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PLUS: How to avoid opioid misuse





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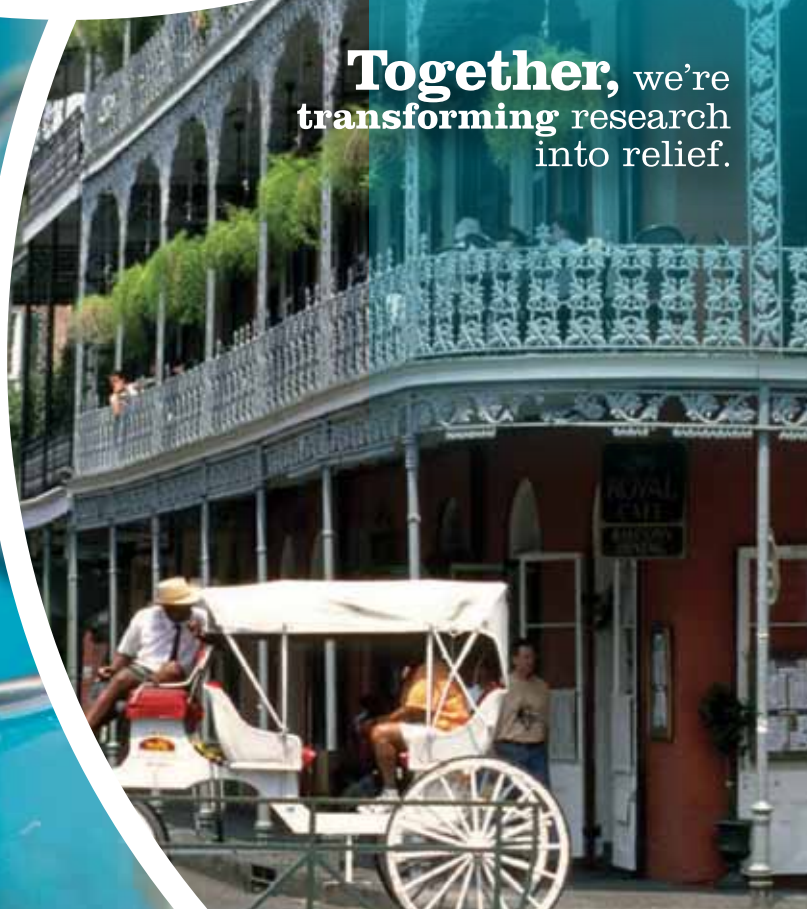
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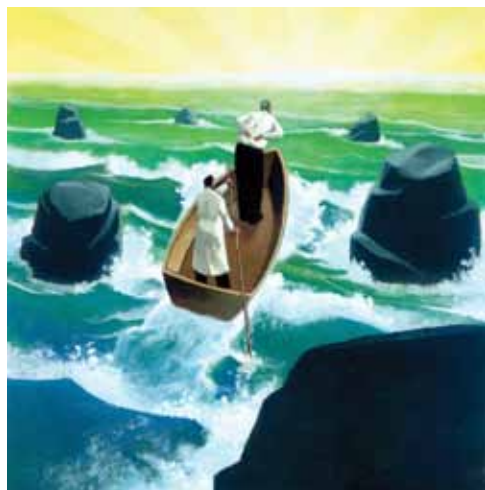


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March 2013

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How to avoid opioid misuse

These practical strategies will help you to identify and monitor the risk of opioid analgesic misuse.

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Opioids have become the standard of care for numerous chronic pain complaints and are the most misused drugs in the United States.¹ The result: A public health issue with challenges for patients with pain, clinicians treating pain, and the broader community. (See “Opioid analgesic misuse: Scope of the problem”¹⁻⁷ on page S3).

Ultimately, clinicians are faced with trying to provide adequate pain relief while predict-

ing which patients are at risk for misuse. An expert panel commissioned by the American Pain Society and American Academy of Pain Medicine (APS/AAPM) reviewed the evidence and issued clinical guidelines for long-term opioid therapy in chronic noncancer pain.⁸ Using the APS/AAPM framework, this article discusses how to:

- identify the risk of problem use in the individual patient
- monitor opioid therapy to ensure safe prescribing
- determine when to terminate opioid therapy in cases of opioid misuse.

Before treatment:

Determine misuse risk

Despite their widespread use, long-term opioid analgesics are not recommended as first-choice therapy.⁸ Evidence supporting long-term efficacy is limited, and studies indicate modest clinical effectiveness.⁹ Concerns also are

Disclosure

Dr. Potter receives grant support from the National Institute on Drug Abuse K23 DA02297 (Potter) and U10 DA020024 (Trivedi) and serves as a consultant to Observant LLC. Ms. Marino reported no potential conflict of interest relevant to this article.



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OPIOID ANALGESIC MISUSE: SCOPE OF THE PROBLEM

Americans consume an estimated 80% of the global supply of prescription opioids.² From 1997 to 2007, average sales of opioid analgesics per person increased 402%.³ Because opioid analgesics are increasingly available in the community,⁴ the prevalence of opioid misuse has followed suit. Opioid analgesics have become the most misused drug class in the United States—second only to marijuana among all illicit substances.¹

Nonmedical users of opioid analgesics numbered 4.5 million in 2011, and 1.8 million opioid analgesic users met diagnostic criteria for dependence or abuse.¹ In 2007, the costs to society of opioid analgesic abuse were estimated at \$25.6 billion due to lost productiv-

ity, \$25.9 billion due to health care costs, and \$5.1 billion due to criminal justice costs, totaling \$55.7 billion.⁵

Regardless of whether opioid analgesics are obtained by prescription or diversion (sharing medication, stolen, or purchased illegally), their misuse in all its forms is a significant public health problem. Opioid analgesic-related emergency department visits increased 111% from 2004 to 2008, to a total of 305,900 visits.⁶ Deaths involving opioid analgesics, including intentional and unintentional overdoses, quadrupled from 1999 to 2008.⁷ Additionally, from 1999 to 2009, national admission rates for treatment of an opioid analgesic-related substance use disorder increased nearly sixfold.⁷

emerging about the safety of long-term opioid use, including iatrogenic opioid-related substance use disorders. Even categorizing opioid misuse is difficult because consensus is lacking on misuse terminology (TABLE 1).^{8,10-12}

On the other hand, many patients with chronic pain do benefit from opioid analgesics, and most who are prescribed long-term opioid therapy do not misuse their medications. The use of opioid analgesics for chronic pain presents an opportunity for misuse in a subset of susceptible people.

Risk factors thought to increase susceptibility include younger age, more severe pain intensity, multiple pain complaints, history of a substance use disorder, and history of a psychiatric disorder.² Identifying individuals with potential for misuse is difficult, however, and clinicians' attempts are not necessarily accurate.¹³

Screening tools. The APS/AAPM guidelines recommend empirically derived screening questionnaires (TABLE 2)⁸ to help you identify misuse potential before initiating opioid therapy. Instruments also are available to monitor misuse for individuals already in treatment. The Screener and Opioid Assessment for Patients with Pain (SOAPP) appears to be the most predictive of misuse potential, although selecting a screening instrument may depend on particular practice needs.¹⁴ These tools are most valuable when used within a comprehensive evaluation that includes the clinical interview with history and pain assessment.

When you identify someone at high risk of opioid misuse, proceed carefully using multiple sources of clinical information. Balance appro-

appropriate pain care with safeguarding against misuse. In the absence of evidence of current misuse, the decision depends on clinical judgment. You might try alternative pain treatments to avoid opioid exposure or consider opioid analgesics with additional monitoring of prescribing (TABLE 3).⁸

Managing risk during treatment

Opioid trial. The APS/AAPM panel⁸ and the World Health Organization analgesic ladder for treating cancer pain¹⁵ recommend an opioid trial before long-term opioids are prescribed. This approach assumes that opioid therapy may not be universally effective and appropriate for all patients and all pain complaints for which opioids are indicated.

By agreeing to an evaluation period, such as 30 days, you and your patient understand that opioid treatment may not continue beyond the trial without an accompanying treatment response. Whereas you may tailor specific outcomes to the individual, a successful response should include:

- reduced pain
- increased function (such as return to work or other valued activities)
- and improved quality of life.

If the agreed-upon outcomes are not met, consider discontinuing the opioid trial and trying alternative treatments. Full discussion of the well-documented strategies for managing opioid therapy is beyond the scope of this article. (See other sources for information about strategies such as opioid rotation, which

The use of opioid analgesics for chronic pain presents an opportunity for misuse in a subset of susceptible people.

TABLE 1
Glossary of of opioid use terminology

Aberrant drug-related behavior

Opioid-related behavior that demonstrates nonadherence to the patient-clinician agreed-upon therapeutic plan⁸

Misuse

Use of an opioid in a manner other than how it is prescribed^{10,11}

Abuse

Illicit opioid use that is detrimental to the user or others¹⁰

Nonmedical use of an opioid for the purpose of attaining a “high”¹¹

A DSM-IV-TR substance use disorder diagnosis, evidenced by a maladaptive pattern of opioid use, leading to clinically significant impairment or distress as manifested by ≥1 of the following criteria in a 12-month period:

- use resulting in failure to fulfill major role obligations
- use when it is physically hazardous
- continued use in spite of legal problems
- continued use despite social or interpersonal problems¹²

Dependence

A DSM-IV-TR substance use disorder diagnosis, evidenced by a maladaptive pattern of opioid use, leading to clinically significant impairment or distress as manifested by ≥3 of the following criteria in a 12-month period:

- tolerance
- withdrawal
- opioid taken in larger amounts or over longer period than intended
- inability to cut down
- great deal of time spent obtaining and using opioids
- reduced activities due to opioid use
- continued use despite physical or psychological problems¹²

DSM, *Diagnostic and Statistical Manual of Mental Disorders*.

involves switching from one opioid to another in an effort to increase therapeutic benefit or reduce harm.^{16,17})

Monitoring aids. In addition to screening and monitoring questionnaires, urine drug screens and prescription monitoring programs (PMPs) can help you objectively monitor for aberrant drug-related behaviors that may indicate misuse.

Urine drug screens can identify substance abuse or dependence and potential problems you might not have detected.² When used appropriately, urine drug screens can provide useful information about an individual's substance abuse potential (such as a positive test for an illicit substance). The absence of a prescribed opioid may be as significant as a positive finding because this may suggest compliance issues or diversion.

Prescription monitoring programs have been established by most states since 2002 through grants from the Department of Justice. PMPs store prescription drug information

from pharmacies in a statewide database and develop algorithms that can detect behaviors suggesting opioid misuse.¹⁸ For example, an algorithm may track factors such as having 5 or more prescribers, 3 or more pharmacies, or 3 or more early refills within 1 year.¹⁹

Individual states administer PMPs differently, but prescribers generally can request information to monitor individual patients and detect illicit behaviors. Although relatively new, PMPs have been shown to reduce prescription sales,²⁰ doctor shopping,¹⁹ and opioid analgesic misuse.²¹ A comprehensive list of state PMPs is available from the Alliance of States with Prescription Monitoring Programs (www.pmpalliance.org/content/pmp-access).

Responding to evidence of aberrant behavior

Even when you follow recommended opioid risk mitigation strategies, expect some individuals to show aberrant drug-taking

Although relatively new, prescription monitoring programs have been shown to reduce doctor shopping and opioid analgesic misuse.

TABLE 2**Questionnaires for screening and opioid misuse risk identification⁸**

Risk assessment tools	
Screeener and Opioid Assessment for Patients with Pain (SOAPP) http://www.painedu.org/soapp.asp	Predicts how much monitoring a patient will need on long-term opioid therapy
Opioid Risk Tool (ORT) http://www.partnersagainstpain.com/printouts/Opioid_Risk_Tool.pdf	Assesses for known conditions that indicate higher risk for medication misuse, including history of substance abuse, age, history of sexual abuse, and psychiatric disorders
Diagnosis, Intractability, Risk, Efficacy (DIRE) http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=5&ved=0CEgQFjAE&url=http%3A%2F%2Fwww.fmdrl.org%2Findex.cfm%3Fevent%3Dc.getAttachment%26riid%3D6613&ei=vJ7IULDHFqKc2AWCilGwAQ&usq=AFQjCNECSYFnam9UATA-Xm_JQ0cjm6Xdiw&bvm=bv.1355534169,d.b2l	Assigns the patient a score of 1 to 3 for each of 4 factors: diagnosis, intractability, risk (psychological, chemical health, reliability, social support), and efficacy
Monitoring tools during long-term opioid therapy	
Pain Assessment and Documentation Tool (PADT) http://www.ucdenver.edu/academics/colleges/PublicHealth/research/centers/maperc/online/Documents/Pain_Assessment_Documentation_Tool_%28PADT%29.pdf	Assesses pain relief, daily functioning, and opioid-related adverse events; also whether patient appears to be engaging in potential aberrant drug-related behaviors
Current Opioid Misuse Measure (COMM) http://www.painedu.org/soapp.asp	Assists in identifying patients exhibiting aberrant drug-related behaviors

behavior, abuse, or even the emergence of a co-occurring substance use disorder. Although evidence is limited regarding best practices in these circumstances, terminating opioid treatment is not necessarily the only option.⁸

Should you identify aberrant drug-related behaviors or any form of opioid analgesic misuse, evaluate the patient to determine the circumstances and immediately address the behavior. For example, using more medication than prescribed may be a sign of inadequately managed pain or clinical status, rather than an indication of abuse.

Referrals may be beneficial as part of your evaluation process. A pain specialist may offer alternative treatment approaches to mitigate medication overuse. An addiction specialist can evaluate patient safety for continued treatment with opioids, facilitate referrals for treatment of a substance use disorder, and provide consultation if discontinuing opioid therapy is appropriate.

Intervention. The patient's pain complaint will persist whether or not you continue opioids, and substance abuse treatment may complement pain management. Even for an

individual who continues opioid therapy, substance abuse treatment can provide tools for understanding and managing substance misuse. For instance, a cognitive-behavioral training program helped curb misuse and increase adherence in high-risk patients on opioid therapy for chronic back pain.²²

Providing specialized care before you consider terminating opioid therapy allows people to address their reasons for misusing. Integrated treatment by a clinician specializing in co-occurring chronic pain and addiction may be particularly beneficial, as pain is an important motivator of individuals seeking treatment for an opioid use disorder.²³

Termination. If, after additional resources and referral, an individual fails to make progress toward the therapeutic goal, you may need to terminate long-term opioid therapy. By making this decision, you may prevent the emergence of an opioid use disorder. Even so, telling someone that you are stopping opioid treatment can be a difficult discussion. The National Institute on Drug Abuse provides a wealth of online resources to assist with these and other opioid misuse conversations.^{24,25}

TABLE 3
Practical strategies for addressing opioid misuse⁸

Before treatment

- Conduct a thorough history, including substances (alcohol and others)
- Consider using empiric screening tools (TABLE 2)
- Evaluate known risk factors
- Consider nonopioid treatment with, or in place of, opioid therapy
- Enhance monitoring for patients at moderate to high risk of misuse
- Incorporate opioid prescribing guidelines into clinical practice
- Set treatment goals and discuss expectations with the patient before starting opioid therapy

During treatment

- Begin opioid trial, and base continuing therapy on clinical response
- Routinely assess the patient; document opioid therapy efficacy, adverse effects, and evidence of misuse
- Perform random urine drug screening, per policy
- Obtain patient information from state's prescription monitoring program
- Address, evaluate, and respond to questionable use, per policy

When things go wrong

- Evaluate behavior and determine course of action if questionable use occurs
- Address questionable use with the patient
- Evaluate benefit of continuing opioid therapy
- Consider referral to an addiction specialist for consultation
- Consider referral to a pain specialist
- Initiate opioid taper if discontinuing; consider addiction consult if opioid use disorder is present

Some preliminary evidence supports off-label use of sublingual buprenorphine for chronic pain, but more research is needed.

Opioid detoxification is complex and should be managed and monitored to mitigate opioid withdrawal symptoms. Unfortunately, very little clinical guidance exists on effective opioid taper strategies for chronic pain patients. Consultation with an addiction specialist is recommended to assist with discontinuing treatment.

**Future directions:
A role for buprenorphine?**

The introduction of transdermal buprenorphine in the United States in 2001 spurred new interest in this medication for treating moderate to severe chronic pain.²⁶ Buprenorphine's reported lower abuse potential may differentiate it from other opioid analgesics.²⁷ Although a 2006 report showed evidence of modest diversion and abuse of buprenorphine,²⁸ survey data and human laboratory

studies demonstrate consistently that the abuse potential is lower—particularly with the combined buprenorphine/naloxone formulation—than with other opioids.²⁹

Sublingual buprenorphine formulations, with and without naloxone, are FDA approved for opioid use disorder and opioid dependence, but not for pain. Thus, it is a medication with analgesic properties that is approved for an opioid use disorder. Some preliminary evidence supports off-label use of sublingual buprenorphine for chronic pain,³⁰ but more research is needed before this approach can be recommended.

Additional clinical studies are examining whether the sublingual formulation's efficacy for pain is comparable to other buprenorphine formulations. If this is supported, buprenorphine may become an appropriate, safer option for patients at risk of misusing who might benefit from continued opioid therapy.

Maintaining a rational, evidence-based approach

Opioid analgesic misuse is a serious public health problem. It would be unfortunate, however, if clinicians were to avoid medically appropriate opioid prescribing for people with chronic pain. Rational, evidence-based strategies to mitigate opioid misuse are the appropriate goal, accompanied by efforts to improve chronic pain treatment with and without opioids. To provide safe and effective opioid therapy, we urge you to develop a proactive approach informed by clinical guidelines, clinical experience, and the scientific literature.

References

1. Results from the 2011 National Survey on Drug Use and Health: summary of national findings. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012. Available at: <http://www.samhsa.gov/data/NSDUH.aspx>. Accessed December 26, 2012.
2. Sehgal N, Manchikanti L, Smith HS. Prescription opioid abuse in chronic pain: a review of opioid abuse predictors and strategies to curb opioid abuse. *Pain Physician*. 2012;15(3 suppl):E567-E92.
3. Manchikanti L, Fellows B, Ailinani H, et al. Therapeutic use, abuse, and nonmedical use of opioids: a ten-year perspective. *Pain Physician*. 2010;13:401-435.
4. Boudreau D, Von Korff M, Rutter CM, et al. Trends in long-term opioid therapy for chronic non-cancer pain. *Pharmacoepidemiol Drug Saf*. 2009;18:1166-1175.
5. Birnbaum HG, White AG, Schiller M, et al. Societal costs of prescription opioid abuse, dependence, and misuse in the United States. *Pain Med*. 2011;12:657-667.
6. Centers for Disease Control and Prevention. Emergency department visits involving nonmedical use of selected prescription drugs - United States, 2004-2008. *MMWR Morb Mortal Wkly Rep*. 2010;59:705-734.
7. Centers for Disease Control and Prevention. Overdoses of prescription opioid pain relievers - United States, 1999-2008. *MMWR Morb Mortal Wkly Rep*. 2011;60:1487-1492.
8. Chou R, Fanciullo GJ, Fine PG, et al. Clinical guidelines for the use of chronic opioid therapy in chronic non-cancer pain. *J Pain*. 2009;10:113-130.
9. Martell BA, O'Connor PG, Kerns RD, et al. Systematic review: opioid treatment for chronic back pain: prevalence, efficacy, and association with addiction. *Ann Intern Med*. 2007;146:116-127.
10. Butler SF, Budman SH, Fernandez KC, et al. Development and validation of the Current Opioid Misuse Measure. *Pain*. 2007;130:144-156.
11. Katz NP, Adams EH, Chilcoat H, et al. Challenges in the development of prescription opioid abuse-deterrent formulations. *Clin J Pain*. 2007;23:648-660.
12. *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed., text rev. Washington, DC: American Psychiatric Association, 2000.
13. Katz N, Fanciullo GJ. Role of urine toxicology testing in the management of chronic opioid therapy. *Clin J Pain*. 2002;18(4 suppl):S76-S82.
14. Moore TM, Jones T, Browder JH, et al. A comparison of common screening methods for predicting aberrant drug-related behavior among patients receiving opioids for chronic pain management. *Pain Med*. 2009;10:1426-1433.
15. World Health Organization. Cancer: WHO's pain ladder. Available at: <http://www.who.int/cancer/palliative/painladder/en>. Accessed December 26, 2012.
16. Fine PG, Portenoy RK. Establishing "best practices" for opioid rotation: conclusions of an expert panel. *J Pain Symptom Manage*. 2009;38:418-425.
17. Ballantyne JC, Mao J. Opioid therapy for chronic pain. *N Engl J Med*. 2003;349:1943-1953.
18. Worley J. Prescription drug monitoring programs, a response to doctor shopping: purpose, effectiveness, and directions for future research. *Issues Ment Health Nurs*. 2012;33:319-328.
19. Katz N, Panas L, Kim M, et al. Usefulness of prescription monitoring programs for surveillance—analysis of Schedule II opioid prescription data in Massachusetts, 1996-2006. *Pharmacoepidemiol Drug Saf*. 2010;19:115-123.
20. Simeone R, Holland, L. An evaluation of prescription monitoring programs, September 1, 2006. Available at: <https://www.bja.gov/publications/pdmpexecsumm.pdf>. Accessed December 26, 2012.
21. Wang J, Christo PJ. The influence of prescription monitoring programs on chronic pain management. *Pain Physician*. 2009;12:507-515.
22. Jamison RN, Ross EL, Michna E, et al. Substance misuse treatment for high-risk chronic pain patients on opioid therapy: a randomized trial. *Pain*. 2010;150:390-400.
23. Potter JS. Co-occurring chronic pain and opioid addiction: is there a role for integrated treatment? Honolulu, HI: American Psychiatric Association Annual Meeting, 2011.
24. National Institute on Drug Abuse. Talking to patients about sensitive topics: communication and screening techniques for increasing the reliability of patient self-report. Available at: <http://www.drugabuse.gov/nidamed/centers-excellence/resources/talking-to-patients-about-sensitive-topics-communication-screening-techniques-increasing>. Accessed January 10, 2013.
25. National Institute on Drug Abuse. Managing pain patients who abuse prescription drugs. Available at: <http://www.drugabuse.gov/nidamed/etools/managing-pain-patients-who-abuse-prescription-drugs>. Accessed January 10, 2013.
26. Pergolizzi J, Aloisi AM, Dahan A, et al. Current knowledge of buprenorphine and its unique pharmacological profile. *Pain Pract*. 2010;10:428-450.
27. Park HS, Lee HY, Kim YH, et al. A highly selective kappa-opioid receptor agonist with low addictive potential and dependence liability. *Bioorg Med Chem Lett*. 2006;16:3609-3613.
28. Substance Abuse and Mental Health Services Administration. Diversion and abuse of buprenorphine: a brief assessment of emerging indicators. Final report, 2006. Available at: <http://buprenorphine.samhsa.gov>. Accessed December 26, 2012.
29. Comer SD, Sullivan MA, Vosburg SK, et al. Abuse liability of intravenous buprenorphine/haloxone and buprenorphine alone in buprenorphine-maintained intravenous heroin abusers. *Addiction*. 2010;105:709-718.
30. Malinoff HL, Barkin RL, Wilson G. Sublingual buprenorphine is effective in the treatment of chronic pain syndrome. *Am J Ther*. 2005;12:379-384.

While opioid analgesic misuse is a serious problem, it would be unfortunate if clinicians avoided prescribing opioids for people in chronic pain.

Steering patients to relief from chronic low back pain: Opioids' role

When and how to initiate opioids is challenging—to say the least—given their potential for abuse and worrisome adverse effects. Here's how to integrate opioids into an overall approach to your patient's chronic low back pain.

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Mr. S, age 57, recalls no specific event that triggered his lower back pain, which began 2 years ago and has been gradually worsening. His pain improves at times and varies in severity day to day. At this visit, he rates the pain as a 7 on a 10-point scale. The pain now interferes with his ability to walk more than 2 to 3 blocks, and when he golfs on weekends, he must now ride in the golf cart. Mr. S describes himself as fortunate, as his back pain has not interfered with his job as an engineer.

Mr. S has no associated leg pain or other neurologic symptoms. Radiography of the lumbosacral spine shows degenerative disc disease and facet joint arthritis. He has tried acetaminophen, then prescription-strength nonsteroidal

Disclosure

The author reported no potential conflict of interest relevant to this article.

anti-inflammatory drugs (NSAIDs) and supervised exercise therapy. He asks you about an opioid prescription.

Is it time to prescribe opioids?

Up to 70% of people experience a low back pain episode at least once in their lifetime, making low back pain among the most common conditions encountered in clinical practice.¹ Low back pain can impair function, ability to work, and quality of life, and it frequently is associated with depression or anxiety.^{2,3}

Physicians prescribe medications more than any other treatments for low back pain.⁴ The analgesic arsenal includes acetaminophen, NSAIDs, opioids, antidepressants, skeletal muscle relaxants, benzodiazepines, anticonvulsants, and others.

The good news for people with acute low back pain is that the natural history is quite favorable: most improve within the first 4 weeks.⁵ The key components of early treatment are self-care education, advice to stay active, and simple analgesics (acetaminophen and NSAIDs). Opioids may be appropriate for time-limited symptomatic relief for selected patients with severe pain,⁶ but no randomized trials have examined opioids for acute low back pain.

The treatment approach is less definitive for individuals such as Mr. S with chronic low back pain (generally defined as >12 weeks' duration). Opioids are commonly prescribed and are the most potent analgesics,⁷ but they are associated with abuse potential and other adverse effects, such as constipation, nausea, and sedation. Furthermore, opioids' clinical benefits for low back pain may be limited, particularly when prescribed for long-term use.⁸

Few studies inform opioid use in low back pain

Two systematic reviews published in 2007 found few placebo-controlled randomized trials of opioids for chronic low back pain, with some trials showing no analgesic benefit of opioids over placebo and no clear evidence of improved function.^{9,10} Two subsequent trials showed moderate benefits of opioids for chronic low back pain—1.5 to 2 points on a 10-point pain scale—compared with placebo.^{11,12}

Observational studies from workers' compensation settings suggest that opioid use by

people with low back pain may worsen outcomes. A cohort study using a Washington State administrative database found poorer function associated with higher opioid doses over time.¹³ Although these investigators applied statistical adjustments for potential confounders, residual confounding probably remained because individuals who were more likely to have poor outcomes may also have been more likely to receive higher opioid doses.

A greater body of evidence exists on the use of opioids for other types of chronic pain, such as osteoarthritis or rheumatoid arthritis. A systematic review found approximately 20% to 30% greater pain relief for noncancer chronic pain from opioids compared with placebo during short-term treatment (average 5 weeks).¹⁴ These results may reasonably extrapolate to estimated benefits from opioids for chronic low back pain, which probably wouldn't respond differently than other types of chronic pain.

Guidelines call for a multifaceted approach

Given the limited evidence and potential for adverse effects, guidelines from the American College of Physicians and American Pain Society (ACP/APS) recommend opioids as part of an overall approach to managing low back pain.⁶

First-line therapy. The ACP/APS guidelines recommend using acetaminophen and NSAIDs as first-line pharmacologic treatment for low back pain.⁶ Although less potent than opioids, these analgesics offer a more favorable balance of benefits to harms.¹⁵ Acetaminophen is associated with liver toxicity and NSAIDs with gastrointestinal bleeding and cardiovascular events, but we can mitigate these risks by avoiding use in people with contraindications and prescribing lower doses for the shortest duration necessary.

The guidelines also recommend an emphasis on self-care, in particular advising people to remain active.⁶ This message has been shown to be more effective than prescribed bed rest in helping individuals with low back pain return to normal function.¹⁶ For chronic low back pain, exercise therapy remains a key intervention with added health benefits. Effective programs focus on core strengthening, flexion/extension movements, directional preference, aerobic fitness, mind-body exercises (such as yoga and Pilates), and

Exercise therapy remains a key intervention for low back pain.

The risk of overdose begins to increase at doses equivalent to morphine, 50 to 100 mg/day, and continues to rise in a dose-dependent fashion.

other techniques.¹⁷ Some evidence suggests that >20 hours of intervention time is more effective than less intensive exercise therapy.¹⁸

Other options. Medication options for individuals who do not respond adequately to acetaminophen and NSAIDs include short-term skeletal muscle relaxants for acute low back pain and antidepressants for chronic low back pain.⁶ Skeletal muscle relaxants are not considered first-line medications because of their high rate of sedation, and they have not been studied well in chronic low back pain. The serotonin norepinephrine reuptake inhibitor duloxetine was FDA approved recently for treating chronic low back pain and appears to have modest effects on pain and function.¹⁹

Complementary and alternative modalities such as spinal manipulation, acupuncture, and massage also are recommended for chronic low back pain, but not as substitutes for exercise therapy.⁶ Psychotherapy is another option, especially for patients with difficulty coping or comorbid psychiatric conditions. Physical modalities such as ultrasound, transcutaneous electrical nerve stimulation, and interferential therapy are not recommended because of a lack of evidence showing benefits.⁶ The role of interventional therapies and surgery is limited for low back pain without evidence of radiculopathy due to herniated disc or spinal stenosis.²⁰

Opioids. In general, reserve opioids for individuals who do not respond to first-line medications and nonpharmacologic therapies. Earlier consideration of opioids may be warranted for people with severe pain and functional limitations or contraindications to first-line medications.

To manage chronic low back pain effectively, be clear with patients that opioids generally do not eliminate pain and, if used, are one part of an overall management plan. The benefits of using opioids are not likely to exceed—and might well be less than—the average 20% to 30% pain relief observed in clinical trials for general chronic pain.

Managing biopsychosocial components. For many individuals, chronic low back pain is best understood as a complex biopsychosocial condition.²¹ Cognitive behavioral therapy can be helpful for those with severe functional limitations related to low back pain or maladaptive coping strategies. They may exhibit fear avoidance (avoiding usual activities out of fear of harming the back) or catastroph-

izing (dwelling on the worst possible outcome of the back pain, such as total disability).²²⁻²⁴ Depression also is common with low back pain and should be appropriately evaluated and treated.¹⁶

For injured workers, opioid therapy is most likely to be effective when used in conjunction with cognitive behavioral therapy, exercise therapy, and functional restoration. Functional restoration is an intervention that includes simulated or actual work tests in a supervised environment to enhance job performance skills and improve strength, endurance, flexibility, and cardiovascular fitness.

Assess risks/benefits when considering opioids

An American Pain Society/American Academy of Pain Medicine (APS/AAPM) guideline on opioid therapy for chronic low back pain or other types of pain emphasizes the need to assess risks related to opioids' abuse potential and to consider potential benefits and other adverse effects, such as increased respiratory depression in individuals with obstructive sleep apnea or increased risk of falls and fractures in older patients.²⁵

Major risk factors for opioid misuse or abuse include a personal or family history of substance abuse—the latter often overlooked but critical. Formal tools such as the Opioid Risk Tool (TABLE) can help you perform and document risk assessment.²⁶ The Opioid Risk Tool categorizes patients as low-, moderate-, or high-risk for aberrant drug-related behaviors, based on a simple point system using 5 criteria.

Risk assessment informs your decisions about whether to start opioids and how to structure follow-up and monitoring. For example, you may deem a higher-risk patient inappropriate for opioids and instead focus on functional restoration, cognitive behavioral therapy, and nonopioid analgesics. Alternatively, you might consider opioids, but only in conjunction with other therapies and with more intense monitoring and follow-up to mitigate potential risks. This plan might include more frequent clinic visits, limited-duration prescription refills (such as a 1 or 2 weeks' supply instead of 1 month), frequent random urine drug screens,²⁷ and close follow-up of prescription drug monitoring program data. (See "How to avoid opioid misuse" on page S2.)

TABLE

Opioid Risk Tool: Assessing opioid abuse potential

Mark each box that applies	Female	Male
1. Family history of substance abuse		
Alcohol	<input type="checkbox"/> 1	<input type="checkbox"/> 3
Illegal drugs	<input type="checkbox"/> 2	<input type="checkbox"/> 3
Prescription drugs	<input type="checkbox"/> 4	<input type="checkbox"/> 4
2. Personal history of substance abuse		
Alcohol	<input type="checkbox"/> 3	<input type="checkbox"/> 3
Illegal drugs	<input type="checkbox"/> 4	<input type="checkbox"/> 4
Prescription drugs	<input type="checkbox"/> 5	<input type="checkbox"/> 5
3. Age (mark if between 16-45 years)		
	<input type="checkbox"/> 1	<input type="checkbox"/> 1
4. History of preadolescent sexual abuse		
	<input type="checkbox"/> 3	<input type="checkbox"/> 0
5. Psychological disease		
ADD, OCD, bipolar, schizophrenia	<input type="checkbox"/> 2	<input type="checkbox"/> 2
Depression	<input type="checkbox"/> 1	<input type="checkbox"/> 1
Scoring totals	_____	_____
0–3 = low risk for aberrant behaviors; 4–7 = moderate risk; ≥8 = high risk.		
<small>ADD, attention-deficit disorder; OCD, obsessive-compulsive disorder. From Webster LR, Webster RM. <i>Pain Med.</i> 2005.²⁶ Used with permission.</small>		

Define measurable, achievable functional goals to help assess benefits from opioids.

Start low

The APS/AAPM guideline recommends that you initiate opioids at low doses (such as hydrocodone 5-10 mg, codeine 60 mg, or oxycodone 5 mg, 2 to 3 times daily) and titrate slowly to reduce the risk of accidental overdose.²⁵ Previously, physicians prescribed opioids with no “ceiling dose,” meaning that doses were titrated up until patients experienced pain relief or intolerable adverse effects. Recent evidence, however, indicates that the risk of overdose in patients prescribed opioids for chronic pain begins to increase at doses equivalent to morphine, 50 to 100 mg/day, and continues to rise in a dose-dependent fashion.²⁸⁻³⁰

Studies are not yet available to show whether patients who do not respond at morphine-equivalent doses <50 to 100 mg/day will respond at higher doses. Anecdotally, however, many patients who do not respond at lower doses also do not appear to respond at higher doses of the same opioid, or respond minimally. Therefore, prescribe opioids at doses equivalent to morphine >100 mg/day only for patients with clearly

demonstrated improvement in pain and function whom you can adequately monitor.

Include these in the treatment plan

As part of the treatment plan, be sure to define measurable, achievable functional goals for all patients to help assess benefits from opioids. For example, walking the dog for 20 minutes 5 times a week is a feasible and measurable functional goal for a 60-year-old patient, whereas a goal to “feel 25 years old again” is not.

Always have an “exit strategy” when starting opioids, with a clear understanding of circumstances that will lead to opioid discontinuation (such as inability to take opioids as prescribed, noncompliance with other recommended interventions or follow-up, or illicit drug use) as well as a plan on how to taper opioids, including resources for managing withdrawal. Outline this opioid management plan in writing, including reasons for discontinuation, making the treatment parameters clear to the patient and other health care providers from the onset.

CASE

Mr. S has no personal or family history of substance abuse, no history of depression or other psychological disorders, and no serious comorbid conditions that are contraindications to opioid therapy. He scores 0 points on the Opioid Risk Tool, and a urine drug screen is negative. You initiate low-dose opioid therapy (oxycodone 5 mg 3 times daily as needed). You set a goal that Mr. S walk 30 minutes 4 times a week, with a longer-term goal of walking 9 holes of golf.

Continually reassess

Consider the period after you initiate opioids as a treatment trial, and constantly re-examine the decision to continue opioids.²⁵ In follow-up, carefully assess for pain and functional status as well as signs of aberrant drug-related behaviors or other adverse effects.

When a patient is not benefiting from opioids in terms of reduced pain and improved function or is experiencing adverse effects, consider whether to discontinue or restructure opioid therapy. You might try a lower dose, intensify monitoring, consider a specialty consultation, or take other measures. Importantly, patients who are discontinued from opioids still need help to manage their pain, as well as withdrawal symptoms and addiction (when present). They frequently benefit from interventions designed to improve function and address psychological comorbidities and maladaptive coping strategies. Options include psychologically informed physical therapy, interdisciplinary rehabilitation, and cognitive behavioral therapy.

CASE

At follow-up in 4 weeks, Mr. S reports his pain level has gone down from an average of 7 out of 10 to 4 out of 10, and he has been able to walk 20 to 30 minutes 4 times a week. He has no signs of aberrant behaviors. You decide to continue opioid therapy at the same low dose and reiterate the importance of reaching and maintaining functional goals. At this point, you plan to continue the opioid medication as long as he shows continued improvement in functionality and has no signs of aberrant behaviors. You schedule the next follow-up visit in 8 weeks.

Patients who are discontinued from opioids still need help to manage their pain.

References

1. Koes BW, van Tulder MW, Thomas S. Diagnosis and treatment of low back pain. *BMJ*. 2006;332:1430-1434.
2. Bair MJ, Robinson RL, Katon W, et al. Depression and pain comorbidity. *Arch Intern Med*. 2003;163:2433-2445.
3. Martin BI, Deyo RA, Mirza SK, et al. Expenditures and health status among adults with back and neck problems. *JAMA*. 2008;299:656-664.
4. Cherkin DC, Wheeler KJ, Barlow W, et al. Medication use for low back pain in primary care. *Spine*. 1998;23:607-614.
5. Pengel LHM, Herbert RD, Maher CG, et al. Acute low back pain: systematic review of its prognosis. *BMJ*. 2003;327:323-327.
6. Chou R, Qaseem A, Snow V, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Ann Intern Med*. 2007;147:478-491.
7. Deyo RA, Smith DH, Johnson ES, et al. Opioids for back pain patients: primary care prescribing patterns and use of services. *J Am Board Fam Med*. 2011;24:717-727.
8. Von Korff M, Kolodny A, Deyo RA, Chou R. Long-term opioid therapy reconsidered. *Ann Intern Med*. 2011;155:325-328.
9. Deshpande A, Furlan A, Mailis-Gagnon A, et al. Opioids for chronic low-back pain. *Cochrane Database of Systematic Reviews*. 2007(3):CD004959.
10. Martell BA, O'Connor PG, Kerns RD, et al. Systematic review: Opioid treatment for chronic back pain: prevalence, efficacy, and association with addiction. *Ann Intern Med*. 2007;146:116-127.
11. Hale ME, Ahdieh H, Ma T, Rauck R. Efficacy and safety of Opana ER (oxymorphone extended release) for relief of moderate to severe chronic low back pain in opioid-experienced patients: a 12-week, randomized, double-blind, placebo-controlled study. *J Pain*. 2007;8:175-184.
12. Katz N, Richard R, Harry A, et al. A 12-week, randomized, placebo-controlled trial assessing the safety and efficacy of oxymorphone extended release for opioid-naïve patients with chronic low back pain. *Curr Med Res Opin*. 2007;23:117-128.
13. Franklin GM, Enass R, Turner JA, et al. Opioid use for chronic low back pain: a prospective, population-based study among injured workers in Washington state, 2002-2005. *Clin J Pain*. 2009;25:743-751.
14. Furlan AD, Sandoval JA, Mailis-Gagnon A, et al. Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects. *CMAJ*. 2006;174:1589-1594.
15. Chou R, Huffman LH. Medications for acute and chronic low back pain: a review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline. *Ann Intern Med*. 2007;147:505-514.
16. Chou R, Huffman LH. Non-pharmacologic therapies for acute and chronic low back pain: a review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline. *Ann Intern Med*. 2007;147:492-504.
17. Hayden JA, van Tulder MW, Malmivaara AV, et al. Meta-analysis: exercise therapy for nonspecific low back pain. *Ann Intern Med*. 2005;142:765-775.
18. Hayden JA, van Tulder MW, Tomlinson G. Systematic review: strategies for using exercise therapy to improve outcomes in chronic low back pain. *Ann Intern Med*. 2005;142:776-785.
19. FDA clears Cymbalta to treat chronic musculoskeletal pain. Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm232708.htm>. Accessed October 7, 2012.

20. Chou R, Loeser JD, Owens DK, et al. Interventional therapies, surgery and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. *Spine*. 2009;34:1066-1077.
21. Waddell G. Biopsychosocial analysis of low back pain. *Baillieres Clin Rheumatol*. 1992;6:523-557.
22. Chou R, McCarberg B. Managing acute back pain patients to avoid the transition to chronic pain. *Pain Management*. 2011;1:69-79.
23. Turner JA, Aaron LA. Pain-related catastrophizing: what is it? *Clin J Pain*. 2001;17:65-71.
24. Vlaeyen JW, Linton SJ. Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. *Pain*. 2000;85:317-332.
25. Chou R, Fanciullo G, Fine P, et al. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. *J Pain*. 2009;10:113-130.
26. Webster LR, Webster RM. Predicting aberrant behaviors in opioid-treated patients: preliminary validation of the Opioid Risk Tool. *Pain Med*. 2005;6:432-442.
27. Peppin JF, Passik SD, Couto JE, et al. Recommendations for urine drug monitoring as a component of opioid therapy in the treatment of chronic pain. *Pain Med*. 2012;13:886-896.
28. Bohnert AS, Valenstein M, Bair MJ, et al. Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA*. 2011;305:1315-1321.
29. Dunn KM, Saunders KW, Rutter CM, et al. Opioid prescriptions for chronic pain and overdose: a cohort study. *Ann Intern Med*. 2010;152:85-92.
30. Gomes T, Mamdani MM, Dhalla IA, et al. Opioid dose and drug-related mortality in patients with nonmalignant pain. *Arch Intern Med*. 2011;171:686-691.

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REFERENCE: 1. Catella-Lawson F, Reilly MP, Kapoor SC, et al. Cyclooxygenase inhibitors and the antiplatelet effects of aspirin. *N Engl J Med.* 2001;345(25):1809-1817.

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EST-878