

Chronic Opioid Analgesic Therapy for Chronic Low Back Pain

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Background: Eleven percent of American adults have chronic low back pain—and many of these individuals have severe, disabling, refractory pain. Many texts recommend against using opioids for these patients without citing original research.

Methods: A MEDLINE literature search was conducted for original research on the use of opioids for chronic noncancer pain. Additional references were also sought from review articles and book chapters. Based on this research and the authors' clinical experience, recommendations were formulated for implementing chronic opioid analgesic therapy (COAT) for patients with chronic low back pain.

Results: No controlled studies were found. Case series reports on a total of 566 patients suggest that COAT is safe and effective for many patients with recalcitrant chronic low back pain. Preexisting substance use disorders, personality disorders, certain medical conditions, and certain occupational factors are relative contraindications to COAT. Methods to prevent and monitor for drug problems among COAT recipients include contracts, family interviews, and drug testing. Pain and overall function are the key monitoring parameters. Once patients attain some relief, an exercise regimen should be initiated. Other nonpharmacologic treatments and nonopioids are also recommended.

Conclusion: Physicians are encouraged to consider COAT for selected patients with severe chronic low back pain who respond inadequately to other treatments. (J Am Board Fam Pract 1996;9:191-204.)

Chronic low back pain frequently frustrates patients and their physicians. Its recalcitrance to a panoply of treatment modalities leaves many patients disabled, desperate, and depressed. In many cases the lack of objective findings, the absence of science to guide clinical management, and patients' pleas for help leave physicians in a mire of sympathy, suspicion, and impotence. Physicians are particularly wary when patients request opioids. Most physicians are taught not to prescribe opioids for chronic noncancer pain, yet many patients with chronic low back pain assert that nothing else provides the same relief.

The issue of opioid prescribing for chronic low back pain is important, not only because of the widespread occurrence and impact of chronic low back pain but also because of the inadequate relief often provided by standard treatment approaches.

In 1989 as many as 80 million Americans suffered from chronic pain syndromes, chronic low back pain being the most common.¹ Five million Americans are disabled by back pain, and one half of these are permanently disabled.² A recent cross-sectional study found that 40.5 percent of subscribers to a health maintenance organization had back pain in a 6-month period, and one fourth of these individuals had pain on at least 90 of the previous 180 days.³ Of all the back pain sufferers, 15.3 percent reported severe pain, and 29.5 percent reported considerable activity limitation.³ The physical, emotional, social, and economic toll of chronic noncancer pain on individuals and families² is often devastating. In 1984 the estimated economic impact of chronic low back pain exceeded \$15 billion.²

Treatment for chronic low back pain is often inadequate. Although exercise is consistently associated with improvement of chronic low back pain,⁴ it often provides relief of insufficient magnitude or duration,⁵⁻⁷ and pain precludes exercise for many patients. Studies on behavioral interventions,⁸⁻¹¹ chiropractic manipulation,¹² transcutaneous electrical nerve stimulation,¹³ and low-

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energy laser stimulation¹⁴ have yielded negative, mixed, or inconclusive findings. Many patients appear to be helped minimally, at best, by all available treatments.

Clearly more effective treatments are needed for patients with chronic low back pain. This article will discuss the reasons why opioids have been overlooked, summarize the empirical evidence regarding chronic opioid analgesic therapy (COAT) for chronic low back pain, and suggest how to select and educate patients, initiate and adjust treatment, monitor for progress and adverse effects, and track prescribing.

Possible Reasons That Opioids Have Been Overlooked

Opioids have been used medicinally for at least 4000 years.¹⁵ Reluctance toward the medicinal use of opioids has been a recent phenomenon. Until early in the 20th century, opiates were available without prescription in the United States, and 1 percent of Americans were addicted to opiates.¹⁶ As a result opiates became controlled substances in 1914. Since then, societal concern about drug addiction, culminating in a so-called "war on drugs," has aroused lay and professional sentiment against opioids.¹⁷ Societal bias against opioids is best exemplified by fear and avoidance of many physicians and some patients, even in the setting of painful, terminal cancer.¹⁸⁻²¹

The reasons that many physicians avoid prescribing opioids include fear of initiating a drug problem,^{22,23} fear of overlooking and exacerbating a preexisting alcohol or other drug problem, fear of other adverse effects, fear of regulatory oversight^{23,24} and malpractice suits, underestimation of the severity of patients' pain and disability,^{18,25} and lack of information.

One reason that physicians' fear of initiating a drug problem might be exaggerated is the common blurring of the distinction between substance dependence (or addiction) and physical (or pharmacologic) dependence.²² Physical dependence is defined by the occurrence of stereotypical withdrawal effects after cessation or abrupt diminution of drug use and by marked tolerance. Marked tolerance is defined as the need for at least 50 percent more of a substance to attain previous effects. Physical dependence in itself need not be problematic, provided individuals are able to avoid withdrawal by continuing to take a sub-

stance. Substance dependence properly refers to "a state, psychic and sometimes also physical, resulting from the interaction between a living organism and a drug, characterized by behavioral and other responses that always include a compulsion to take the drug on a continuous or periodic basis in order to experience its psychic effects, and sometimes to avoid the discomfort of its absence. Tolerance may or may not be present."²⁶ Addiction refers to "a chronic disorder characterized by the compulsive use of a substance resulting in physical, psychological, or social harm to the user and continued use despite that harm."²⁷ Patients who take moderate to high doses of opioids for several weeks often develop physical dependence, which need not be and, as is discussed below, usually is not accompanied by substance dependence or addiction.

Physicians' fears about overlooking and exacerbating preexisting alcohol and other drug problems by prescribing opioids is not unfounded, since physicians often fail to recognize these problems.^{28,29} How physicians can assess for alcohol and other drug problems before initiating COAT is described elsewhere.³⁰ Alternatively, physicians can refer prospective COAT recipients for assessment by an expert in alcohol and other drug problems.

Fear of regulatory oversight and legal jeopardy is also understandable. Physicians can be subject to malpractice suits from adverse effects of nonstandard therapies. Many state licensure board members are averse to long-term prescribing of opioids for pain.³¹ Some states discourage prescribing by requiring special prescriptions that add to physicians' paperwork and remind them at the point of patient contact that their prescribing is being monitored.³¹ Recent clarifications of regulations, however, are supporting physicians who prescribe opioids rationally for intractable pain.^{31,32}

Physicians commonly underestimate the extent of pain, disability, and suffering endured by their patients with chronic pain.³³ If physicians were more aware of their patients' plight, they might perceive differently the risk-benefit balance of COAT.

Adverse effects besides alcohol and other drug problems add to physicians' restraint in prescribing opioids. Most side effects, however, can be avoided or ameliorated,³⁴ as described below.

Table 1. Summary of Case Series Reports on COAT for Chronic Low Back Pain.

Study	N	Pain	Regimens	Follow-up	Outcomes	Adverse Effects
Taub, 1982 ³⁶	313	Mixed	Codeine, meperidine, methadone, oxycodone; methadone equivalent; usually 10-20 mg, up to 40 mg	Up to 6 yr	Vague; "all benefited"	Little tolerance was noted; 13 (4%) patients "presented management problems"; one half of these had previous substance abuse but were managed well with strict rules.
Tennant and Uelman, 1983 ³⁷	22	Chronic back pain	Not stated	Not stated	15 (68%) were able to return to work	None stated; no abuse
France et al, 1984 ³⁸	16	Chronic back pain 2-14 yr	Codeine, methadone, oxycodone; methadone equivalent of 3-20 mg	6-22 mo	13(8%) had 75%-99% improvement; 3 (19%) had 50%-74% improvement.	None
Urban et al, 1986 ³⁹	5	Phantom limb pain	Methadone 10-20 mg	12-26 mo	All had at least 50% relief	None
Tennant et al, 1988 ⁴⁰	52	Mixed	Mixed, methadone equivalent 10-240 mg	Mean 12 yr	46 (88%) reported "adequate relief"	20 had constipation; 9 (17%) showed "abuse behaviors"
Portenoy and Foley, 1986 ⁴¹ Portenoy, 1989 ⁴²	58	20 patients had back pain; some had neuropathy	10-60 mg parenteral morphine	6 mo-10 yr	16 (28%) had adequate relief; 16 (28%) had partial relief; 7 (12%) had little to no relief	2 had personality change; 2 developed myoclonus; 4 showed abuse behaviors
Zenz et al, 1992 ⁴³	100	Mixed including neuropathic pain	Morphine, buprenorphine, dihydrocodeine	2 wk-4 yr	51 (51%) had good relief; 28 (28%) had partial relief	Constipation; no abuse or addiction

Empirical Evidence on Chronic Opioid Analgesic Treatment for Chronic Noncancer Pain

In 1990 Portenoy³⁵ reviewed seven case series reports of COAT for chronic noncancer pain.³⁶⁻⁴² An additional report has been published since then.⁴³ These studies are summarized in Table 1. They suggest that COAT ameliorated pain for most of the 566 patients studied, many of whom had chronic low back pain.

While these reports are encouraging, they cannot be considered definitive. Although the chronicity and severity of the pain in many of these subjects suggests that spontaneous improvement of pain would not have been likely, the natural history of most chronic back pain is characterized by frequent and unpredictable relapses and remissions.³ In addition, since these patients were presumably selected for the severity of their pain, regression to the mean could have accounted for some of the apparent benefit of COAT. Controlled trials, which would address these shortcomings, have not been performed.

In Tennant and Uelman's study,³⁷ an exercise program was provided along with COAT, and most patients showed improvement in function. It stands to reason that opioids might help patients with chronic low back pain indirectly by allowing them to participate in exercise, which would be important, since exercise is currently believed to be the most effective treatment for chronic low back pain.⁴ The other studies did not include interventions aimed specifically at improving physical function, and changes in functional status were not reported.

Most of the studies reported a low rate of alcohol and other drug problems. Such problems were found in 17 percent of Tennant and coworkers' 52 patients,⁴⁰ 7 percent of Portenoy's 58 patients,^{41,42} 4 percent of Taub's 313 patients,³⁶ and none of the patients followed in the four other studies.^{37-39,43} In addition, other studies of COAT found low rates of alcohol and other drug problems for patients with restless leg syndrome,^{44,45} neuroleptic-induced dyskinesias, and intractable

dyspnea.⁴⁶ All of these studies are flawed, however, in that their methods of assessing for alcohol and other drug problems were not described and might not have been rigorous or standardized. In addition, it is not known whether their subjects were selected for COAT on the basis of apparent low risk for alcohol and other drug problems or other attributes.

Another study suggests indirectly that chronic pain might be less of a risk factor for alcohol and other drug problems than some people believe.⁴⁷ Polatin et al⁴⁷ conducted a standardized, validated alcohol and other drug assessment of patients with chronic pain who were entering a functional rehabilitation program. Of 200 subjects, 72 (36 percent) exhibited a lifetime history of an alcohol and other drug problem. (Although this figure exceeds the 26.6 percent lifetime prevalence found in a national representative sample,⁴⁸ this comparison with historical controls might not take into account special attributes of the population studied by Polatin et al.) Sixty-eight of the 72 pain patients had an alcohol or other drug problem that predated the onset of their chronic pain syndrome. In only 4 subjects did an alcohol or drug disorder arise after the onset of chronic pain. Thus, in the patients studied, chronic pain might have only rarely precipitated new alcohol and other drug problems. This conclusion must be regarded as tentative, since the study sample could have been somewhat homogeneous, the possibility that chronic pain exacerbated quiescent alcohol and other drug problems was not addressed, and the patients' use of opioids was not reported.

There has been some concern that opioids might be less efficacious for neuropathic pain than musculoskeletal pain. Clinical observations by Zenz et al⁴³ and Portenoy et al⁴⁹ suggest that neuropathic pain can respond well to opioids, though higher doses might be necessary.

In summary, then, reports on hundreds of patients who have received COAT for chronic low back pain and other noncancer pain syndromes suggest that opioids are safe and effective treatment for many patients with chronic low back pain. More definitive conclusions await rigorous, controlled trials. Until such trials are conducted, however, there appears to be enough evidence now to support the careful use of COAT for selected patients.

Selecting Patients for COAT

At this time it seems prudent to reserve COAT for patients with moderate to severe pain and substantial functional interference from pain that is refractory to other treatments. Current or previous alcohol and other drug problems, drug diversion (illicit distribution of controlled substances), personality disorders, certain medical conditions, suicidal behavior, and occupational factors can be relative contraindications to COAT.

A history of alcohol and other drug problems, especially opioid problems, can put COAT recipients at greater risk for developing alcohol and other drug problems with COAT.⁴¹ Preexisting alcohol and other drug problems, however, need not be an absolute contraindication to COAT. Patients with these problems have succeeded with COAT when contracts, as described below, are consistently utilized and applied.³⁶⁻⁵⁰ Providing adequate pain relief with COAT can help reduce self-medication of pain with alcohol or other sedatives.

Patients with a history of drug diversion are presumably at risk for recidivism. Public criminal records can occasionally reveal drug diversion that patients do not report. In some communities physicians and pharmacists can report suspicious drug-related behaviors to, and receive such information from, a pharmacy network. Such reports are not, however, always accurate, as "drug seeking" in the eyes of one clinician might in another's eyes be an understandably desperate attempt to seek pain relief. Indeed the term pseudoaddiction has been applied to patients whose apparent drug-seeking behaviors emanate from uncontrolled pain and not addiction.⁵¹ Thus reports of drug-seeking behaviors need not be absolute contraindications to COAT.

Patients in chronic pain who also have antisocial, borderline, or other personality disorders often present management challenges. Although these disorders might not be absolute contraindications to COAT, they indicate the need for close supervision and strict enforcement of provisions of written contracts.

Some medical conditions can increase the risk of COAT.³⁴ Hepatic insufficiency and, for some preparations, renal insufficiency can extend the half-life of opioids and their metabolites. Preexisting constipation or urinary retention are often exacerbated by COAT. Patients with respiratory disease who require maximal respiratory drive are

Table 2. Chronic Pain Grade.

1. How would you rate your pain on a 0-10 scale at the present time, that is, right now, where 0 is "no pain" and 10 is "pain as bad as could be"? (Circle only one number)										
0	1	2	3	4	5	6	7	8	9	10
<i>No pain</i>					<i>Pain as bad as could be</i>					
2. In the past 6 months, how intense was your worst pain rated on a 0-10 scale where 0 is "no pain" and 10 is "pain as bad as could be"?										
0	1	2	3	4	5	6	7	8	9	10
<i>No pain</i>					<i>Pain as bad as could be</i>					
3. In the past 6 months, on the average how intense was your pain rated on a 0-10 scale where 0 is "no pain" and 10 is "pain as bad as could be"? (That is, your usual pain at times you were experiencing pain).										
0	1	2	3	4	5	6	7	8	9	10
<i>No pain</i>					<i>Pain as bad as could be</i>					
4. About how many days in the last 6 months have you been kept from your usual activities (work, school, or housework) because of your pain? _____										
5. In the past 6 months, how much has your pain interfered with your daily activities rated on a 0-10 scale where 0 is "no interference" and 10 is "unable to carry on any activities"?										
0	1	2	3	4	5	6	7	8	9	10
<i>No interference</i>					<i>Unable to carry on any activities</i>					
6. In the past 6 months, how much has your pain changed your ability to take part in recreational, social, and family activities rated on a 0-10 scale where 0 is "no change" and 10 is "extreme change"?										
0	1	2	3	4	5	6	7	8	9	10
<i>No change</i>					<i>Extreme change</i>					
7. In the past 6 months, how much has your pain reduced your ability to work (including housework) where 0 is "no change" and 10 is "extreme change"?										
0	1	2	3	4	5	6	7	8	9	10
<i>No change</i>					<i>Extreme change</i>					

Scoring instructions for the Chronic Pain Grade: Multiply the sum of the responses from items 1, 2, and 3 by 3.33 to obtain the Characteristic Pain Intensity (CPI). Obtain the Disability Day Index from the response to item 4, assigning 0 points for 0 to 29 days, 1 point for 30 to 49 days, 2 points for 50 to 69 days, and 3 points for more than 69 days. Multiply the sum of the responses from items 5, 6, and 7 by 3.33 to obtain the Disability Score. Obtain the Disability Index from the Disability Score, assigning 0 points for a score of 0 to 29, 1 point for 30 to 49, 2 points for 50 to 69, and 3 points for 70 to 100. Add the Disability Day Index and the Disability Index to obtain Disability Points (DP). Grade I (low disability-low intensity) is defined as a CPI of < 50 and DP < 3. Grade II (low disability-high intensity) is defined as a CPI of 50 or greater and DP < 3. Grade III (high disability-moderately limiting) is defined as DP of 3 or 4 regardless of CPI. Grade IV (high disability-severely limiting) is defined as DP of 5 or 6 regardless of CPI.

From Von Korff.⁵²

at particular risk for opioid-related respiratory depression. The withdrawal syndrome associated with sudden cessation of opioids is not life threatening unless patients have underlying coronary artery disease, metabolic disorders, or other major systemic illness. Suicidal or cognitively impaired patients can be at risk for overdose, although the passive suicidal behavior often linked to chronic pain can improve with COAT.

Inquiries about occupational issues might be im-

portant. Because of the potential for cognitive blunting, COAT might not be appropriate for patients who work in fields of importance to public safety, including transportation, law enforcement, and health care. Some patients with pending disability or legal determinations might exaggerate their reports of pain, which can prompt physicians inappropriately either to initiate COAT or to increase doses of opioids. Patients who are already receiving compensation for disability might not be as prone to exaggerate reports of pain, since these patients do not seem to have a worse prognosis than patients who do not receive such compensation.³

In assessing patients' eligibility for COAT, two standardized questionnaires are particularly useful. The Chronic Pain Grade described by Von Korff et al,⁵² which has been validated for 1213 primary care patients with back pain, provides a brief, convenient, quantitative measure of the severity of back pain (Table 2). Patients with Grade III or IV chronic low back pain would be eligible for COAT. The Roland scale assesses for functional impairment due to back pain.⁵³ The version of the Roland scale shown in Table 3 has been modified by Deyo to include

sciatica (personal communication RA Deyo, MD, December 1993).

Educating Potential COAT Recipients

Patient education is an important step in initiating COAT. It is important to ensure that patients and their families have appropriate expectations about improvement, possible adverse effects, and measures for preventing and monitoring for addiction. Formal informed consent procedures are

Table 3. The Roland Scale.*

When your back or leg hurts, you may find it difficult to do some of the things you normally do. This list contains some sentences that people have used to describe themselves when they have back pain or sciatica. When you read them, you may find that some stand out because they describe you today. As you read the list, think of yourself today. When you read a sentence that describes you today, put a check in the Yes column. If the sentence does not describe you today, then put a check in the No column.

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	1. I stay at home most of the time because of my back problem or leg pain (sciatica).
<input type="checkbox"/>	<input type="checkbox"/>	2. I change position frequently to try to get my back or leg comfortable.
<input type="checkbox"/>	<input type="checkbox"/>	3. I walk more slowly than usual because of my back problem or leg pain.
<input type="checkbox"/>	<input type="checkbox"/>	4. Because of my back problem or leg pain, I am not doing any of the jobs that I usually do around the house.
<input type="checkbox"/>	<input type="checkbox"/>	5. Because of my back problem or leg pain, I use a handrail to get upstairs.
<input type="checkbox"/>	<input type="checkbox"/>	6. Because of my back problem or leg pain, I lie down to rest more often.
<input type="checkbox"/>	<input type="checkbox"/>	7. Because of my back problem or leg pain, I have to hold on to something to get out of an easy chair.
<input type="checkbox"/>	<input type="checkbox"/>	8. Because of my back problem or leg pain, I try to get other people to do things for me.
<input type="checkbox"/>	<input type="checkbox"/>	9. I get dressed more slowly than usual because of my back problem or leg pain.
<input type="checkbox"/>	<input type="checkbox"/>	10. I only stand up for short periods of time because of my back problem or leg pain.
<input type="checkbox"/>	<input type="checkbox"/>	11. Because of my back problem or leg pain, I try not to bend or kneel down.
<input type="checkbox"/>	<input type="checkbox"/>	12. I find it difficult to get out of a chair because of my back problem or leg pain.
<input type="checkbox"/>	<input type="checkbox"/>	13. I find it difficult to turn over in bed because of my back problem or leg pain.
<input type="checkbox"/>	<input type="checkbox"/>	14. My appetite is not very good because of my back problem or leg pain.
<input type="checkbox"/>	<input type="checkbox"/>	15. I have trouble putting on my socks or stockings because of the pain in my back or leg.
<input type="checkbox"/>	<input type="checkbox"/>	16. I only walk short distances because of my back problem or leg pain.
<input type="checkbox"/>	<input type="checkbox"/>	17. I sleep less well because of my back problem or leg pain.
<input type="checkbox"/>	<input type="checkbox"/>	18. Because of my back or leg pain, I get dressed with help from someone else.
<input type="checkbox"/>	<input type="checkbox"/>	19. I sit down for most of the day because of my back problem or leg pain.
<input type="checkbox"/>	<input type="checkbox"/>	20. I avoid heavy jobs around the house because of my back problem or leg pain.
<input type="checkbox"/>	<input type="checkbox"/>	21. Because of my back or leg pain, I am more irritable and bad tempered with people than usual.
<input type="checkbox"/>	<input type="checkbox"/>	22. Because of my back problem or leg pain, I go upstairs more slowly than usual.
<input type="checkbox"/>	<input type="checkbox"/>	23. I stay in bed most of the time because of my back problem or leg pain.

Assign each Yes response 1 point, and sum. Lower scores indicate better function.

* From Roland and Morris⁵³; adapted by RA Deyo.

recommended. Patients and their family members should understand that COAT is not a panacea. Patients with moderate to severe pain typically report that COAT reduces their pain by one half, as expressed on a 0 to 10 rating scale.

Patients should be educated about the potential side effects of opioids, which have been summarized by Foley.³⁴ Respiratory depression and sedation are rarely problems for long-term opioid users, since tolerance to these effects develops rapidly. Most patients also become tolerant to nausea after 1 to 2 weeks, though sometimes switching to another opioid or adding an antiemetic is necessary. In contrast, if constipation and urinary retention occur, they tend to persist. Constipation, however, usually responds to dietary or pharmaceutical interventions, especially if improved analgesia allows patients to return to greater activity. Other effects, such as pruritus and vivid

dreams, are idiosyncratic.

Although there is a paucity of studies on the cognitive effects of opioids on patients with chronic pain, most patients report that cognitive blunting usually resolves within 2 weeks after initiation or augmented dosing of opioids. Patients who note persistent cognitive effects often find these effects less disruptive than the mental distraction they suffered from more severe pain.

Many patients will have stereotypical fears about drug problems that must be allayed before they will consider COAT. They must understand the difference between physical dependence and addiction and the risk of each from COAT. Many potential COAT recipients feel reassured when the physician enumerates all of the measures that will prevent and facilitate early awareness of drug problems (Table 4). When monitoring measures are described as protection against hidden

Table 4. A Sample Contract for Chronic Opioid Analgesic Treatment.

Narcotics, such as morphine, Percocet, and codeine, are the strongest known pain relievers. Studies suggest that they can be very helpful for some patients with chronic pain. Some patients report being able to do more when they take narcotics, but others do not. Most patients report considerable, but not complete, pain relief.

I understand that taking narcotics might impede my ability to concentrate and think clearly, though this side effect usually decreases in time. Side effects may also include constipation, dizziness, itching, nausea, and difficulty urinating. If I already have these problems, I have told my doctor.

I understand that taking narcotics regularly for a long period of time usually causes physical dependence. This means that if I stop taking the medications suddenly, I could experience withdrawal symptoms, such as tearing, runny nose, difficulty sleeping, agitation, abdominal pain, and severe discomfort. I also understand that taking narcotics over a long period of time might put me at risk for developing an addiction. This means that I could become preoccupied with taking narcotics or other drugs to the point that other important aspects of my life, such as family, friends, work, and health, could suffer.

I understand that individuals who have addictions are often unaware of their addictions. Thus, it will be very important while I take narcotics that my doctor follow me closely to assess whether I am developing an addiction. To conduct this ongoing assessment for addiction, I understand that my doctor may need to check my urine for narcotics and other drugs. My doctor might also need to be in contact with my family members and/or friends, because the symptoms of addiction might be recognized by others I know before I recognize them myself.

WOMEN: Taking regular doses of narcotics during pregnancy can be harmful to developing babies. I am definitely not pregnant now, and I will make sure as best I can that I will not become pregnant while I am taking narcotics.

1. I will do my best to take my medication exactly as prescribed by my doctor. I will not take medications in excess of my doctor's instructions.
2. I will avoid alcohol on days in which I am taking narcotics. I will avoid all illicit drugs.
3. If I feel tired or mentally foggy, I will not drive, operate heavy machinery, or serve in any capacity related to public safety.
4. I will submit a urine specimen whenever my doctor requests to test for narcotics and other drugs to help monitor me for addiction. My doctor might ask that a

clinic staff member observe me as I produce the specimen.

5. I allow my doctor to contact my other family members, my friends, and people I work with to help monitor my progress.
6. If my doctor recommends, I will see a specialist for the purpose of determining whether I am developing an addiction.
7. I understand that my doctor will not be available to prescribe medication during evenings and weekends. My doctor's partners might not provide me with refills by phone, especially at night or on weekends. It is my responsibility to call my doctor at least three business days in advance of running out of medications.
8. I will receive addictive medications (narcotics, sleeping pills, tranquilizers, stimulants) from no one besides my regular doctor or my doctor's partners. If I have an emergency that may require additional pain medicine, I will call my doctor's office first if at all possible. The only exception would be if an emergency requires me to go straight to an emergency room without first calling my doctor's office. If this happens, I will alert the doctor at the emergency room or hospital to my special arrangement for pain medicine, and I will notify my doctor that I received pain medicine from another doctor.
9. I will bring to every visit all of the unused pain medication I have been prescribed.
10. I allow my doctor to receive information from *any* health care provider or pharmacist in this state about use or possible misuse, or abuse of alcohol and other drugs. This permission shall expire only upon my written cancellation of this agreement.
11. I will have all of my medications filled at one pharmacy: _____ I give my doctor permission to contact all other pharmacies and physicians and ask them not to provide me with any addictive medications. This permission shall expire only upon my written cancellation of this agreement.
12. I understand that my doctor will gradually take me off my narcotics if I do not follow the above plan, or if my doctor believes that my being on narcotics is harming me or not helping me.
13. *For women:* I will do everything I can to avoid getting pregnant while I take these medications. To the best of my knowledge, I am not pregnant now.

Individuals My Doctor May Contact for Information on My Condition

Name	Address	Phone	Relation
1.			
2.			
3.			

Patient and Date

Doctor and Date

drug problems, most patients who are understandably concerned about privacy are accepting of these intrusions. Resistance to such moni-

toring could stem from active problems with alcohol or other drugs and might be a contraindication to COAT.

Because COAT is not considered standard treatment, and because physicians might wish to document patients' agreement with terms for prescribing, formal informed consent procedures are recommended. Some physicians who prescribe COAT prefer to reserve written contracts for patients who exhibit possible signs or symptoms of drug problems. Others prefer to establish written agreements for monitoring when COAT is initiated but enact certain provisions as needed. The latter approach can avoid misunderstandings and help protect physicians from regulatory and other legal action. A sample contract is shown in Table 4.

Rationale for Choosing Monitoring Parameters

Although there is consensus that COAT recipients should be monitored for drug problems, there is controversy regarding exactly what should be monitored. It has been recommended that physicians monitor patients receiving addictive medications for substance misuse, abuse, and dependence. (Dependence in this instance refers to substance dependence as defined by the DSM-IV, not physical dependence) Applying these terms to COAT recipients, however, can create problems.

The DSM-IV defines substance dependence as the recurrence or persistence of at least three out of seven possible criteria.⁵⁴ Two of these seven criteria may be fulfilled solely through pharmacologic dependence, which in the absence of other negative consequences would cause problems only if patients inadvisedly and suddenly stop their opioids. The other criteria could easily be misinterpreted to apply to COAT recipients, even when COAT produces net benefit. The primary DSM-IV definition of substance abuse is "a maladaptive pattern of substance use leading to clinically significant impairment or distress" such as "failure to fulfill major role obligations," recurrent substance use in physically hazardous situations, or "continued substance despite persistent or recurrent social or interpersonal problems."⁵⁴ According to these definitions, diagnoses of drug-related problems could be made for individuals who choose to endure adverse effects or risks of opioids that, taken as directed, produce a net benefit in pain and overall function. In addition, judgments whether pain or substance use leads to failure of role obligations can be very subjective. Thus the DSM-IV definitions of drug abuse and dependence should not be applied to opioid use by COAT recipients.

Misuse, as this term is applied to prescription drugs, denotes the use of substances in a manner not advised by the prescriber.⁵⁵ Misuse of prescribed opioids is a concern to the degree that it places patients at risk for adverse consequences. Drug problems might commence with misuse. One potential reason why patients would use opioids beyond how they are prescribed, however, might be overly cautious prescribing. For example, failure to provide extra or emergency doses for expected exacerbations of pain can result in use that physicians call misuse but patients insist is necessary and not harmful. To the extent that underdosing by physicians leads to extra dosing by patients, misuse would carry little risk.

Clinicians often regard drug-seeking behavior as an indicator of a drug problem. There is little agreement, however, regarding the meaning of this term. Some clinicians apparently use this term to connote excessive, persistent, or manipulative requests for controlled substances. Clinicians, however, often do not agree whether particular requests are excessive, persistent, or manipulative. As stated above, it can be difficult to determine at times whether such requests stem from drug problems or insufficient analgesia (pseudoaddiction).⁵¹ Thus behaviors that clinicians would label drug-seeking do not always indicate drug problems.

Physical function parameters, such as flexibility and strength, are sometimes suggested as objective measures of progress for patients with chronic low back pain. Still, many patients report subjective improvement in pain without exhibiting improvement in such functions. Furthermore, measures of such function might not be sufficiently reliable to yield clinically useful comparisons with time.^{56,57}

The suggested monitoring parameters for COAT recipients are pain and global function—the chief targets of any treatment for chronic pain. Global function refers to general biomedical, psychologic, and social function, including intellectual and cognitive function, mood state, interactions with family members and friends, self-care, maintaining a residence, and involvement in other pursuits, such as work, school, community, organized religion, and hobbies. Serious alcohol and other drug problems manifest as declines in global function. Thus, monitoring global function also accomplishes monitoring for alcohol and other drug problems.

Monitoring COAT Recipients

Implementing a monitoring scheme is an important part of caring for COAT recipients. An approach to monitoring is described in this section. Until opioid dose titration is completed, visits are recommended every 1 to 2 weeks, and more frequent telephone contacts might be necessary. Monthly visits are recommended through the first year of COAT. Subsequently, it might be safe to decrease the frequency of visits to quarterly for patients whose pain, function, and medication use have been stable. On the other hand, in many states, no more than a 1-month supply of opioids may be prescribed at one time. Periodic joint visits with close contacts of the patient are desirable to assess for global function, as described above. If such visits are logistically difficult, then periodic telephone calls to close contacts may be substituted.

In assessing pain, patients' subjective reports must be accepted as valid. The autonomic responses and nonverbal cues that help clinicians gauge the severity of acute pain are blunted or absent in many patients with chronic pain.⁵⁸ Periodic administration of the Chronic Pain Grade can help document progress.⁵² This instrument, shown in Table 2, consists of seven items that measure pain intensity, disability days, and interference with function. The 6-month time delimiter for each item can be adjusted according to the frequency with which the questionnaire is administered. Using a 3-month time delimiter can allow more frequent measures with less recall bias (M Von Korff, personal communication, September, 1993). Some individuals manifest no improvement in pain measures yet cite considerable pain relief; for these individuals, the primary benefit of opioids might be a dulled sense of suffering, which is an important component of the perception of pain (M Backonja, personal communication, August, 1994).

Changes in function related to back pain can be assessed by the self-administered Roland scale (Table 3)⁵³ (RA Deyo, MD, personal communication, December 1993). This instrument consists of 23 yes-no items on specific functions that are commonly affected by back pain. This instrument has been shown to be sensitive to clinically relevant changes with time.^{59,60}

It is also important to assess clinically for the dysfunction that typically manifests with drug problems. Such dysfunction occurs in the areas of

biomedical health, mental health, relationships with family members, other social relationships, work or school, legal problems, and finances.³⁰ Function in these areas is best assessed through periodic joint interviews with patients and other close contacts, such as family members or close friends, since patients with drug problems do not always appreciate or admit to functional decline.

With time one should expect pain and function to vary approximately inversely. In other words, patients who realize some pain relief should exhibit functional improvement, or at least they should not exhibit functional decline. All functional downturns should be investigated. Possible causes include an exacerbation of the chronic pain syndrome, other medical problems, depression or another psychiatric disorder, an alcohol or other drug problem, and another adverse effect of opioids. Investigation of such downturns might include in-depth history taking, discussions with the patient's family members and close friends, a general physical examination, diagnostic studies relating to the back, examination for physical signs of alcohol and other drug problems, urine drug testing, checking with other physicians and pharmacists about unauthorized prescribing, and assessments by alcohol and other drug experts and other mental health experts—preferably those who endorse the potential utility of COAT for chronic noncancer pain. It is helpful to have patients agree to these measures before receiving COAT.

If COAT appears responsible for functional declines that cannot be ameliorated, or if no other causes for functional declines can be defined, then COAT should be decreased or discontinued. If there is doubt, an alcohol or other drug expert should be consulted while the patient continues on COAT. A patient's refusal to accept a physician's recommendation to undergo an alcohol or drug assessment is grounds to terminate COAT. To prevent withdrawal, opioids should be tapered during the course of 1 to 4 weeks, with longer tapers for higher doses of longer acting opioids. Patients who cannot taper themselves might need to receive very frequent prescriptions for small quantities of opioids. Physicians with expertise in alcohol and other drug problems can assist in detoxification.

Urine drug tests are sometimes helpful when a drug problem is suspected. Since individuals with prescription drug problems usually take multiple

Table 5. Controlled Substances Flow Sheet and Care Plan.

Medication: _____				Primary Provider: _____					
Date of Contract: _____				Others Familiar With Pt: _____					
Date	Dose/Sig/#	#days to last	Date of next visit	If pt requests more, prescribe:*			Comments	Initials	Avg mg used per day†
				Ad lib	Some	None			
_____	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____
_____	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____
_____	_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____

* Some = Prescribe enough to hold patient until the next visit, preferably with the primary provider.
 † Complete this column at the next visit. Compute: Total mg prescribed/days prescription lasted.

drugs,⁶¹ screening for several commonly abused substances is recommended when a problem with opioids is suspected. Urine drug tests cannot distinguish patients who are taking larger than expected quantities of a particular opioid preparation. Such tests, however, can sometimes be sensitive to patients who are taking additional opioid preparations. For example, patients receiving prescriptions for morphine only, which produces a positive test for opioid metabolites, should not test positive for methadone or oxycodone. Because the kinds and sensitivities of assays vary across clinical laboratories, physicians are advised to consult with the laboratory toxicologist before ordering urine opioid tests for COAT recipients. Urine drug testing can be subject to laboratory error. Laboratory certification by the National Institute on Drug Abuse (NIDA) is a mark of quality. Unexpected negative urine drug screening results could be due to drug diversion or laboratory error, and a repeated test by a different laboratory might be indicated. Retaining and freezing one half of each urine sample provides the best opportunity for investigating unanticipated results. To prevent false negatives as a result of deception, patients who are suspected of drug problems should be observed as they produce specimens for drug testing.

Tracking Prescribing Patterns

Physicians' failure to recognize increases in their own prescribing activity can result in delayed or missed diagnoses of drug problems or diversion. Group practices are especially susceptible to this error. Maintaining controlled substances flow sheets and care plans can help clinicians be aware

of trends in their prescribing patterns for individual patients and maintain continuity and consistency among multiple health care providers (Table 5).

Medical Management

The principles of prescribing opioids for patients with chronic low back pain or other noncancer pain are similar to the principles of prescribing opioids for acute, postoperative, and cancer pain.^{58,62,63} Opioid dosing should be tailored to the courses of patients' pain. Patients with predictable or infrequent exacerbations of pain might prefer intermittent dosing of opioids. Patients whose sleep is interrupted by pain would benefit from higher doses at night. For patients with continuous pain or frequent, unpredictable exacerbations of pain, regular dosing of opioids is preferable. Regular dosing can be advantageous in that patients build tolerance more quickly to some adverse effects, patients need not constantly focus on their pain to decide whether to medicate, and the pain is not reinforced by the act of taking medication. Nonopioid analgesics (acetaminophen and nonsteroidal anti-inflammatory agents) and nonpharmacologic treatments often enhance analgesia and should be administered along with opioids.

For moderate pain weaker opioids such as codeine, hydrocodone, and oxycodone could suffice. At higher than usual doses, the side effects of these agents often outweigh their increase in analgesia.^{57,61} Beware of exceeding the recommended doses of nonopioid components of combination agents, such as the acetaminophen contained in Percocet and Roxicet.

Table 6. Recommended Starting Doses of Opioids for Acute, Postoperative, and Cancer Pain.

Drug	Approximate Equianalgesic Oral Dose	Approximate Equianalgesic Intravenous Dose	Recommended Starting Oral Dose	Recommended Starting Intravenous Dose
Morphine	30 mg q3-4h around the clock 60 mg q3-4h single or intermittent dose	10 mg q3-4h	30 mg q3-4h	10 mg q3-4h
Morphine SR (MS-Contin)	90 mg q8-12h	Not available	60 mg q8-12h	Not available
Codeine	130 mg q3-4h	75 mg q3-4h	60 mg q3-4h	60 mg q2h
Hydromorphone (Dilaudid)	7.5 mg q3-4h	1.5 mg q3-4h	6 mg q3-4h	1.5 mg q3-4h
Hydrocodone (Vicodin)	30 mg q3-4h	Not available	10 mg q3-4h	Not available
Levorphanol (Levo-Dromoran)	4 mg q6-8h	2 mg q6-8h	4 mg q6-8h	2 mg q6-8h
Meperidine (Demerol)	300 mg q2-3h	100 mg q3h	Not recommended	100 mg q3h
Methadone	20 mg q6-8h	10 mg q6-8h	20 mg q6-8h	10 mg q6-8h
Oxycodone (in Percocet)	30 mg q3-4h	Not available	10 mg q3-4h	Not available
Oxymorphone (Numorphan)	Not available	1 mg q3-4h	Not available	1 mg q3-4h

Note: At higher doses of opioids, cross-tolerance between opioids may be incomplete. Therefore, when switching opioids at higher doses, start with one third to one half the calculated equianalgesic dose.
From Jacox.⁶²

For more severe pain stronger agents, such as morphine, hydromorphone, levorphanol, and methadone, are preferred.^{58,62} Partial agonists and mixed agonist-antagonists, such as pentazocine, propoxyphene, and butorphanol, are not recommended for chronic pain because high doses can induce symptoms of psychosis. Meperidine can cause myoclonus and seizures, and oral absorption is erratic. For patients with gastrointestinal dysfunction, transdermal fentanyl is convenient, although fentanyl and its congeners can cause muscle rigidity at high doses, and doses must be individualized because absorption varies with each patient.

Recommended starting doses of opioids for acute, postoperative, and cancer pain are shown in Table 6. For patients with chronic noncancer pain who are expected to fulfill role expectations at home, work, or school, starting at lower doses of opioids can allow them to maintain function as they adjust and build tolerance to side effects. If analgesia is insufficient and side effects are tolerable, doses of opioids are typically increased by 100 percent in 1 week for patients receiving the lowest doses of the shortest-acting opioids, or by

20 percent to 30 percent every 4 weeks for patients on the highest doses of the longest-acting opioids. There is no absolute ceiling for doses, because tolerance to respiratory depression for most individuals is vast.

Usually the first step in managing persistent side effects is switching opioids. Recently published pain treatment guides,^{58,62} available free of charge through the Agency for Health Care Policy and Research (800-358-9295), provide more detailed information. Once chronic low back pain patients attain some relief with COAT, they might be more responsive to other kinds of treatment. Most COAT recipients will have endured a long period of inactivity and should at least be placed on an exercise regimen. Other physical therapies and psychotherapies should be tried, even if they were not successful previously, because patients might respond more favorably without the limitation, distraction, and frustration of more severe pain.

Experience with chronic pain patients and with methadone maintenance suggests that COAT can be continued for many years and perhaps indefinitely. Nevertheless, the long-term and short-term

risks and benefits of COAT have yet to be evaluated rigorously by randomized controlled trials.

Summary

Recalcitrant, disabling, severe chronic low back pain (chronic low back pain) is quite common. Opioids have been overlooked as a possible treatment for many reasons. Several case series studies suggest that chronic opioid analgesic therapy is safe and effective for at least a subset of patients with chronic low back pain. Until randomized controlled trials provide more definitive data, trials of COAT could be warranted for severe, disabling chronic low back pain that is recalcitrant to other treatments, particularly in the absence of previous alcohol or other drug problems or drug diversion, personality disorders, and certain medical disorders. Eligible patients should be educated about the possible adverse effects of COAT, including physical dependence. The difference between physical dependence and addiction and the plan for preventing and monitoring for drug problems should be explained. Written contracts are recommended. Patient contact should occur weekly during titration and monthly for at least several months thereafter. Pain and function are the most important parameters to follow, and periodic contacts with close family members are helpful for monitoring function. Functional downturns can signal opioid or other drug problems, an adverse effect of opioids, a psychiatric disorder, or another medical problem. Investigations of functional downturns might include discussions with family members, a urine drug screening test, an alcohol and drug consultation, and a trial of discontinuance of COAT. Prescribing should be tracked on flow sheets. Constipation should be managed expectantly. Other side effects often resolve in time or with switching opioids. Initial treatment can begin with codeine analogs, but severe pain often requires morphine, methadone, hydromorphone, or levorphanol, for which there is no absolute ceiling dose. COAT should be administered with non-opioid analgesics, and nonpharmacologic treatments are often helpful.

For some patients with severe recalcitrant chronic low back pain, COAT is unique in its potential to provide pain relief and enhance quality of life. Physicians are encouraged to try COAT for selected patients and, when necessary, educate regulators about its legitimacy as well.

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