and

satisfaction, and perception about managing chronic pain patients on a 10-item scale (e.g., 1=not at all, 10-completely). This questionnaire was only administered at baseline.

2. General Health Questionnaire (GHQ).⁴² This 12-item measure was originally developed to assess psychological well-being and distress among workers. The items assess levels of depression, anxiety, somatic symptoms and social isolation. Each item has four possible responses (e.g., 0="not at all" to 3="much more than usual"). It has been translated into 38 different languages and is known to have adequate reliability (range 0.78 to 0.95).⁴³ This questionnaire was only administered at baseline.
3. Opioid Therapy Survey (OTS).⁴⁴ This is a 10-item questionnaire created through our center designed to assess practice behavior and confidence related to opioid therapy for the treatment of chronic pain among primary care physicians. This scale was initially tested as part of an online survey and adapted for this study. Each item consists of a statement (e.g., "Treatment of chronic pain is a problem in my practice.") that is rated on a scale between 1 = strongly agree to 5 = strongly disagree. This was administered at baseline and at 1-year follow-up.
4. Concerns About Analgesic Prescriptions (CAAP).³⁹ This is a 22-item measure previously developed for primary care physicians in England and adopted for the United States. For each item the providers are asked to rate how true each statement is from 0 = never true to 5 = always true. The measure includes four subscales: (1) Adverse Behavioral Effects, (2) Profession Scrutiny, (3) Other Adverse Effects, and (4) Efficacy beliefs. Scores from this measure have been

found to predict both frequency of prescribing opioids and reluctance to prescribe opioids.³⁹ Each of the individual item responses are reported in this study. This survey was administered at baseline and at 1-year follow-up.

5. Test of Opioid Knowledge (TOK).⁴⁰ This is a 25-item multiple choice quiz from practice guidelines on good practice of opioids for persistent pain adapted from the published guidelines.^{22,45} It was developed based on a review of the literature and with input from psychologists and anesthesiologists knowledgeable about chronic pain and opioids prescribing. The items from the TOK were reviewed and approved by consensus by pain specialists in our clinic (Brigham and Women's Hospital). It contains questions about how to manage prescription opioids for patients with chronic pain, and questions on both the physical and behavioral effects of opioids. Each item has an option of four responses with only one response being the correct best answer. This test was administered only at baseline.
6. Addiction Behavior Checklist (ABC).⁴⁶ This is a 20-item instrument designed to track behaviors characteristic of addiction related to prescription opioid medications in chronic pain populations. Items are focused on observable behaviors during and between clinic visits. This checklist was found to have adequate validity and reliability. A cut-off score of 3 or greater showed optimal sensitivity and specificity in determining whether a patient is displaying inappropriate opioid use.

Chronic Pain Patient Measures

The following measures were administered to each of the patients who participated in the study.

1. Demographic Questionnaire.⁴⁷ This baseline questionnaire collected basic demographic information about the patients, including: 1) age, 2) gender, 3) racial background, 4) education level, 5) marital status, 6) history of medical problems, 7) history of substance abuse (including treatment experience, activity in AA/NA, etc.), 8) history of psychiatric treatment and trauma, and 9) active litigation and disability or worker's compensation payments.
2. The Brief Pain Inventory (BPI).⁴⁸ This self-report questionnaire, formerly the Wisconsin Brief Pain Questionnaire,⁴⁹ is a well-known measure of clinical pain and has shown sufficient reliability and validity. The questionnaire provides information about pain history, intensity, and location as well as the degree to which the pain interferes with daily activities, mood, and enjoyment of life. Scales (rated from 1 to 10) indicate the intensity of pain in general, at its worst, at its least, and pain "right now." A figure representing the body is provided for the patient to shade the area corresponding to his or her pain. Test-retest reliability for the BPI reveals correlations of .93 for worst pain, .78 for usual pain, and .59 for pain now. Research suggests the BPI has adequate validity.⁴⁸ BPI scores correspond with clinical judgments of pain as reflected in pain medication use and the amount of patient-reported activity interference. The BPI was administered at baseline and at 6-month follow-up.
3. Pain Catastrophizing Scale (PCS).⁵⁰ The PCS is a 13-item instrument that examines three components of catastrophizing: Rumination, Magnification, and

Helplessness. The PCS is found to predict levels of pain and distress among clinical patients and scores have been related to thought intrusions.⁵¹ It has good psychometric properties with adequate reliability and validity⁵⁰ and is associated with levels of pain, depression and anxiety. The PCS was administered at baseline and at follow-up.

4. The Pain Disability Index (PDI).⁵² This inventory consists of seven questions designed to measure the degree to which patients believe that their pain interferes with their functioning in family/home responsibilities, recreation, social activities, occupation, sexual behavior, self-care, and life-support (eating and sleeping) activity. Patients respond to each item on 0- to 10-point scales anchored with descriptors ranging from “no disability” to “total disability.” This measure has adequate internal consistency (Cronbach alpha = .86) and test-retest reliability (0.91) and is a valid measure of disability.⁵³ The PDI was administered at baseline and at follow-up.
5. The Hospital Anxiety and Depression Scale (HADS).⁵⁴ The HADS is a 14-item scale designed to assess the presence and severity of anxious and depressive symptoms. Seven items assess anxiety, and seven items measure depression, each coded from 0 to 3. The HADS has been used extensively in clinics and has adequate reliability (Cronbach’s Alpha = .83) and validity, with optimal balance between sensitivity and specificity.⁵⁵ It has been translated into many languages and is widely used around the world in clinical and research settings. The HADS was administered at baseline and at follow-up.

6. Screener and Opioid Assessment for Pain Patients-Revised (SOAPP-R).³² The SOAPP-R is a 24-item, cross-validated, self-administered screening instrument revised from the original SOAPP v.1.³³ used to help determine risk potential for aberrant drug-related behavior. Items are rated from 0=never to 4=very often, and their sum is the total SOAPP-R score. The SOAPP-R has been shown to have good predictive validity, with an area under the curve ratio of 0.88 (95% confidence interval [CI], .81-.95). Test-retest reliability was .71 with a coefficient alpha of 0.74. A cutoff score of 18 shows adequate sensitivity (.86) and specificity (.73). A combined factor analysis of the SOAPP v.1 revealed five factors: 1) history of substance abuse, 2) legal problems, 3) craving medication, 4) heavy smoking, and 5) mood swings. Support has been found for the internal reliability and predictive validity of the SOAPP-R. An accumulated score of 18 or higher is considered positive. The cross validation study of 302 patients from 5 centers revealed a mean score on the SOAPP-R of 20.5 (SD=10.7; range 1-62).³⁴ The SOAPP-R was used as part of the initial evaluation.
7. Current Medication Misuse Measure (COMM).³⁵ This 17-item self-reported questionnaire helps to track current aberrant medication-related behaviors during opioid treatment. All items are rated from 0=never to 4=very often, with a total maximum score of 68. Construct validity has been shown to be adequate, with positive correlates with urine toxicology results ($p < 0.05$). Test-retest reliability was .86 with a 95% CI ranging from .77 to .92. The overall accuracy of the COMM for predicting current aberrant drug-related behavior, as measured by the area under the curve ratio, was .81 (95% CI, .74-.86; $p < .001$) and coefficient α

(.86) for the 17 items suggests adequate reliability. A cutoff score of 8 yielded a sensitivity of 0.75 and specificity of 0.65. An accumulated cutoff score of 9 or higher is considered positive. The COMM was administered as a follow-up measure.

8. Monthly assessments. All patients were contacted by telephone once a month and were asked to complete an assessment of their pain (now, average, worst, least), activity interference (routine daily activity, social and outdoor activity, sleep, appetite and ability to work), mood, benefit from treatment, medications, side effects (for those taking opioids only), number of times they were seen in a clinic, number of times they went to the emergency department of a hospital, and the number of days that they were admitted to a hospital over the past month (see Appendix).
9. Opioid Compliance Checklist.³¹ All patient participants completed this 8-item compliance checklist every month as part of their monthly phone interview and this information was included in the summary report for providers in the Specialist centers. On the checklist the participants answered yes/no questions about their use of opioids that reflected items typically found on an opioid agreement to determine whether they had: 1) taken the opioid medication as prescribed, 2) used only one pharmacy, 3) received opioid prescriptions from only one provider, 4) taken precaution not to lose or misplace their pain medication, 5) not run out of their prescription pain medication early, 6) kept all scheduled medical appointments, 7) not “borrowed” opioid medication from others, and 8) avoided the use of any illegal or unauthorized substances. Any responses which

suggested noncompliance were documented. This measure has been shown to have adequate validity and reliability.³¹ We have found that any positive 'yes' response on the items is predictive of future opioid misuse. Those patients who were not taking opioids at the time of the interview were not asked to respond to the first 5 items of the OCC.

Patient Inclusion/Exclusion Criteria

Patients with a diagnosis of chronic noncancer pain were recruited to participate in this 6-month trial. Patients were included if they (1) had chronic pain for > 6 months' duration, (2) averaged 4 or greater on a pain intensity scale of 0 to 10, (3) were able to speak and understand English, (4) had been prescribed or were eligible to be prescribed opioid therapy for pain, and (5) were under the care of a primary care physician.

Patients were excluded from participation if they meet any of the following criteria: (1) diagnosis of cancer or any other malignant disease, (2) acute osteomyelitis or acute bone disease, (3) present or past DSM-IV diagnosis of schizophrenia, delusional disorder, psychotic disorder, or dissociative disorder that would be judged to interfere with study participation, (4) pregnancy, (5) any clinically unstable systemic illness judged to interfere with treatment, (6) a pain condition requiring urgent surgery, and (7) an active addiction disorder, such as cocaine or IV heroin use, (positive on the Mini International Neuropsychiatric Interview; M.I.N.I. v.5.0)¹⁵ that would interfere with study participation.

Patients were recruited through flyers placed in the centers and were invited to participate by their treating physicians. Patients were followed up with a letter describing

the study and an informed consent form that they were instructed to complete and mail back to the research assistant assigned to this study. All patients received a \$50 gift card for completing the packet of questionnaires at the start of the study. Patients were informed that they would be called each month to obtain information about their health status and compliance with their medication. They were informed that information from the study would be shared with their providers, but that their information was protected through the guidelines of a confidentiality certificate through the NIH (www.nidcr.nih.gov) as a research participant and that personal identifiable information would be protected from disclosure in any legal proceedings.

When patients completed their 6-month phone interviews they were mailed a follow-up packet of questionnaires. The packet consisted of the BPI, HADS, PCS, PDI, COMM, and exit interview questions. Included was a self-addressed stamped envelope. Patients were paid \$50 once the completed follow-up packet was received. Packets were resent if they were not received within a month of the mailing and all patients were called to verify that they had received the second packet of questionnaires.

Statistical Analyses

The primary endpoints for this study were the overall provider ratings on the Opioid Therapy Survey and Concerns About Analgesic Prescriptions questionnaires and the differences among centers on the patient-reported Opioid Compliance Checklist (OCC). We also included secondary measures in order to gain some understanding of the factors that might have the greatest effect on improving provider confidence and patient compliance. Analyses were conducted using SPSS (IBM, version 22.0). Total scores and average values were calculated for the baseline measures and the pre- and post-

study questionnaires (BPI, PCS, PDI, and HADS) and Pearson Product Moment correlations were run among the variables. Both parametric (t-test), and nonparametric analyses (chi-square or Wilcoxon tests) were used to compare results from the two types of treatment centers (Specialist and Generalist) depending on the variables. Preliminary multivariate analyses were also conducted among those baseline and follow-up variables that showed differences between groups.

We anticipated that the feedback monitoring program and patient support would contribute to higher opioid compliance, particularly among the subjects in the Specialist centers. In a randomized trial of substance misuse treatment for chronic pain patients on opioid therapy,¹⁵ we found that 73.7% of high-risk control patients met criteria for aberrant drug behavior using the triangulation data of self-report, physician ratings, and urine toxicology results. As a preliminary study, this proposed clinical research was powered based on the expected post-treatment outcomes of the trial after 6 months of tracking in the clinic. We predicted that physicians in the Specialist clinics would demonstrate improved overall rated confidence in prescribing opioids (Opioid Therapy Provider Survey, 1=strongly agree; 5=strongly disagree) compared with those in the Generalist treatment arm. We also predicted that patients in the Specialist clinics would demonstrate a lower OCC percentage compared with patients who were followed in the Generalist clinics. Finally, we assumed an attrition rate of 15%, so we anticipated at the start of the trial that we would need to recruit more subjects in each treatment arm to obtain the intended goal of 50 in each group.

Work Plan and Deliverables Schedule

This was a proposed 2-year prospective controlled trial designed to determine the

benefit of interventions to improve opioid prescribing practices among PCPs (see study timeline in Table 1). This study aimed to assess how improved care coordination, careful monitoring with provider feedback, and provider education might influence the quality of care of patients with chronic pain on prescription opioids within primary care. The proposal stated that 20 PCPs and 100 patients would be recruited and all patients would be followed for 6 months. We were able to recruit and follow substantially more participants than initially proposed (see study schema in Figure 1). We collected considerable data and are still collecting data from a few remaining patient participants. This report includes the preliminary findings of the study, although it is anticipated that additional analyses will be performed.

Study sites

Specialist Centers. We identified and recruited five primary care centers as Specialist Centers associated with Brigham and Women's Hospital for participation in this study. All centers were within the Partners Healthcare System (www.partners.org). All centers were also located within the Metropolitan Boston area and all of the staff had access to the same electronic medical record (EMR) system. Providers who agree to participate in the study were given the name and contact information of the nurse practitioner at the Pain Management Center at Brigham and Women's Hospital (Elizabeth Scanlan) and were encouraged to contact her through clinical messaging or email to help facilitate any referral to the Pain Center. The primary care providers in the Specialist centers were informed of the intent to manage the patients using a team approach with the pain management specialists. The providers were also informed that those patients who were lower risk could be treated as usual by the PCP and that those

seen as moderate or high risk would be offered to be evaluated further at the BWH Pain Center by a pain specialist. Whether patients were evaluated or treated at the Pain Center was up to the discretion of the PCP. No directives were given to the PCPs as to what type of treatment would be necessary for which medical condition unless requested by the PCP. Each of the centers was offered informational sessions on risk assessment, opioid management, urine toxicology screening, and alternative treatments for pain. Only two of the centers requested that these sessions be offered to their staff members. All of the participating PCPs were informed that individual support regarding any particular patient could be offered if needed.

Generalist Centers. We identified five Generalist Centers for recruitment of providers and patients for the Generalist condition. All of the centers were located within the greater Boston Metropolitan area but were outside of the Partners Healthcare System. In the Generalist condition, all patients were managed by the provider alone and these centers represented the “treatment as usual” condition. We found that two centers employed the use of a pain center and patients were referred for specialty care when needed, even though these specialty pain centers were not affiliated with the primary care centers. Providers from the two other centers tended to keep the patients “within network” and would not refer their patients for specialty care. Two of the Generalist centers were stand-alone facilities and the other two were affiliated with a network healthcare system (e.g. Cambridge Health Alliance). The Generalist centers did not have access to the electronic medical record system employed by the Specialists centers, even though they may have had their own system of electronic record keeping.

The providers from these centers were not offered educational sessions on pain management and did not receive the monthly patient evaluations.

Patient Recruitment

We recruited and followed a combined total of 253 chronic pain patients (126 Specialist and 127 Generalist). All patients were followed over 6 months. Baseline demographic data (e.g., age, gender, race) are presented in Table 2. Two Generalist centers granted permission to send flyers and a cover letter from the providers to potential patients. The providers in other centers preferred to mention the study to the patients in person during their clinic visit and to receive verbal permission before contact information was mailed out.

Adverse Events

We identified no study-related adverse events. Four subjects passed away after enrolling in the study: one from significant heart disease, and the other three due to multiple medical comorbidities. None of the deaths were related to participation in the study. There were also no perceived study-related accidents or injuries, although three patients reported minor injuries from falls during their 6-month trial. We tracked the overall number of hospitalizations and emergency department visits and non-study related accidents or injuries. Because no trial medications are involved in this study and the intervention only included monitoring, we did not anticipate that there would be any study-related adverse events. We tracked all active patients for potential adverse events, emergency room visits, hospitalizations, and injuries.

Attrition

Four hundred seven patients (n=407) were screened for participation in this study. Most of the 154 subjects who were not enrolled either were not interested or did not meet the study inclusion criteria (e.g., no pain, non-English speaking). Thirty patients (11.9%) who initially agreed to participate in this study dropped out or were discontinued. Eleven (n=11) patients signed the consent form but did not complete the baseline packet of questionnaires and were eventually un-enrolled from the study. Although these subjects did not start the study, they were still listed as dropouts because they had signed the consent form. Attempts were made to call those participants several times and those who were not reached by phone we sent a letter about the study. They were informed that if they were not heard from within four weeks that it would be assumed that they no longer wanted to participate and that they would be withdrawn from the study. Four study patients (1.6%) withdrew midway through the study due to concerns over time commitment or were excluded because they were determined to no longer be eligible (e.g. they no longer had pain). We had incidences when patients could not be contacted by phone for the monthly assessments within the two-week window for each month, which happened about 8% of the time, but all were eventually contacted and there were no missing monthly-report data. Overall, the study attrition rate of 11.9% was below the anticipated amount of 15%.

The initial proposal included the use of an electronic pain assessment program known as Pain Assessment Interview Network - Clinical Advisory System (PainCAS) for patients in the Specialist group. The PainCAS program is a systematic computer-administered assessment for chronic pain patients.⁵⁶⁻⁵⁸ It is an electronic assessment and tracking program designed to provide a comprehensive evaluation of pain patients

including (1) demographic information (e.g., age, gender, medical history), (2) pain assessment and quality of life evaluation (e.g., pain intensity, activity interference, mood, medication use, side effects), and (3) and an electronic version of the SOAPP-R.³³⁻³⁴ For follow-up clinic appointments, the PainCAS assessment includes an electronic version of the Current Opioid Misuse Measure (COMM).³⁵ The PainCAS program was designed to offer a summary of patient information with a pain diagram and risk assessment scores that could be integrated into an electronic medical record (EMR) system.

Unfortunately, difficulties were encountered in using PainCAS during this trial due to problems within the program (there were a number of glitches in the software that needed to be resolved) and in delivering it to the patients within primary care centers. As a result, many of the subjects in the Specialist group were not given an opportunity to use PainCAS. Although the overall feedback by patients and providers in an initial study⁵⁸ has been positive in using an electronic pain assessment program, we did not have enough comparison data to determine its perceived benefit in this study.

RESULTS

Primary Care Provider Baseline and Outcome Data

Fifty six (n=56) primary care providers participated in this study. Forty four (n=44; 78.6%) were internal medicine physicians, eight (14.3%) were nurse practitioners, and four (7.2%) were physician assistants. Ages of the providers ranged between 27 and 65 (average 44.3 years \pm 9.6), 58.9% were female, and 76.8% were Caucasian (Table 2). About seventy percent (69.6%) were working full time and they averaged 46.2 (\pm 16.0) hours working per week. They had an average of 13.8 (\pm 10) years of experience (range

2 to 36 years) and typically saw 47.9 (± 31) patients per week. Forty seven (83.93%) described their practice location as urban, two described their practice as rural (3.6%), and seven (12.5%) described their practice as a combination of both urban and rural. Only 10 (17.9%) of the 56 providers indicated that they had any specialty education or training in chronic pain management.

Of the respondents, the NPs and PAs were all women. No other differences were found on background and work-related issues based on gender. None of the non-physicians (NPs and PAs) reported having specialty training in pain and, in general, the non-physicians reported feeling insufficiently trained in prescription opioids and lacked confidence in prescribing opioids compared with the physicians ($p < 0.05$). When asked about their work environment over the past week most of the PCPs reported feeling moderate general stress (mean=5.4; 1=no stress, 10=worse stress possible) and moderate work-related stress (5.5/10; Table 3). They reported sleeping an average of 6.8 hours, exercising 3.2 days a week and most felt satisfied about their work (mean=6.8; 1=not at all satisfied, 10=completely satisfied). Regarding their perception of the importance placed on reducing patients' pain in their practice, they rated this as very important (mean=8.0; 1=not important, 10=extremely important). They also believed that patients' pain and distress frequently interfered with their ability to carry out their work (mean=5.6; 1=not at all, 10=completely). Even though at times they felt emotionally drained from their work (mean=5.9; 1=never, 10=all the time) they believed that they were positively influencing the lives of patients through their work (mean=7.9; 1=never, 10=all the time).

Overall, the PCPs showed only adequate opioid knowledge on the KOT averaging 17.2 correct of 25 items (Table 2: 68.8%). The percent correct ranged between 56% (14/25) to 88% (22/25). Older providers scored significantly higher on the KOT than younger providers ($r=.30$; $p<0.05$). No other differences were found on the KOT based on gender or specialty. Most of the respondents chose the correct answer in all but 4 of the 25 items. The responders tended to choose incorrect answers on 1) the percent of babies born with withdrawal symptoms of opioid-dependent mothers (most chose the higher 60% vs. 50%), 2) principle treatment outcome for chronic opioid therapy (most chose physical function vs. pain relief), and 3) when to refer for specialty care (most chose both current and past drug problems vs. current drug problems only). The majority of responders also, when asked when opioid therapy should be reconsidered, chose when “addiction is suspected” rather than “after two or three upward adjustments of dose and pain relief is not achieved.”

The GHQ was included as a valid and reliable measure of emotional well-being and assessed perceived problems with cognition, sleep, depression, anxiety, and somatic symptoms among the clinicians. Overall the providers reported stable mood with most items rated as being better than or same as usual. No differences were found on the GHQ scores based on age, gender or specialty. Scores on the GHQ were found to be unrelated to prescription attitudes.

From the results of the baseline CAAP provider responses, most felt that chronic pain patients were stressful to deal with (83.9% - often, almost always or always true) and expressed a reluctance to prescribe opioids without a clear diagnosis (92.9%; Table 4). Most were concerned about medication dependence (89.3%) and opioid misuse

(89.3%) and overall felt that managing chronic pain patients was stressful (89.3%). Many felt pressure to prescribe opioids (78.5%), were worried about drug-drug adverse interactions (87.5%) and believed that patients may become addicted when prescribing opioids (82.2%). More than half expressed a lack of confidence in prescribing opioids (53.5%) and felt that they were not sufficiently trained in prescribing opioids (53.6%). Many also were not satisfied at baseline with the support (62.5%) and communication they received from pain specialists in managing their chronic pain patients based on their responses on the OTS (Table 5). The majority, however, shared a willingness to prescribe opioids for chronic pain patients with adequate support and direction from pain specialists (71.4%). Most expressed dislike of the transition notes from the pain center (87.5%, item #9).

Younger providers tended to feel more reluctant to prescribe opioids, had more concern about medication misuse, had less overall confidence in prescribing opioids and managing pain patients, felt less well trained in prescribing opioids, and believed that treating pain was a problem in their practice compared with older providers ($p < 0.05$; Table 6). The younger providers also expressed less willingness to prescribed opioids even with support from pain specialists. Although younger providers were also less knowledgeable about opioids, opioid knowledge alone was not found to be related to concerns about analgesic prescriptions.

All providers completed the baseline questionnaires and were asked to complete the CAAP and OTS questionnaire items one year after starting the study. Table 4 presents the differences in responses on the CAAP among the 56 providers between baseline and 1 year follow-up. Little change was noted in reluctance to prescribe

opioids, in perceiving chronic pain patients to be stressful, and in having ongoing concerns about drug interactions, physical dependence of opioids, and medication misuse. There was a significant increase in the number who expressed worry about their pain patients being addicted to opioid medication (pre=82.2%, post=91.6%) and two thirds of the providers continued to worry that prescribing opioids may harm their patients.

After one year there was a significant reduction in the number of providers who admitted to lacking confidence in prescribing opioids (pre=53.5% , post=36.2%; $p<0.01$) and many expressed increased confidence in identifying patients at risk for misuse of pain medication on the Opioid Therapy Survey (pre=42.9%, post=63.9%, $p<0.01$, Table 5). There was also a significant increase in the number of providers who felt that they had been sufficiently trained in prescription opioids for patients with noncancer pain (Table 4; pre=46.4%, post=68.1%, $p<0.05$). Also there was a noticeable improvement in the level of dissatisfaction with communication with pain specialists from 62.5% before the study to only 23.4% after one year ($p<0.01$).

Patient Baseline and Outcome Data

We recruited 253 chronic pain patients from the participating primary care centers (126 from the Specialist clinics and 127 from the Generalist clinics). Overall, no significant demographic differences in recruitment among the centers were found. Of all the patients ($n=253$), 151 were female (59.7%) and 102 were male (40.3%; Table 7). One hundred seventy seven (72.5%) participants were Caucasian, (79 male and 98 female), 41 participants (16.8%) were African American (14 males, 27 females), 23 subjects (9.4%) were Hispanic (5 male and 18 female), and 3 participants (1.2%) were

either Asian (n=2) or American Indian (n=1). There were significant differences in ethnicity between the Specialist and Generalist centers with the Specialist centers being more diverse ($p<0.01$). We had initially hoped to recruit at least 15% minorities and succeeded in recruiting 27.5% minorities overall.

Although the majority of the subjects had back pain, only ten percent reported having low back pain alone. A great majority of the patients (74.7%) reported having multiple pain sites. Pain intensity scores typically averaged over 6 on a 0-10 scale and “least pain” tended to average 5/10. Despite the high pain scores, most reported getting 50% relief from their pain medication. Results of the BPI indicated that the pain greatly interfered with daily activity with most interference in normal work, including work outside the home and housework. Ratings on the PDI also suggested significant disability regarding work, recreation, sexual and social activities, and family and home responsibilities (Table 8). Total scores on the HADS reflected elevated anxiety and depression and overall high negative affect. Scores on the SOAPP-R averaged above the cutoff of 18 for risk of opioid misuse.

Two hundred and seven (87.0%) of the patients reported taking prescription opioids at the time of the first monthly interview and 46 subjects (18.2%) were either being considered for prescription opioids or had missing data regarding their medication. Patients were not prescribed opioids either because they had been considered for opioid therapy but had not started (n=39), or the provider decided to discontinue opioids after the subject was recruited to the study (n=7). No demographic differences were found between those not taking opioids and those who were prescribed opioids for pain. Of those patients prescribed opioids at baseline, 57.5%

were prescribed short-acting opioids alone (oxycodone 62.7%, hydrocodone 36.0%, hydromorphone 9.3%, morphine 8.0%), 17.2% were prescribed long-acting opioids alone (methadone 40.0%, oxycodone 36.0%, hydrocodone 4.0%, hydromorphone 4.0% and transdermal fentanyl 4.0%) and 21.8% were prescribed both short acting and long acting opioids. Four patients (1.6%) were prescribed suboxone alone and 9 (3.6%) were prescribed tramadol alone.

Baseline telephone interview data after one month indicated moderately high pain intensity scores (average 7.0/10; Table 9), elevated routine daily activity interference, and problems with sleep and mood. Those participants who reportedly were taking opioids were asked to identify any side effects on a yes or no scale. Symptoms commonly associated with prescription opioids were frequently identified (e.g. dry mouth, weakness, sweating, headache and constipation). A majority of the subjects (74.8%) reported that they had gone to a health clinic over the past month and all of the participants combined averaged over two appointments within a month of the interview. Eleven percent (11.3%) of the subjects stated that they had gone to the emergency room of a hospital and 5.9% stated that they had been admitted to the hospital.

All patients were asked a series of yes and no questions each month about their compliance with their medication using the Opioid Compliance Checklist (Table 10).³¹ Positive responses on this checklist have been shown to predict future opioid misuse. These questions reflect what is typically included in an opioid agreement.²³⁻²⁸ At the start of the study one out of five patients (17.6%) reported running out of their medication early (Table 10). Sixteen percent (15.7) stated that they had taken their

opioids other than the way that it was prescribed and 16% (15.5) reported that they had missed a scheduled appointment. Six percent admitted that they had used an illegal substance and six percent stated that they had gotten prescriptions from more than one provider. Only two percent reported lost prescriptions or borrowing medication from others (Table 10).

All patients were followed for 6 months and participated in monthly telephone interviews. Final phone interview data are presented in Table 11. No significant differences were found between baseline scores and 6-month follow-up on the interview items. The average pain scores remained relatively constant (pre=7.0, post=6.7) and most continued to report above average activity interference (daily routine pre=6.8/10, post=6.7/10). While 87% were taking opioids at the start of the study, fewer patients (79%) stated that they were taking opioids for pain at the end of the 6-month monitoring period. Many of the same reported side effects at baseline were identified by the end of the study with dry mouth (47.5%), constipation (34.5%), sweating (31.6%), and headache (29.4%) being most frequently endorsed. Weakness (pre=27.9%; post=24.3%) and dizziness (pre=19.7; post=16.4%) were experienced less often (Tables 9 & 11). Although not significant, the subjects reported going to the clinic (pre=74.8%, post=63.1%) and going to the emergency room (pre=11.3%, post 12.1%) less often. There was a slight increase in the number of patients who reported being admitted to the hospital (pre=5.9%, post=7.9%).

Over the course of the 6-month monitoring period the patients reported greater compliance with their opioid medication. At the start of the study 17.6% of the patients admitted to running out of their medication early and 15.7% were taking their medication

other than the way it was prescribed. By the end of the study 8.7% admitted to running out of the medication early, and 11.6% claimed using their medication other than how it was prescribed (Table 12). Although they still admitted missing scheduled appointments at about the same rate (pre=15.5%, post=13.6%), the patients were more inclined to report using one pharmacy (multiple pharmacies pre=12.7%, post= 9.9%) and less inclined to admit using illegal substances (mostly THC; pre=6.3%, post=5.6%) at the end of the 6-month study period. Getting prescriptions from more than one provider (pre=5.9%, post=6.4%) remained unchanged while there was an increase in the number of subjects who reported lost or stolen prescription pain medication by the end of the study (pre=2.0%, post=4.7%). None of the subjects admitted to borrowing opioid medication from others at the end of the study (Tables 10 and 12) .

Comparisons between the Specialist and Generalist groups on the percent of subjects admitting to one or more behaviors on the OCC are presented in Table 13. Fifty percent (50.0%) of the patients from the Generalist clinics and 49.2% of the patients in the Specialist centers at baseline reported at least one behavior on the OCC. All subjects showed an increase in opioid compliance (decreased scores) after 6 months, although no significant differences were found between treatment conditions.

Table 14 presents the responses of the patients on the exit interview items. By the conclusion of the 6-month trial, most patients reported feeling satisfied about the way their pain was tracked (74.2%) and satisfied about the way the study tracked their medication use and side effects on a monthly basis (74.6%). Few felt that their participation in the study was a burden to them (8.6%) and many thought that feedback to their physician helped their care (75.9%). Overall, a third of the patients felt that the

monthly monitoring helped them to be compliant with their medication (29.4%), while a quarter of the subjects (22.6%) felt that the close monitoring kept them out of the emergency room or hospital. In general, quality of life among many of the patients did not improve over the course of the 6-month study. Many claimed that the monthly calls could help to prevent future problems (40.6%) and they also felt that their doctors were comfortable in prescribing pain medication and in managing their pain (65.6%). Most continued to acknowledge ongoing concerns from family and friends about their use of prescription pain medication (74.9%).

Differences between Specialists and Generalist Groups

Differences were examined between patients from the Specialist and Generalist clinics. Among the patients from the Specialist clinics, 55 (51.4%) were evaluated and treated at the BWH Pain Management Center and 52 (48.6%) were treated alone by their PCP. Although some patients were referred for evaluation and treatment from the Generalist centers, the PCP was the sole prescriber of the opioids and managed the patients alone.

In comparing demographic differences between centers, significant differences were found on ethnicity (more minorities in the Specialist centers), but no other differences were found between the Specialist and Generalist centers (Table 7). No differences were found between centers on pain catastrophizing, disability, and mood, although the Generalist patients showed higher SOAPP-R scores compared with the Specialist patients (Table 8).

Differences were examined between centers on the baseline phone interview data and presented in Table 9. Those in the Specialist centers reported a higher

percentage of taking prescription opioids ($p < 0.01$). No other differences were found between centers on pain intensity, activity interference, side effects, and healthcare utilization and responses on the Opioid Compliance Checklist (Table 10) at the time of the first phone interview.

Tables 11 and 12 show the differences between the subjects in the Specialist centers and Generalist centers based on the phone interview at the end of the 6-month trial. Those patients from the Specialist centers tended to report increased interference with sleep and appetite. They also tended to report going to the Emergency Department of the hospital more than the Generalists. Likewise, those in the Generalist condition reported going to the clinic more than those from the Specialist clinics. Although the patients admitted to fewer amounts of aberrant behavior on the Opioid Compliance Checklist at the end of the study (Table 13), no significant differences were found between groups. Overall, few differences were found between centers. Differences are presented between centers on the patient exit interview questions (Table 14). Again, no differences were found on the exit interview items between centers.

Differences were also examined between providers from the Specialist centers and Generalist centers on the CAAP and OTS questions at baseline and at 1 year follow-up. Concern remained among all the providers about prescribing opioids, physical dependence, drug-drug interactions, and patients becoming addicted on the CAAP, but no significant differences were found between the providers in each of the centers (Table 15). At baseline, the providers in the Specialist centers more often felt that pain patients were difficult to treat in their practice compared with the providers in the Generalist centers (Table 16). Few differences were found between the Specialist

and Generalist centers on the CAAP and OTS at 1-year follow-up (Table 17 and 18). However, despite few significant changes in pre-and post-responses on the OTS among the Generalist group, significant differences were found on the OTS between baseline and follow-up for the Specialist providers (Table 20). These providers felt that pain patients were less of a problem in their practice ($p<0.01$), that they were more confident in managing pain patients ($p<0.05$), that they were more satisfied the communication with pain specialists ($p<0.01$), including transition notes ($p<0.001$), that they were better able to identify patient risk ($p<0.05$), and that overall they felt more comfortable in prescribing opioids ($p<0.01$).

DISCUSSION

This 2-year prospective controlled trial was designed to determine the benefit of interventions to improve chronic pain patient compliance and opioid prescribing practices among PCPs. The results of this study demonstrated perceived improvement in the number of providers who 1) could identify patients at risk for misuse, 2) were more satisfied with communication with the pain center, and 3) felt sufficiently trained in the prescription of opioids. To a lesser degree, there were a number of providers by the end of the study who felt that treating patients was less of a problem in their practice. Overall, the primary care providers remained concerned about opioid addiction and dependence and they still felt a need for direction and support from pain specialists. Compared with providers in the Generalist centers, the Specialist reported significant improvement in confidence in managing chronic pain patients. Anecdotal feedback from the primary care providers in the Specialists group suggested that they were very busy and were not always in a position to closely follow their pain patients who were

prescribed opioids. They felt that the monthly tracing and summary reports were very beneficial in closely monitoring their challenging pain patients. Those providers in the Generalist group also seemed to be pleased that their patients were being monitored, but they did not demonstrate a change in attitude the way that those providers who were given monthly feedback did.

A difficulty encountered in this study, beyond our control, was the fact that some patients and providers in the Generalist condition were receiving support from pain specialists. Overall, all the patients seemed satisfied with the close monitoring and they did not perceive the study to be a burden. The majority felt their their doctor was more comfortable in managing their pain. A third of the patients felt that the monthly monitoring helped them to be compliant with their medication and 41% felt that it helped to prevent future problems. Overall, however, few differences were found between the patient groups. The education and feedback supplied to the primary care providers seemed to significantly influence the degree of confidence they had in managing chronic pain patients. In combination, all the providers reported greater comfort in identifying risk, prescribing opioids, and managing pain patients. This finding leans support to future identification of challenging chronic pain patients within primary care and improved tracking of the patinets and better communication with pain specialists.

The results indicate a general concern and reluctance of primary care providers to manage the prescribing of opioids among their chronic pain patients, in agreement with past studies.³⁸⁻⁴⁰ Many PCPs in our study, even though frequently faced with the need to manage chronic pain patients, reported little training in pain management and opioid therapy. The majority of the providers were concerned about medication misuse,

abuse, and addiction. Overall they felt that chronic pain patients were stressful and they worried about harm associated with taking opioids for a long period of time. In general, however, most of the providers expressed a willingness to prescribe opioids if they were supported by a pain specialist. Although improved by the end of the study, many still felt that communication with a pain specialist was inadequate. These results underscore the need for continuing education among primary care providers about pain management in general and opioid prescribing in particular and the need for improved means of communication with pain specialists.

A surprise finding of this study was that younger providers expressed more concern about opioids than older providers, unlike past surveys.³⁹ This has implications for the future when older providers give up their practices through either retirement or relocation. A typical scenario might be when a primary care provider retires and a younger provider inherits a practice with many chronic pain patients who have been managed for years on chronic opioid therapy. In this situation, the younger providers may express unease about continuing to write opioids for noncancer pain and prefer to taper the patients off their opioids against the will of the patients. Some of this reluctance to continue to prescribe opioids may be based on media exposure to the problem of opioid abuse and the results of studies indicating the high incidence of noncompliance among patients taking prescription opioids for pain. This, in turn, places pressure on other providers or pain centers to assume responsibility to manage the opioid therapy among these patients.

Although the clinicians seemed knowledgeable about prescription opioids, not all felt confident in managing chronic pain patients. This lends support to the importance of

providing more training among primary care physicians. Many states are beginning to require annual training in pain management and substance abuse in order for providers to renew their medical licenses.⁵⁹ The results of this study point to further emphasis on the importance of training in pain and opioid therapy management and for the need for improved communication among pain management specialists and primary care providers.

This investigation was proposed as a preliminary study designed to assess provider confidence in managing chronic pain patients. More structured interventions could be useful through comprehensive specialty support, risk assessment, and shared summary reports. Additional strategies such as use of electronic tracking programs and phone apps may be valuable to improve communication between primary care providers, pain specialists and chronic pain patients. There is evidence that improved communication among providers can increase adherence among chronic pain patients.¹⁵ Electronic medical records with shared clinical messaging and software programs designed to track compliance among pain patients may continue to prove to be helpful in increasing provider confidence in comfortably managing challenging chronic pain patients.

There are a number of limitations of this study that deserve mention. First, not all providers chose to participate, and it is uncertain whether these results might be affected by selection bias based on willingness to participate. It is possible that those with the strongest feelings about prescription opioids for chronic noncancer pain were not included. Second, this study involved a limited number of primary care participants and this could have affected the chance to find significant differences. Although the

results are reflective of other surveys among primary care physicians,^{12,38,39} collection of similar data from other regions of the country would be beneficial. Third, this is a self-report study and no information was obtained about actual prescribing practices. The decision to prescribe opioids, the type of opioids that were prescribed, and the particular protocols followed by the providers in managing high-risk chronic pain patients were not determined. Although these limitations reflect real-world practice issues, the degree to which providers followed accepted opioid therapy guidelines of risk assessment for all patients, routinely used an opioid agreement, collected regular urine toxicology screens, and carefully monitoring patients prescribed opioids for pain was not determined.^{25,37} Actual physician practices were based on the discretion of the individual providers. Finally, we failed to collect some data that might have been useful. For instance, we did not ask about side effects of those patients who were not taking opioids. As a result we could not compare those taking opioids with those who were not based on the number of side effects reported. We also did not repeat the Test of Opioid Knowledge to determine whether there were improvements in general knowledge of opioids by the conclusion of the study, and we did not determine how many of the patients from the Generalist centers had been seen by a pain specialist.

CONCLUSIONS

Despite these limitations, the results of this survey are promising. It would appear that careful monitoring of patients from primary care centers who are prescribed opioids for chronic pain can be beneficial. Although many primary care clinicians have concerns about prescribing opioids, they are willing to prescribe for and manage chronic pain patients if they have suitable support and direction from pain specialists. The results

also indicate that younger providers have greater concerns about prescription opioid user than older providers and greater attention in improving the knowledge and support of younger primary care providers should be encouraged. This report contains our preliminary outcome findings and we will continue to analyze the data and report on components of these results in months to come.

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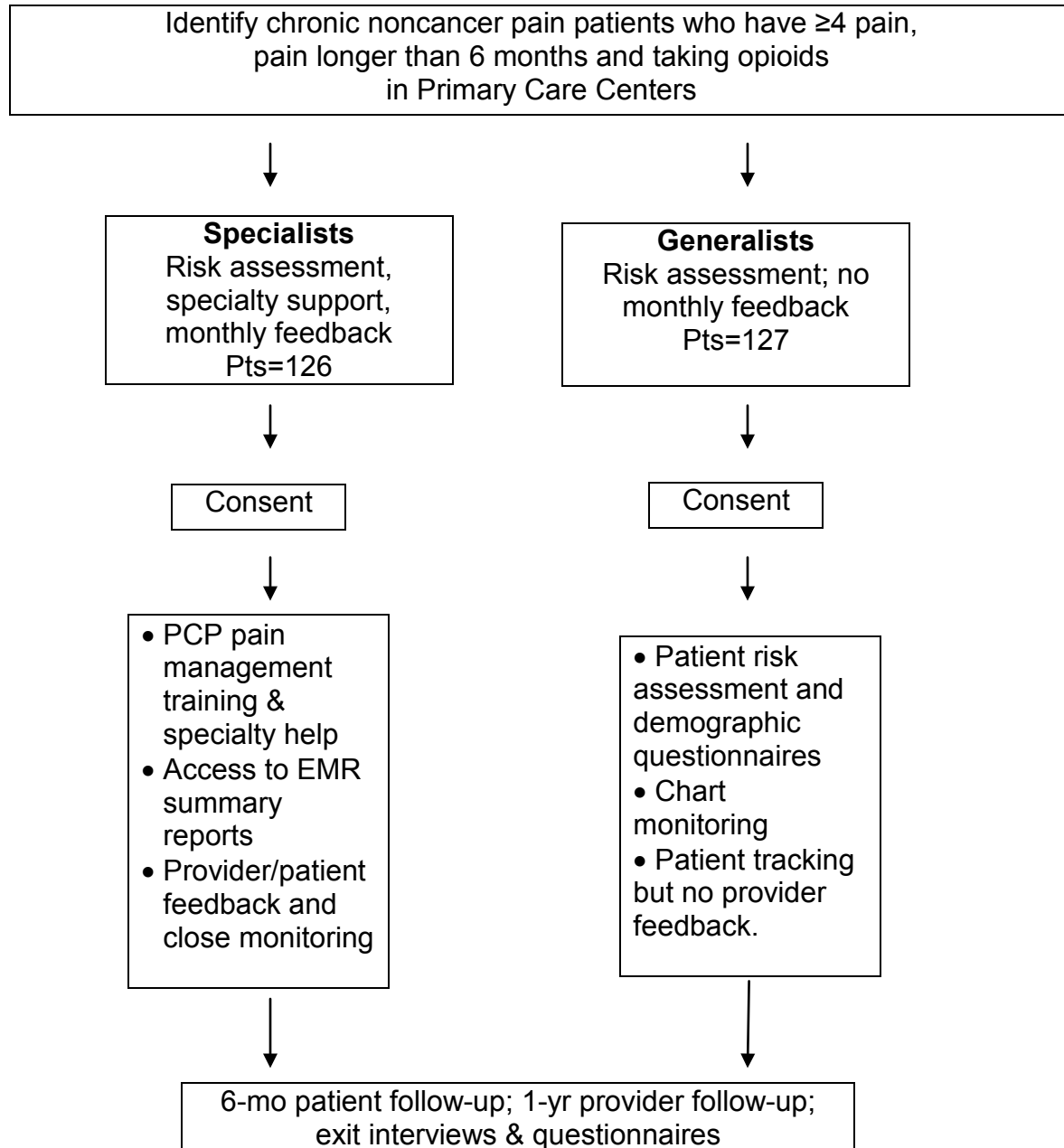
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Table 1. Proposed Study Timeline

Months of Study	0	3	6	9	12	15	18	21	24	Final Report
Develop measures and Software										
Recruit subjects										
Baseline measures										
Pain management training										
Clinic-based assessment										
Post-study measures										
Data Analyses										

Figure 1.
STUDY SCHEMA



- Outcomes:
1. Provider pain treatment confidence ratings
 2. Patient treatment satisfaction
 3. Opioid compliance
 4. Healthcare utilization

Table 2. Demographic data and questionnaire scores of the PCPs (n=56).

VARIABLE	
Age (years)	44.3 ±9.6 (range 27 to 65)
Gender (% female)	58.9%
Race (% Caucasian)	76.8 %
Work full time (% yes)	69.6 %
Practice location (% urban)	83.9 %
Training in pain (% yes)	17.9 %
Average hours working each week	46.2±16 (range 12-100)
Years of practice	13.8±10 (range 2-36)
Ave # of patients seen weekly	47.9±31(range 9-200)
Test of Opioid Knowledge (25 items) [‡]	17.2±2.1 (range correct 14-22)
General Health Questionnaire (12 items) [†]	9.91±2.7 (range 6-20)

[‡] multiple choice responses on current knowledge about opioids with a single best answer

[†] ratings on 4 possible responses from 0 to 3; typically “not at all” to “much more than usual”

Table 3. Primary Care Survey, work-related issues. (n=56).

QUESTIONNAIRE ITEMS	
How important is reducing patients' pain? ^β	8.0±1.5
I feel I have positively influenced the lives of others [#]	7.9±1.1
How satisfied with work this past week? [‡]	6.8±1.6
How many hours did you sleep with past week?	6.8±0.9
I feel emotionally drained at work? [#]	5.9±2.4
How much do pain patients interfere with work? [≠]	5.6±2.3
How much work-related stress? [†]	5.5±2.0
How much general stress this past week? [†]	5.4±1.9
How many days did you exercise for 30 mins?	3.2±1.8

[†]1=no stress; 10=worst stress possible

[‡]1=not at all satisfied; 10=completely satisfied

^β1=not important; 10=extremely important

[≠]1=not at all; 10=completely

[#]Rate how true these statements are regarding work: 1=never; 10=all of the time

Table 4. Pre-post comparisons of physician responses on the Concerns About Analgesic Prescription Questionnaire (1 year follow-up; n=56).

CAAP variables: 0=never true; 5=always true (% often true, almost always true & always true)	Baseline (n=56)	Follow-up (n=56)	p[‡]
I am reluctant to prescribe opioids in patients with no clear diagnosis. (#21)	92.9	100.0	NS
I worry that my patients may develop physical dependence on opioid analgesics. (#22)	89.3	87.3	p=.02
Medication misuse is a real risk when patients are prescribed strong analgesics. (#13)	89.3	85.1	NS
I am concerned that patients may become addicted to strong opioids. (#7)	82.2	91.6	NS
I am concerned about the potential for adverse drug-drug interactions in polymedicated patients. (#12)	87.5	85.1	NS
I find patients with chronic pain very stressful to deal with. (#14)	83.9	83.0	p=.04
I am concerned that if I prescribe opioids to non-malignant pain patients I will be committed to this treatment for a long time. (#4)	80.4	83.0	NS
I feel pressured by patients to prescribe something for their pain. (#9)	78.5	84.8	NS
I worry that prescribing opioid analgesics may harm my patients. (#19)	73.2	74.4	NS
I feel that I will incur additional workload by prescribing opioid medications to patients. (#5)	71.4	75.0	NS
I worry about prescribing opioid analgesics because they are sedating or can cause confusion. (#18)	73.3	70.1	NS
I believe that patients will be non-adherent to their prescribed medications. (#6)	60.7	61.6	NS
I believe that I am more likely to prescribe an opioid when the patient is very distressed. (#2)	64.3	55.3	NS
I feel sufficiently trained in the prescription of opioids to patients experiencing chronic non-malignant pain. (#3)	46.4	68.1	p=.001
I feel that cases of inappropriate medical use of opioids in the media discourage me from prescribing these drugs. (#20)	76.7	36.2	NS

CAAP variables: 0=never true; 5=always true (% often true, almost always true & always true)	Baseline (n=56)	Follow-up (n=56)	p[‡]
I worry about prescribing opioid analgesics because they impair clear thinking for my patients. (#17)	48.2	53.2	NS
I see no option but to prescribe opioid analgesics for some patients. (#16)	53.5	42.5	NS
I lack confidence in the area of prescribing analgesics for some patients. (#15)	53.5	36.2	p=.002
I believe that medication diversion is likely to occur when patients are prescribed strong opioid medications. (#11)	47.3	39.2	NS
I believe that chronic pain is more of a social or emotional problem than a medical one. (#10)	50.0	36.2	NS
I am concerned about scrutiny or professional sanction for prescribing opioid analgesics.(#8)	42.9	42.6	NS

[‡]Wilcoxon Signed Ranks test

NS = nonsignificant

Table 5. Pre-post comparisons of all providers on the Opioid Therapy Survey responses (% strong agree and agree; 1 year follow-up; N=56).^β

Opioid Therapy Survey Items	Baseline (n=56)	Follow-up (n=56)	p [‡]
Treating pain patients is a problem in my practice (#1).	80.4	82.9	NS
I am willing to prescribe opioids with support from pain clinic (#7).	71.4	83.0	NS
I fear my patients will become addicted to opioids (#8).	69.6	70.2	NS
I am dissatisfied with communication with pain specialists (#6).	62.5	23.4	p=.002
I follow a recommended opioid therapy protocol (#5).	60.7	78.7	NS
Will prescribe opioids when other treatments are ineffective (#3).	55.3	55.3	NS
I can identify patients at risk for misuse of pain medication (#4).	42.9	63.9	p=.003
I am confident in my ability to manage patients with chronic pain (#2).	42.9	44.7	NS
I am satisfied with the transition notes from the pain center (#9).	12.5	30.4	p=.001
The consistent approach of my practice has helped me feel comfortable in prescribing opioids (#10).	7.2	23.4	p=.003
Exit interview questions:^β			
I am satisfied with the way this study tracked my patients' pain (#11).	-	63.0	-
I am satisfied with the way this study tracked my patient's medication and side effects (#12).	-	60.8	-
The monthly patient phone calls helped prevent future problems (#17).	-	44.4	-
This study helped keep my patients out of the ER and hospital (#15).	-	26.1	-
This study helped my patients be more compliant with their medication (#14).	-	23.9	-
This study was an added burden (#13).	-	6.4	-

^βPercent rating either "strongly agree," or "agree" on 1=strongly agree to 5=strongly disagree scale.

Table 5. Pre-post comparisons of all providers on the Opioid Therapy Survey responses (% strong agree and agree; 1 year follow-up; N=56).^β

Table 6. Correlations of age of the providers and concerns at baseline about opioid use and pain patient management (N=56).

QUESTIONNAIRE ITEMS	%
Reluctant to prescribe opioids	-0.46*
Concern about medication misuse	-0.35*
Lack confidence to prescribe opioids	-0.31*
Feel sufficiently trained to prescribe opioids	0.30*
Lack confidence in managing pain patients	-0.30*
Treating pain is a problem in my practice	-0.29*
Pain patients stressful to deal with	-0.27
Willing to prescribe with support	-0.22
Believe pts will be non-adherent	-0.16
Concerned with long-term commitment	-0.15

*p<0.05

Table 7. Baseline demographic and patient description items (n=253)

VARIABLE	TOTAL (N=253)	Specialist (N=126)	Generalist (N=127)	p value
Age	53.7±11.3	52.8±11.8	54.7±10.5	NS
Gender (% female)	59.7	65.1	54.3	NS
Ethnicity (%)				
Caucasian	72.5	59.7	85.8	X ² =21.8***
African-American	16.8	24.3	9.2	
Hispanic	9.4	14.5	4.2	
Other	1.2	1.6	0.8	
Pain site:				
Low back	8.9	9.6	8.1	NS
Multiple sites	74.7	71.9	77.2	NS
Pain Intensity (24 hours, 0-10):				
Worse	8.0±1.9	8.1±1.9	7.9±1.8	NS
Least	4.9±2.4	5.1±2.6	4.8±2.2	NS
Average	6.2±1.8	6.2±1.9	6.2±1.6	NS
Now	6.4±2.4	6.4±2.5	6.4±2.3	NS
Pain relief % (24 hours – 0-100):	52.0±25.2	52.9±23.9	51.2±26.4	NS
Pain Interference: (0-10)				
General activity	6.9±2.3	6.9±2.5	6.9±2.5	NS
Mood	6.1±2.8	6.0±3.0	6.0±3.0	NS
Walking ability	6.2±3.0	6.0±3.2	6.0±3.2	NS
Normal work (work & housework)	7.0±2.5	7.0±2.7	7.0±2.3	NS
Relations with others	5.0±3.1	5.0±3.2	5.0±3.0	NS
Sleep	6.8±2.9	6.9±2.9	6.6±3.0	NS
Enjoyment of life	6.8±2.7	6.7±2.8	6.9±2.6	NS

NS=nonsignificant

* p<0.05; *** p<0.001

Table 8. Baseline patient comparison questionnaire scores between the Specialist and Generalist groups (n=253)

VARIABLE	TOTAL (N=253)	Specialist (N=126)	Generalist (N=127)	p value
Pain Catastrophizing Scale (PCS)	26.1±12.6	24.7±13.2	27.5±12.3	NS
Pain Disability Index (PDI-Total)	43.4±15.7	43.7±15.8	43.2±15.7	NS
Family/home responsibilities	6.5±2.6	6.6±2.6	6.5±2.5	NS
Recreation	7.1±2.4	7.3±2.4	6.8±2.4	NS
Social Activity	6.2±2.8	6.1±2.8	6.3±2.7	NS
Occupation	7.3±2.7	7.2±2.8	7.3±2.7	NS
Sexual behavior	6.9±3.2	6.8±3.2	7.1±3.2	NS
Self-care	4.8±3.0	4.6±3.1	4.9±2.9	NS
Life-support activity	4.5±3.1	4.6±3.2	4.4±3.0	NS
Hosp Anxiety and Depression Scale (HADS)				
Anxiety	9.6±4.5	9.5±4.5	9.7±4.6	NS
Depression	9.1±4.6	8.9±4.6	9.2±4.6	NS
Total score	18.6±8.2	18.3±8.1	18.9±8.3	NS
SOAPP-R	23.4±12.9	20.8±10.5	25.9±14.5	t=3.1*

*p<0.05

Table 9. Patient month 1 phone interview data (n=238) .

Variable	All Patients (N=238)	Specialist (N=116)	Generalist (N=122)	p-value
Pain now [‡]	6.3±2.3	6.4±2.4	6.2±2.3	NS
Average pain [‡]	7.0±1.9	7.0±1.9	7.0±1.9	NS
Interference: [‡]				
Routine daily	6.8±2.6	6.8±2.7	6.8±2.4	NS
Social	6.5±2.8	6.5±3.0	6.6±2.7	NS
Outdoor/rec	7.1±2.7	7.1±2.7	7.9±2.8	NS
Sleep	6.5±3.1	6.6±3.1	6.3±3.2	NS
Appetite	3.8±3.3	3.9±3.4	3.7±3.1	NS
Work	7.2±2.7	7.4±2.9	7.0±2.5	NS
Mood	6.2±2.8	6.2±2.8	6.2±2.8	NS
Meds (%yes)	87.0	94.0	80.3	X ² =9.8**
Side effects: (%yes)				
Dry mouth	48.6	49.5	47.4	NS
Weakness	27.9	28.8	26.8	NS
Sweating	29.3	29.7	28.9	NS
Headache	26.0	27.9	23.7	NS
Constipation	36.5	32.4	41.2	NS
Itching	26.9	24.3	29.9	NS
Dizziness	19.7	18.0	21.6	NS
Nausea	17.8	17.1	18.6	NS
Visual prob.	13.0	14.4	11.3	NS
Confusion	14.4	13.5	15.5	NS
Sneezing	7.7	8.1	7.2	NS
Nightmares	11.1	11.7	10.3	NS
Over past mo.				
Gone to clinic (%yes)	74.8	77.6	72.1	NS
# times gone to clinic	1.7±3.4	1.5±2.0	1.9±4.4	NS
Gone to ED (%yes)	11.3	12.9	9.8	NS
# times gone to ED	0.2±0.5	0.2±0.5	0.2±0.5	NS
In hosp (%yes)	5.9	7.8	4.1	NS
# of days in hosp	0.2±0.9	0.2±0.8	0.2±1.0	NS

**p<0.01

‡0-10 scale

NS=nonsignificant

Table 10. Patient month 1 Opioid Compliance Checklist responses (n=238).

Variable: Over the past month have you: (% yes)	All pts (N=238)	Specialists (N=116)	Generalists (N=122)	p-value
Ran out of pain medication early	17.6	17.6	17.7	NS
Taken opioids other than prescribed	15.7	13.9	17.7	NS
Missed scheduled appointments	15.5	18.1	13.1	NS
Used more than one pharmacy	12.7	14.8	10.4	NS
Used an illegal substance	6.3	6.0	6.6	NS
Prescriptions from more than one provider	5.9	6.5	5.2	NS
Lost or misplaced opioid medication	2.0	2.8	1.0	NS
Borrowed opioid medication from others	2.5	2.6	2.5	NS

NS=nonsignificant

Table 11. Follow-up 6-month patient phone interview data (n=214).

Variable	All Pts (n=214)	Specialist (n=107)	Generalist (n=107)	p-value
Pain now [‡]	6.11±2.4	6.4±2.4	5.8±2.4	NS
Average pain [‡]	6.7±2.0	6.9±2.0	6.5±1.9	NS
Interference: [‡]				
Routine daily	6.7±2.5	6.8±2.5	6.5±2.6	NS
Social	6.5±2.9	6.6±2.9	6.3±2.9	NS
Outdoor/rec.	6.9±2.8	6.9±2.8	6.9±2.8	NS
Sleep	6.2±3.1	6.7±3.0	5.7±3.2	t=2.4*
Appetite	4.3±3.3	4.7±3.4	3.8±3.1	t=2.0*
Work	6.8±2.9	6.8±3.0	6.9±2.8	NS
Mood	6.1±2.8	6.5±2.7	5.8±2.9	NS
Meds (%yes)	79.0	84.1	73.9	NS
Side effects: (% yes)				
Dry mouth	47.5	49.5	45.1	NS
Constipation	34.5	34.7	34.1	NS
Sweating	31.6	29.5	34.1	NS
Headache	29.4	29.5	29.3	NS
Weakness	24.3	24.2	24.4	NS
Itching	19.8	20.0	19.5	NS
Visual problems	14.7	11.6	18.3	NS
Nausea	18.1	17.9	18.3	NS
Confusion	10.2	8.4	12.2	NS
Sneezing	9.0	5.3	13.4	NS
Dizziness	16.4	15.8	17.1	NS
Nightmares	9.6	9.5	9.8	NS
Over past mo.				
Gone to clinic (%yes)	63.1	54.2	72.0	X ² =7.2**
# times gone to clinic	1.4±2.4	1.1±2.2	1.6±2.6	NS
Gone to ED (%yes)	12.1	15.9	8.4	NS
# times gone to ED	0.1±0.4	0.2±0.5	0.1±0.4	NS
In hosp (%yes)	7.9	11.2	4.7	NS
# of days in hosp	0.2±1.0	0.4±1.3	0.1±0.4	t=2.2*

[‡]0-10 scale

* p<0.05; ** p<0.01

NS=nonsignificant

Table 12. Follow-up 6-month patient Opioid Compliance Checklist responses (N=214).

Variable: Over the past month have you: (%yes)	All pts (n=214)	Specialists (n=107)	Generalists (n=107)	p-value
Missed scheduled appointments	13.6	15.0	12.3	NS
Taken opioids other than prescribed	11.6	12.1	11.1	NS
Ran out of pain medication early	8.7	9.9	7.4	NS
Used more than one pharmacy	9.9	11.0	8.6	NS
Prescriptions from more than one provider	6.4	6.6	6.2	NS
Used an illegal substance	5.6	4.7	6.5	NS
Lost or misplaced opioid medication	4.7	3.3	6.2	NS
Borrowed opioid medication from others	1.4	.9	1.9	NS

NS=nonsignificant

Table 13. Differences between the Specialist and Generalist groups on percent of patients who admitted to 1 or more “yes” responses on the OCC at month 1 and at 6-month post-treatment (n=204).

OCC %>0	Month 1	Month 6	p-value
Specialist (n=108)	49.2	38.5	NS
Generalist (n=96)	50.0	40.0	NS
TOTAL (204)	49.5	39.2	NS

NS=nonsignificant

Table 14. Patient 6-month exit interview response items (strongly agree, agree, neither agree or disagree, disagree, or strongly disagree) between patient groups.

Exit Interview Survey Items (% Strongly agree or agree)	TOTAL (n=214)	Specialist (n=107)	Generalist (n=107)	X²
1. I am satisfied with the way this study tracked my pain.	74.2	66.7	81.8	NS
2. I am satisfied with the way this study tracked my various activities.	74.2	65.7	82.8	NS
3. I am satisfied with the way this study tracked my medication use and side effects.	74.6	66.7	82.7	NS
10. My doctor seems comfortable in managing my pain.	65.6	65.6	65.7	NS
9. My doctor seems comfortable in prescribing my pain medication.	65.3	68.0	62.6	NS
8. In general, monthly phone calls to patients like me help to prevent future problems.	40.6	38.8	42.4	NS
5. The monthly interview questions about my use of medication helped me to be more compliant with my medication.	29.4	26.5	32.3	NS
13. My family and friends are more comfortable with my medication use.	25.1	22.1	28.1	NS
6. This study helped to keep me out of the emergency room and hospital.	22.6	20.6	24.5	NS
11. My quality of life has improved over the course of this study.	20.2	21.2	19.2	NS
7. The feedback to my doctor about my progress did NOT help my care.	24.1	27.1	21.1	NS
4. This study was an added burden.	8.6	11.1	6.1	NS
12. My relationship with my doctor has NOT improved.	15.4	15.5	15.3	NS

NS=nonsignificant

Table 15. Baseline comparisons of provider responses between the Specialist and Generalist groups on the Concerns About Analgesic Prescription Questionnaire

CAAP variables: 0=never true; 5=always true (% often true, almost always true & always true)	Specialist (n=33)	Generalist (n=23)	p
I am reluctant to prescribe opioids in patients with no clear diagnosis. (# 21)	90.9	95.6	NS
I worry that my patients may develop physical dependence on opioid analgesics. (#22)	87.9	91.3	NS
Medication misuse is a real risk when patients are prescribed strong analgesics. (#13)	87.9	91.2	NS
I am concerned about the potential for adverse drug-drug interactions in polymedicated patients. (#12)	84.8	91.2	NS
I find patients with chronic pain very stressful to deal with. (#14)	90.9	73.9	NS
I am concerned that patients may become addicted to opioids. (#7)	84.9	78.3	NS
I am concerned that if I prescribe opioids to non-malignant pain patients I will be committed to this treatment for a long time. (#4)	84.8	73.9	NS
I feel pressured by patients to prescribe something for their pain. (#9)	81.8	73.8	NS
I worry that prescribing opioid analgesics may harm my patients. (#19)	72.7	73.9	NS
I worry about prescribing opioid analgesics because they are sedating or can cause confusion. (#18)	78.7	65.1	NS
I feel that I will incur additional workload by prescribing opioid medications to patients. (#5)	72.7	69.5	NS
I believe that I am more likely to prescribe an opioid when the patient is very distressed. (#2)	66.7	60.8	NS
I believe that patients will be non-adherent to their prescribed medications. (#6)	60.6	60.8	NS
I see no option but to prescribe opioid analgesics for some patients. (#16)	51.5	56.5	NS
I believe that opioids are an effective treatment for patients with chronic non-malignant pain. (#1)	42.4	65.2	NS
I lack confidence in the area of prescribing analgesics for some patients. (#15)	63.7	39.1	NS
I believe that chronic pain is more of a social or emotional problem than a medical one. (#10)	48.5	52.1	NS
I worry about prescribing opioid analgesics because they impair clear thinking for my patients. (#17)	48.5	47.7	NS

I believe that medication diversion is likely to occur when patients are prescribed opioid medications. (#11)	46.9	47.8	NS
I feel sufficiently trained in the prescription of opioids to patients experiencing chronic non-malignant pain. (#3)	48.5	43.5	NS
I am concerned about scrutiny or professional sanction for prescribing opioid analgesics. (#8)	36.4	52.2	NS
I feel that cases of inappropriate medical use of opioids in the media discourage me from prescribing these drugs. (#20)	48.5	39.1	NS

NS=nonsignificant

Table 16. Baseline provider Opioid Therapy Survey responses between the Specialists and Generalists (% strongly agree and agree; N=56).^β

OTS Items	Specialist (n=33)	Generalist (n=23)	p[‡]
Treating pain patients is a problem in my practice (#1)	84.8	73.9	X ² =14.6**
I am willing to prescribe opioids with support from pain clinic (#7)	69.7	73.9	NS
Fear patients will become addicted to opioids (#8)	66.6	73.9	NS
I follow a recommended opioid therapy protocol (#5)	51.5	73.9	NS
Dissatisfied with communication with pain specialists (#6)	69.7	52.2	NS
Will prescribe opioids when other treatments are ineffective (#3)	54.6	56.5	NS
I can identify patients at risk for misuse of pain meds (#4)	33.4	56.5	NS
I am confident in ability to manage pain patients (#2)	39.4	47.8	NS
I am satisfied with transition notes from pain center (#9)	9.1	17.3	NS
The consistent approach of my practice has helped me feel comfortable in prescribing opioids (#10)	3.0	13.0	NS

^βPercent rating either "strongly agree," or "agree" on 1=strongly agree to 5=strongly disagree scale.

NS=nonsignificant

*p<0.05

Table 17. 1-year follow-up comparisons of provider responses between the Specialist and Generalist groups on the Concerns About Analgesic Prescription Questionnaire

CAAP variables[‡] (% often true, almost always true & always true)	Specialist (n=29)	Generalist (n=18)	p
I am reluctant to prescribe opioids in patients with no clear diagnosis. (#21)	100.0	100.0	NS
I am concerned that patients may become addicted to strong opioids. (#7)	89.6	94.5	NS
I worry that my patients may develop physical dependence on opioid analgesics. (#22)	89.6	82.3	NS
I am concerned about the potential for adverse drug-drug interactions in polymedicated patients. (#12)	86.2	83.3	NS
I feel pressured by patients to prescribe something for their pain. (#9)	89.6	76.5	NS
Medication misuse is a real risk when patients are prescribed strong analgesics. (#13)	93.0	72.2	NS
I am concerned that if I prescribe opioids to non-malignant pain patients I will be committed to this treatment for a long time. (#4)	86.2	77.8	NS
I find patients with chronic pain very stressful to deal with. (#14)	93.0	66.7	NS
I worry that prescribing opioid analgesics may harm my patients. (#19)	75.8	72.2	NS
I worry about prescribing opioid analgesics because they are sedating or can cause confusion. (#18)	65.5	77.8	NS
I feel that I will incur additional workload by prescribing opioid medications to patients. (#5)	86.2	55.6	NS
I feel sufficiently trained in the prescription of opioids to patients experiencing chronic non-malignant pain. (#3)	72.4	61.1	NS
I believe that patients will be non-adherent to their prescribed medications. (#6)	51.7	77.9	$\chi^2=11.53^*$
I believe that I am more likely to prescribe an opioid when the patient is very distressed. (#2)	48.2	66.6	NS
I believe that opioids are an effective treatment for patients with chronic non-malignant pain. (#1)	58.6	55.6	NS
I worry about prescribing opioid analgesics because they impair clear thinking for my patients. (#17)	44.8	66.7	NS
I am concerned about scrutiny or professional sanction for prescribing opioid analgesics. (#18)	27.5	66.7	NS

I believe that medication diversion is likely to occur when patients are prescribed strong opioid medications. (#11)	25.0	61.2	NS
I see no option but to prescribe opioid analgesics for some patients. (#16)	41.3	44.4	NS
I feel that cases of inappropriate medical use of opioids in the media discourage me from prescribing these drugs. (#20)	34.4	39.0	NS
I believe that chronic pain is more of a social or emotional problem than a medical one. (#10)	37.9	33.3	NS
I lack confidence in the area of prescribing analgesics for some patients. (#15)	41.3	27.8	NS

‡ 0=never true; 5=always true

NS=nonsignificant

* p<0.05

Table 18. 1-year follow-up provider Opioid Therapy Survey responses between the Specialists and Generalists (% strong agree and agree; N=47).^β

Opioid Therapy Survey Items	Specialist (n=29)	Generalist (n=18)	p[‡]
Treating pain patients is a problem in my practice (#1)	79.3	88.9	NS
I am willing to prescribe opioids with support from pain clinic (#7)	79.3	88.9	NS
I follow a recommended opioid therapy protocol (#5)	75.8	83.3	NS
Fear patients will become addicted to opioids (#8)	68.9	72.2	NS
I can identify patients at risk for misuse of pain meds (#4)	58.6	72.2	NS
Will prescribe opioids when other treatments are ineffective (#3)	55.2	55.6	NS
I am confident in ability to manage pain patients (#2)	37.9	55.6	NS
I am satisfied with transition notes from pain center (#9)	27.5	35.3	NS
Dissatisfied with communication with pain specialists (#6)	17.2	33.3	NS
The consistent approach of my practice has helped me feel comfortable in prescribing opioids (#10)	27.5	16.7	NS

^βPercent rating either "strongly agree," or "agree" on 1=strongly agree to 5=strongly disagree scale.

Table 19. 1-year pre-post comparisons of providers in the **Generalist** group on the Opioid Therapy Survey responses (% strong agree and agree; N=18).^β

Opioid Therapy Survey Items	Baseline	Follow-up	p [‡]
Treating pain patients is a problem in my practice (#1)	72.3	88.9	NS
I am willing to prescribe opioids with support from pain clinic (#7)	77.7	88.9	NS
I fear patients will become addicted when prescribed opioids (#8)	72.2	72.2	NS
I am dissatisfied with communication with pain specialists (#6)	44.5	33.3	X ² =27.5 **
I would likely prescribe opioids when other treatments are ineffective (#3)	50.0	55.6	NS
I follow a recommended opioid therapy protocol (#5)	51.7	75.8	NS
I am confident in ability to manage pain patients (#2)	38.9	55.6	NS
I can identify patients at risk for misuse of pain meds (#4)	55.6	72.2	NS
I am satisfied with transition notes from pain center (#9)	17.6	35.3	NS
The consistent approach of my practice has helped me feel comfortable in prescribing opioids (#10)	16.7	16.7	NS

^βPercent rating either "strongly agree," or "agree" on 1=strongly agree to 5=strongly disagree scale.

* p<0.05; ** p<0.01; *** p<0.001

Table 20. 1-year pre-post comparisons of providers in the **Specialist** group on the Opioid Therapy Survey responses (% strong agree and agree; N=29).[§]

Opioid Therapy Survey Items	Baseline	Follow-up	p [‡]
Treating pain patients is a problem in my practice (#1)	82.8	79.3	X ² =21.4 **
I am willing to prescribe opioids with support from pain clinic (#7)	72.4	79.3	NS
I fear patients will become addicted when prescribed opioids (#8)	79.3	68.9	NS
I am dissatisfied with communication with pain specialists (#6)	69.0	17.2	X ² =36.0 **
I would likely prescribe opioids when other treatments are ineffective (#3)	55.2	55.2	NS
I follow a recommended opioid therapy protocol (#5)	51.7	75.8	NS
I am confident in ability to manage pain patients (#2)	41.3	82.7	X ² =25.8 *
I can identify patients at risk for misuse of pain meds (#4)	34.5	58.6	X ² =18.3 *
I am satisfied with transition notes from pain center (#9)	6.8	27.5	X ² =37.5 ***
The consistent approach of my practice has helped me feel comfortable in prescribing opioids (#10)	3.4	27.5	X ² =31.1 **

[§]Percent rating either "strongly agree," or "agree" on 1=strongly agree to 5=strongly disagree scale.

* p<0.05; ** p<0.01; *** p<0.001

APPENDIX

(Provider and Patient Questionnaires)

1. Provider Background Questionnaire
2. Concerns About Analgesic Prescription
3. General Health Questionnaire
4. Opioid Therapy Survey
5. Test of Opioid Knowledge
6. Monthly phone interview questions
7. Patient exit Interview questions
8. Provider exit study questions

Background Questionnaire

Instructions:

The following confidential questions help us to understand your experience working in primary care. Please answer as honestly as possible.

1. Degree

_____ M.D. _____ P.A. _____ N.P. _____ Other (please specify)

2. Sex:

_____ Female _____ Male

3. Ethnicity:

Please indicate with which group you most closely identify.

_____ African American, Caribbean American or African

_____ Asian American or Asian

_____ Caucasian

_____ European American or European

_____ Hispanic/Latino

_____ Native American

_____ Pacific Islander

_____ Middle Eastern American or Middle Eastern

_____ Other (please specify)

4. Please indicate which statement best describes you:

_____ Working full-time _____ Working part-time

5. How many hours per week do you typically work? _____ Hours

6. How many hours per week are you engaged in clinical practice? _____ Hours

7. How many years have you worked in your field? _____ Years

8. Approximately how many patients do you see in an average week?

_____ Patients per week

9. How would you best describe your practice location?

_____ Rural _____ Urban _____ A combination of urban and rural

10. Do you have any specialty education or training in chronic pain management?

_____ Yes _____ No

If yes, please indicate what type of training below:

11. How much stress have you experienced, in general, in the PAST WEEK?

(Please circle)

No
Stress 1 2 3 4 5 6 7 8 9 10 Worst
Stress
Possible

12. How much *work-related* stress have you experienced in the PAST WEEK?

(Please circle)

No
Stress 1 2 3 4 5 6 7 8 9 10 Worst
Stress
Possible

13. How satisfied have you been about your work in the PAST WEEK?

(Please circle)

Not at all
Satisfied 1 2 3 4 5 6 7 8 9 10 Completely
Satisfied

14. Based on the past week alone, how many hours did you sleep on a typical night?

_____ Hours

15. How many days *per week* do you typically engage in physical exercise for at least 30 minutes? _____ Days

16. Please rate the importance you place on reducing patients' pain in your practice.

(Please circle)

Not
Important 1 2 3 4 5 6 7 8 9 10 Extremely
Important

17. How much does patients' pain or distress interfere with your ability to carry out your work?

(Please circle)

Not at all 1 2 3 4 5 6 7 8 9 10 Completely

For the next two questions, please rate how true you believe each statement to be with regard to your work.

18. I feel emotionally drained from my work.

(Please circle)

Never 1 2 3 4 5 6 7 8 9 10 All of the
Time

19. I feel that I am positively influencing the lives of other people through my work.

(Please circle)

Never 1 2 3 4 5 6 7 8 9 10 All of the
Time

Concerns About Analgesic Prescription

Below are a number of statements about pain and pain medications. Considering your experience and beliefs about these statements please rate how often you believe these statements are true for you. Chose any rating between 0 (never) to 5 (always).

0=Never True	1=Almost Never True	2=Seldom True	3=Often True	4=Almost Always True	5=Always True
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1	I believe that opioids are an effective treatment for patients with chronic non-malignant pain.	0	1	2	3	4	5
2	I believe that I am more likely to prescribe an opioid when the patient is very distressed.	0	1	2	3	4	5
3	I feel sufficiently trained in the prescription of opioids to patients experiencing chronic non-malignant pain	0	1	2	3	4	5
4	I am concerned that if I prescribe opioids to non-malignant pain patients I will be committed to this treatment for the long term.	0	1	2	3	4	5
5	I feel that I will incur additional workload by prescribing opioid medications to patients	0	1	2	3	4	5
6	I believe that patients will be non-adherent to their prescribed medications	0	1	2	3	4	5
7	I am concerned that patients may become addicted to strong opioids	0	1	2	3	4	5
8	I am concerned about scrutiny or professional sanction for prescribing opioid analgesics	0	1	2	3	4	5
9	I feel pressured by patients to prescribe something for their pain	0	1	2	3	4	5
10	I believe that chronic pain is more of a social or emotional problem than a medical one.	0	1	2	3	4	5
11	I believe that medication diversion is likely to occur when patients are prescribed strong opioid medications	0	1	2	3	4	5
12	I am concerned about the potential for adverse drug-drug interactions in polymedicated patients	0	1	2	3	4	5
13	Medication misuse is a real risk when patients are prescribed strong opioid analgesics	0	1	2	3	4	5
14	I find patients with chronic pain very stressful to deal with.	0	1	2	3	4	5
15	I lack confidence in the area of prescribing analgesics for chronic pain.	0	1	2	3	4	5
16	I see no option but to prescribe opioid analgesics for	0	1	2	3	4	5

	some patients						
17	I worry about prescribing opioid analgesics because they impair clear thinking for my patients.	0	1	2	3	4	5
18	I worry about prescribing opioid analgesics because they are sedating or can cause confusion.	0	1	2	3	4	5
19	I worry that prescribing opioid analgesics may harm my patients.	0	1	2	3	4	5
20	I feel that cases of inappropriate medical use of opioids in the media discourage me from prescribing these drugs.	0	1	2	3	4	5
21	I am reluctant to prescribe opioids in patients with no clear diagnosis.	0	1	2	3	4	5
22	I worry that my patients may develop physical dependence on opioid analgesics.	0	1	2	3	4	5

General Health Questionnaire

We want to know how your health has been in general over that last few weeks. Please read the questions below and each of the four possible answers. Circle the response that best applies to you. Thanks you for answering all the questions. Have you recently:

1. Been able to concentrate on what you're doing?

Better than usual Same as usual Less than usual Much less than usual

2. Lost much sleep over worry?

Not at all No more than usual Rather more than usual Much more than usual

3. Felt you were playing a useful part in things?

More so than usual Same as usual Less than usual Much less than usual

4. Felt capable of making decisions about things?

More so than usual Same as usual Less than usual Much less than usual

5. Felt constantly under strain?

Not at all No more than usual Rather more than usual Much more than usual

6. Felt you couldn't overcome your difficulties?

Not at all No more than usual Rather more than usual Much more than usual

7. Been able to enjoy your normal day-to-day activities?

More so than usual Same as usual Less than usual Much less than usual

8. Been able to face up to your problems?

More so than usual Same as usual Less than usual Much less than usual

9. Been feeling unhappy and depressed?

Not at all No more than usual Rather more than usual Much more than usual

10. Been losing confidence in yourself?

Not at all No more than usual Rather more than usual Much more than usual

11. Been thinking of yourself as a worthless person?

Not at all No more than usual Rather more than usual Much more than usual

12. Been feeling reasonably happy, all things considered?

Opioid Therapy Survey

Name: _____ Date: _____

Age: _____ Gender: M F

Years since highest degree (e.g., MD): _____

Please answer the following questions with

1=Strongly Agree; 2=Agree; 3=Uncertain/Neutral; 4=Disagree; 5=Strongly Disagree:

1. Treatment of chronic pain is a problem in my practice. 1 2 3 4 5
2. I am confident in my ability to manage a patient with chronic pain. 1 2 3 4 5
3. I would likely prescribe opioids for chronic pain when other treatments are ineffective. 1 2 3 4 5
4. I am satisfied that I can identify patients who are at risk for misuse of pain medication. 1 2 3 4 5
5. I follow a defined protocol of an opioid agreement, risk assessment and regular urine drug screens once I make the decision to prescribe opioids. 1 2 3 4 5
6. I am dissatisfied with the communication between the Pain Center and my practice regarding the treatment of chronic pain patients. 1 2 3 4 5
7. I am willing to prescribe opioids for patients referred from the Pain Center with their support and direction. 1 2 3 4 5
8. I fear patients will become addicted when prescribed opioids for pain. 1 2 3 4 5
9. I am satisfied with the transition notes from the Pain Center. 1 2 3 4 5
10. The consistent approach to chronic opioid therapy through the Pain Center and my practice has helped me to feel comfortable in prescribing opioids for chronic pain. 1 2 3 4 5

Test of Opioid Knowledge

This short test asks you to consider current knowledge of opioid analgesics and recommended “best prescribing practice” as you now understand it. For each question below circle the single best answer from the four provided.

1. What percentage of patients taking opioids will experience at least one adverse side effect?
 - a) 60%
 - b) 70%
 - c) 80%
 - d) 90%
2. What does the following statement define?
“A state of adaption in which exposure to a drug induces changes that result in a diminution of one of the drugs effect over time.”
 - a) Withdrawal
 - b) Tolerance
 - c) Addiction
 - d) Dependence
3. What percentage of babies born to women taking chronic daily opioids show symptoms of drug withdrawal?
 - a) 45%
 - b) 50%
 - c) 55%
 - d) 60%
4. Which one of the following is a clinical feature of opioid toxicity?
 - a) Mydriasis
 - b) Anxiety
 - c) Rhinorrhea
 - d) Myoclonic jerks
5. Which of the following is common sign of opioid withdrawal?
 - a) Lacrimation
 - b) Pinpoint pupils
 - c) Confusion
 - d) Slow respiration

6. It is recommended that patients on long-term opioid treatment should be reviewed at least:
- Weekly
 - Monthly
 - Every two months
 - Every three months
7. Opioid therapy should be reconsidered when:
- side effects occur
 - if after an upwards adjustment of dose, pain relief is not achieved
 - addiction is suspected
 - after two or three upward adjustments of dose, pain relief is not achieved.
8. Immediate release opioid preparations may be considered:
- In cases of intermittent, transient severe pain where the patient is pain free between episodes
 - For transient exacerbations of pain that is otherwise reasonably controlled
 - For incident pain (e.g., weight bearing)
 - Only a and b
9. Long-term administration of opioids is associated with endocrine impairment which lead to the following (circle the incorrect answer):
- Hypogonadism
 - Amenorrhea
 - Increased libido
 - Infertility
10. Behaviors such as drug hoarding, attempts to obtain extra supplies, and request for early prescriptions or increased dose, that cease when pain is relieved is referred to as:
- Pseudoaddiction
 - Addiction
 - Physical dependence
 - Tolerance
11. Tramadol:
- Should only be used in cancer patients
 - Has mu receptor effects depending on dose
 - Can be administered both orally and transdermally
 - Can be used safely in patients with recent history of opioid misuse

12. Which one of the following is a risk of opioid misuse:

- a) Patient gender
- b) Years of education
- c) Poor social support
- d) Age

13. If addiction risk factors are detected:

- a) Patient should not receive any opioid therapy
- b) Patient should receive opioid therapy as normal
- c) Patient should be given only weak opioids
- d) Patient should be closely monitored and supported while using opioids

14. Which of the following statements are correct?

- a) Injectable opioids should not be used for the management of persistent pain except in extraordinary conditions
- b) Both oral and injectable opioids can be used for the management of persistent pain
- c) Injectable opioids should only be used when oral opioids have been ineffective
- d) Injectable opioids can be used for persistent pain when requested by the patient

15. What does the following statement define?

“A state of adaptation that is manifested by a withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.”

- a) Psychological dependence
- b) Physical dependence
- c) Addiction
- d) Tolerance

16. Which of the following is correct?

- a) Women of child bearing age receiving opioid therapy should be advised against conceiving
- b) Pregnant women should never be prescribed opioids
- c) Both of the above
- d) The possibility of having to treat neonatal withdrawal syndrome should not rule out the use of opioids in pregnancy

17. The principal treatment outcome(s) for chronic opioid therapy should be improvement in:

- a) Physical function
- b) Social function
- c) Pain relief
- d) Psychological function

18. Advice from or referral to a specialized service should be considered:

- a) If current problem drug use or problem alcohol use is suspected
- b) If the patient has a history of problem drug or problem alcohol use
- c) If the patient has a relevant psychiatric problem
- d) Only a and b

19. Which of the following factors preclude the use of opioids:

- a) Current psychosis
- b) Current risk of suicide
- c) No objective findings that support the patients pain complaint
- d) None of the above

20. Which of the following are appropriate uses of opioids:

- a) As a sleeping aid
- b) To reduce anxiety
- c) Both of the above
- d) None of the above

21. For patients with neuropathic pain opioid therapy should only be considered:

- a) After the use of co-analgesics such as antidepressants or anticonvulsants
- b) After the use of non-opioid analgesics such as acetaminophen or NSAIDs.
- c) After neither of the above
- d) After both of the above

22. If opioids were started while the patient is in the hospital:

- a) Complete discontinuation of opioids should be considered upon discharge from the hospital
- b) Outpatient prescriptions should always be provided by the patient's PCP
- c) An agreement should be made between the hospital and the patient's PCP about which one should provide the repeat prescription
- d) Repeat prescriptions should be available from both the hospital and the PCP

23. Under which conditions should patients treated with opioids should receive counseling regarding driving:

- a) If their use constitutes drug misuse or dependency
- b) If they have just started treatment
- c) If their dose of opioids has been recently adjusted upwards
- d) All of the above

24. During assessment for opioid therapy, screening for risk factors should include:

- a) Depression
- b) Substance misuse
- c) All other medications being used
- d) Urine toxicology
- e) All of the above

25. Which is the best way to arrange the initial dosing for opioid therapy in a opioid naïve patient?

- a) Start with a relatively low dose
- b) Start with a dose that is likely to be effective
- c) Choose a starting dose based on the severity of the patients pain
- d) Start with a high dose and reduce it if this causes intolerable side effects

MONTHLY PHONE INTERVIEW

NAME: _____ TODAY'S DATE: _____

Thank you for participating in the Primary Care Pain Study. As you know, this study asks that you complete survey information once a month. We would appreciate your response to the following questions concerning your impressions of your pain.

- 1. What is your level of pain now?
 0 1 2 3 4 5 6 7 8 9 10
 No Pain Worse Possible Pain
- 2. What is your average level of pain over the past month?
 0 1 2 3 4 5 6 7 8 9 10
 No Pain Worse Possible Pain
- 3. How much has your pain interfered with the following?
 - a. Routine daily activities 0 1 2 3 4 5 6 7 8 9 10
 No interference Extreme interference
 - b. Social activities 0 1 2 3 4 5 6 7 8 9 10
 No interference Extreme interference
 - c. Outdoor and recreational activities
 0 1 2 3 4 5 6 7 8 9 10
 No interference Extreme interference
 - d. Sleep
 0 1 2 3 4 5 6 7 8 9 10
 No interference Extreme interference
 - e. Appetite
 0 1 2 3 4 5 6 7 8 9 10
 No interference Extreme interference
 - f. Ability to work
 0 1 2 3 4 5 6 7 8 9 10
 No interference Extreme interference
- 4. How much has your pain affected your mood (depression, anxiety, irritability)?
 0 1 2 3 4 5 6 7 8 9 10
 None/stable mood Worse Possible Mood
- 5. Are you currently taking pain medication? Yes No
 What medications are you taking for your pain? _____

6. Do you have any of the following side effects? (circle) constipation dizziness, dry mouth, headache, itching, confusion, nausea, nightmares, sneezing, sweating, visual problems, weakness
Other: _____

- 7. Have you seen your doctor or gone to the clinic this past month Yes No # of times _____
- 8. Have you gone to the emergency room this past month? Yes No # of times _____
- 9. Have you been in the hospital this past month? Yes No # of days _____
- 10. Anything else you would like to tell me?

Thanks you very much for completing this survey.

Patient Exit Interview

Participant ID _____

Today's Date: _____

Thank you for participating in the OPERA (*Opioid Prescription Evaluation and Risk Assessment*) study. Please consider your overall experience in this study and select only one response for each question. On a scale of 1-5, how much do you agree or disagree with the following statements?

1. I am satisfied with the way this study tracked my pain.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

2. I am satisfied with the way this study tracked my various activities.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

3. I am satisfied with the way this study tracked my medication use and side effects.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

4. This study was an added burden to me.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

5. The monthly interview questions about my use of medication helped me to be more compliant with my medication.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

6. This study helped to keep me out of the emergency room and hospital.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

7. The feedback to my doctor about my progress did **NOT** help my care.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

8. The electronic pain assessment program was useful in identifying important aspects of my pain. (Check if not applicable_____).

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

9. In general, monthly phone calls to patients like me help to prevent future problems.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

10. My doctor seems comfortable in prescribing my pain medication.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

11. My doctor seems comfortable in managing my pain.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

12. My quality of life has improved over the course of this study.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

13. My relationship with my doctor has **NOT** improved

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

14. My family and friends are more comfortable with my medication use

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

Please include any other comments you have about this study. Thank you.

Provider Exit Study Questions

Provider ID _____ Date: _____

Thank you for participating in the OPERA (*Opioid Prescription Evaluation and Risk Assessment*) study. Please consider your overall experience in this study and circle only one response for each question. On a scale of 1-5, how much do you agree or disagree with the following statements?

1. Treatment of chronic pain is a problem in my practice.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

2. I am confident in my ability to manage a patient with chronic pain.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

3. I would likely prescribe opioids for chronic pain when other treatments are ineffective.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

4. I am satisfied that I can identify patients who are at risk for misuse of pain medication.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

5. I follow a defined protocol of an opioid agreement, risk assessment and regular urine drug screens once I make the decision to prescribe opioids.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

6. I am dissatisfied with the communication between the Pain Center and my practice regarding the treatment of chronic pain patients.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

7. I am willing to prescribe opioids for patients referred from the Pain Center with their support and direction.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

8. I fear patients will become addicted when prescribed opioids for pain.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

9. I am satisfied with the transition notes from the Pain Center.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

10. The consistent approach to chronic opioid therapy through the Pain Center and my practice has helped me to feel comfortable in prescribing opioids for chronic pain.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

11. I am satisfied with the way this study tracked my patient's pain.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

12. I am satisfied with the way this study tracked my patient's medication use and side effects.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

13. This study was an added burden to me.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

14. This study helped my patients to be more compliant with their medication.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

15. This study helped to keep my patients out of the emergency room and hospital.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

16. The electronic pain assessment program (painCAS) was useful in identifying important aspects of my patients' pain and risk of misuse.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree

17. In general, the monthly patient phone calls help to prevent future problems.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree