# Managing Chronic Pain in People With or in Recovery From Substance Use Disorders

## A Review of the Literature*

**CONTENTS**



TREATMENT IMPROVEMENT PROTOCOL (TIP) SERIES **54**

*This document is available online only (http://www.kap.samhsa.gov) and supports TIP 54, Managing Chronic Pain in People With or in Recovery From Substance Use Disorders.

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Substance Abuse and Mental Health Services Administration
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www.samhsa.gov

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# Section 1—A Review of the Literature

## Overview

This literature review summarizes the research that supports the Substance Abuse and Mental Health Services Administration's Treatment Improvement Protocol (TIP) 54, *Managing Chronic Pain in Adults With or in Recovery From Substance Use Disorders*. The TIP provides pointed, practical guidance to primary care physicians and other clinicians who treat chronic noncancer pain (CNCP) in people with a history of substance use disorders (SUDs). The TIP does not recommend an approach that is radically different from treating CNCP in the general population. Rather, it acknowledges that the uncertainties and challenges that come with managing CNCP in any patient may be exacerbated when the patient has an SUD.

This literature review presents the evidence on which the TIP's recommendations are based. Where sufficient evidence does not exist, the TIP is based on the clinical experience and judgment of the TIP's consensus panel of experts.

This literature review is available online only. It will be updated online every 6 months for 5 years from the date of initial publication.

## The Prevalence of Pain

Although no exact figures exist, chronic pain appears to be prevalent in the United States. The 2006 National Center for Health Statistics (NCHS) report on health in the United States contains a special supplement on pain, in which NCHS reports that 54 percent of adults ages 20 and older had pain that lasted from 3 months to more than a year. Sixty percent of people ages 65 and older reported pain that lasted more than a year.

Chronic pain is common among people with SUDs (Larson et al., 2007; Peles, Schreiber, Gordon, & Adelson, 2005; Rosenblum et al., 2003; Sheu et al., 2008). Rosenblum et al. (2003) found that the prevalence of chronic pain among people with SUDs was at least as high as in the general population and that CNCP was especially common among patients on methadone maintenance therapy (MMT).

### *Many Challenges, Limited Research*

There is scant research to guide treatment for CNCP in patients with or in recovery from SUDs. One research limitation concerning the long-term safety and effectiveness of opioid therapy for the treatment of chronic pain is the short duration of trials (Højsted & Sjøgren, 2007). In a review of randomized controlled trials of oral opioids, Moore and McQuay (2005) found that, of 35 trials, the longest was 8 weeks. Most were 3 days to 4 weeks. None of these studies looked at addiction as an adverse event. As one researcher said, "[T]here remains a significant disconnect between the limited data on long-term opioid therapy [for CNCP] and the firm conclusions many are willing to assert" (Katz, 2007, p. 306).

A further concern is whether patients—regardless of their SUD status before beginning opioid therapy—will develop iatrogenic addiction as a result of opioid therapy. No conclusive evidence

shows that patients with SUDs or histories of SUDs are more at risk of becoming addicted to prescription opioids than patients without such backgrounds; nor is there evidence demonstrating that these patients can be safely treated with opioids. (No studies within the parameters of this literature review endorse withholding opioid medications from patients *solely* on the basis of past or current SUDs. However, clinical experience shows that, in some patients, the risks of opioid therapy outweigh the benefits.)

There are no clear figures on the incidence of addiction in chronic opioid therapy, in part because, as Ballantyne (2007, p. 53) points out, "[W]e have no accepted definitions or criteria for addiction arising during opioid pain treatment." The *Diagnostic and Statistical Manual of Mental Disorders,* Fourth Edition, Text Revision (DSM-IV-TR) (American Psychiatric Association [APA], 2000), does not use the term *addiction* and instead uses *substance dependence*. However, DSM-IV-TR (APA, 2000) criteria for substance dependence may not be fitting in a differential diagnosis of patients on chronic opioid therapy. DSM-IV-TR (APA, 2000) criteria for substance dependence include the criteria of tolerance and withdrawal, but most patients on chronic opioid therapy will develop increased tolerance to or become physically dependent on these medications. To the pain expert, however, expected physical dependence to medication does not equate with addiction or abuse (Passik & Kirsh, 2005). Therefore, studies that define addiction using the DSM-IV-TR (APA, 2000) criteria may not be relevant to pain practitioners seeking criteria with which to assess the risks opioids pose to their patients (Banta-Green, Merrill, Doyle, Boudreau, & Calsyn, 2009; Savage, 2002). Without the DSM-IV-TR (APA, 2000) criteria, however, clinicians are left with vague means to assess SUDs that may arise with chronic opioid therapy. (This issue is discussed further in Tools To Predict Aberrant Drug-Related Behaviors and Screen for Future Analgesic Abuse.)

To standardize usage, the American Academy of Pain Medicine (AAPM), the American Pain Society (APS), and the American Society of Addiction Medicine issued a consensus statement in 2001 on the use of the terms *addiction, physical dependence, tolerance*, and other terms common to addiction and pain practitioners:

> **addiction.** A primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.
>
> **physical dependence.** A state of adaptation that is manifested by a drug-class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, or administration of an antagonist.
>
> **tolerance.** A state of adaptation in which exposure to a substance induces changes that result in a diminution of one or more of the substance's effects over time.

*Recovery* is another term without a commonly agreed-on meaning. As noted by the Betty Ford Institute (2007), although the public—especially the population in recovery—does not require a standard or formal definition to lead substance-free lives, the research community has been hindered by this lack of a definition. Without a shared definition and accepted measures, research

on current and theoretical recovery models cannot be compared, inhibiting an understanding of recovery processes and outcomes.

Laudet (2007) identified some problems that stem from a lack of a definition of recovery: (1) difficulty measuring the success of treatment services; (2) hindered clinical practice and research, including great variation in treatment outcomes; (3) no estimates of how many people are "in recovery"; and (4) continued negative misperceptions, as the public remains focused on addiction and abuse, not recovery.

Many studies included in this review do not define key terms such as *addiction* and *abuse*. Others use entirely different terms such as *substance misuse* or *dependence*. Similarly, terms used to describe race or ethnicity, aberrant drug-related behaviors (ADRBs), socioeconomic status, and other concepts vary. When key terms are defined, they are frequently defined differently across studies, making comparisons difficult. Because some studies interchanged *Black* with *African American* and *White* with *Caucasian*, this literature review uses the terms Black and White regardless of which terms the authors used. Other terms could not be confidently standardized, so they are used as researchers presented them.

## Tools To Assess Pain

The Visual Analog Scale (VAS) and other one-dimensional measures for pain were developed to assess levels of acute pain, not CNCP. Many one-dimensional tools typically used to assess pain levels have been studied and validated in years past for acute pain. VAS, for example, has been in use since 1923 and is accepted as valid. Tools that measure pain level are regularly used in patients with CNCP. Although the use of these tools is widespread, a literature review by Green et al. (2003) reported several studies that showed that clinicians agree with a patient's reported pain severity only when the patient reports low pain severity. When a patient reports high pain severity, clinicians tend to discount patient reports. Lorenz et al. (2009) found that the Numeric Rating Scale (NRS) was highly accurate if administered properly, but was associated with an underestimation of pain if administered informally by practitioners. Research by Shi, Wang, Mendoza, Pandya, and Cleeland (2009) found that levels of a patient's pain reported during clinic visits are lower than pain recalled from the week before the appointment, suggesting that assessing the level of worst pain recalled in the past week may provide a closer assessment of a patient's pain experience.

Researchers and clinicians widely agree that, because CNCP is a multifaceted condition, initial and followup assessments must include more than a measure of a patient's current levels of pain intensity (Brunton, 2004; Haefeli & Elfering, 2006; Karoly, Ruehlman, Aiken, Todd, & Newton, 2006; Sullivan & Ferrell, 2005). If used alone, one-dimensional pain scales cannot provide an adequate understanding of the toll that CNCP takes on a patient's well-being, nor can they assess other factors that influence a patient's experience of pain and suffering, including functionality, coping strategies, depression, and co-occurring disorders. Exhibit 1 lists commonly used tools to measure pain levels and multidimensional aspects of pain. Information on how to obtain the tools is located in Appendix B of the TIP.

**Exhibit 1 Tools To Measure One-Dimensional and Multidimensional Aspects of Pain**

| Type | Tool |
|---|---|
| One-Dimensional Tools (pain level) | Faces Pain Scale (FPS)<br>NRS<br>Verbal Rating Scale/Graphic Rating Scale<br>VAS |
| Multidimensional Tools | Brief Pain Inventory<br>McGill Pain Questionnaire |

Primm et al. (2004) identified many studies conducted in the 1990s that sought to determine whether various assessment tools for pain were valid across cultures, nationalities, and languages. No single tool has been shown to be appropriate for use with all populations, so clinicians should make informed decisions about which tool, if any, to use (Bird, 2003; Brunton, 2004). Several recent studies have looked at whether pain measurement tools are valid across particular demographics. Some of these tools are discussed below.

### *Pain Assessment Tools and Patients With Cognitive Impairments*

Few studies have attempted to assess the validity of pain intensity scales with minority patients with cognitive impairments (CIs) (Ware, Epps, Herr, & Packard, 2006). Ware et al. (2006) evaluated four pain assessment tools for reliability and validity with patients who were cognitively impaired and members of minorities: FPS-Revised (FPS-R), Verbal Descriptor Scale (VDS), NRS, and Iowa Pain Thermometer (IPT). The study consisted of 68 subjects (68 percent female) in an acute-care facility in Georgia. Seventy-four percent were Black, 16 percent were Hispanic, and 10 percent were Asian. Fifty-nine percent had no CI, 18 percent had mild CI, 22 percent had moderate CI, and 1 had severe CI. (CI was defined as a score of 23 or less on the Mini Mental Status Exam.) Ware et al. (2006) modified two of the scales somewhat for their study group. VDS used six descriptive terms (no pain, mild pain, moderate pain, severe pain, extreme pain, and most intense pain imaginable), which were assigned a score of 0–6. FPS-R was enlarged, and the facial markings were darkened and slightly separated so that patients could see them better. The authors found that all subjects could complete FPS-R, that 94 percent could complete both IPT and VDS, and that 90 percent could complete NRS. Subjects who were cognitively impaired preferred the FPS-R tool, whereas subjects who were cognitively intact preferred NRS. Regarding validity, the tools all correlated highly with one another, with the exception of FPS-R. The low degree to which this tool correlated with the others suggests, as have other studies, that the FPS-R measures pain affect (how pain is emotionally experienced) as well as pain intensity. The four tools were found to be valid and reliable with older minority adults with CI.

Smith (2005) reviewed the literature about tools that could be used to assess pain in adults with nonverbal CIs. She looked at six tools that required administration by trained clinicians: (1) Comfort Checklist, (2) Discomfort Scale in Dementia of the Alzheimer's Type, (3) Observed Pain Behavior Scale, (4) Checklist of Nonverbal Pain Indicators, (5) Pain Assessment in Advanced Dementia, and (6) Pain Assessment in the Dementing Elderly. She also looked at two tools that rely on reports from caregivers: Proxy Pain Questionnaire and Assessment of

Discomfort in Dementia. Smith concludes that knowing the patient well is a crucial component of interpreting these tools correctly.

### *Pain Assessment Tools and Ethnic Minorities*

Recent studies have examined ethnic differences in pain intensity and assessment of pain intensity, as well as whether basic pain tools are valid across ethnic groups.

Cintron and Morrison (2006) reviewed literature for 1990 to 2005 and found 35 studies concerning minorities and aspects of pain and pain management. Three studies looked at the effects of patient race/ethnicity on pain assessment, none of which examined CNCP. One study suggested Blacks and Hispanics were more likely than Whites to have their pain underestimated by clinicians; one found that minority patients were less likely than Whites to have their pain recorded; and a third found that patient race/ethnicity was not a predictor of disparities in pain assessment between patients and clinicians in emergency departments.

Edwards, Moric, Husfeldt, Buvanendran, and Ivankovich (2005), in a numerically balanced and closely matched group of 291 White, Hispanic, and Black participants, found no differences among groups regarding their reports of pain severity, depression, psychopathology, or pain-related disability. In this study, there were no significant differences among ethnic groups regarding VAS scores. Ethnic minorities were found to rely more on prayer and hoping and on religious activities as coping strategies, which correlated with higher pain scores and was a predictor of disability. The correlation could indicate that people in greater pain prayed more or that prayer as a coping strategy displaced more successful coping methods.

Portenoy, Ugarte, Fuller, and Haas (2004) surveyed 1,335 people with pain to explore the relationship between ethnicity and CNCP. Subjects were 34 percent White, 33 percent Black, and 33 percent Hispanic. The study consisted of a telephone survey conducted in English or Spanish. Respondents with chronic pain were asked about pain severity (0–10 scale), pain interference (0–10 on several factors), elements of pain management (e.g., insurance, medications), socioeconomic status (SES), and demographics. The researchers found a large variation in pain-related attitudes and perceptions, but these varied largely within, not across, groups. They found that socioeconomic disadvantages—low income, unemployment, and low education level—were more important than race or ethnicity in predicting disabling pain. Disabling pain was defined as pain of high intensity that brought high interference. The researchers conclude that low SES and education level are risk factors for disabling pain; racial and ethnic minorities are more likely to possess those risk factors.

### *Pain Assessment Tools and Geriatric Patients*

Few studies have examined CNCP in adults ages 60 and older, and comparatively few elderly people are in pain management programs (Barber & Gibson, 2009; Chodosh, Ferrell, Shekelle, & Wenger, 2001). Clinicians should not assume that geriatric patients who do not report pain are pain free (Chodosh et al., 2001; Veterans Health Administration [VHA], 2004). As with younger patients, geriatric patients should be encouraged to self-report pain (VHA, 2004). Older patients, however, may have hearing or vision impairments that affect their ability to accurately report

their pain using certain tools. For example, an older adult's poor vision may make using FPS difficult (Charette & Ferrell, 2007).

One-dimensional pain severity measures are reliable with geriatric patients, but they may have limited use with people who have low levels of education, hearing and vision impairments, and moderate to advanced CIs. Elderly people tend to report their current pain, so these tools may not elicit information about past or recurring pain (Charette & Ferrell, 2007).

### *Pain Assessment Tools and Women*

No studies within the parameters of this literature review examined whether gender affected the validity of pain rating tools.

## Barriers to Treatment

Although studies on ethnic differences in the prevalence and experience of pain are inconclusive, considerable evidence documents disparities in the treatment of pain. Cintron and Morrison (2006) reviewed literature from 1990 to 2005 on pain assessment and treatment. They found that 10 of 17 studies reported significant disparities in prescribing pain medications, with Blacks and Hispanics more likely to have their pain underestimated by clinicians and more likely to receive fewer or no analgesic medications compared with Whites. The researchers found no studies that addressed whether clinicians are less likely to prescribe opioids to minority patients because of concerns about diversion or drug abuse. (Minority patients are not more likely to misuse opioids.) Cintron and Morrison (2006) cited a 2005 study by Cicero, Inciardi, and Munoz showing that more than 91 percent of OxyContin abuse is by Whites.) According to Cintron and Morrison (2006), "We do not know whether provider race or ethnicity affects analgesic prescription patterns or whether racial and ethnic concordance between providers and patients modulates the disparities seen in prescription patterns" (p. 1469). Cintron and Morrison's review showed more attention to patient-related barriers, such as that Blacks wait longer than Whites and others to seek treatment, and less attention to system-related barriers, such as minorities' relative lack of access to pain specialists and to pharmacies that stock prescribed analgesic medication compared with access of Whites.

Green, Todd, Lebovits, and Francis (2006) note many predictors of pain care disparities. These include SES, race and ethnicity, language, geography, age, gender, health literacy, and comorbidities, including SUDs.

Brennan, Carr, and Cousins (2007) describe cultural/attitudinal, educational, legal, and system-related barriers to adequate pain treatment. Cultural barriers include the belief that pain is inevitable, ordained, or deserved; that pain is harmless or even beneficial; and that people who complain of pain are weak. Other barriers described by Brennan et al. (2007) include "opiophobia" and misconceptions among patients and clinicians regarding addiction and opioid impairment of quality of life. Lack of adequate clinician training in pain management can perpetuate these myths. Primm et al. (2004) note that language barriers can prevent an adequate assessment.

Green, Baker, and Ndao-Brumblay (2004) looked specifically at access to pain treatment, sources of health care, attitudes and perceptions about pain management, and referrals and use patterns in White and Black patients with chronic pain. Green et al. (2004) sent a 50-item questionnaire to 354 Blacks and 300 Whites who had been pain clinic patients for at least 2 years. The final sample comprised 237 respondents (57 percent White and 68 percent women; the percentage of female respondents was the same for both races). Blacks were, on average, younger than Whites (ages 47 and 53, respectively). Whites had higher annual household incomes, employment rates, and education levels compared with Blacks. Both groups had similar duration of pain before treatment at the pain clinic, but Blacks were more likely to have waited years to seek treatment, rather than the few months reported by Whites. Green et al. (2004) found that 58 percent of the respondents asked to be referred to a pain specialist, with no difference between the groups. However, 68 percent of Blacks felt they should have been referred to a pain specialist earlier than they had been, compared with 56 percent of Whites. Regarding the issue of access to pain management, Green et al. (2004) found that most respondents (90 percent) had health insurance. Black respondents (33 percent) were more likely than White respondents (12 percent) to have Medicaid. If Medicaid does not cover certain pain treatment modalities or provides less coverage for them, this type of insurance could be a factor in the quality of pain treatment that Medicaid patients receive. Fewer Whites reported difficulty paying for health care in the past year, and more Blacks reported that chronic pain was a major reason for financial hardship, perhaps resulting from co-payments. The study found that Blacks were less likely than Whites to have a primary care clinician (87 percent and 91 percent, respectively), but Blacks used the emergency department as a regular source of care more than Whites (11.5 percent and 3.0 percent).

Nampiaparampil, Nampiaparampil, and Harden (2009) conducted a randomized controlled study of the role of physician demographics (ethnicity, gender, specialty, and professional status) on their decisions regarding treatment plans for intense low back pain. Subjects were given one of two fictitious patient profiles that were similar in all respects except that one was presented as a Black male patient with Medicaid and the other was presented as a White male patient with Blue Cross health insurance. The researchers asked physicians to rank on a 0–10 scale ("not at all likely" to "extremely likely") their likelihood of prescribing various treatments, such as medications (including opioids), physical therapy, nerve blocks, surgery, and others. Subjects were also asked to rate the likelihood that (1) they would prescribe a stronger pain medication if the patient's pain remained severe, (2) the patient would be satisfied with treatment, and (3) the patient had overreported symptoms. Ninety of 92 physicians returned the surveys. Patient ethnicity/SES did not significantly affect treatment decisions; however, some physician characteristics did reach significance. Surgeons were more likely than others to favor surgery ($p = .01$), physical therapy ($p = .004$), and exercise ($p = .004$). Men were more likely to prescribe physical therapy ($p = .02$), whereas women were more likely to prescribe psychological counseling ($p = .02$). Surgeons, psychiatrists, and neurologists were less likely than other physicians to prescribe stronger pain medications if the patient's pain had not subsided with the initial treatment modality ($p = .02$).

## Screening Tools for Substance Use Disorders

A full discussion of screening and assessment for SUDs is outside the scope of this literature review. However, more indepth information on these issues can be found in other publications, such as:

- TIP 47, *Substance Abuse: Clinical Issues in Intensive Outpatient Treatment* (CSAT, 2006).
- *Helping Patients Who Drink Too Much: A Clinician's Guide* (National Institute on Alcohol Abuse and Alcoholism, 2007).
- TIP 42, *Substance Abuse Treatment for Persons With Co-Occurring Disorders* (CSAT, 2005).

## Co-Occurring Conditions and Disorders

Research shows well-established associations among CNCP, SUDs, and co-occurring disorders such as depression, anxiety, post-traumatic stress disorder, and somatoform disorders. In a study of 500 consecutive pain patients, Manchikanti et al. (2007) found that patients with depression abused drugs more than did patients without depression (12 percent and 5 percent, respectively).

Wasan et al. (2007) found a relationship between psychiatric history and ADRB among 228 patients on opioid therapy for CNCP, who were followed for 6 months. Psychiatric morbidity of subjects was determined as high or low according to patient scores on an abbreviated version of the Prescription Drug Use Questionnaire (PDUQ; Compton, Darakjian, & Miotto, 1998) (only the five questions relating to psychiatric health were used). Answering "yes" to two or more questions constituted a high score; one yes response was a low score. Wasan et al. (2007) developed the Drug Misuse Index based on several quantitative tools—the Screener and Opioid Assessment for Patients with Pain, Current Opioid Misuse Measure, and Prescription Opioid Therapy Questionnaire—and a urine drug test to assess patients for opioid misuse and ADRBs. Those with high scores were younger, had taken opioids longer, reported more often that pain interferes with their relationships, and showed more ADRBs than those with low scores. The two groups did not differ significantly in their reports of pain intensity. The study suggests that psychiatric morbidity is a risk factor for misuse of prescription opioids.

Saffier, Colombo, Brown, Mundt, and Fleming (2007) used the Addiction Severity Index (ASI) to assess comorbid conditions in 908 patients on opioid treatment for chronic pain. They found that patients with chronic pain have higher rates of psychiatric comorbidity (27 percent reported lifetime depression, anxiety, or suicidal thoughts or attempts) than the general population (3 percent).

## Tools To Predict Aberrant Drug-Related Behaviors and Screen for Future Analgesic Abuse

Several studies since 2002 have considered the relationship between ADRBs and addiction. Some studies sought to identify predictors of aberrant behaviors and to develop screens for risk of future opioid abuse, whereas others examined the relationship between aberrant behaviors and current opioid misuse or abuse (Exhibit 2).

**Exhibit 2 Studies by Type of Tool**

| Type of Tool | Study |
|---|---|
| Assess Risk of Future Abuse | Adams et al., 2004<br>Atluri & Sudarshan, 2004<br>Butler, Budman, Fernandez, & Jamison, 2004<br>Friedman, Li, & Mehrotra, 2003<br>Michna et al., 2004<br>Webster & Webster, 2005 |
| Assess Current Opioid Abuse | Butler et al., 2007<br>Lusher, Elander, Bevan, Telfer, & Burton, 2006<br>Manchikanti, Cash, Damron, Manchukonda, Pampati, & McManus, 2006<br>Manchikanti, Singh, Damron, Beyer, & Pampati, 2003<br>Passik, Kirsh, Donaghy, & Portenoy, 2006<br>Weaver & Schnoll, 2002<br>Wu et al., 2006 |

### *Assess Risk of Future Abuse*

#### Self-Administered Tools

Most of the tools to screen for risk of future abuse in pain patients are self-administered. Adams et al. (2004) developed and piloted the Pain Medication Questionnaire (PMQ), a 26-item instrument based on literature and clinician experience that asks patients to rate their behavior on a five-point scale with verbal ("agree" to "disagree") rather than numeric (0 to 4) anchors. PMQ scores in the top third of possible scores indicate high risk, and those falling in the bottom third are low risk. The authors administered PMQ to 84 patients (60 percent on opioid therapy) at a pain treatment center. Although PMQ asks about potentially aberrant behaviors regarding medications in general and not opioid analgesics in particular, the authors predicted that respondents with high PMQ scores would be at a high risk of opioid abuse. PMQ scores were analyzed with several other variables, such as functional ability, psychosocial distress, and pain level. Adams et al. (2004) found that patients taking opioids had significantly higher PMQ scores than subjects who were not taking opioids. Also, high PMQ scores were associated with greater physical disability and impairment, as well as psychosocial distress such as depression, unemployment, and a history of SUDs. However, the authors report only a limited association between PMQ score and substance abuse.

Holmes et al. (2006) administered PMQ to a larger sample of patients with chronic pain and found that the high-scoring PMQ group was 2.6 times more likely to have a known substance use problem and 3.2 times more likely to ask for early prescription opioid refills than were other groups. The researchers also looked at the relationship between PMQ scores and treatment outcomes. Of the 271 patients who started the interdisciplinary pain management program, 39 completed PMQ before and after treatment. The mean PMQ scores of these patients decreased from 22.71 ($SD = 9.1$) before treatment to a 17.82 ($SD = 8.64$) after treatment, in effect moving from the moderate-risk range to the low-risk range. Considered separately, the mean PMQ scores of all three groups (high, moderate, and low risks) decreased with successful completion of the pain treatment program, with the high-risk group showing the greatest gains, from a mean of

35.00 (*SD* = 7.56) before treatment to a mean of 22.94 (*SD* = 10.31) after treatment. Buelow, Haggard, and Gatchel (2009) validated a 23-item version of the PMQ and found a decline in pretreatment and posttreatment risk, particularly for patients who started treatment in a high-risk group.

The Screener and Opioid Assessment for Patients with Pain (SOAPP) (Butler et al., 2004) predicts which patients with chronic pain may develop problems with chronic opioid therapy. SOAPP is a 24-item questionnaire, which, like PMQ, was developed by a panel of practitioners. Butler et al. (2004) administered SOAPP to 175 hospital-based patients who were taking opioids for pain or who were being considered for chronic opioid therapy. Six months after completing SOAPP, 95 patients were assessed using PDUQ, urine drug tests, and clinician assessment of serious drug use behavior. Of the 44 patients who displayed at least one ADRB, 31 scored higher than 11 on PDUQ (classifying them as "positive" for an SUD), 8 others were believed by 2 staff members to have serious drug problems, and 5 had positive urine drug test results. The authors conclude that SOAPP can be a valuable tool in assessing which patients are likely to have difficulty managing their medications.

Højsted and Sjøgren (2007) found PMQ (Adams et al., 2004) to be thoroughly validated and the SOAPP tool (Butler et al., 2004) "reasonably well validated" (p. 507). Banta-Green et al. (2009) cautioned that the PDUQ was developed in specialty pain clinics; they found low internal validity with the tool administered to patients treated for pain in a general practice setting.

Friedman et al. (2003) reviewed several substance use questionnaires (e.g., CAGE, Michigan Alcoholism Screening Test) to develop a 14-item, self-administered, true/false screening tool for addiction risk. Test subjects were 48 chronic pain patients in an urban hospital; all but 1 were on opioid therapy; and 14 had recent histories of SUDs. Results showed that "questions that related to smoking helped identify substance abusers from pain patients on chronic opioids" (p. 184) and that prior treatment for SUDs is a risk factor for opioid abuse in the CNCP population. In this study, family history of substance abuse, psychosocial criteria, history of emotional or physical abuse, and employment status did not correlate with opioid abuse.

Webster and Webster (2005) point out two issues with brief screening tools: they typically identify which patients already have SUDs, not who will develop them, and they do not screen specifically for opioid abuse (p. 437). Webster and Webster (2005) developed the Opioid Risk Tool (ORT) to determine which patients on opioids for CNCP are likely to develop ADRBs. The authors weighted many responses by gender, according to known links between the risk factors for abuse (personal and family history of SUDs, age, preadolescent history of sexual abuse, and certain psychiatric disorders) and substance abuse. In this study, abuse meant "the deliberate overuse of controlled or illegal substances" and addiction meant "the pursuit of such substances for no medical purposes, despite resulting physical or psychological harm" (p. 433). One hundred eighty-five patients completed ORT. Webster and Webster (2005) found that ORT showed a high degree of sensitivity, predicting the probability a patient will display 1 or more of 23 aberrant behaviors if prescribed opioids for chronic pain. Although it was not clear whether any aberrant behavior was the result of the undertreatment of pain, the authors tried to avoid undertreating pain, giving patients the optimal level of opioids for pain relief, balanced by side effects. Clinicians saw subjects weekly until optimal pain relief was achieved; then they saw

patients monthly. Optimal pain management for some subjects required several hundred milligrams of morphine equivalents. Study subjects were monitored for a year for ADRBs.

Webster and Webster (2005) classified patients into three risks groups based on their ORT scores (high, moderate, and low). Eighteen subjects scored as low risk (67 percent were women); 123, as moderate risk (59 percent were women); and 44, as high risk (52 percent were women). More than 94 percent of low-risk subjects displayed no aberrant behavior. Of those patients at high risk, 91 percent displayed an aberrant behavior. Webster and Webster (2005) found that obtaining opioids from other clinicians was the most common aberrant behavior for both men and women, followed by unauthorized dose escalation and abnormal blood or urine drug test results. The three risk groups showed no differences according to gender, age, or pain type. The authors report that 38 subjects had their opioid therapy discontinued before the study ended because of nonadherence to agreed use (11 because of alcohol or illegal substance abuse, 21 because of nonadherence to prescribed medications, and 6 because of nonadherence to clinic procedures). The authors note that the prevalence of ADRBs among CNCP patients undergoing opioid therapy was much higher than expected: 41 percent of the total sample showed at least one aberrant behavior.

**Clinician-Administered Tools**

Michna et al. (2004) theorized that chronic pain patients with histories of SUD and legal problems would more likely display ADRBs with opioid therapy than would other patients. Their study involved 6 clinicians treating 145 patients with opioids for chronic pain. Opioid treatment among the study group averaged 5 years. Michna et al. (2004) were concerned with particular ADRBs described by Chabal, Erjavec, Jacobson, Mariano, and Chaney (1997):

- Multiple unsanctioned escalations in dose
- Episodes of lost or stolen prescriptions
- Frequent unscheduled visits to the pain center emergency department
- Excessive phone calls to the clinic
- Concern expressed by a significant other about patient's use of opioids
- Unanticipated positive results in urine drug tests

Michna et al. (2004) developed three questions to predict the likelihood of these ADRBs:

- Is there a history of alcohol or substance abuse in your family, even among your grandparents, aunts, or uncles?
- Have you ever had a problem with drugs or alcohol or attended Alcoholics Anonymous or Narcotics Anonymous meetings?
- Have you ever had any legal problems or been charged with driving while intoxicated or driving under the influence (DUI)?

Patients with 0 or 1 yes responses were classified as low risk, and patients with 2 or 3 yes responses were defined as high risk ($n = 45$). Patients who were determined to be high risk displayed more ADRBs, especially positive urine drug test results and reports of lost or stolen prescriptions, than the low-risk patients. Factors most predictive of subjects in the high-risk group were a positive urine drug test result, a high dose of opioid medication, and the need for a

cigarette within an hour of waking: these factors identified 71.7 percent of the high-risk group. A third of the high-risk patients did not show ADRBs, suggesting that these factors were better used to "predict minimal aberrant drug behavior in low-risk patients than to predict drug behavior problems in high-risk patients" (Michna et al., 2004, p. 256). The authors also found that age, gender, marital status, pain site, average pain intensity, pain duration, and duration of opioid use were not significant predictors of high-risk classification. More predictive were a family history of substance abuse and a personal history of illicit drug use. The authors do not suggest that being at risk for these behaviors can predict addiction or that patients with an addiction history cannot or should not be prescribed opioids, but they suggest careful monitoring of high-risk patients. The authors also recommend that an initial assessment include urine drug tests and determination of both the need for higher doses of opioids and dependence on nicotine.

Atluri and Sudarshan (2004) conducted a retrospective study to identify clinician-rated predictors of prescription opioid abuse and to determine whether these predictors could be formulated into an opioid abuse screening tool for clinicians. This study examined the records of 107 chronic pain patients who had been dismissed from the clinic for prescription opioid misuse ("inappropriate use group") and compared them with a control group comprising 103 randomly selected patients treated with opioids for chronic pain who did *not* exhibit evidence of opioid misuse. Atluri and Sudarshan (2004) used six categories of patient behavior to predict opioid abuse:

- Focus on opioids
- Opioid overuse
- Other substance use
- Low-functional status
- Unclear etiology of pain
- Exaggeration of pain

Following a multivariate analysis that showed an association between each criterion and opioid abuse, the authors developed a screening tool based on these items. Each positive finding scored as 1 point, allowing patients to be scored on a 0–6 scale. The researchers considered 3 or fewer points to be low risk and 4 to 6 points to indicate a high risk of opioid abuse. In the control group, the average score was 2. Seventy-seven percent of patients in the inappropriate use group scored more than 3 points, compared with 16 percent in the control group. Twenty-three percent of patients in the inappropriate use group scored as low risk, compared with 84 percent in the control group. The authors conclude that careful patient selection is crucial to successful opioid therapy, and they caution that "entertaining the concept of pseudoaddiction in chronic pain without considering the likelihood of opioid abuse may lead to a poor outcome" (Atluri & Sudarshan, 2004, p. 337).

### *Assess Current Opioid Abuse*

Fear of iatrogenic opioid addiction or of exacerbating a patient's current substance use problem is one reason clinicians hesitate to prescribe opioid medications for chronic pain patients. Differences in definitions and study parameters make comparing studies on this subject impossible.

Manchikanti et al. (2003) modified the tool developed by Atluri and Sudarshan (2004) to assess the nonmedical use of prescription medications in 500 patients in an interventional pain clinic. Manchikanti et al. (2003) administered the 27-item tool to 100 patients with a history of drug abuse ("abuse group") and to 400 patients without this history ("non-abuse group") to determine the tool's ability to differentiate these two groups. The authors defined abuse as misuse of controlled substances, including obtaining controlled substances from other sources, escalating doses without approval from the prescribing clinician, and violating the controlled substance agreement. All patients had been taking controlled substances before being admitted to the practice. Demographics were categorized according to gender, age, weight, duration of pain, mode of pain onset (traumatic or nontraumatic), and history of previous spine injury. No measured demographic factors were significant, except for age and mode of pain onset. The researchers found that three sections of the tool that looked at behavioral aspects (excessive opioid needs, deception or lying to obtain controlled substances, and current or prior intentional doctor shopping) predicted abuse or non-abuse in 95 percent of cases. In this study, Manchikanti et al. (2003) found that a history of substance (including alcohol) abuse was not a predictor of opioid abuse.

Manchikanti, Cash, et al. (2006) looked at the prevalence of opioid abuse and illicit drug use in 500 chronic pain patients and again found no significant relationship between current opioid abuse and a history of illegal drug use. Prevalence of current opioid abuse was associated with the mode of onset of pain, as well as with the number of regions of the body affected with pain. Sixteen percent of people whose pain began suddenly with an auto accident abused opioids, compared with 11 percent whose pain came gradually and 4 percent whose pain came from other incidents. The prevalence of opioid abuse increased as the number of body regions in pain increased. Of patients who were abusing opioids, 5 percent reported pain in one region, 11 percent reported pain in two regions, and 14 percent reported pain in three regions. In this study, 84 percent of patients reported pain in two or more regions. The duration of pain was not a predictor of patient opioid abuse.

All 500 patients underwent rapid urine drug testing, which detected the presence of nine drugs. Drug test results were considered positive if one of these drugs was detected. When amphetamine, methamphetamine, and marijuana were detected, patients were retested to rule out false-positive results. Manchikanti, Cash, et al. (2006) found that illegal drug use was higher in people younger than 45. They found no evidence of illegal drug use in patients older than 65. Of those subjects who used illicit drugs in the past, 51 percent currently used illicit drugs. The researchers found that 16 percent of the patients using illicit drugs were also abusing prescription opioids.

Wu et al. (2006) conducted a prospective study of 136 patients using opioids who were followed monthly for 1 year and observed for addiction behaviors using the Addiction Behaviors Checklist (ABC). This study did not attempt to assess risk, but rather documented problem behavior. ABC is a list of 20 questions about addiction behaviors manifested since the last appointment and up to and including the current appointment. Clinicians completed ABC through patient interviews, observations, and chart review. Responses were not weighted. Scores 3 or higher indicate that patients need careful observing, including frequent urine drug tests. Thirty-eight subjects did not complete the full year because of nonadherence or for other reasons.

The subjects of this study were all veterans in a major metropolitan Department of Veterans Affairs (VA) pain clinic. All but eight subjects were men. Some clinic patients were not admitted into the study because they showed signs of problem opioid use, which may have resulted in fewer problems manifesting in the study subjects. Researchers examined interrater reliability and validity indicators for individual items and sum score and introduced sensitivity and specificity results for cutoff scores. At the 4-month visit, patients were also tested with PDUQ (Compton et al., 1998) to establish validity for ABC.

Global clinical judgment was a key outcome criterion in the study (Wu et al., 2006). At each visit, after administering ABC, clinicians were asked, "Do you think the patient is using medications appropriately?" The researchers found ABC to be valid and reliable, with correlations between clinician global judgment about medication misuse and most ABC responses. Items most frequently associated with a negative response to the global judgment were "difficulty using medication agreement," "increased use of narcotics" (since last visit), and "patient demands for analgesic meds."

Unlike many tools that ask patients whether they have ever engaged in a particular aberrant behavior, such as taking more medication than prescribed, the Current Opioid Misuse Measure (COMM) developed by Butler et al. (2007) asks about patient behavior only in the 30 days before the appointment. They used experts to develop an initial 40-item self-administered questionnaire to measure current misuse of medication. A pilot test and retest of the tool enabled researchers to distill the original 40 items down to 17 questions that suggest which patients are misusing or abusing medications. COMM asks patients to rate drug-related behavior over the past 30 days on a 4-point scale ranging from "never" (0) to "very often" (4). Butler et al. (2007) looked at how COMM scores correlated with the Aberrant Drug Behavior Index, a measure they created based on results of several assessments, including PDUQ, urine drug tests, and clinician opinion based on a brief questionnaire about the patient. The researchers found that a cutoff score of 9 on COMM yielded a sensitivity of 0.77 and a specificity of 0.66. The researchers recommend a conservative cutoff score to err on the side of obtaining false-positive results.

To determine whether COMM could capture changes over time, the authors reassessed 86 of the original subjects 90 days after administering the initial questionnaire. In the reassessment, 4 of 26 people originally classified as misusing or abusing their medications were shown to be no longer doing so, and 9 of 60 who were originally classified as not abusing their mediations were classified as misusing or abusing their medications at the reassessment.

In the studies cited above, all researchers caution against using a single tool to exclude people—even high-risk individuals, however defined—from opioid therapy or to determine whether a patient is abusing the medications prescribed. Although DSM-IV-TR (APA, 2000) criteria defining abuse and addiction are acknowledged to be of limited use to clinicians who treat chronic pain, there is no consensus on the significance of any ADRBs (Chou et al., 2009). In other words, no history of aberrant behaviors predicts the risk of current prescription opioid abuse, and no current aberrant behavior is a clear sign of opioid abuse.

## Pain Management Guidelines

Exhibit 3 lists the formal guidelines that exist on treating chronic pain. None of these guidelines were developed specifically for patients with or in recovery from SUDs, although many issues overlap.

### Exhibit 3 Formal Guidelines and Topics Covered

| Guidelines | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clinical Guidelines for the Use of Chronic Opioid Therapy in CNCP (Chou et al., 2009) | X | X | | X | | | | | | | | | X | | X | | X |
| Assessment & Management of Chronic Pain (Institute for Clinical Systems Improvement, 2011) | X | X | X | | X | X | X | X | | | | | X | X | | X | |
| Opioids in the Management of Chronic Noncancer Pain: An Update of American Society of Interventional Pain Physicians' Guidelines (Trescot et al., 2008) | X | X | | | X | | X | | | | | | X | X | X | X | X |
| Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (Department of Veterans Affairs & Department of Defense [VA/DoD], 2010) | X | X | X | X | X | | | | | | | | X | X | X | X | X |

1 = substance use disorders
2 = co-occurring disorders
3 = contraindications/rationale for opioids
4 = tapering/detoxification
5 = pharmacological treatments by name
6 = nonpharmacological treatments
7 = adjuvant therapies
8 = complementary and alternative medicine
9 = medical marijuana
10 = methadone/naltrexone/buprenorphine maintenance therapy
11 = HIV/AIDS pain
12 = acute/perioperative pain in CNCP
13 = treatment agreements
14 = initial assessment
15 = monitoring and followup
16 = aberrant drug-related behaviors
17 = diversion and law enforcement

## Special Topics in CNCP Management

### *Episodes of Acute or Postoperative Pain*

As clinicians increasingly write prescriptions for opioids, it becomes more likely that patients needing treatment for acute pain will have been exposed to chronic opioid therapy. Very few randomized controlled trials (and none within the range of this literature review) address treating acute pain in patients who are opioid dependent and have had previous long-term exposure to licit or illicit opioids. However, it is widely suggested that these patients may require larger doses of analgesia for their acute pain and that they may need to take analgesia for acute pain longer than opioid-naïve patients (Brill, Ginosar, & Davidson, 2006; Carroll, Angst, & Clark, 2004; Mehta & Langford, 2006; Rupp & Delaney, 2004). Tolerance is only one reason CNCP patients may require more opioids for their acute pain. Progression of the disease that causes chronic pain is another possibility, as is opioid-induced hyperalgesia (Carroll et al., 2004), overexertion, and increased emotional stress (Schnoll & Weaver, 2003). Carroll et al. (2004) note that it is especially important to treat postoperative pain in CNCP patients because such patients are at increased risk of their postsurgical pain becoming chronic.

Patients with acute pain who are opioid dependent, whether they consume illicit or prescription opioids, will have similar acute pain treatment needs:

- Before surgery, patients should take their maintenance opioid dose on the day of surgery, even though they may have been advised to stop taking food and liquid the night before.
- For acute pain after surgery, patients should be prescribed enough opioids to fill their baseline need (which may be difficult to determine if the patient uses illicit opioids, such as heroin) (Brill et al., 2006; Carroll et al., 2004; Rupp & Delaney, 2004).
- After the baseline need is met, additional medication should be prescribed for pain (Brill et al., 2006; Carroll et al., 2004; Rupp & Delaney, 2004).
- Patients should be prescribed medications on a regular, not as-needed, basis (Carroll et al., 2004; Mehta & Langford, 2006).
- Predicting individual requirements to prevent opioid withdrawal and to manage postoperative pain is difficult (Carroll et al., 2004; Mehta & Langford, 2006), so this process must be managed closely.

### *HIV and Pain*

Pain in people with HIV/AIDS is prevalent and undertreated, and it is greatly undertreated in AIDS patients who have a history of injection drug use (Breitbart & DiBiase, 2002). Data are unclear about whether the prevalence of pain is greater among patients with AIDS who also have SUDs than among patients with AIDS who do not have SUDs (Swica & Breitbart, 2002).

Swica and Breitbart (2002) reviewed 14 studies on pain management in patients with HIV/AIDS and SUDs. They categorized pain associated with AIDS into three types:

- Pain directly related to HIV/AIDS, such as Kaposi's sarcoma and organomegaly

- Pain caused by HIV/AIDS therapy, such as surgery and chemotherapy
- Pain unrelated to HIV/AIDS therapy, such as disc disease and diabetic neuropathy

The researchers found that the most severe pain reported was associated with peripheral neuropathy, extensive Kaposi's sarcoma, headache, oral and pharyngeal pain, abdominal pain, chest pain, arthralgias and myalgias, and painful dermatologic conditions. Women with HIV report pain more frequently and report more intense pain than men with HIV. Women are twice as likely as men to be undertreated for pain.

Swica and Breitbart (2002) found only two clinical trials that looked at opioid analgesia for pain in HIV patients. Both small trials (44 patients and 35 patients) found that patients with moderate to severe chronic pain, including those with a history of injection drug use, could be treated safely and effectively with opioids.

Prescribers should keep in mind that many patients with AIDS are managing a complex regimen of oral medications and may appreciate the transdermal route of administration for chronic opioid therapy. In addition, opioids and adjuvants may interact with antiretroviral medications and raise the risk of toxicity (Basu, Bruce, Barry, & Altice, 2007).

### *Pain Patients in Methadone-/Buprenorphine-/Naltrexone-Assisted SUD Treatment*

Data on pain patients in medication-assisted recovery are sparse. Patients in MMT and people who actively use drugs may have developed tolerance to opioids and may need higher starting and maintenance treatment doses (Breitbart & DiBiase, 2002; Brill et al., 2006; Mehta & Langford, 2006; Peles et al., 2005). In these patients, preventing withdrawal is the first step in pain management (Breitbart & DiBiase, 2002).

Patients in medication-assisted opioid treatment may be less able to tolerate pain (Mehta & Langford, 2006) and should receive opioids for analgesia in addition to their daily maintenance treatment (Brill et al., 2006; Savage, Kirsh, & Passik, 2008). Long-acting opioids for pain should be prescribed at regular intervals, and recovery activities should be intensified (Breitbart & DiBiase, 2002; Brill et al., 2006; Mehta & Langford, 2006; Peles et al., 2005). Mehta and Langford (2006) recommend against methadone for pain for patients in MMT because of its long half-life.

### *Marijuana/Cannabinoids in the Treatment of Pain*

Recent literature on cannabinoids for pain suggests that they show little value for acute pain but hold promise for chronic pain. However, harms may outweigh benefits (Martin-Sanchez, Furukawa, Taylor, & Martin, 2009).

Five placebo-controlled studies on chronic pain used Sativex, and one used Marinol. Pain conditions studied were multiple sclerosis, rheumatoid arthritis, HIV neuropathy, and various types of chronic neuropathic pain. Most studies involved subjects whose pain conditions were not helped by other treatments. The number of subjects ranged from 20 to 125, and all studies were for less than 12 weeks. All studies showed that medications reduced pain when compared

with a placebo. Other benefits, such as improved sleep, were noted, and there were few side effects or adverse events, including intoxication.

For example, Notcutt et al. (2004) conducted the first study that looked at a sublingual spray delivery route for cannabis-based medicinal extracts. They studied tetrahydrocannabinol (THC), cannabinol, a mixture of THC and cannabinol, and a placebo as relief for 34 patients with refractory chronic pain. In this *N*-of-1 study, Notcutt et al. (2004) specifically recruited subjects who were not cannabinoid naïve. Patients self-titrated and quickly learned to titrate to optimum pain relief without intoxication. The 8-week trial showed reduced depression, better quality of sleep, and reduced pain levels.

Few studies involved smoked cannabis. Given the known health risks that accompany smoking, the fast rate the substance enters the bloodstream, and the modest pain relief demonstrated (Russo, 2008), smoked cannabis is not recommended for relief of chronic pain. Researchers call for more intense research on the role of cannabinoids in chronic pain therapy.

## Prevalence of Problems Associated With Opioid Therapy for CNCP

Højsted and Sjøgren (2007) reviewed literature from 1977 to 2006 that concerned the prevalence of problems associated with chronic opioid therapy. They found 25 reports that studied CNCP and 6 other studies dealing with opioid treatment for other conditions, such as sickle cell disease, cancer, and migraine headaches. In these studies, problems with opioids (defined as addiction, dependence, ADRBs, abuse, and misuse) were determined based on observations of aberrant behavior, results from urine drug tests, and DSM-IV-TR (APA, 2000) criteria. In this review, Højsted and Sjøgren found that looking at aberrant behavior rendered prevalence rates from 0 to 50 percent in the CNCP population. Problems with opioid use varied widely among studies using DSM-IV-TR (APA, 2000) criteria, as well, with prevalence among studies ranging from 1.9 percent to 37.0 percent. The authors note that study-to-study comparisons are difficult to make not only because researchers define addiction and other terms differently, but also because some studies compare patients with addiction problems with the entire sample (those taking and those not taking opioids), whereas others compute prevalence by comparing patients with addictions only with patients taking opioids.

In a study of 196 CNCP patients on opioid therapy (Ives et al., 2006), 32 percent of patients misused opioids. Misuse was defined as:

- Negative urine drug test results for prescribed opioids.
- Positive urine drug test results for nonprescribed opioids or controlled substances.
- Evidence that opioids were obtained from other prescribers.
- Opioid diversion.
- Forged prescriptions.
- Cocaine or amphetamines found in urine drug test results.

The average study patient was 52 years old, White, and male. All subjects signed treatment contracts agreeing not to share medications, not to abuse alcohol or illicit drugs, and to conform to other conditions. Patients were seen regularly until their pain was stabilized, and then they were monitored periodically for a year. More than 40 percent of patients who misused substances

had urine drug test results that showed cocaine or amphetamines use. Patients in this study included those whose pain was considered difficult to manage and who were suspected of misusing opioids by the referring clinician. Multivariate analysis associated misuse with age (48–54 years), past abuse of cocaine or alcohol, and a DUI or drug conviction. Pain score, race, income level, education level, depression score, disability score, and literacy level did not predict misuse.

Edlund, Sullivan, Steffick, Harris, and Wells (2007) looked at whether patients who were prescribed opioids for CNCP had higher rates of prescription opioid misuse, illegal non-opioid drug use, "problem misuse" of prescription opioids or illicit non-opioid drugs, and any problem alcohol use compared with those who do not take prescription opioids. The authors extracted data on 9,279 individuals participating in a Healthcare for Communities nationwide survey of participants in 60 U.S. communities (Sturm et al., 1999). "Opioid misuse" included using any nonprescribed opioid, as well as not using prescription opioids exactly as prescribed, in the 12 months before the survey. People with "problem opioid misuse" were defined as respondents with opioid misuse who also reported at least one of two indicators of problems: tolerance and psychological problems resulting from use (e.g., paranoia) and a loss of interest in things. Two hundred eighty-two respondents reported opioid use of at least 1 month. Edlund et al. (2007) found that opioid misuse was significantly higher in users of prescription opioids (14.5 percent) than in non-users (3.0 percent), as were rates of problem opioid misuse (7.3 percent and 0.5 percent, respectively). The researchers also found that users of prescription opioids reported more use and problem use of illicit drugs than those not taking prescription opioids (12.6 percent and 7.7 percent, respectively). However, the researchers found that depression was much more likely than prescription opioid use to be associated with both illegal drug use and problem illegal drug use.

Fishbain, Cole, Lewis, Rosomoff, and Rosomoff (2007) reviewed the 1966–2006 literature on patients with CNCP receiving opioid analgesic therapy, seeking to discover the extent to which opioid addiction occurs in these patients. These researchers analyzed 24 studies (2,507 subjects) that addressed abuse/addiction, and they calculated a combined rate of 3.27 percent. Fishbain et al. (2007) found 17 studies that excluded subjects with a history of abuse or addiction; the rate of abuse/addiction among patients with no history of abuse was 0.19 percent. The studies had varying definitions of *addiction* (e.g., "drug-seeking," "abuse," "drug problem"), with two studies defining addiction as psychological dependence or craving.

Fishbain et al. (2007) also analyzed 17 studies (2,466 subjects) addressing ADRBs, which yielded an abuse/addiction rate of 11.5 percent. Those studies excluding patients with a history of SUDs showed 0.59 percent exhibiting ADRBs. Urine drug testing resulted in a higher percentage of patients exhibiting ADRBs (20.4 percent) (no opioids in urine or opioids other than prescribed medication found) than clinician observation (11.5 percent). No studies considered undertreatment of pain as a factor. The authors conclude that a small number of patients exposed to opioids develop addiction or abuse their medications but a higher number demonstrate ADRBs or use illicit drugs or alcohol.

To examine sex differences in rates and correlates of ADRB, Back et al. (2009) administered the PMQ to 49 men and 72 women at a university outpatient pain management clinic. Of these 121 patients, 115 were taking prescription opioids for CNCP. In this study, the PMQ was modified to

include statements about selling medication, forging prescriptions, administering medications in ways other than as directed, and obtaining medications from the Internet or illicit sources. Patients were also assessed for other substance use. Patients were predominately White and had experienced CNCP for 10 years. The average age was 52.

Back et al. (2009) found that men and women in this study had high rates of taking prescription medications for reasons other than pain (41 percent men; 46 percent women) and taking more medication than prescribed (57 percent men; 50 percent women). However, only two ADRBs showed statistically significant differences by gender: saving unused medications for later use (48 percent men; 68 percent women; $p = .04$) and taking additional medications (e.g., sedatives) to increase the effectiveness of pain medications (20 percent men; 39 percent women; $p = .04$). Although women in this study reported less effective pain treatment compared with men, the effectiveness of pain treatment did not correlate with PMQ score for either men or women. Rates of ADRBs also were not associated with number of years with CNCP.

## Addiction or Pseudoaddiction?

Weismann and Haddox (1989) coined the term *pseudoaddiction* to describe ADRBs that resulted from undertreated pain, not addiction. Few studies on pseudoaddiction exist. Elander, Lusher, Bevan, Telfer, and Burton (2004) looked at addiction or pseudoaddiction as explanations for observed ADRBs. The study took place in a U.K. hospital and involved 51 patients with sickle cell disease (episodic acute pain, not chronic pain). In the study, ADRBs included arguments with staff about pain management, nonadherence to opioid therapy, tampering with analgesic delivery systems, using illicit drugs, and other commonly described aberrant behaviors, called "concern-raising" behaviors in the study. Elander et al. (2004) tried to estimate the reliability of interrater assessment of concern-raising behaviors, calculate a frequency of concern-raising behaviors, present examples of patient views of these behaviors, and examine how concern-raising behaviors were associated with other factors, such as coping strategies, DSM-IV-TR (APA, 2000) symptoms of substance dependence, pain and illness measures, sociodemographics, and problem behavior unrelated to illness. The most frequently patient self-reported behaviors were arguments with hospital staff and cannabis use outside the hospital. The researchers classified patient-reported behaviors as pain-related/pseudoaddiction or non-pain related/dependence, depending on its association with attempts to control pain. They found that concern-raising behaviors were associated with pain rather than with genuine dependence or problem behavior.

Passik et al. (2006) examined the relationship between the undertreatment of pain and rates of aberrant drug-taking behaviors in a study involving 73 patients with AIDS-related pain and a history of SUDs and 100 patients with cancer pain and no SUD history. In addition to the history of SUDs, members of the AIDS group were more likely than members of the cancer group to be male, young, members of a minority group, less educated, unemployed, and single. The AIDS group also reported more past and current psychiatric problems. Passik et al. (2006) used the Pain Management Index (PMI) to assess adequacy of pain treatment. More than 75 percent of subjects were not adequately treated for pain, and AIDS patients were significantly more likely than cancer patients to have inadequate treatment. Researchers assessed aberrant behaviors by asking open-ended questions about use of street drugs, diversion of prescription medication, misuse of prescribed medications, and other commonly acknowledged aberrant behavior. On

average, the AIDS group showed significantly more aberrant behaviors (mean: 6.1, median: 5.0) than the cancer group (mean: 1.4, median: 1.0).

Passik et al. (2006) found that, in the sample as a whole, the number of aberrant behaviors increased as adequacy of pain management decreased; however, a significant association between prevalence of aberrant behaviors and adequacy of pain relief disappeared when looking at the two groups individually. PMI score did not affect the number of aberrant behaviors reported by AIDS patients, suggesting that in AIDS patients adequate pain relief will not lessen the prevalence of aberrant behaviors. The authors remark, "It is telling that the adequacy of analgesia did not affect the type or frequency of aberrant behavior: pain alone is not the driving force behind these behaviors in complex patients" (p. 180). This study showed the importance of understanding more of what constitutes "aberrant" versus "common" behaviors in various patient populations.

Trafton, Oliva, Horst, Minkel, and Humphreys (2004) studied the following questions:

- Do pain patients have the same severe SUDs as patients without pain?
- Do pain patients have differing treatment needs and healthcare utilization practices?
- Does pain alter the presentation of SUDs?

As a part of the Multisite Opioid Substitution Treatment study, Trafton et al. (2004) looked at a sample of 251 veterans (97 percent male, 53 percent Black) in opioid substitution treatment clinics in 8 major U.S. cities. Subjects were administered ASI, the short-form 36 for veterans (SF-36V) Quality of Life Index, and the High-Risk Injection Practices Questionnaire and asked questions about health services outside the VA system. Based on scores from the SF-36V Index, patients were divided into two categories based on their pain severity. The "no pain" group comprised patients reporting no pain to mild pain ($n$ = 121), and the "pain" group comprised patients reporting moderate to severe pain ($n$ = 130). These two groups did not differ significantly in age, education level, race, marital status, legal histories, family or social problems, previous drug overdoses, and histories and patterns of substance use. Patients in the pain group were more likely to be unemployed or employed part time compared with those in the no pain group.

Trafton et al. (2004) found that subjects had higher pain levels than the general U.S. population, and they also had severe SUDs that were not related purely to analgesic needs. However, subjects with pain misused opioids more than the no pain group in the 30 days before the study (2.3 days and 0.8 days, respectively) as well as over their lifetimes (2.9 years and 0.9 years).

The subjects with pain in the study by Trafton et al. (2004) had greater treatment needs than those without pain. They reported three times the number of days with medical problems and had higher percentages of depression, anxiety, and suicidal ideation than did the no pain group, with significant differences reported at the levels above moderate pain. Subjects in the pain group also reported more days of inpatient medical and psychiatric treatment than the no pain group.

In this study, "every substance abused more frequently in the chronic pain population, namely non-prescribed opioid medications … has been recognized as a primary or adjunctive analgesic drug, suggesting that pain drives patients to selectively self-administer only those substances that

actually work to relieve it" (Trafton et al., 2004, p. 29). Subjects reporting pain did not tend to misuse other drugs, such as cocaine. In this study, patients with no pain were not likely to misuse opioids; misuse was associated with comorbid pain and SUDs.

Larson et al. (2007), however, found that persistent pain was associated with misuse of not only opioids but all substances (including alcohol) following detoxification. The researchers studied the prevalence of pain as well as the relationship between persistent pain and substance use following detoxification. The study comprised 397 people enrolled in an urban residential detoxification program. Data were gathered through patient assessments at the start of the study and every 6 months for 2 years (122 participants completed at least 1 interview within the 24-month period, and 275 subjects completed the 24-month interview). Pain status was classified as persistent pain, intermittent pain, and no pain. Substance use included alcohol, cocaine, and heroin/opioids as substance of first or second choice.

Larson et al. (2007) measured a high prevalence of persistent pain in their subjects. At baseline, 16 percent of patients reported persistent pain. At the 24-month followup, subjects with persistent pain showed increased odds of using any substance (OR 4.6; CI 2.3–9.3) relative to the group with no pain. The odds remained when models were adjusted (AOR 4.2; CI 1.9–9.3).

Passik et al. (2006, p. 179) remark, "There is little agreement among physicians about aberrant behaviors beyond viewing illegal behaviors as worrisome. Behaviors considered aberrant by physicians may in fact be common." Because interpretation of behavior is culturally influenced (Elander et al., 2004; Kirsh, Witcomb, Donaghy, & Passik, 2002; Passik et al., 2006; Weissman, Gordon, & Bidar-Sielaff, 2004), clinical responses to ADRBs should be "guided by information about the actual prevalence and nature of aberrant drug-taking behaviors in distinct medically ill populations" (Passik et al., 2006, p. 179).

Furlan, Sandoval, Mailis-Gagnon, and Tunks (2006) conducted a meta-analysis comparing efficacy of opioids with placebos and other drugs for CNCP. The analysis included 41 studies (6,019 subjects) conducted through 2005. Of 41 randomized trials, 25 excluded people with histories of SUDs, and information about substance use history went unreported in others. Only three studies gathered data on the incidence of opioid addiction that developed during the trials. Based on the trials analyzed, Furlan et al. (2006) conclude, among other things, that:

- Opioids reduced CNCP and improved functional outcomes better than placebos; they proved more effective than placebos for neuropathic and nociceptive pain.
- Strong opioids (oxycodone and morphine) were significantly better than nonsteroidal anti-inflammatory drugs (NSAIDs; e.g., naproxen) or tricyclic antidepressants (TCAs; e.g., nortriptyline) for pain relief, but not for functional outcomes.
- Weak opioids (propoxyphene, tramadol, and codeine) did not significantly outperform NSAIDs or TCAs for pain relief or functional outcomes.
- The duration of the trials was too short to detect ADRBs even when screening for addiction occurred, and "none of the studies have been methodologically sound enough to allow for conclusions about opioid addiction or abuse" (2006, p. 1592).

## Treatment Agreements

Federation of State Medical Boards (2002), APS and AAPM (2009), and many practitioners (e.g., Fishman, 2007; Gourlay, Heit, & Almahrezi, 2005; Heit, 2003; Passik & Kirsh, 2005; Sullivan & Ferrell, 2005; Ziegler, 2007) advocate for agreements between CNCP patients and clinicians that spell out expectations of chronic opioid therapy and consequences of contract breaches. There is little evidence that these agreements result in better outcomes (Chou et al., 2009).

Heit (2003) points out several benefits and limitations of treatment agreements. Opioid agreements, in theory, establish boundaries, document treatment plans, delineate duties and expectations of the clinician and patient, help diagnose addiction or relapse, and indicate changes in treatment plans. They can also contribute to a negative perception of patients, contribute to an atmosphere of distrust, and give clinicians a false sense of security. Heit remarks that clinicians must implement treatment agreements in an atmosphere of trust.

Arnold, Han, and Seltzer (2006) examined four reasons to implement opioid treatment agreements:

- **Adherence to treatment.** The researchers found no empirical evidence for the effectiveness of agreements in supporting patient adherence to opioid therapy.
- **Informed consent.** They acknowledge that, to the degree agreements spell out the risks and alternatives of therapy, most opioid agreements satisfy the legal requirement of informed consent.
- **Legal risk.** The authors distinguish between the legal demands and the ethical demands of informed consent. They argue that, because agreements function primarily to restrict a patient's behavior concerning controlled substances, they may actually inhibit patient participation in his or her health care. The researchers also looked at the ability of opioid agreements to offer legal protection to clinicians by reducing the probability of frivolous lawsuits by patients, for example. Given the lack of evidence for this claim and a competing theory that agreements may actually make it easier for patients to sue clinicians, the authors conclude that "opioid contracts may thus have mixed effects upon physicians' legal risks" (Arnold et al., 2006, p. 294).
- **Efficiency.** They report that no evidence supports the idea that agreements improve practice efficiency. Implementing opioid agreements is not wholly without risks, including the possibility of prejudice and discrimination, negative effects on clinician–patient dynamics and other ethical ramifications, and the potential for the undertreatment of pain. The authors note that the lack of evidence in favor of using agreements does not mean that agreements are ineffective, but they caution clinicians to critically examine the meaning and value of such agreements for their practice.

Manchikanti, Manchukonda, et al. (2006) studied 500 patients in a multidisciplinary interventional pain management center to learn whether adherence monitoring had an impact on opioid abuse. Adherence monitoring included a patient agreement addressing the acquisition of controlled substances, periodic monitoring and drug testing, pill counts, and education. In this study, abuse was defined as receiving controlled substances from any place other than the designated prescribing clinician. This study did not examine whether patients were taking

prescription medications as directed or whether they were engaged in illegal opioid abuse. The researchers gathered evidence from records, pharmacies, referring clinicians, and treating clinicians. Compared with previous studies by the same lead researchers, which measured the rates of patients' abuse of controlled substances at 17.8 percent, this 2006 study found that 9 percent of patients abused controlled substances after adherence monitoring was introduced, nearly a 50-percent reduction. In the 2006 study, 5 percent of those abusing opioids obtained them through doctor shopping and 4 percent obtained them from drug traffickers.

Hariharan, Lamb, and Neuner (2007) conducted a retrospective chart review of 330 patient agreements made at the General Internal Medicine Clinic at the Medical College of Wisconsin between 1998 and 2003. The researchers defined patient adherence to the agreements as "patients receiving stable doses of contracted medications at prescribed intervals, and adhering to the conditions of the contract agreement" (p. 485). The clinic implemented patient agreements for chronic opioid therapy in 1998. By 2000 the practice was standard. Researchers collected demographic data for all patients, including type of insurance, type of pain, and type of opioid prescribed (long-acting, short-acting, or combination therapy). Researchers documented urine drug test results for marijuana or cocaine and tracked the reasons for contract cancellations. Contract cancellations were categorized as (1) positive urine drug test result; (2) prescription opioid abuse, such as forging prescriptions or filling prescriptions from various sources; (3) violating contract rules; and (4) other, such as transfer of care to a pain specialist. Patients were evenly divided between men (52 percent) and women and Blacks (48 percent) and Whites. Most patients were 40 to 55 years old (42 percent), 33 percent were younger than 40, and 25 percent were older than 55. Sixty percent reported low back pain or fibromyalgia.

Over the study period, clinicians canceled 17 percent of the contracts, primarily for positive urine drug test results (50 percent). However, less than 45 percent of patients were subject to urine drug tests. Hariharan et al. (2007) report that clinicians did not systematically monitor patients for complying with opioid agreements. Seven percent of patients were terminated for violating contract rules. More patients (20 percent) ended opioid therapy voluntarily rather than being discontinued by their clinician. The researchers found no association between contract cancellation and any patient characteristic or type of pain. The researchers conclude that opioid agreements can be a beneficial part of chronic opioid therapy, but that pain assessment and contract monitoring (drug testing) should be standardized.

The Management of Opioid Therapy for Chronic Pain Working Group of the Department of Veterans Affairs & Department of Defense (VA/DoD, 2010) reviewed the literature on treatment agreements and found that "there is very little evidence regarding the efficacy of treatment agreements as part of chronic opioid therapy for patients with chronic noncancer pain" (p. 33). It found no controlled trials and seven limited studies that yielded mixed results (Burchman & Pagel, 1995; Dunbar & Katz, 1996; Fagan, Chen, Diaz, Reinert, & Stein, 2008; Goldberg, Simel, & Oddone, 2005; Hariharan, Lamb, & Neuner, 2007; Kirkpatrick, Derasari, Kaira, Miller, & Beede, 1994; Wiedemer, Harden, Arndt, & Gallagher, 2007).

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# Appendix—Methodology

Starting in September 2007, professional librarians from the Center for Substance Abuse Research (CESAR) at the University of Maryland conducted a series of searches to locate literature that discussed both chronic noncancer pain (CNCP) and substance use disorders (SUDs) as it pertained to topics relevant to this Treatment Improvement Protocol (TIP). The TIP's major topics are:

- Patient assessment.
- Pain management.
- Patient education.
- Monitoring adherence/aberrant drug-related behaviors.

Special topics included:

- HIV/AIDS.
- Acute pain/perioperative pain.
- Marijuana in the treatment of chronic pain.
- Patients on medication for opioid use disorders.

The TIP was not developed to advise clinicians on how to treat the many individual types of CNCP such as low back pain, neck pain, fibromyalgia, or migraines. Instead, evidence was sought that would be relevant to a clinician who may treat any type of chronic pain in patients with a history of SUDs. The literature search was complex because, in most databases used, much of the information was not indexed in a way that facilitated the search.

The following databases were searched:

- PubMed
- PsycInfo
- SOCIndex
- Academic Search Premier

Searches were limited to publications in English from 2001 to 2007, involving human subjects. In general, searches combined the concepts of "chronic pain" OR "chronic noncancer pain" AND "substance use disorder" OR "SUD" "addiction" OR "substance abuse" with topical search terms. Search terms were tailored to particular databases. For example, to search PubMed for articles about comorbid conditions in the target patient, the following strategy was used:

- Apply limits.
- Combine pain [medical subject heading (MeSH)] serially with dual diagnosis [MeSH] and comorbidity.

- Combine substance-related disorders [MeSH] OR substance abuse treatment centers [MeSH] AND pain [MeSH]. Combine result serially with depression [MeSH], anxiety [MeSH], somatoform disorders [MeSH], physical deconditioning [text], stress disorders, post-traumatic [MeSH], sleep disorders [MeSH], cognition disorders [MeSH], mental disorders [MeSH].

Returns were reviewed carefully first by CESAR librarians for relevance, and abstracts of items found relevant were sent to JBS International, Inc., for further culling. Because the experience and expression of pain are mediated in part by culture, research on non-U.S. subjects was eliminated with few exceptions made for studies with no U.S. equivalents. Articles that focused on treating SUDs as opposed to treating CNCP were also eliminated as beyond the scope of the TIP.

The searches were updated periodically while the TIP was in development using the search terms: chronic pain, pain management, chronic noncancer pain, chronic nonmalignant pain, pain patient, pain intervention and recovery, substance use disorder or substance abuse, opioid or prescription drug abuse.

In addition to the articles located by the electronic searches, some articles were retrieved because they were recommended by consensus panelists or were identified through references in the articles previously consulted.

# Section 2—Links to Select Abstracts


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