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# Do Patients Know They Are on Pain Medication Agreements? Results from a Sample of High-Risk Patients on Chronic Opioid Therapy

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## Abstract

**Objective—**Pain medicine agreements are frequently recommended for use with high-risk patients on chronic opioid therapy. We assessed how consistently pain medicine agreements were used and whether patients were aware that they had signed a pain medicine agreement in a sample of HIV-infected adults prescribed chronic opioid treatment.

**Design—**We recruited patients from a longitudinal cohort of community-based HIV-infected adults and recruited the patients' Primary Care Providers (PCPs). Patients completed in-person interviews and PCPs completed mail-based questionnaires about the patients' use of pain medicine agreements. Among patients prescribed chronic opioid therapy, we analyzed the prevalence of pain medicine agreement use, patient factors associated with their use, and agreement between patient and clinician reports of pain agreements.

**Results—**We had 84 patient-clinician dyads, representing 38 PCPs. 72.8% of patients fit diagnostic criteria for a lifetime substance use disorder. PCPs reported using pain medicine agreements with 42.9% of patients. Patients with pain medicine agreements were more likely to be smokers (91.7% vs. 58.3%; p=.001) and had higher mean scores on the Screener and Opioid Assessment for Patients with Pain ($\mu$=26.0 (SD=9.7) vs. $\mu$=19.5 (SD=9.3); p=.003). Patients reported having a pain medicine agreement with a sensitivity of 61.1% and a specificity of 64.6%.

**Conclusion—**In a high risk sample, clinicians were using agreements at a low rate, but were more likely to use them with patients at highest risk of misuse. Patients exhibited low awareness of whether they signed a pain medicine agreement.

### Keywords

pain medicine agreements; opioid analgesics; chronic pain; patient-clinician agreement

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The study authors have no conflicts of interest to report.

## Introduction

The use of prescription opioid analgesics to treat chronic non-cancer pain (CNPC) is increasing [1, 2]. At the same time, nonmedical use and abuse [3-5], emergency department visits [6], and overdoses [7] related to opioid analgesics have increased, raising concerns about the risks associated with prescribing opioid analgesics for the long-term treatment of CNPC [8].

Written pain medicine agreements, also referred to as pain contracts or opioid treatment agreements, are recommended as a tool to manage the risks of opioid misuse among patients on long-term opioid therapy [9-11]. Pain medicine agreements are documents signed by the patient and clinician that outline the expectations and obligations of both during opioid treatment [12]. They are considered by some to be a form of "informed consent" and a tool to promote shared decision-making [12, 13]. The use of pain medicine agreements is controversial for a number of reasons, including the lack of evidence of their efficacy in reducing opioid misuse [9, 14], the high literacy level required to understand standard pain agreements [15], and findings indicating that clinicians' judgments about who is at risk for misuse are inaccurate and may be influenced by unconscious bias [16, 17]. Some have expressed concerns that the use of pain agreements may erode relationships between patients and clinicians [13, 18].

Communication between patients and their clinicians regarding clinical decision-making is often inadequate and barriers to communication are heightened in vulnerable patients [19-22]. Previous studies suggest that patients and their health care providers are often discordant in their reports of information discussed in clinic visits, and patients are frequently unable to recall what they were told by their clinicians immediately after medical visits [19-24].

To our knowledge, no studies have examined whether patients who sign pain medication agreements are aware that they have done so. In order to investigate this, we surveyed a sample of indigent HIV-infected individuals prescribed opioid analgesics for chronic pain; we also surveyed their primary care providers (PCPs) about their patient enrolled in the study. We assessed the prevalence of using pain medication agreements and the correspondence between patient and PCP reports of having a pain medicine agreement.

## Methods

### Sample recruitment

We described recruitment of the study participants previously [16, 17]. Briefly, patient-participants ("patients") were enrolled into a two-year longitudinal study of pain and the use and misuse of opioid analgesics (the Pain Study). We recruited participants into the Pain Study from the pre-existing Research on Access to Care in the Homeless (REACH) Study, a longitudinal cohort of HIV-infected indigent adults who were recruited from the community in San Francisco using probability sampling [25]. One year into the Pain Study, we contacted the PCP named by each Pain Study participant who was active in follow-up, provided consent for us to contact their PCP, and named a physician (MD or DO), Nurse Practitioner (NP), or Physician Assistant (PA) who provided them regular care. We restricted the sample to patients/PCP dyads for which the PCP completed a questionnaire about their patient and the patient (according to the PCP) had been prescribed an opioid analgesic for more than one consecutive month in the prior year. To compare PCP reports about their patient (measured over the past year) to patient self-reports (measured every 3 months), we selected the patient quarterly interview that occurred closest in time to the date

the PCP completed the patient questionnaire and included the three prior quarterly interviews.

## Procedures

All procedures with patients took place at the UCSF Clinical and Translational Research Institute's Tenderloin Clinical Research Center (TCRC), a University-affiliated, community-based research field site in the Tenderloin neighborhood in San Francisco. Patients completed structured interviews every 3 months. We recruited and collected data from PCPs through postal mail using a protocol based on Dillman's Tailored Design Method [26]. PCPs completed one questionnaire about each of their patients in the Pain Study and one questionnaire about themselves. The Institutional Review Board at UCSF approved study protocols and both patients and PCPs provided written informed consent.

## Measures

**Reports of pain medicine agreements—**We asked PCPs, "Did [this patient] have a written pain medicine agreement active anytime during the past year?" At each quarterly interview with patients, we asked, "Do you currently have a pain medicine agreement with any healthcare provider, clinic, hospital, or Emergency Room?" Study interviewers defined a pain medicine agreement as "something that you sign that describes the conditions, or rules, for using pain medicines." Interviewers explained that pain medicine agreements are sometimes called "contracts" and that some healthcare providers have patients sign these agreements/contracts when they give them prescriptions for pain medicines. We asked participants who endorsed pain medicine agreements with whom they had an agreement: their primary healthcare clinic, an Emergency Room, a provider who specializes in pain or a pain clinic, and/or any other provider. To describe the pattern of reporting pain medicine agreements, we classified patients as never, intermittently (at least one but not all quarterly interviews), or consistently (at all quarterly interviews) endorsing a pain medicine agreement with their PCP over the year. Because it is possible that pain medicine agreements were enacted during the year, we also classified patients as to whether they endorsed a pain medicine agreement at the quarterly interview that occurred closest in time to the date the PCP completed the questionnaire about their patient.

**Patient self-reported variables—**At enrollment, patients self-reported their age, sex at birth (male vs. female), race (white, African-American, or other/ mixed race), education (<high school vs. ≥high school), and income in the past 30 days. We administered the Brief Pain Inventory at each quarterly interview [27]. Patients reported the intensity of their pain "at its worst" over the past week on a 0-to-10 scale and, based on results from a cut-point analysis [28, 29], we categorized patients as having severe pain (vs. none, mild or moderate pain) during the year if they reported scores ranging from 8-10 at any quarterly interview. At each quarterly interview, we asked patients to identify opioid analgesics prescribed to them in the past 3 months to treat pain, and who prescribed the analgesics.

Patients reported their smoking status at enrollment (currently smoking every day or some days vs. not currently smoking). We administered the Diagnostic Interview Schedule IV (DIS-IV) alcohol and drug (including cocaine, amphetamines, and heroin/opiates) modules at enrollment [30]. We categorized patients as qualifying for a lifetime history of an alcohol use disorder (AUD) or substance use disorder (SUD; for cocaine, amphetamines, and/or heroin/opiates) if they met criteria for lifetime abuse and/or dependence, as defined by the DSM-IV [31]. At enrollment, we administered the 14-item Screener on Opioid Assessment for Patients with Pain (SOAPP-14), a tool designed to screen for patients at risk for developing opioid analgesic misuse during long-term opioid therapy [32].

### Data analysis

We tested bivariate associations between patient characteristics and PCP report of whether the patient had a pain medicine agreement in the past year. We tested the agreement between PCP and patient reports of having a pain medicine agreement using Cohen's kappa. We set the PCP's report of whether or not the patient had a pain medicine agreement as the gold standard and calculated the sensitivity (proportion of patients endorsing a pain medicine agreement among those whose PCPs reported that they had one) and specificity (proportion of patients reporting that they did not have a pain medicine agreement among those who did not have one according their PCP) of patient reports.

## Results

Of the 296 participants enrolled in the Pain Study, 240 were active in follow-up one year into the study, provided consent to contact their PCPs, and identified a physician, NP, or PA who provided them ongoing medical care. The 240 participants identified 90 unique providers. Of the 90 PCPs, 61 (67.8%) returned questionnaires corresponding to 169 (70.4%) patients. Of the 169 patients, 84 (49.7%) were reported by their PCPs to have been prescribed opioid analgesics to be taken regularly for more than a month during the past year. A total of 38 PCPs provided data for these 84 patients, with PCPs each contributing data for 1 to 9 patients. These 84 patients and their 38 PCPs compose the sample for this analysis.

Over half of the patients (57.1%) were male and the average age was 50.3 years. Half (51.2%) of the patients were African American, 35.7% were white, and 13.1% were mixed or other race. Three-fourths (72.8%) fit diagnostic criteria for a lifetime history of a heroin, cocaine or methamphetamine use disorder. All patients reported having opioid analgesics prescribed to them, with only 4 reporting prescriptions from a provider other than their PCP. A total of 40 patients endorsed having a pain medicine agreement and 39 reported a pain agreement with their PCP. (Table 1)

According to their PCPs, 42.9% (n=36) of patients who were prescribed opioid analgesics to treat chronic pain had signed a pain medicine agreement. Patients with pain medicine agreements (compared to those without) were more likely to be smokers (p=.001) and had higher mean SOAPP scores (p=.003). (Table 1)

Of the 36 patients whose PCP reported having a pain medicine agreement, 16.7% consistently endorsed, 44.4% intermittently endorsed and 38.9% never endorsed having one during the study year. Of the 48 patients without a pain medicine agreement, 4.2% consistently endorsed, 31.2% intermittently endorsed, and 64.6% never endorsed having one. When we categorized participants as ever endorsing (i.e. consistently or intermittently) a pain medicine agreement with their PCP over the year versus never endorsing one, we found patients reported pain agreements with a sensitivity of 61.1%, specificity of 64.6%, and had only fair agreement with their PCP (kappa=0.25) [33]. When we evaluated patients' reports of pain agreements occurring at the quarterly interview closest in time to their PCP reports, we found poor agreement between patient and PCP reports (kappa=0.18) [33]. (Table 2)

## Discussion

In this sample of patients at high risk for opioid analgesic misuse who were receiving regular opioid analgesic prescriptions from their PCPs, we found that 42.9% had signed a pain medication agreement. However, less than 20% of patients who had signed a pain agreement with their PCP consistently reported having one over the course of a year. A third

of patients reported having a pain agreement when their PCP indicated that they had not signed one. These findings may provide a partial explanation for why there is a lack of evidence demonstrating effectiveness of pain medicine agreements in mitigating opioid analgesic misuse [14].

This study involved a sample of HIV-infected indigent patients with high rates of substance use disorders. All patients were receiving chronic opioid treatment from their primary care providers and most were receiving care in the safety net health care system [17], where access to pain specialists is limited [28]. We chose this sample because it represents a patient population at high risk for developing misuse of opioid analgesics [34-36], and for who pain medicine agreements and other risk management strategies are often suggested [9-11]. Patients with substance use disorders report high rates of pain [37, 38] and are prescribed long-term opioid therapy at increased frequency compared with patients without such histories [39, 40].

Patients in this study demonstrated low awareness of having pain agreements. This finding may reflect poor patient comprehension of pain agreement documents, which are typically written at a high literacy level [15], or barriers to communication between patients and their PCPs. Previous work has shown that communication difficulties tend to be heightened for racial and ethnic minority groups and those with low socio-economic status and/or low literacy [20, 22, 41]. Several studies have demonstrated that patients have difficulty understanding information given to them by their clinicians, and are frequently unable to recall what they were told immediately after medical visits [23]. Further, although we do not have detailed information on clinic visits for this study, it is likely that discussions about chronic pain and risk management competed with other priorities given the complexities of and comorbidities within the sample patient population [42, 43].

Our findings are similar to research demonstrating that many patients, especially those with low educational attainment, low literacy, or minority race status, exhibit poor comprehension of informed consent in clinical practice [44, 45]. Patients' limited understanding of informed consent may reflect the complex language of consent forms [46, 47] or poor clinician training about obtaining informed consent [48]. Successful interventions to improve patients' comprehension of informed consent, which may be transferable to pain agreements, have included improving the readability of consent forms, offering patients additional written materials, and using teach-back methods that involve iteratively testing comprehension and providing feedback until full comprehension is achieved [49, 50].

Our finding that patients reported having pain medicine agreements inconsistently over the study year may have resulted from PCPs enacting pain agreements part-way through the year, although we found low sensitivity for patients' reports occurring closest in time to their PCPs' reports. It is also possible that PCPs asked patients to sign pain agreements at one point in time without having ongoing conversations about the agreements during opioid treatment. To explain our finding that one-third of patients without a pain medicine agreement (according to PCPs) reported having one with their PCP, we considered the possibility that patients were receiving opioid analgesics from and had pain agreements with other providers. However, our data do not support this possibility.

Despite the high risk profile of our study sample, clinicians reported relatively low rates of using pain medicine agreements. While low, the rates were higher than reported in previous studies of pain managements in primary care [51-55]. Similar to previous work, PCPs in our study appeared to have preferentially used pain agreements with patients at higher risk for

misuse [54, 55]. The low use of pain agreements overall may reflect PCPs' lack of confidence in their efficacy [14].

We note several limitations. We relied on self-report for all data. While we believe patient self-report of whether or not they have a pain medicine agreement with their PCP provides a representation of their understanding, we relied on PCP reports of pain agreements and set this report as our gold standard. Over half of patient questionnaires were completed by clinicians who referred to their patients' charts (data not shown), but clinicians may have been inaccurate. One-third of recruited PCPs, representing one-third of the patient sample, chose not to enroll in the study, raising the possibility of selection bias. The majority of patients in our sample had histories of alcohol or substance use disorders, which may have impacted their ability to remember conversations about pain agreements. However, as these are the patients at highest risk of opioid misuse, they may represent a population for whom pain agreements are most recommended.

## Conclusions

Pain medicine agreements are often recommended when prescribing opioid analgesics to patients at high risk of misuse [9-11], but there is limited evidence for their effectiveness [9, 14]. This study suggests that high risk patients who are prescribed opioid analgesics to treat chronic pain may not be aware whether they have signed a pain medicine agreement, making it unlikely that pain agreements could affect behavior. Strategies that have improved the informed consent process, including use of language at or below a sixth grade reading level and use of teach-back methods to assess and improve comprehension [49, 50], may help increase patient understanding of pain medicine agreements, but conclusions on the effectiveness of such strategies awaits further study.

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## Table 1

Patient self-reported characteristics for the overall sample and stratified by whether the patient had a pain medicine agreement, as reported by their primary care provider (PCP) (N(%) unless noted)

| | Overall sample (N=84) | PCP reported patient had a pain agreement (N=36) | PCP reported patient did not have a pain agreement (N=48) | p-value[a] |
|---|---|---|---|---|
| Age (mean (SD)) | 50.3 (7.4) | 51.5 (5.1) | 49.3 (8.6) | 0.19 |
| Income (median (IQR)) | $900 (99) | $900 (110) | $901 (84) | 0.55 |
| Male sex at birth | 48 (57.1) | 23 (63.9) | 25 (52.1) | 0.28 |
| Race | | | | |
| white | 30 (34.9) | 13 (36.1) | 17 (35.4) | 0.54 |
| African-American | 43 (51.2) | 20 (55.6) | 23 (47.9) | |
| other or mixed race | 11 (13.1) | 3 (8.3) | 8 (16.6) | |
| Less than high school education | 27 (32.5) | 11 (30.6) | 16 (34.0) | 0.74 |
| Pain of severe intensity [b] | 72 (85.7) | 34 (94.4) | 38 (79.2) | 0.06 |
| Prescription for long-acting opioid [b] | 49 (58.3) | 20 (55.6) | 29 (60.4) | 0.66 |
| Current smoker at baseline | 61 (72.6) | 33 (91.7) | 28 (58.3) | 0.001 |
| Lifetime history of substance use disorder [c] | 59 (72.8) | 26 (72.2) | 33 (73.3) | 0.91 |
| Lifetime history of alcohol use disorder [d] | 48 (58.5) | 23 (63.9) | 25 (54.4) | 0.38 |
| Screener and Opioid Assessment for Patients with Pain total score (mean (SD)) | 22.3 (10.0) | 26.0 (9.7) | 19.5 (9.3) | 0.003 |

[a] p-value from test of association between patient characteristic and whether the patient had a pain medicine agreement (reported by PCPs)

[b] ever endorsed at quarterly interviews during year covered by the PCP's report

[c] n=81; DIS-IV diagnosis of abuse or dependence relating to cocaine, methamphetamine, and/or heroin/opiates

[d] n=82; DIS-IV diagnosis of abuse or dependence relating to alcohol

## Table 2

Sensitivity and specificity of patient self-reports and agreement with their PCPs about whether they had a pain medicine agreement, with PCP report set as the gold standard

| Patient report of pain medicine agreements [a] | Sensitivity | Specificity | % Agreement | Kappa |
|---|---|---|---|---|
| Patient reported a pain agreement with their PCP at one or more interviews during the study year | 61.1% | 64.6% | 63.1% | 0.25 |
| Patient reported pain agreement with their PCP at the interview closest in time to their PCP's report | 36.1% | 81.3% | 61.9% | 0.18 |

[a] Compared to PCP report of whether the patient had a written pain medicine agreement during the past year