

SUPPLEMENT TO

M A N A G E D

Care

Innovations in Pain Management: New Therapeutic Options And Tools for Disease Management

Based on a satellite symposium held at the Academy of
Managed Care Pharmacy 2006 Educational Conference, Chicago

HIGHLIGHTS

- Prevalence and Economic Implications of Chronic Pain

- Treatment Options for Chronic Pain Management:
Opioids Revisited

- Disease Management Tools for Chronic Pain

- Case Studies: Managing Debilitating Chronic Pain

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SELF-STUDY CONTINUING EDUCATION ACTIVITY

Innovations in Pain Management: New Therapeutic Options and Tools for Disease Management

Continuing education credit is offered to pharmacists who read pages 2 through 19 of this publication, complete the post-test on page 21, and submit the evaluation form on page 20. Estimated time to complete this activity is 2.0 hours.

Target audience

Pharmacy directors, clinical pharmacists, and other appropriate personnel in the managed care and pharmacy benefit management sectors.

Purpose and overview

This publication is based on the Academy of Managed Care Pharmacy (AMCP) Breakfast Symposium held in Chicago on Oct. 6, 2006. Chronic pain is a disorder that persists for months or years and frequently is not fully relieved by traditional analgesics. It is a major public health problem that warrants an understanding of the treatment options available to health care practitioners. The articles in this publication review the scope of the problem; pain as a diagnosis; opioid use, abuse, and addiction; and the disease management tools to support outcomes of patients treated with opioid analgesics. Case studies that discuss management techniques for debilitating pain also are presented.

Pharmacists can play an important role in improving patient outcomes. They can positively affect patient care by collaborating with prescribers and patients to ensure that pharmacologic treatment is optimized and that patients receive education on the proper use of opioid analgesics.

This publication serves as an important educational tool for pharmacists and other health care decision makers so that they can make informed decisions on the management of chronic pain.

Educational objectives

After reading this publication, participants will be able to:

- Describe the prevalence and economic implications of chronic pain in the United States.
- Discuss the various pharmacotherapeutic agents prescribed for the treatment of chronic pain.
- Develop a comprehensive treatment plan utilizing a rational approach to the initiation and the management of opioid therapy.
- Evaluate the application of disease management tools utilized by multidisciplinary teams to support improved outcomes of patients treated with opioid analgesics.

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S U P P L E M E N T T O

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Prevalence and Economic Implications Of Chronic Pain

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Chronic pain is a serious and costly public health issue in the United States and is the most common reason that people seek medical care.

Defining pain is difficult because of the many factors involved, such as cause, location, intensity, duration, and the emotional state of the person experiencing the pain. The International Association for the Study of Pain defines pain as “an unpleasant sensory and emotional experience associated with actual and potential tissue damage, or described in terms of such damage” (IASP 1994).

Pain is commonly classified as inflammatory, caused by wounds or medical conditions like rheumatoid arthritis, or neuropathic, for example, diabetic neuropathy. Pain is further distinguished as being acute or chronic. Acute pain after an injury or surgery typically resolves either spontaneously or within a limited period of time. The longer pain lasts, however, the more susceptible it is to other influences, and the greater the possibility that it will become chronic. Chronic pain involves the repetitive firing of pain signals in the nervous system over an extended period of time, ranging from several weeks to years, and can be continuous or intermittent (NIH 2007). Whether pain is acute or chronic, medical treatment may be necessary to relieve the pain. Often, ancillary treatment such as physical therapy and psychiatric counseling also may be necessary (Utah University Health Care 2006).

Prevalence of chronic pain

Just as it is difficult to define pain, it also is difficult to determine the prevalence of pain.

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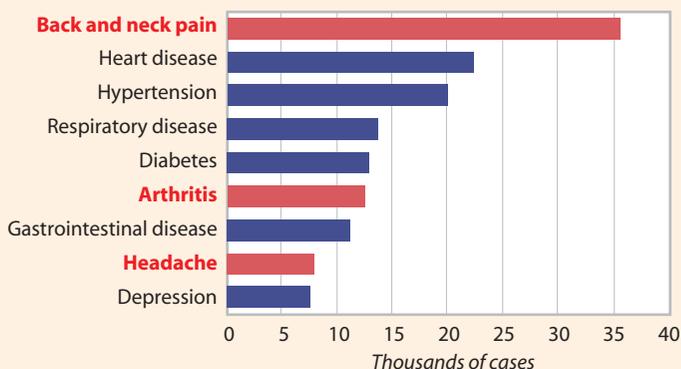
In the United States, chronic pain accounts for 10 to 20 percent of primary care visits (Marcus 2005). Data collected from multiple studies done in developed nations in North America, Europe, and Australia show that the prevalence of chronic pain ranges from 10 to 55 percent (IASP 2003). In the first comparative analysis of direct costs of common chronic conditions among adults in a managed care population done by Fishman and colleagues (1997), back and neck pain in a managed care population had the highest treated prevalence (Figure 1).

The constant factor in chronic pain is that it entails a significant use of health care resources, and is among the most disabling and costly medical conditions in the United States (Eisenberg 1993).

Common chronic pain conditions

Chronic pain is associated with many medical conditions. Musculoskeletal disease is the most common cause of nonmalignant chronic pain, which includes arthritis, osteoarthritis, and other rheumatic conditions. According to the American Pain Foundation (APF), arthritis affects 1 in 6 Americans, and more than 26 million Americans between the ages of 20 and 64 are subject to chronic back pain (APF 2006). In fact, two thirds of American

FIGURE 1
Treated prevalence of the 10 leading chronic conditions in a managed care population



SOURCE: FISHMAN 1997

adults will have back pain sometime during their lifetime, and back pain is a leading cause of disability in Americans younger than 45 years of age (APF 2006). Nine of ten Americans have nonmigraine headaches every year (APF 2006), and more than 25 million Americans suffer from migraines, which appears to go undiagnosed in half the people who are afflicted with them (Lipton 2003).

Other common types of chronic pain include jaw and lower facial pain, which affects 20 million Americans, and fibromyalgia, which affects 4 million Americans (APF 2006, Utah University Health Care 2006). Pain also is associated with mood disorders, such as depression, anxiety, phobias, and posttraumatic stress disorders — patients suffering from depression often seek medical care first for the physical symptoms of depression, such as headache or abdominal pain (Culpepper 2004).

Chronic pain is responsible for a variety of sleep disorders, including difficulty falling asleep, awakening frequently during the night, and reduced time in rapid eye movement or REM sleep (Menefee 2000). It is estimated that 1 in 3 Americans lose more than 20 hours of sleep each month because of pain (APF 2006).

In addition, neuropathic pain affects about 4 million

TABLE
Economic impact of pain in the United States

- The National Institutes of Health estimates that pain costs more than \$100 billion each year.
- Chronic pain, including direct and indirect costs, is estimated to cost close to \$50 billion annually.
- Low back pain accounts for 93 million lost work days every year and costs more than \$5 billion in health care.
- Arthritis pain costs more than \$4 billion in lost income, productivity, and health care.
- Headache and migraine sufferers lose more than 157 million workdays because of headache pain and spend more than \$4 billion a year on medications.

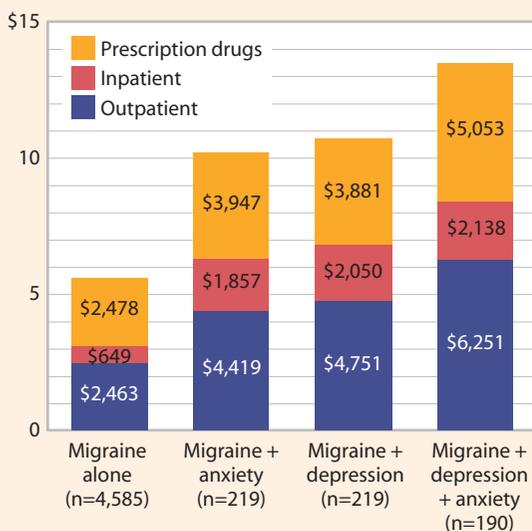
SOURCE: APF 2006, UTAH UNIVERSITY HEALTH CARE 2006

people in the United States (Backonja 2003). Some common types of peripheral neuropathic pain syndromes include post-herpetic neuralgia (a complication of shingles), spinal cord injury, and central poststroke pain. Approximately 70 percent of patients who have cancer experience significant pain during their illness, and fewer than half of these patients receive adequate treatment for their pain (APF 2006, Utah University Health Care 2006).

FIGURE 2

Managed care costs for migraine and painful neuropathic disorders

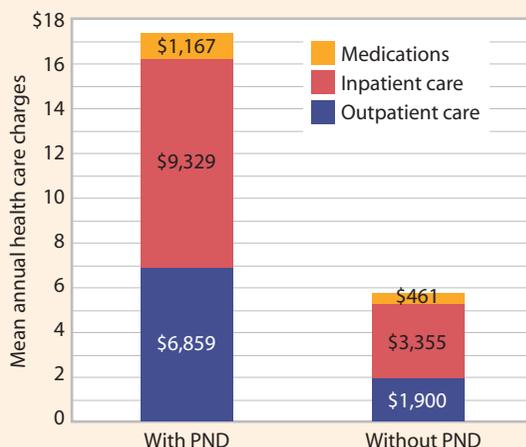
Total medical costs in adult migraineurs with and without comorbid depression or anxiety, or both
In thousands (\$)



SOURCE: PESA 2004

Charges among managed care patients with painful neuropathic disorders (PND)

Calendar year 2000
In thousands (\$)



SOURCE: BERGER 2004

Economic impact of chronic pain

The direct and indirect costs of chronic pain have been estimated at more than \$100 billion annually (Table, page 3). Compared with other disease states, such as heart disease — a primary cause of mortality in the United States — the costs for chronic pain are far greater. For example, based on year-1992 claims from adults in a 400,000-member staff-model health maintenance organization in the Seattle area, Fishman and colleagues (1997) found that expenditures for chronic pain were approximately \$28 million more than the costs associated with heart disease, \$86 million more than the costs for hypertension, and \$108 million more than the costs for respiratory disease. Fourteen percent of the study population had two or more chronic conditions.

An examination in 1998 of costs for back pain revealed that the annual pharmacy costs for prescription drugs accounted for \$14 billion, whereas inpatient care and office-based physician visits totalled \$42 billion (Luo 2004). One national study found that total direct medical costs for all patients with migraine were more than twice as high as the total medical costs for control subjects (Figure 2). An analysis of a 3-million-member managed care health-claims database for the year 2000 showed that patients with neuropathic pain disorders incurred annual health care charges that exceeded \$17,000 (Figure 2).

The cost of chronic pain far outweighs the cost of drugs in any specific category, including the triptans, opioids, nonsteroidal anti-inflammatory drugs, and the COX-2 inhibitors.

Pain sufferers often seek alternative therapies such as acupuncture and chiropractic, although the extent and associated costs are not fully known. One national survey found that in 1990, Americans made 425 million visits to providers of alternative therapies — far exceeding the number of visits to all U.S. primary care physicians (388 million). The expenditures associated with these therapies amounted to nearly \$14 billion, three quarters of which was paid out of pocket, an amount comparable to total out-of-pocket costs for all hospitalizations in the United States annually (Eisenberg 1993).

Summary

Chronic pain is a major public health issue that affects the quality of life and productivity. It is costly and has a significant impact on health resource utilization. Management of chronic pain requires a multidisciplinary approach that focuses on disease management and takes into account the need for ongoing support by family members and other caregivers. Managed care pharmacies can play an important role in pain management to effect positive outcomes and reduce health resource utilization.

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Treatment Options for Chronic Pain Management: Opioids Revisited

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Pain is the most common reason that patients visit physicians, clinical facilities, and pharmacies (Lipman 1993). Pain management, however, is not well taught in medical schools, and health care professionals often have little understanding of what pain is about.

Undertreating pain

There is an old yet accurate definition of pharmaceutical care that is still pertinent today. It is defined as the responsible provision of drug therapy for the purpose of achieving definite outcomes to improve a patient's quality of life (Hepler 1990). Because 9 in 10 American adults suffer from pain at least once a month and more than 26 million Americans suffer severe pain monthly, the burden on managed care and the health care system is considerable (Pain in America 1999). In fact, \$1 of every \$10 spent on health care is used for the treatment and care of musculoskeletal conditions (Medscape Wire 2000). Kaiser Permanente of Oregon found that during the period 1993 and 1994, pain was one of the 10 most common reasons for calls to nurses at telephone advice centers, and that inadequate pain management was one of the most frequent member complaints (Donovan 1999).

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Genetic polymorphism: The case for multiple dosage forms on the formulary

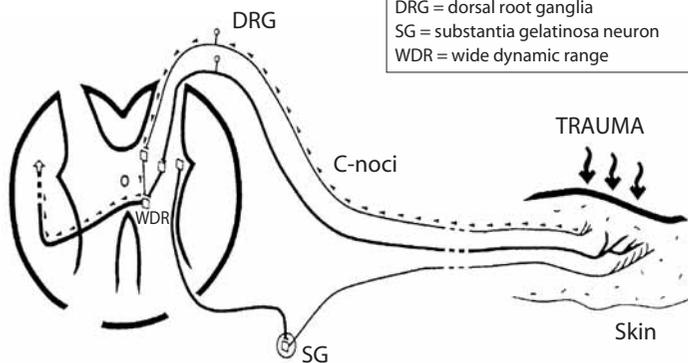
Unfortunately, no one agent can be effective against chronic pain because of significant interpatient variability in the response to opioids. Nineteen different subsets of the μ -opioid receptor gene have been cloned in a mouse model, and five have been identified in humans (Pasternak 2005, Landau 2006). Clinically, this means that five patients might each require a different opioid to control their pain as a result of the varying density of these receptors within each central nervous system (CNS). Thus, trials of different opioids at full dose for several weeks must be initiated to determine the ultimate effect on individual patients. Pain that does not respond to one or two opioids is not necessarily opioid resistant. The lack of response is more likely a function of polymorphism and favors finding the most effective opioid for each patient to alleviate pain.

In polymorphism, each allele of a gene within a population expresses different phenotypes. The μ -agonists (e.g., morphine), k -agonists (e.g., oxycodone), and mixed μ -agonist/monoamine reuptake inhibitors (e.g., tramadol) elicit different responses, depending on the type of pain involved. Oxycodone, for example, might have a higher affinity for the k -receptor, and thus might be more effective than a μ -agonist in managing visceral pain, such as gallbladder or pancreatic pain. If a patient does not respond to an opioid after several dose increases, then rotation to a different opioid may be warranted. Likewise, unwanted side effects also warrant rotation to a different opioid.

Response to pain

Pain response is a function of two phenomena: physiologic windup and neuronal plasticity. The first phenomenon is a highly augmented response to repetitive afferent (C-fiber) input. Nociception is the transmission of a noxious stimulus from the periphery to the CNS and the spinal cord (Figure 1). If a nerve is subject to continued firing from the injury site to the CNS, the neuron becomes sensitized. Pain management now becomes more costly and risky than pain prevention as more medica-

FIGURE 1
Nociceptive pain pathway



SOURCE: ROBERTS 1986

tion is required and the chance of side effects is increased. The objective — and this is an important concept — should be to prevent pain from returning, not chase it away.

The second physiologic response, neuronal plasticity, involves changes in the CNS that occur in response to repetitive afferent nociceptive input. Within the human CNS, there are more than 36 anatomical structures and biochemical mediators that change quantitatively or qualitatively in response to ongoing pain stimulus. Thus, throughout the nociceptive cascade, from the periphery where the transduction occurs to the modulatory aspects of the nociceptive cascade, changes take place in response to the continual firing of the neurons that carry sensory messages (Figure 2).

Disease management, then, requires the use of medications that minimize risks and maximize outcomes. Immediately after surgery, for example, noxious stimuli should be decreased to prevent continual neuronal firing. In the postoperative phase, medication may be required on an “as-needed basis,” because immediate and certain pain relief should be provided. In the presence of an ongoing noxious stimulus, however, the management goal is to maintain continuous pain relief.

Opioid therapy

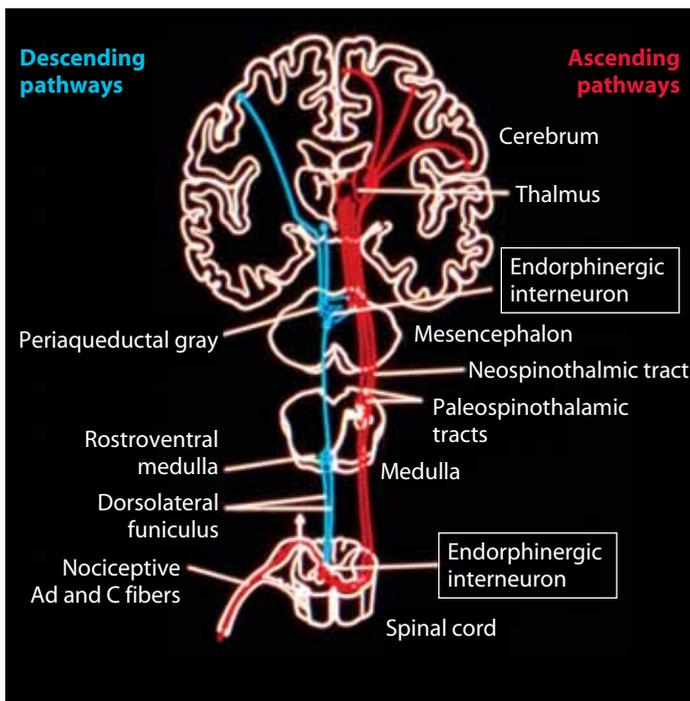
There is a common myth that patients in pain will not skip an opioid dose. In fact, if pain is controlled for a few days, patients often try to skip doses of short-acting opioids. The reasons for this action are often twofold: the patient’s fear of adverse drug ef-

fects, and concerns raised by family and friends over a drug’s effect. To achieve long-term compliance, there is an important place for controlled-release medications that require less frequent dosing. Consequently, the clinical arena has sought to develop consistent, predictable, and long-acting medications.

It is true that dependence and tolerance can occur with opioids; however, they are rare effects in patients who have pain from physiologic causes. A recent article in the *Morbidity and Mortality Weekly Report* reported on increased deaths from methadone prescribed by primary care physicians (Caraveti 2005). The deaths occurred between days 4 and 6 of methadone usage; however, steady-state serum levels are not achieved before day 10 of usage. Unfortunately, patients had been instructed to double or triple their doses if steady-state levels had not yet been reached. The lack of understanding regarding the lengthy beta-elimination half-life of the drug resulted in increased mortality, which is why controlled-release medications have been developed.

Controlled-release and extended-release medications are an important addition to the pain management armamentarium (Table 1). Morphine is available in mul-

FIGURE 2
Ascending and descending transmission of pain impulses



multiple dosage forms, and, ideally, the patient is kept on one form or carefully transferred if necessary to another. Oxycodone, which was available in several generic forms, is now a single product due to a Federal court ruling that upheld the patent on OxyContin. Oral oxymorphone, available as Opana ER, is another choice in this class. Hydromorphone, which was available for a short time as Palladone, has been withdrawn as a result of a dangerous interaction between the drug and alcohol usage, but work is in progress on a long-acting dosage form of hydromorphone.

None of these drugs is the proverbial magic bullet, but their availability, as a result of genetic polymorphism, is important to pain management. Although the science of polymorphism is not yet fully understood, the rational approach to pain management calls for having multiple dosage forms of opioids on formularies to accommodate the needs of individual patients. In addition to long-acting forms of analgesia, short-acting forms are also necessary for breakthrough pain.

Fear of addiction

Addiction is the compulsive use of a substance resulting in physical, psychological, or social harm to the user, with use that continues despite this harm (Rinaldi 1988). In 2001, a consensus statement from the American Academy of Pain Medicine (AAPM), the American Pain Society (APS), and the American Society of Addiction Medicine (ASAM) agreed with this definition, and amended it in recognition of the genetic and environmental factors associated with addiction (Heit 2003). The amended statement said that addiction is a primary chronic neurobiologic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. Addiction also is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.

Pseudoaddiction. Pseudoaddiction, first defined in 1989 and endorsed by ASAM in 1997, involves seemingly inappropriate drug-seeking behavior, such as demanding doses before they are scheduled, and becoming involved in a vicious cycle of anger, isolation, and avoidance, all leading to complete distrust of the prescriber (Weissman 1989). Often, pseudoaddiction is the result of an uninformed prescriber and a patient who is seeking medication for a legitimate need. It is important, therefore, to ensure that sufficient doses are available for breakthrough pain when it occurs so that analgesia can be established. In some cases, this may call for increasing the opioid dose by 50 percent. Com-

TABLE 1
Oral long-acting opioid dosage forms

Pharmacologically long acting	Pharmaceutically long acting
<ul style="list-style-type: none"> • Methadone • Levorphanol 	<ul style="list-style-type: none"> • Morphine (MS Contin, Oramorph SR, Kadian, Avinza, and generics) • Oxycodone (OxyContin) • Oxymorphone (Opana ER) • Hydromorphone (long-acting form in development)

plaints will typically resolve when analgesia is established.

Iatrogenic addiction. Iatrogenically induced addiction is far less prevalent. Several investigations have shown that treatment-induced addiction in patients provided with narcotics can range up to .03 percent (Medina 1977, Porter 1980, Perry 1982). These studies, however, were retrospective, not controlled, and likely underestimated the presence of iatrogenic addiction. Still, the true prevalence of iatrogenic addiction is probably far less than most clinicians believe, and a very low risk exists for the development of addiction related to pain treatment.

Drug dependence. Drug dependence has been associated with many medications, including steroids, and occurs nearly universally with opioid usage of more than 7 to 10 days. This physiologic/pharmacologic phenomenon is related to drug abstinence and occurs upon the abrupt discontinuation, substantial dose reduction, or the administration of an antagonist to a drug (Rinaldi 1988). Drug dependence should be distinguished from addiction, which is rare when opioids are used for pain control.

Drug tolerance. Tolerance to opioid analgesia is less common than is generally believed. It has been thought that increased doses of opioids are required to maintain analgesia, when in fact, tolerance to analgesia commonly occurs in the first few days to 2 weeks of therapy. When a patient is titrated to the opioid dose needed to provide comfort, dose increases are rarely required unless the pathology increases or another variable occurs (Lipman 2004). Tolerance to respiratory depression, sedation, psychomotor impairment, or nausea occurs predictably 5 to 7 days after consistent administration of an opioid.

Dose requirements might increase or decrease for any variety of pharmacological and psychological reasons. Patients who demand that their opioid doses be increased are not necessarily drug tolerant or addicted. Instead, their drug-seeking behavior might be an indication of

undertreatment, or might also be a sign of pseudo-addiction or pseudotolerance. Pseudotolerance may be due to such factors as disease progression, a new disease, increased physical activity, a lack of compliance, a change in medication, a potential drug interaction, addiction, or defiant behavior (Pappagallo 1998).

Breakthrough pain

Two studies have found the occurrence of breakthrough pain in 52 to 64 percent of inpatients, 67 percent of outpatients referred for cancer pain services, and 80 percent of home-based hospice patients (Portenoy 1990, Fine 1998). One multicenter study examined 228 patients with several types of chronic nonmalignant pain (Portenoy 2006). Although control at baseline was achieved for all patients' pain, 76 percent reported excruciating breakthrough pain episodes, 52 percent of which occurred in lower back pain patients. The number of daily breakthrough episodes ranged from 1 to 12, the time to maximum intensity ranged from 0 to 180 minutes, and the duration lasted between 1 and 720 minutes.

Preventing breakthrough pain is critical; however, if enough medication is provided to prevent these peaks of pain, the patient will become overmedicated and suffer undue adverse events. Instead, sufficient medication should be provided on a normal background schedule with a regular noxious stimulus to control the pain most of the time. A short-acting medication, optimally the same opioid, then should be provided to control any breakthrough pain. This approach demonstrates why it is important to have both long- and short-acting opioids on a formulary.

It is important not to confuse incident pain with breakthrough pain. Incident pain occurs during physical therapy or during an activity that causes temporary pain. It is usually nociceptive and can be anticipated with an immediate-release drug, typically a short-acting opioid. Idiopathic/spontaneous pain is unpredictable, usually neuropathic, and can be prevented with adjuvant agents. End-of-dose failure also should not be mistaken for breakthrough pain — this type of pain occurs when medicine wears off more quickly than anticipated. For patients with end-of-dose failure, doses should be extended. In these instances, pain diaries may be useful.

Duration of opioid use

Opioids should be continued in patients with chronic nonmalignant pain provided the patients meet certain criteria: They should either do well initially with tapering but experience an increase in pain toward the end of the prescribed time, or fail more than one blind tapering. These patients also should be motivated to take an opioid at a lower dose, typically about 10 percent of the pretaper dose, and also take a longer-acting form.

An opioid agreement can be useful for some patients.

Although it is not a legal document, both patient and physician sign the contract. It stipulates the specific reason for the medication, identifies the opioids, explains the patient's role, and states that no refills will be provided after hours nor will extra refills be given. (See "The Opioid Agreement," page 17).

Summary

Pain is a public health disaster. Although it remains largely undertreated, pharmacists and pharmacy managers can do much to correct the problem. Change will require the education of patients and health care professionals on the facts pertaining to addiction, drug dependence, and drug tolerance. Evidence-based resources, including guidelines published by the APS, should be consulted.

A variety of short- and long-acting drugs are available, not the least of which are the opioids. Fears regarding addiction and uncertainty about tolerance have precluded the comprehensive use of these drugs, and varying dose requirements complicate the picture. What is known, however, is that dose titration must be performed with the goal of preventing breakthrough pain. Fortunately, sufficient drug formulae have been developed to accommodate this need. Pain is the primary reason why people come into the health care system, and it is incumbent upon health care professionals to eliminate insufficient pain control, using the drugs available to the patient's best advantage.

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Disease Management Tools for Chronic Pain

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Pain management is under intense scrutiny in the United States, and chronic pain remains undertreated. Still, great progress has occurred in our understanding of pain in the last decade. As a result, the standard of care in treating chronic pain now includes the judicious use of opioids. Whenever pain is treated with controlled substances, however, another market can be expected to grow — that which is vying for access to these substances with the intention of misuse. Pain management in our society takes place against a backdrop of addiction, diversion, and misuse. Thus, all stakeholders in pain management, including practitioners, patients, regulators, insurance companies, and pharmaceutical producers need to develop realistic strategies for the appropriate use of pain medicines in an increasingly drug-abusing world.

Responsibility of health care providers

All health care providers must acknowledge that prescription drug abuse has become a legitimate public health concern, not an isolated event or one created purely by the media. This reality requires that physicians conduct a medical evaluation and risk assessment prior to prescribing opioids and closely monitor patients during the course of treatment. We must recognize our limitations, which include available time, psychiatric expertise, settings, and resources, and obtain as-needed consultations. Ultimately, we must aim for rational pharmacotherapy while complying with state and federal guidelines that govern opioid use.

The following discussion describes several disease management strategies and tools that practitioners can

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implement in the primary care setting to manage their chronic pain patients more effectively and with a greater degree of confidence and safety.

Poor documentation as a barrier to pain control

In a large survey conducted by the Eastern Cooperative Oncology Group more than a decade ago, poor pain assessment was rated by 76 percent of physicians as the single most important barrier to adequate pain management. Other barriers uncovered by the survey included patient reluctance to report pain and take analgesics (both 62 percent) as well as physician reluctance to prescribe opioids (61 percent) (von Roenn 1993).

Today, poor recognition and documentation of pain continues to be a stumbling block to appropriate pain management, despite the availability of useful assessment tools and screening instruments. A recent review of 520 randomly selected medical and radiation oncology visits to a community hospital-based outpatient practice found that quantitative assessment of pain scores was virtually absent (less than 1 percent), and qualitative assessment of pain occurred in only 60 percent of cases (Rhodes 2001). Of patients with significant pain, 28.2 percent had no mention of their pain in the physician note, and 47.9 percent had no documented analgesic treatment. More importantly, however, this investigation also demonstrated that relatively simple measures could be put in place to remedy this problem. When health assistants at the practice were trained to measure and document pain scores using a simple visual analog scale, documentation of pain scores increased from 1 percent to 75.6 percent (Rhodes 2001).

In addition to qualitative and quantitative pain assessments, other instruments such as urine toxicology screens (UTSs) may help clinicians manage therapy with controlled prescription drugs. Evidence suggests, however, that like pain assessments, this tool is also poorly implemented. In a review of the medical records of 111 randomly selected patients who underwent UTSs in a cancer center, Passik and investigators found that UTS documentation in the medical record was infrequent: 37.8 percent of the records listed no reason for obtaining the test; the ordering physician could not be identified in 29

percent of the records; and 89 percent of the records did not include the findings of the UTS. The result, however, was more likely to be documented when positive (Passik 2000a).

Assessment of addiction risk: screening instruments

Assessing the risk for aberrant behavior and addiction in the context of opioid therapy is a complex task. Addiction may have genetic, familial, social, psychiatric, and spiritual determinants; thus, a psychiatric interview and evaluation should touch on each of these areas (Passik 2004). Several screening tools have also been developed to help the clinician more efficiently estimate the risk of noncompliant opioid use, sometimes in a self-report format that can be completed by the patient before his or her visit. Several of these instruments are briefly described below. The results of these screening tools can help determine how closely a patient should be monitored during his or her course of opioid therapy.

Opioid Risk Tool (ORT)

The Opioid Risk Tool (ORT) is shown in Figure 1. In a preliminary study among patients prescribed opioids for chronic pain, the ORT exhibited a high degree of sensitivity and specificity for determining which individuals were at risk for opioid-related aberrant behaviors (Webster 2005). The self-administered screening was taken by 185 new patients receiving treatment in a pain clinic. The ORT measured the following risk fac-

tors associated with substance abuse: personal and family history of substance abuse; age; history of pre-adolescent sexual abuse; and certain psychological diseases. Patients received scores of 0–3 (low risk), 4–7 (moderate risk), or 8 (high risk), indicating their probability of displaying opioid-related aberrant behaviors. All patients were monitored for aberrant behaviors for 12 months after their initial visits. For patients in the low-risk category, 17 of 18 (94.4 percent) did not display an aberrant behavior, whereas 40 of 44 high-risk patients (90.9 percent) displayed such behavior (Webster 2005).

Screening Instrument for Substance Abuse Potential (SISAP)

The Screening Instrument for Substance Abuse Potential (SISAP) is a 5-item test that also helps clinicians categorize patients according to their risk for abusing prescribed opioids (Figure 2, page 12). The SISAP requires that the physician already know the patient or have collateral information to confirm the accuracy of the given answers. The SISAP was designed based on the National Alcohol and Drug Use Survey. Using the first half of the survey, two previously validated alcohol use items were combined with three illicit drug use items. These five questions identified those with a history of alcohol and/or illicit drug use. Although SISAP scores accurately predicted low-risk patients (low false-negative rate), it had a relatively high false-positive rate. In a validation study, 18 percent of patients were incorrectly classified as substance abusers (Coombs 1996).

FIGURE 1
Opioid Risk Tool

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 box 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		
OCD, bipolar, schizophrenia	<input type="checkbox"/> 2	<input type="checkbox"/> 2
Depression	<input type="checkbox"/> 1	<input type="checkbox"/> 1
<hr/>		
Scoring totals:	_____	_____

Administration

- On initial visit
- Prior to opioid therapy

Scoring

- 0–3: low risk (6%)
- 4–7: moderate risk (28%)
- ≥ 8: high risk (> 90%)

SOURCE: WEBSTER 2005
OCD - obsessive compulsive disorder

FIGURE 2**Screening instrument for substance abuse potential**

Question	Caution
1. How many alcoholic drinks/day?	Men: ≥5 drinks/day or 17/week Women: ≥4 drinks/day or 13/week
2. How many alcoholic drinks/week?	
3. Use of marijuana/hashish in last year?	Admission of recent use
4. Have you ever smoked cigarettes?	Persons who are younger than 40 years and smoke
5. What is your age?	

SOURCE: COAMBS 1996

 Screener and Opioid Assessment for Patients in Pain (SOAPP)

The Screener and Opioid Assessment for Patients in Pain (SOAPP) is a 14-item, self-administered form that includes questions about a patient's level of pain, drug history, family history of substance use, and other topics. The SOAPP was validated over a 6-month period in 175 patients who were taking or were being considered for long-term opioid medication for chronic, non-cancer-related pain (Butler 2004).

The validation studies suggest that the SOAPP has adequate sensitivity and selectivity and satisfactorily identifies individuals at high risk for drug abuse. However, it may not be representative of all patient groups, such as minority populations. A score of 7 or greater will identify 91 percent of those who are at high risk (Butler 2004). The SOAPP helps clinicians become more aware of those patients who have difficulty controlling their use of opioids and who may therefore require extra help with monitoring and management (Butler 2004). It may also be of value to those clinicians who are reluctant to prescribe opioids for pain management, by helping them recognize that most patients are not at a high risk for developing opioid addiction or misuse (Butler 2004).

Predictors of opioid misuse in patients with chronic pain

The incidence and prevalence of opioid misuse in patients treated for chronic pain in an outpatient setting are unclear and remain a topic of debate. Little is also known about the risk factors for opioid abuse in the outpatient setting. To investigate these issues, researchers conducted a prospective cohort study to determine the one-year incidence rate and predictors of opioid misuse among 196 patients enrolled in a chronic pain disease management program within an academic general internal medicine practice. Opioid misuse was catego-

rized by the following: a negative UTS for prescribed opioids; UTS positive for opioids or controlled substances not prescribed by the practice; evidence of procurement of opioids from multiple providers; diversion of opioids; prescription forgery; or stimulant usage (cocaine or amphetamines) on UTS (Ives 2006).

The mean patient age was 52, with 55 percent of the population male and 75 percent white. Of those patients studied, 62 (32 percent) committed opioid misuse. The most common drugs detected on UTS were cocaine and amphetamines (40.3 percent of misusers). The misusers were more likely than the nonmisusers to be younger (48 years vs. 54 years), male (59.6 percent vs. 38 percent), have a history of past alcohol abuse (44 percent vs. 23 percent), have a history of past cocaine abuse (68 percent vs. 21 percent), or have a previous drug or DUI conviction (40 percent vs. 11 percent). Race, income or education levels, depression, disability, or pain scores, and literacy levels were not associated with opioid misuse (Ives 2006).

Smoking: Predictor of aberrant drug use?

Tobacco use is highly prevalent among substance misusers, and both the SISAP and SOAPP include its usage as a factor in determining risk (Butler 2004, Coombs 1996). A recent study of 160 substance-dependent patients in an inner-city residential substance abuse treatment program revealed that smoking increased the desire to abuse drugs and that substance use almost always increased smoking levels or the number of urges to smoke (Rohsenow 2005). Evidence also suggests that smoking may be used as a form of substance replacement in those trying to abstain (Conner 1999).

Ongoing assessment and documentation: The 4 A's

During long-term opioid treatment, proper monitoring is essential for optimal pain management and is an

important aspect of compliance with state guidelines. The Pain Assessment and Documentation Tool (PADT) (Figure 3, page 14) is a simple charting device developed to focus on key outcomes and provide a consistent way to document progress in pain management therapy over time. This brief, two-sided chart note can be easily included in the patient’s medical record. According to the clinicians involved its creation, the PADT was designed to be “intuitive, pragmatic, and adaptable to clinical situations” (Passik 2004b).

The expert panel responsible for the development of the PADT considered items under four main domains: pain relief, patient functioning, adverse events, and drug-related behaviors. These domains have been labeled as “The 4 A’s”: analgesia, activities of daily living (ADLs), adverse events, and aberrant drug-related behaviors.

The 4 A’s allow practitioners to focus on the treatment goals, as well as create documentation areas for pain practices.

Analgesia

The analgesia component employs a pain scale of 0 to 10 (0 indicates “no pain” and 10 indicates “bad as it can be”). Patients are asked to indicate their average pain level during the past week, as well as the worst level of pain they experienced during that period. They also are asked to rate the percentage of pain relief obtained with their prescription medication.

Activities of Daily Living

The section on ADLs asks patients to indicate whether their functioning with the current pain reliever(s) is better, the same, or worse since their last assessment with the PADT. The activities include physical functioning, family and social relationships, mood, sleep patterns, and overall functioning.

Adverse Events

This section asks whether the patient is experiencing any side effects from the pain medication. It is a key component of the ongoing assessment, because the primary goal of pain management is to achieve high analgesia with as benign a side-effect profile as possible (Passik 2000b). Common potential side effects from opioids include nausea, constipation, drowsiness, fatigue, and mental cloudiness.

Aberrant Behavior

The final “A” — and perhaps the most problematic — is potential aberrant drug-related behavior. On the form, the physician must complete this section. It includes issues that may or may not indicate an abuse or addiction problem, including: purposeful over-sedation; negative mood change; appearance of intoxication; involvement in an automobile or other accident; frequent requests for early renewals; unauthorized dose increases; reports of lost or stolen prescriptions; and attempts to obtain prescriptions from other physi-

TABLE

Differential diagnosis considerations for assessing aberrant drug-taking behaviors

Differential diagnosis	Explanation
Addiction	Out-of-control behaviors and compulsive drug use despite harm
Pseudoaddiction	Undertreated pain that leads to desperate acting out. Patients may turn to alcohol, street drugs, or “doctor shopping” to meet their need for pain relief. These behaviors subside with adequate pain control.
<i>Psychiatric diagnoses</i>	
Organic mental syndrome	Patients often are confused and have stereotyped drug-taking
Personality disorder	Patients are impulsive, have a sense of entitlement, and may engage in chemical-coping behaviors
Chemical coping	Patients place too much emphasis on the meaning of their medications; they are overly drug-focused
Depression, anxiety, and situational stressors	Patients are marked by their desire to self-medicate their mood disorder or current life stressor(s)
Criminal intent	This category is concerned with the subset of criminals who are intent on diverting medications for profit

ADAPTED FROM PASSIK 2004A

FIGURE 3
Pain assessment and documentation tool: The 4 A's

Analgesia

If 0 indicates "no pain" and 10 indicates "pain as bad as it can be," on a scale of 0 to 10, what is your level of pain for the following questions?

1. What was your pain level on average during the past week? (Please circle the appropriate number)

No pain 0 1 2 3 4 5 6 7 8 9 10 Pain as bad as it can be

2. What was your pain level at its worst during the past week?

No pain 0 1 2 3 4 5 6 7 8 9 10 Pain as bad as it can be

3. What percentage of your pain has been relieved during the past week? (Write in a percentage between 0% and 100%) _____

4. Is the amount of pain relief you are now obtaining from your current pain relievers enough to make a real difference in your life?

Yes No

5. **Query to clinician:** Is the patient's pain relief clinically significant?

Yes No Unsure

Adverse Events

1. Is patient experiencing any side effects from current pain relievers?

Ask patient about potential side effects:

	None	Mild	Moderate	Severe
a. Nausea	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Vomiting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Constipation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Itching	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Mental cloudiness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Sweating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Fatigue	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. Drowsiness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Other _____		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j. Other _____		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Patient's overall severity of side effects?

None Mild Moderate Severe

SOURCE: PASSIK 2004

Activities of Daily Living

Please indicate whether the patient's functioning with the current pain reliever(s) is Better, the Same, or Worse since the patient's last assessment with the PADT.* (Please check the box for Better, Same, or Worse for each item below.)

	Better	Same	Worse
1. Physical functioning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Family relationships	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Social relationships	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Mood	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Sleep patterns	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Overall functioning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

* If the patient is receiving his or her first PADT assessment, the clinician should compare the patient's functional status with other reports from the last office visit.

Potential Aberrant Drug-Related Behavior

Please **check** any of the following items that you discovered during your interactions with the patient. Please note that some of these are directly observable (e.g., appears intoxicated), while other may require more active listening and/or probing. Use the "Assessment" section below to note additional details.

- Purposeful oversedation
- Negative mood change
- Appears intoxicated
- Increasing unkempt or impaired
- Involvement in car or other accident
- Requests frequent early renewals
- Increased dose without authorization
- Reports lost or stolen prescriptions
- Attempts to obtain prescriptions from other doctors
- Changes route of administration
- Uses pain medication in response to situational stressor
- Insists on certain medications by name
- Contact with street drug culture
- Abusing alcohol or illicit drugs
- Hoarding (i.e., stockpiling) of medication
- Arrested by police
- Victim of abuse
- Other _____

cians (Passik 2004a). This issue is discussed in more detail below.

Classifying assessment findings: Does every problem indicate addiction?

Potential aberrant drug-related behavior has a complex differential diagnosis (Table, page 13). Addiction is only one of several possible explanations and is more likely when actions such as multiple unauthorized dose increases occur, or when the patient obtains opioids from multiple prescribers. Pseudoaddiction should also be considered if the patient reports distress related to unrelieved pain. Aggressive requests for higher doses of pain medication or occasional and unauthorized dosage increases, may be signs that the patient has been driven to uncharacteristic behaviors because of unrelieved pain, not because of addiction (Passik 2004a).

Impulsive drug use may also indicate the presence of a psychiatric disorder, the diagnosis of which may have therapeutic implications. For example, patients with borderline personality disorder may be categorized as exhibiting aberrant drug-taking behaviors if they are using prescription medications to express fear and anger. Similarly, patients who self-medicate with opioids to treat symptoms of anxiety or depression, insomnia, or problems of adjustment may be classified as aberrant drug takers (Passik 2004a).

Aberrant drug-related behaviors may sometimes be related to mild encephalopathy, and the patient exhibits confusion regarding the appropriate therapeutic regimen. Problematic behaviors rarely imply criminal intent, such as when patients give a false account of pain, with the intention of selling or diverting medications. These diagnoses are not mutually exclusive and a thorough psychiatric assessment is vitally important to properly categorize questionable behaviors in both the population without a history of substance abuse and that of known substance abusers with a high incidence of psychiatric comorbidities (Passik 2004a).

Conclusion

Pain management is under intense scrutiny in this country today. Chronic pain is still undertreated. We

must use standards of good practice, documentation, rational prescribing, opioid agreements, UTs, and other methods to protect our patients and ourselves. A growing number of screening tools are becoming available, but more work must be performed within this evolving discipline.

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Case Studies: Managing Debilitating Chronic Pain

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Managing chronic pain in the primary care setting presents many challenges. Although opioids are probably the safest and most effective drugs available for treating pain, they carry risks for both patients and physicians, which often makes it difficult for clinicians who are inexperienced in pain management to use them effectively and with confidence.

In a primary care setting, physicians spend very limited time with each patient. In that brief period, they often must manage common conditions, such as high cholesterol and hypertension, along with a range of other patient issues and complaints. Often, we are asked to make decisions about treating chronic pain. For example, when a patient asks me to refill a prescription for an opioid, I must consider whether I have done a sufficient workup. Have I screened for addiction? Have I gotten the patient to sign an opioid agreement? Primary care physicians are advised to do both with regard to chronic pain management while complying with Health Plan Employer Data and Information Set (HEDIS) guidelines regarding blood pressure and chronic disease markers like lipid levels and hemoglobin A1C. Not surprisingly, many primary care physicians question their ability to provide quality medical care while also controlling the risks inherent in pain management.

The cases presented here from my physician practice highlight some of the challenges in pain management that are likely to be encountered in a primary care setting.

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Case 1: Failed back syndrome

The patient is a 48-year-old woman taking 3 oxycodone HCl/acetaminophen pills, 4 times daily, for failed back syndrome. Prior to beginning treatment, the patient entered into an opioid agreement with our practice that specified a maximum of 360 pills every 30 days. After several years on this regimen, the patient's husband called to report that she was spending excessive time in bed and was calling in early for refills. In addition, she reported stolen medication at least once since beginning treatment. When we confronted the patient with these issues, she complained that her pain had gotten worse and the current dose was not working.

Management options. In the limited time available, how should the primary care physician manage this patient? Options include gradually withdrawing the patient's current medication and replacing it with a stronger agent, based on the belief that she has developed tolerance, or possibly treating her underlying depression. Many primary care physicians frequently choose the latter approach, believing that all patients with chronic pain suffer from depression.

An equally likely explanation is that the patient is suffering from pseudoaddiction, a term used to describe patient behaviors that can occur when pain is undertreated. As in this case, patients with unrelieved pain can begin focussing on obtaining medications even when they have an adequate supply. As described herein by Lipman (see "Treatment Options for Chronic Pain Management: Opioids Revisited," page 5), pseudoaddiction can be difficult to distinguish from true addiction, but usually shows deteriorating physical and psychosocial functioning despite dose increases.

Undertreatment or tolerance? Unfortunately, we do not know if we are undertreating this patient or if the patient has developed tolerance to the drug's effects. Often, a therapeutic trial with another higher potency opioid will determine if more aggressive treatment of the pain will improve function. When this patient was put on low-dose, extended-release morphine, her condition improved; she got out of bed, began interacting with her family, and no longer called in early for refills or re-

ported lost medication. Essentially, this good response demonstrated that we had been undertreating her.

A key issue in this case is that the patient's husband had expressed concern over his wife's treatment. Family members commonly report doctors to medical boards, and also are a good collateral source of information about patient function. Although a physician may have crafted a good coordinated plan and talked it over with the patient, family members also must be involved.

Case 2: New patient on opioids

A 58-year-old man with diabetes, hypertension, and hyperlipidemia, new to the practice, presents on a Friday afternoon with no chart. He is asking for a refill of oxycodone, 80 mg 3 times a day, which he says he takes for the pain resulting from a neck fusion. Because it is the start of the weekend, and there is no way to get more information on this patient, your options are: 1) refill the oxycodone; 2) refuse to refill and have the patient withdraw in the ER; or 3) refer the patient to a pain specialist.

It is quite common for new patients to come in with just enough medication to make the visit but with no medical records. Although referral to a pain specialist is a good option, it does not address the immediate problem of treating the patient's pain. Unfortunately, in some areas of the country, it can take up to 3 months to get an appointment with a pain specialist, so how can the patient be managed in the meantime? State medical boards advise against prescribing an opioid until medical records can be reviewed and a careful history and physical examination have been completed.

Attempt due diligence. This man was actually my patient, and I was able to get more information before I prescribed a limited supply of oxycodone. I called his primary care physician in Arizona, who confirmed that he had been treating him. At my request, the physician faxed a portion of the patient's chart and the magnetic resonance imaging (MRI) results. Although this information could conceivably have been fabricated by a determined and resourceful addict, I was confident that I had done due diligence to obtain the necessary information and documentation.

Small refills until a relationship is established. The most appropriate option here is to provide a small dose of the oxycodone until you establish a good patient-doctor relationship and get more information from the patient during follow-up appointments. With time you

The opioid agreement

Opioid agreement — or opioid therapy patient agreement — addresses some of the issues and concerns regarding opioid use in managing chronic pain. Opioid agreements are intended to improve adherence to therapy and to improve therapeutic relationships by initiating an alliance between the patient and the physician.

Opioid agreements may:

- Vary in tone and demeanor; language attempts to invoke a sense of cooperation and equality. Often devote considerable space to explanations of their utility and value.
- Stress rights and responsibilities of both the health care provider and the patient.
- Offer broad, generalized, and nonconfrontational guidelines and avoid proscriptions or commandments.

Some agreements may be more dogmatic in tone; language is more authoritative, more concerned with the presentation of detailed rules and procedures. These agreements tend to outline specific consequences for breaking the contract, and usually contain less in the way of educational information.

Each type of agreement offers advantages and certain disadvantages:

- Less-confrontational agreements enable patients to feel they are taking a more active role in their therapy, which may improve compliance.
- Less-explicit language might decrease compliance because the patient has not been given strict, unambiguous rules to follow.

Dogmatic agreements may have the advantage of providing very clear guidelines, but they may make patients feel that they are not trusted, or that they are not being treated as rational, decision-making adults. Such contracts also may unwittingly stigmatize opioids by fostering the impression that opioid use is bad or dangerous.

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will understand the condition of the neck pain and can prescribe treatment with greater expertise and comfort.

The problem of not having enough information on a new patient is very common. It is difficult for physicians to gather it, partly because of the rapid pace of a primary care practice. When my patient comes in 2 weeks later, I may not recall the circumstances of the initial visit. Yet, primary care providers are asked to screen patients for potential opioid abuse or addiction. That's something that even the experts have difficulty doing.

Case 3: Acute low back pain

The patient is a 46-year-old man who came in because he felt a "pop" in his back while doing yard work. He rates

the pain as a 7 out of 10 that radiates down his left leg, with numbness between his first and second toe, and says he is barely able to get out of bed in the morning. On examination, he stands fixed in a 5-degree forward flexion. You correctly diagnose a herniated L4-5 disc. What advice could you give that would lead to the most rapid recovery? Your advice should include prescribing hydrocodone bitartrate/acetaminophen and cyclobenzaprine HCl, 2 days of bed rest, ice for 2 days followed by heat, encouraging the patient to walk despite the pain, and possibly physical therapy.

Treat pain first or encourage early activity? The most common answer is to give the patient hydrocodone bitartrate/acetaminophen and cyclobenzaprine. Indeed, that may be a good choice, because if you can decrease his pain, the patient may become more active. The best approach, based on prevailing opinion, is to make the patient walk around despite some pain. This approach probably represents the single most significant advancement in back pain management in the last 25 years — getting patients up and active as soon as possible. This new aggressive treatment is more significant than disc-replacement surgery, MRI, and ultrasound-guided epidural steroid injections.

Early movement and activity for patients with back pain has become such an integral component of treatment that countries, such as Australia, have created public service announcements discouraging bed rest and time off from work and, instead, encouraging people to get moving early. The theory is that walking and movement loads the joints and the ligaments and stimulates the body's natural healing and repair processes.

Case 4: Fibromyalgia syndrome

The patient is a 34-year-old woman with a diagnosis of fibromyalgia syndrome and complaints of diffuse pain throughout her body. She is taking hydrocodone bitartrate/acetaminophen, which she says provides only a little relief. The patient refuses to follow any of the guidelines issued by the American Pain Society for fibromyalgia syndrome, including physical therapy, exercise and behavioral therapy, and counseling programs. She is, however, extremely conscientious about showing up for her office appointments when she needs to refill her prescription. What is the best way to handle this common scenario in primary care practices?

Let's say the options are: 1) prescribe duloxetine (Cymbalta), which has shown positive results in recent randomized trials in treating fibromyalgia syndrome; 2) switch to a stronger opioid and have the patient sign an opioid treatment agreement; or 3) decide on a mutual goal-setting agreement.

Mutual goal setting. Probably the best option is to have a mutual goal-setting discussion. Unfortunately, as primary care physicians we are not always successful in

TABLE 1
Exit strategy

- Develop strategy for ending opioid therapy before beginning treatment
- Discuss criteria for treatment failure with patient prior to treatment onset
 - Lack of significant pain reduction
 - Lack of improvement in function
 - Persistent side effects
 - Persistent noncompliance
- Document method for tapering off opioids if trial is not successful

getting our patients to meet treatment goals. For example, we can advise weight reduction but cannot control their weight, and although we encourage medication compliance, blood glucose monitoring, and cessation of smoking and ask them to eat healthier foods, we cannot make them do those things. But we can prescribe an opioid to help relieve the patient's pain or recommend another treatment. We can withhold medication until we have evidence that the patient is complying with other components of the treatment plan, such as exercising or physical therapy.

Exit strategy. Specialists in pain management always recommend that primary care physicians develop an exit strategy before starting a patient on an opioid (Table 1), which requires criteria for treatment failure and a documented plan for tapering the patient off the opioid. It is far easier to stop an opioid if you talk to patients about stopping treatment before you start it. Warn patients, for example, that if the pain level does not improve or func-

TABLE 2
Universal precautions

- Diagnosis with reasonable differential
- Psychological assessment including risk of addictive disorders
- Rational nonopioid therapeutic trial
- Pre-trial assessment of pain/function
- Informed consent (verbal or written/signed)
- Treatment agreement (verbal or written/signed)
- Careful, time-limited trial of opioid therapy
- Reassessment of pain/function
- Regular assessment of aberrant behavior
- Recordkeeping

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tion does not increase, you will begin to taper the dose. Also remind them of the opioid agreement they signed at the beginning of treatment.

Universal precautions. Everyone is familiar with the “universal precautions” associated with blood. They came into being when it became clear that seemingly low-risk patients could communicate bloodborne illnesses, such as hepatitis C. As a result, we now assume that everyone is high-risk, and wearing protective gloves and/or eyewear is standard operating procedure. Today, we also practice universal precautions with regard to opioid use, as codified in the Federation of State Medical Boards Model Guidelines on the use of controlled substances, published in 2004, as well as in individual state guidelines (Table 2). Most of these policies are designed to encourage providers to use more opioids, with the understanding that a responsibility also exists to minimize the potential for abuse of controlled substances. California, for example, designed the Intractable Pain Act of 1990. This act stipulated that providers who followed the guidelines cannot be held accountable or prosecuted for their patients’ use or misuse of opioids.

These guidelines and policy statements do not require that a physician prescribe an opioid — it still requires clinical decision making. A physician cannot simply eliminate opioids as a treatment option because he or she is not comfortable in prescribing one. Opioids are powerful, highly effective drugs when used appropriately. And although the state medical boards encourage the use of opioids, they also closely monitor opioid prescribing and dispensing habits. Thus, the reason for universal precautions, which include a differential diagnosis; a psychological assessment; a written or oral pretreatment agreement; and regular assessment of patient functioning.

Case 5: GI bleed

The patient is a 78-year-old woman with diffuse arthritis. She suffered a gastrointestinal bleed on ibuprofen, but did well on valdecoxib until it was removed from the market. Following the bleed, she was prescribed a proton-pump inhibitor and naproxen, which has been reported to have the fewest side effects compared to other nonsteroidal anti-inflammatory drugs. Unfortunately, the patient experienced another GI bleed, and her primary care physician must now select a different treatment for her pain. Management options include hydrocodone bitartrate/acetaminophen, amitriptyline, and

propoxyphene napsylate/acetaminophen. Or, should she learn to live with her pain?

Opioids versus tricyclic antidepressants? The best choice of the options given in this case is hydrocodone bitartrate/acetaminophen. Although, as a category, tricyclic antidepressants are good nonspecific analgesics, the Beer’s List considers amitriptyline as one of the worst drugs for someone of this patient’s age. Propoxyphene napsylate/acetaminophen is a similarly inappropriate choice for this patient — recent HEDIS criteria recommend that it not be used at all, but it is particularly dangerous in older populations.

Unfortunately, because this patient has experienced GI bleeds even while taking over-the-counter medications, and you have been diligent in your efforts to treat her pain, she may have already concluded that there is nothing more to be done. This attitude is very common in the elderly. Despite the fact that the uncontrolled pain will greatly impact her activities of daily living, social interactions, and sleep patterns, she will have resigned herself to a less functional life. This case provides a good example of why we should use opioids to treat chronic pain.

Case 6: Urgent care

You are working Urgent Care on a Friday night. Your next patient is in a darkened room shielding her eyes from what little light is in the room. She is one of your migraine patients who has an opioid agreement with you for no more than one meperidine/phenergan injection a week. She comes in every week on Friday. The question is why? There are several possibilities, including the pressure at the end of the work week, addiction, or withdrawal.

Addiction or withdrawal? It is possible that this patient’s behavior represents addiction; however, there are other more likely options. The correct diagnosis also could be rebound headache resulting from meperidine withdrawal. Even though many hospitals have removed meperidine from their formularies, it remains a commonly used intramuscular injection for acute pain. Specialists in pain management, however, believe it is a bad drug. With repeated exposures, and because of the very long half-life of the metabolite normeperidine, she could be experiencing withdrawal. As a result, even giving her this medication only once every week could cause a rebound headache. Thus, the best treatment for this patient is to change treatment and stop giving her the meperidine injections.

CONTINUING MEDICAL EDUCATION ASSESSMENT/EVALUATION/CERTIFICATE REQUEST
Innovations in Pain Management: New Therapeutic Options and Tools for Disease Management

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The cost of this activity is provided at no charge through an educational grant from Endo Pharmaceuticals.

EXAMINATION: Place an X through the box of the letter that represents the best answer to each question on page 21. There is only ONE correct answer per question. Place all answers on this form:

	A.	B.	C.	D.
1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

PROGRAM EVALUATION

So that we may assess the value of this self-study program, we ask that you fill out this evaluation form.

1. Have the activity's objectives, listed below, been met?

Describe the prevalence and economic implications of chronic pain in the United States.

 Yes No

Discuss the various pharmacotherapeutic agents prescribed for the treatment of chronic pain.

 Yes No

Develop a comprehensive treatment plan utilizing a rational approach to the initiation and the management of opioid therapy.

 Yes No

Evaluate the application of disease management tools utilized by multi-disciplinary teams to support improved outcomes of patients treated with opioid analgesics.

 Yes No

(evaluation continues next column)

2. Was this publication fair, balanced, and free of commercial bias?
 Yes No

If no, please explain: _____

3. Did this educational activity meet your needs and contribute to your personal effectiveness? Please indicate your level of agreement:

- Strongly agree.....5*
- Agree4*
- Neutral.....3*
- Disagree2*
- Strongly disagree1*

Did it improve your ability to:

Treat/manage/support patients?
 5 4 3 2 1 N/A

Communicate with patients?
 5 4 3 2 1 N/A

Manage your pharmacy practice?
 5 4 3 2 1 N/A

Other _____

 5 4 3 2 1 N/A

4. Effectiveness of this method of presentation:

	<i>Very</i>				
<i>Excellent</i>	<i>good</i>	<i>Good</i>	<i>Fair</i>	<i>Poor</i>	
5	4	3	2	1	

5. What other topics would you like to see addressed? _____

6. Comments _____

CONTINUING EDUCATION POST-TEST

Innovations in Pain Management: New Therapeutic Options and Tools for Disease Management

Please tear out the combined answer sheet/evaluation form on page 20. On the answer sheet, place an X through the box of the letter corresponding with the correct response for each question. There is only one correct answer to each question.

- 1. Chronic pain is often associated with:**
 - a. Headaches
 - b. Mood disorders
 - c. Sleep disorders
 - d. All of the above
- 2. Which condition has the highest treated prevalence in a managed care population?**
 - a. Heart disease
 - b. Cancer
 - c. Back and neck pain
 - d. Arthritis
- 3. The yearly health care costs of chronic pain in the United States, both direct and indirect, are estimated to be:**
 - a. \$5 billion
 - b. \$200 million
 - c. \$86 million
 - d. \$50 billion
- 4. How much of every \$10 spent on health care is used for the treatment and care of musculoskeletal conditions?**
 - a. \$1
 - b. \$2
 - c. \$3
 - d. \$4
- 5. Pseudotolerance may result from several factors. Which of the following is not one of these factors?**
 - a. Progression of disease
 - b. Change in medication
 - c. Potential drug interaction
 - d. Decrease in physical activity
- 6. For patients with end-of-dose failure, doses should be:**
 - a. Decreased
 - b. Extended
 - c. Increased
 - d. Eliminated
- 7. An opioid contract is considered a legal document.**
 - a. True
 - b. False
- 8. In a study conducted by the Eastern Cooperative Oncology Group, what percentage of physicians rated poor pain assessment as the single most important barrier to adequate pain management?**
 - a. 40 percent
 - b. 55 percent
 - c. 70 percent
 - d. 76 percent
- 9. The Screening Instrument for Substance Abuse Potential test requires that the physician already know the patient or have collateral information to confirm the accuracy of the given answers.**
 - a. True
 - b. False
- 10. Which of the following four domain areas, or the "4 A's" of the Pain Assessment and Documentation Tool is incorrect?**
 - a. Anesthesia
 - b. Analgesia
 - c. Activities of daily living
 - d. Aberrant drug-related behaviors

