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This supplement to *The Journal of Family Practice* was supported by educational grants from Endo Pharmaceuticals and Ortho-McNeil-Janssen Pharmaceuticals. It has been edited and peer reviewed by *The Journal of Family Practice*.

SUPPLEMENT TO
THE JOURNAL OF FAMILY PRACTICE

Available at jfponline.com VOL 59, NO 9, SUPPL 2 / SEPTEMBER 2010

PROTECT YOUR PATIENTS, PROTECT YOUR PRACTICE

Practical risk assessment in the structuring of opioid therapy in chronic pain

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Introduction

Primary care clinicians play a crucial role in the assessment and management of chronic pain. As many as one-third of primary care patients report having chronic pain.[1] As a result, primary care clinicians are expected to have skills in a broad array of analgesic strategies, including analgesic pharmacotherapy. Ideally, drug treatments for pain are combined with nonpharmacologic strategies, including specific psychological and rehabilitative approaches that also may enhance comfort and promote functional restoration.

Opioid medications are frequently prescribed by primary care clinicians for chronic pain.[2] Unfortunately, the increased availability and prescription of opioid analgesics in recent years have been accompanied by a parallel increase in prescription opioid abuse and misuse and related morbidity and mortality.[3-5] Prescription drug abuse is an increasingly serious public health problem, and this reality has reinforced the view that primary care clinicians must possess skills in risk assessment and management, as well as the ability to optimize the potentially favorable effects of opioid drugs on pain and function.

To help address the problem of prescription drug abuse while still allowing for the prescription of opioids for pain relief, policy makers involved in the development of health care regulations have started adopting the principle of balance. According to the Pain & Policy Studies Group, balance is defined as the "dual obligation of governments to establish a system of control to prevent abuse, trafficking, and diversion of narcotic drugs while, at the same time, ensuring their medical availability."[6] The Pain & Policy Studies Group recently indicated that the utilization of balance in state pain policy steadily increased from 2000 through 2008.[6]

The growing acceptance of a balanced approach to drug policy is a positive step in addressing the 2 public health problems

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This CME/CE-certified activity is based on a roundtable discussion held on January 19, 2010.
Release date: September 1, 2010
Expiration date: September 30, 2011
Estimated time to complete activity: 1 hour

CO-PROVIDER STATEMENT

This educational initiative is co-provided by Curatio CME Institute, Penn State College of Medicine, the University of Tennessee College of Pharmacy, and EduPro Resources LLC. This activity has been created in collaboration with the American Pain Foundation and Friends Research Institute and in consultation with the National Institute on Drug Abuse.

This activity is supported by educational grants provided by Endo Pharmaceuticals and Ortho-McNeil-Janssen Pharmaceuticals.

ACTIVITY OVERVIEW

The use of opioid analgesics for the treatment of chronic pain is controversial. Several sources indicate that morbidity and mortality that result from the misuse of prescription opioids is on the rise. Other literature suggests that the overall risk of opioid abuse is low among pain patients. This supplement serves as a guide for how primary care clinicians who are considering the use of opioids in patients with chronic pain can assess a patient's risk for opioid abuse and how opioid therapy can be positioned in the overall management of chronic pain.

TARGET AUDIENCE

This activity has been designed to meet the educational needs of primary care physicians, nurses, nurse practitioners, physician assistants, and pharmacists who treat pain and chronic pain patients.

LEARNING OBJECTIVES

Upon completion of this activity, participants should be able to:

- Describe the indications, assessment, and patient selection criteria needed to consider a patient for a trial of opioid therapy
- Assess patients for the risk of drug misuse, abuse, and addiction, and assign a level of risk to each patient ("risk stratification")
- Formulate and implement treatment plans that structure therapy according to federal and state regulatory requirements

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Research Grant Archimedes, Baxter Healthcare Corporation, Calloway Labs, Cephalon, Endo Pharmaceuticals, Flamek Corporation, Fralex, GW Pharmaceuticals, King Pharmaceuticals, Pfizer, Purdue Pharma, Tempur-Pedic, United BioSource Corp, Wyeth

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of poorly relieved pain and prescription drug abuse. Progress at the clinical level requires clinicians to adopt an approach that might be considered "balance at the bedside," ie, minimizing risk through careful patient selection and drug administration while ensuring that appropriate patients receive optimal opioid therapy. The key principles for assessment and management of the risks associated with misuse, abuse, addiction, and diversion are described below.

Importance of the initial pain assessment

A comprehensive pain assessment is essential prior to the prescription of opioid medications. Pain can be categorized as either acute or chronic.[7] Acute pain can be defined temporally as pain that follows tissue damage and typically lasts days to weeks. Chronic pain can last 3 or more months, or it can be characterized as pain that persists beyond the healing of a lesion, is related to a lesion that is unlikely to heal, or recurs frequently. Acute pain is associated with an easily identifiable lesion and behavioral responses that are protective of the painful area. Chronic pain often has multiple contributing factors and is associated with global disability, depressed mood, and sleep disturbances.

Pain can also be characterized according to inferred pathophysiology—specifically, nociceptive, neuropathic, or psychogenic pain (TABLE 1). Nociceptive pain results from ongoing tissue damage; neuropathic pain results from "disease or dysfunction of the peripheral or central nervous system."[7] Neuropathic pain is diagnosed by its etiology (eg, pain persisting after acute herpes zoster), its association with neurologic findings, and/or its phenomenology, which may include a dysesthetic ("abnormal") pain quality, such as burning, tingling, or an electrical-like quality. Determining that pain likely has a neuropathic component is useful because it suggests specific approaches to therapy, as described in a recent evidence-based treatment guideline.[8] Lastly, psychogenic pain, which can be defined as pain resulting from psychological distress or pathology, is difficult to diagnose and manage because of a lack of clinical trial data and guideline recommendations in the medical literature.

Obtaining a patient's medical history and performing a thorough physical exam is an essential part of the initial pain assessment process and allows the clinician to determine a differential diagnosis regarding the etiology of the pain.[9] Once a plausible diagnosis has been made, the clinician can determine the benefit-to-harm ratio of potentially useful therapies, including opioid therapy. A comprehensive medical review should also assess the nature of the pain complaint, factors that in-

Important components of a comprehensive medical review for patients with chronic pain[10]:

- Location, duration, intensity, type, and patterns of pain
- Factors that reduce or intensify pain
- Impact of pain on functioning, mood, sleep
- Current and prior medical and psychiatric conditions, including a history of chemical dependence
- Previous use of pain medications and side effects
- Patient's expectations of medical treatment
- Description of the social environment at home and who has access to the home
- Involvement with insurance claims and litigation related to chronic pain, or other involvement with the legal system
- Patient history and physical examination, including family history, determination of any psychosocial factors that may affect treatment, and thorough evaluation of the pain condition

TABLE 1 Examples of neuropathic and nociceptive pain conditions

Pain type	Examples
Neuropathic pain	• Diabetic neuropathy • Trigeminal neuralgia • Postherpetic neuralgia • Poststroke central or thalamic pain • Postamputation phantom limb pain
Nociceptive pain	• Inflammatory or traumatic arthritis • Myofascial pain syndromes • Ischemic disorders

TABLE 2 **Patient-based behaviors and the likelihood of opioid addiction[15]**

Pattern may suggest addiction[a]	Pattern suggests therapeutic use
Adverse consequences/harm due to use • Intoxicated/somnolent/sedated • Declining activity • Irritable/anxious/labile mood • Increasing sleep disturbance • Increasing pain complaints • Increasing relationship dysfunction	**Favorable therapeutic response to use** • No significantly altered consciousness • Stable or improving activity • Stable or improved mood • Stable or improved sleep • Stable or improving pain • Improving relationships
Impaired control overuse/compulsive use • Reports lost or stolen prescriptions or medications • Frequent early renewal requests • Urgent calls or unscheduled visits • Abusing other drugs or alcohol • Withdrawal signs noted at clinic visits • Observers report overuse or sporadic use	**Able to use as prescribed** • Rare or no medication incidents • Uses medications as prescribed • Doses discussed at clinic visits • No alcohol or drug abuse • Has expected amount of medication left • No withdrawal signs • Observers report appropriate use
Preoccupation with use due to craving • Frequently misses appointments unless opioid renewal expected • Does not try nonopioid treatments • Cannot tolerate most medications • Requests medications with high reward • No relief with anything except opioids	**Seeking pain relief, not opioid reward** • Keeps most appointments • Shows up for recommended evaluations • Gives reasonable treatment recommendations a fair trial • Medication sensitivities and favorable responses not related to abuse liability of medication • Adopts self-management strategies (can demonstrate/discuss techniques)

[a] Any of these behaviors may occur from time to time in patients using opioids appropriately for pain relief or when pain is inadequately relieved. A pattern of these behaviors in the context of titrated pain therapy suggests the need for further evaluation. **Source:** Savage SR. Assessment for addiction in pain-treatment settings. *Clin J Pain*. 2002;18:S28-S38.

fluence the expression of pain, and current and previous medical, psychosocial, and psychiatric conditions, including current or previous substance abuse. Determining family history of medical and psychiatric problems, including substance use disorder, is also helpful.

Practical interpretation of opioid terminology

Understanding the terms associated with addiction, physical dependence, and tolerance is a starting point when clinicians are considering opioid therapy for people with chronic pain. *Addiction* is a chronic illness defined in the context of substance abuse by compulsive behavior, continued use despite harm, impaired control over drug use, and craving.[11,12] *Physical dependence* is a state of adaptation that is manifested by development of a withdrawal syndrome due to abrupt cessation, rapid dose reduction, or decreasing blood levels of a drug, or the administration of the drug's antagonist.[11,12] Physical dependence can

Summary of important opioid terminology:

- Tolerance and physical dependence alone are not signs of addiction
- Physical dependence is an expected consequence of chronic opioid therapy
- Tolerance cannot be assumed if there is evidence of worsening pain due to pathology or distress
- Inquiring about specific behaviors is essential for clarifying the differential diagnosis of aberrant drug-related behavior
- Pseudoaddiction can be attributed to inadequately controlled pain; egregious behaviors, such as the use of illicit drugs, cannot be ascribed to pseudoaddiction alone

become self-reinforcing, as individuals may continue to take opioids to reduce the discomfort of abstinence. It is best to consider this phenomenon and addiction to be separate, since the vast majority of patients who are opioid-treated presumably are physically dependent but not addicted.[12] *Tolerance* is defined as a state of adaptation in which repeated drug exposure reduces the efficacy of the drug over time.[11,12] Dose escalation and increased complaints of pain over time require a differential diagnosis that includes tolerance, but these issues can have myriad other causes ranging from progression of disease to psychological or social distress. Like physical dependence, tolerance is entirely distinct from addiction.

In contrast to physical dependence and tolerance, a large number of drug-related behaviors may appear in the clinical setting and may indicate an emerging problem of drug abuse or addiction. Known as aberrant drug-related behaviors or "red-flag" behaviors, these phenomena are essential to identify, assess, and address drug abuse both proactively and reactively during any therapy with a potentially abusable drug.[13] These behaviors, if they occur, should be viewed as having a differential diagnosis; some are more likely than others to indicate drug abuse or even addiction (**TABLE 2**).[11,13-15]

Persistent requests for a specific drug or dose escalation, the expression of desperation over recurrent symptoms, or even, in some contexts, hoarding of medication or occasional unapproved dose escalation should not immediately be assumed to be a substance use disorder.[14] These behaviors may be related to desperation over uncontrolled pain (so-called "pseudoaddiction," characterized by aberrant drug-related behaviors that improve when pain control improves) or an alternative psychiatric diagnosis, such as an anxiety disorder or personality disorder.[11] Behaviors such as the intravenous injection of oral opioid medications, concurrent use of illicit drugs, use of prescription drugs from other sources, doctor shopping, or progressive decline in social functioning seem more likely to reflect the emergence of a true addiction.[13,14]

Preparing the primary care clinician for prescribing opioid therapy

Clinicians who manage patients receiving opioid therapy for the treatment of chronic pain have a dual responsibility to treat the pain and minimize the risk of abuse and diversion of opioid analgesics (and other substances). The foundations of meeting this responsibility lie in understanding federal and state regulations governing the prescribing of these medications and the ability to apply the broad principles of best practice for opioid prescribing.[16]

The federal CSA dictates how opioids and other controlled substances are regulated in the United States and is part of the Comprehensive Drug Abuse Prevention and Control Act of 1970. This legislation provides specific instruction regarding the production and distribution of controlled substances to limit their nonmedical use.[17]

The Drug Enforcement Administration (DEA) was created to enforce the CSA through prevention, detection, and investigation of the nonmedical use of controlled substances.[17] The DEA sets production quotas and regulates all aspects of distribution of controlled substances, including those relating to prescribers, pharmacies, and research.[17] The production quotas set by the DEA are designed to balance the needs of certain controlled substances, such as morphine, for legitimate medical and research use.[17] Any prescribing that is likely to lead to diversion to the illicit market is illegal and considered to be drug trafficking. If a person

Points to address in preparing your practice to prescribe and manage opioid therapy:

- In addition to performing a thorough patient medical examination and risk assessment, clinicians must be aware of federal and state regulations, which differ by state, regarding the prescription of controlled substances
- The Controlled Substances Act (CSA) outlines the federal rules and regulations pertaining to the prescription of controlled substances; it is enforced by the DEA
- Clinicians should consider referral to a pain medicine or addiction specialist when they do not have the time or expertise to adequately evaluate a patient with chronic pain

TABLE 3 **Status of prescription drug monitoring programs by state; data updated as of April 2010[19]**

Status	States
States that have operational PDMPs[a]	Alabama, Arizona, California, Colorado, Connecticut, Hawaii, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Mississippi, Nevada, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, West Virginia, Wyoming
States that have enacted legislation to establish a PDMP, but it is not fully operational	Alaska, Florida, Kansas, Minnesota, Oregon, New Jersey, South Dakota, Washington, Guam (US territory)
States currently without PDMP legislation	Arkansas, Delaware, District of Columbia, Georgia, Maryland, Missouri, Montana, Nebraska, New Hampshire, Wisconsin

[a] PDMPs, prescription drug monitoring programs.
The National Alliance for Model State Drug Laws. *Status of state prescription drug monitoring programs (PDMPs.)* 2010.

in your care develops serious nonadherence behavior, and this is assessed as likely involving diversion, the clinician must stop prescribing to avoid engaging in clinical behavior that could be viewed as unlawful.

The DEA has also established "scheduling" categories for drugs. Schedule I drugs are deemed to have extremely high abuse potential (eg, heroin) and no beneficial medical use.[17] Most commonly prescribed opioids are classified as either Schedule II or Schedule III, which consist of agents with recognized medical uses.[17] Schedule III drugs have a lower abuse potential than drugs classified as Schedule I or II.[17]

Each state also has its own rules and regulations regarding distribution and prescription of controlled substances, including opioids. One purpose of state medical regulations is to oversee the practice of medicine.[17] State regulations can also classify drugs as having a higher level of abuse than indicated by the DEA; when state and federal regulations differ, clinicians are required to comply with whichever is more stringent.[17] According to the Model Policy of the Federation of State Medical Boards, physicians are not sanctioned solely for prescribing opioids for legitimate medical reasons.[18] The board defined inappropriate treatment of pain as nontreatment, undertreatment, overtreatment, and continued use of medications lacking a demonstrated benefit.

To improve their ability to monitor the prescription medications that patients receive, two-thirds of states have developed Prescription Drug Monitoring Programs (PDMPs) (**TABLE 3**).[19] These programs can provide assistance to physicians in some states, allowing for the monitoring of doctor shopping, for example. Clinicians should be familiar with their jurisdiction's requirements for compliance in prescribing controlled substances.[20]

Federal and state laws and regulations do not prevent the prescription of opioids to pain patients, including patients who have clinically defined addiction. Federal law does, however, prohibit the prescription of an opioid for the purpose of addiction treatment or detoxification, except by clinicians who are specifically licensed to do so.[21] Several resources are available that discuss the responsible use of opioids and provide information on federal and state prescription guidelines (**TABLE 4**).[22]

The US Food and Drug Administration (FDA) is intimately involved in the regulation of controlled prescription drugs. The job of the FDA is to approve and monitor prescription medications in the United States. The adoption of the 2007 FDA Amendments Act expanded the regulatory role of the FDA by giving the agency a mandate to develop a Risk Evaluation and Mitigation Strategy (REMS) program to be applied to newly approved and some currently available opioid medications.[7] The stated purpose of REMS is to reduce the risk of prescription drug abuse. It is unclear at this time how REMS will affect prescription of opioid therapies or whether it will contribute to a reduction in drug abuse, but it is likely that any REMS plan may include any of the following: patient, clinician, and pharmacy education; registries for monitoring; or the use of specialty pharmacies.

TABLE 4 Resources for information on federal and state prescribing regulations[22]

Organization	Link to resource
American Academy of Pain Medicine	http://www.painmed.org/clinical_info/guidelines.html
American Pain Foundation	http://www.painfoundation.org/learn/resources/
American Pain Society	http://www.ampainsoc.org/pub/cp_guidelines.htm http://www.ampainsoc.org/links/clinician1.htm
Federation of State Medical Boards	http://www.fsmb.org/PAIN/resource.html
American Academy of Pain Management	http://www.aapainmanage.org/literature/Publications.php
Pain and Policy Studies Group: database of state laws, regulations, and other official government policies	http://www.painpolicy.wisc.edu/matrix.htm
Drug Enforcement Agency: Controlled Substances Act	http://www.justice.gov/dea/pubs/csa.html

American Geriatrics Association. *Pharmacological management of persistent pain in older persons*. New York, NY: American Geriatrics Association; April 2009. AGS Clinical Practice Guideline.

The role of specialist referral

A key step in the decision making surrounding selection of a patient for a trial of long-term opioid therapy is an honest appraisal of the clinician's skills and system of care in relation to the needs of the individual. If the assessment suggests that a person may be an appropriate candidate for opioid treatment, the primary care clinician must decide whether he or she can manage alone or whether it would be more beneficial to comanage or refer the patient to a pain specialist.

Ideally, the primary care clinician has access to pain specialists who are knowledgeable about opioid therapy and addiction medicine specialists who are knowledgeable about pain. The key to a successful referral is that the specialist and primary care clinician communicate clearly with each other.[23] The primary care clinician must be explicit about the reason for referral (eg, further assessment and diagnostic evaluation, second opinion or reinforcement of an ongoing treatment plan, a request for comanagement of opioid therapy, or consideration of other interventions). Given the complexity of chronic pain and the opioid issue, it often is best if the primary care clinician speaks directly with the specialist.[23]

Assessing the risk of prescription opioid abuse

Determining whether long-term opioid therapy is appropriate for an individual with chronic pain requires the clinician to assess whether such an approach is consistent with conventional medical practice, whether the efficacy of an alternative therapy is equivalent or better, the patient's risk for adverse events, and whether the patient will responsibly take the medication over time. For many primary care clinicians, the last ques-

Assessing risk in daily practice:

- Assessing the risk for abuse of individuals with chronic pain is a crucial step in determining their suitability for opioid therapy
- Risk assessment depends on a careful history, review of medical records, and a urine drug test (UDT); risk assessment tools (ORT, DIRE, SOAPP) can also be used
- The assessment should lead to risk stratification with respect to the relevant outcomes of abuse, addiction, and diversion
- Clinicians may choose not to treat patients at high risk, but if they do decide to treat such patients, referral or comanagement with a specialist may be valuable
- The application of universal precautions to the management of chronic pain is encouraged; this approach ensures that risk assessment, stratification, and management over time are included whenever long-term opioid therapy is prescribed

TABLE 5 **Impact of opioid abuse risk status on the management of chronic pain[31]**

Risk level	Characteristics	Management
Lower risk	No history of substance abuse; minimal if any risk factors	Can be managed by primary care clinician
	History of substance abuse (not prescription opioids); significant risk factors	Comanage patient with addiction and/or pain specialists. If aberrant behaviors are observed or persist, consider assigning to high-risk category
	Patient previously assigned to low risk exhibiting aberrant behaviors	
High risk	Active substance abuse, history of prescription opioid abuse	Opioids may not be appropriate; refer to specialist who manages patients with comorbid pain and addiction; continue to manage patient's medical care, including pain relief, and monitor specialized care
	Patient previously assigned to medium risk exhibiting aberrant behaviors	

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tion may be the most challenging. Clinicians must assess and stratify the risk of aberrant drug-related behaviors and the disorders they reflect (drug abuse, addiction).[9] Risk assessment is a key step in predicting who is likely to abuse opioid medications; patients without exigent risk factors have a low likelihood of opioid abuse, whereas high-risk individuals are much more likely to abuse opioid medications.[24]

Several patient factors that increase the risk of prescription opioid abuse have been identified, including age (young), sex (male), past alcohol or cocaine use, previous drunk driving or drug conviction, history of a mental health disorder (eg, depression, anxiety), family history of substance abuse, and personal history of drug abuse.[25-28] In contrast, individuals with no previous history of abuse, especially middle-aged and older adults, have a low risk of abusing opioids.[9]

Information about an individual's drug use can be acquired through interview, the use of screening tools, and objective information, such as the results of routine laboratory testing.[15] The purpose of the interview is to determine the patient's past and present history of drug or alcohol abuse; relevant family history; and psychosocial and psychiatric status. The interview should be conducted in a nonjudgmental manner, with specific questioning about alcohol consumption, use of illicit drugs, and use of abusable prescription drugs. Motivational interviewing may be employed to help address and modify drug-taking patterns. Patient or family behavior during the office visit and findings from the physical examination can reveal subtle details as to whether a person may have substance abuse problems.

In screening for the purpose of risk stratification, a clinician may decide to request a UDT. This tool is useful in determining whether a patient is taking any illegal drugs or unreported prescription drugs, is not taking drugs as prescribed, or is consuming excessive amounts of alcohol.[29,30] A pretreatment UDT may be particularly useful in patients for whom there are concerns about use or misuse prior to the initiation of opioid therapy. A typical UDT initially screens qualitatively for illegal narcotics (eg, cocaine, heroin, marijuana) as well as selected prescription drugs (eg, morphine, hydrocodone, fentanyl, benzodiazepines).[31] The refusal of a patient to consent to a screening UDT can be indicative of a level of mistrust or secretive behavior that could predict problems with future opioid therapy.[29]

Several screening tools have been developed to help clinicians gauge the likelihood that a person may be at risk for abusing opioid medications. The purpose of these tools is to assess abuse risk ranging from low to high.[16] The Opioid Risk Tool (ORT), Screener and Opioid Assessment for Patients with Pain (SOAPP), and revised SOAPP tools can be self-administered.[24,32,33] Clinician-administered tools include the ORT; the Diagnosis, Intractability, Risk, and Efficacy (DIRE) instrument; Cut down, Annoyed, Guilty, Eye opener–Adapted to Include Drugs (CAGE-AID); and the Current Opioid Misuse Measure (COMM).[34-36]

TABLE 6 **A universal precautions approach to pain management in daily practice[29]**

Tool	Description
Diagnosis with appropriate differential	• Identify and treat cause of pain • Treat symptoms if cause can not be identified • Address comorbid conditions
Assess addiction history	• Obtain personal and family history of substance abuse • If abuse is found, determine whether addiction disorder is present
Informed consent	• Clinician discusses treatment plan with patient • Clinician answers patient questions about medical condition and proposed treatment
Treatment agreement	• Obtain written or verbal acknowledgment of patient's and clinician's expectations and obligations
Pre- and postintervention assessment	• Assess pain and function pretreatment to let clinician gauge later whether treatment plan is effective
Appropriate trial of opioid	• Opioids are not first-line therapy, but do not use as a last resort • When appropriate, combine other therapies with opioids
Reassess pain score and level	• Regularly reassess to help justify continued use of therapeutic approach
Regular assessment of the 4 *A*'s	• Assessing the 4 *A*'s will help direct therapy: – Analgesia – Activity level – Adverse effects – Aberrant behavior
Periodically review pain diagnosis and co-morbid conditions, including addiction	• Status of an illness may change over time, so determine if treatment needs to change as well
Documentation	• Proper documentation will reduce medicolegal problems and risk of regulatory sanction • Document the following[40]: – Reason for prescribing opioids – Treatment plan – Consultations with other clinicians – Prescriptions and refills – Follow-up plan – Periodic reviews of patient status

If considering use of a screening tool, clinicians should select one based on the type of practice they have, the most common types of patients they see, how much time they have, and their personal experiences with other various tools.[16] For example, the ORT may be most useful in high-volume clinics that typically see low-risk patients, because the test is quick but susceptible to deception.[16] The ORT tool contains five yes-or-no questions that the patient can complete while in the waiting room or when administered by a clinician as part of the patient intake process.[37] Scores of 0 to 3 represent low risk, scores of 4 to 7 represent moderate risk, and scores of 8 or more represent high risk.[37] The SOAPP-R may be used most effectively in clinics that have a large proportion of higher-risk or deceptive patients.[16,33] The SOAPP-R contains 24 items rated on a 0 to 4 scale; a score of 22 or greater indicates a high risk for opioid abuse.[33]

The determination of a patient's risk for opioid abuse—risk stratification—should be used to help guide development of an analgesic treatment plan (**TABLE 5**).[31] Individuals who are actively abusing drugs typically are not considered candidates for opioid therapy in the primary care setting. Those who

are stratified into relatively high risk but are not actively abusing drugs may be candidates if the clinician can create a structured program that includes frequent monitoring and additional psychological support.[9] In these situations, the clinician may consider comanagement or referral to a pain or addiction specialist prior to initiating opioid therapy.[9] Highly structured programs have been shown to be effective at improving adherence and therapeutic outcomes in high-risk patients.[38]

Another way clinicians can conceptualize risk assessment is through the use of universal precautions.[29] The rationale behind a universal precautions approach is that a minimal level of precaution should be applied to all patients.[29] This approach ensures that risk is always considered, potentially reduces the stigma of opioid therapy, and may identify problems among patients who initially raise no concerns.[29] This model can be applied in daily practice through the adoption of specific procedures (**TABLE 6**).[29]

Positioning opioid therapy in chronic pain treatment

The use of opioid therapy for the treatment of chronic noncancer pain is controversial. Neither existing controlled trials nor large observational studies provide sufficient evidence to conclude that long-term therapy is safe and effective. Nevertheless, pain specialists mostly agree that a subpopulation of individuals with chronic pain can gain substantial long-term benefit from these drugs without evident problems related to adverse effects or aberrant drug-related behavior. In 2009, the American Pain Society (APS) and the American Academy of Pain Medicine (AAPM) released a multidisciplinary joint guideline document for the use of opioids in the treatment of chronic noncancer pain.[9] This joint guideline was derived from a systematic review of the literature and subsequent grading of the evidence. As such, it is an evidence-based guideline, but the absence of strong evidence in many important domains necessitated the use of expert consensus opinion for the purpose of providing recommendations meant to improve treatment outcomes.

The APS-AAPM guidelines state that chronic opioid therapy should be considered for all people with moderate to severe chronic pain. The guidelines, however, recommend implementing chronic opioid therapy only if a cautious risk-benefit analysis suggests that there are no other equally good or better options and the benefits in terms of pain relief and functional restoration exceed the risks associated with both adverse drug effects and chemical dependency outcomes.[9,39] Therapy should be initiated in an explicit therapeutic trial, the outcomes of which determine whether longer-term therapy is justified. The latter point offers a framework for treatment: the decision to offer long-term therapy, whether or not the patient is currently receiving an opioid, should be viewed as a separate decision in need of a documentable rationale based on risk-benefit analysis.

Key elements of any pain treatment plan to address if an individual is deemed to be a good candidate for opioid therapy include therapeutic goals, optimizing administration, expected follow-up intervals, how therapy will be monitored, alternative therapies, combination therapy, and when opioid therapy will be tapered or discontinued.[9] Goals of therapy may include reduction of pain, improvement in quality of life, and stabilization or improvement of physical activity, mood, sleep, work, relationships, and recreation.[15] Both clinicians and their patients should understand that complete pain relief may not be achievable with

Positioning of opioid therapy in the treatment of chronic pain:

- Chronic opioid therapy should be viewed as a trial in which continued use is based on meeting treatment goals
- The decision on whether or not opioid therapy is appropriate is based on conventional practice for a specific type of pain, the availability of alternative therapies with equivalent or better treatment efficacy, the presence of comorbid medical conditions, and the likelihood that the individual will responsibly adhere to the indicated opioid therapy
- Goals of therapy include reduction in pain, improvement in quality of life, and stabilization or improvement of physical activity, mood, sleep, work, relationships, and recreation

any therapy, including opioids; rather, a more achievable goal might be pain reduction to a level that allows resumption of more normal activity and overall improvement in quality of life.[9] ■

COMPLETE THE POSTTEST AND CME/CE EVALUATION ONLINE:

http://www.curatiocme.com/posttest/ChronicPainJFP

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CLIP-AND-SAVE RESOURCE

Clinical reference tool for risk assessment relating to opioid therapy

1) Brief overview of urine drug testing (UDT)[30,41]:
   - Used as a monitoring tool for prescribed medications; can identify substances not prescribed or recommended
   - Routine UDT should test for:
     - Cocaine
     - Amphetamines/methamphetamines/ecstasy
     - Opiates*
     - Methadone
     - Marijuana
     - Benzodiazepines

     * Buprenorphine, fentanyl, pentazocine, meperidine, propoxyphene, and sometimes oxycodone are not typically detected in a routine UDT for opiates.
   - Controversial topics relating to the use of UDT:
     - Negative UDT of prescribed medications may have several causes, including:
       - Could be due to patient running out of medication early; medication supply is insufficient for adequate pain control
       - Condition where there is a rapid metabolism of the prescribed substance
       - Assay threshold for drug reporting is too low
     - A positive UDT for tetrahydrocannabinol (THC) is unlikely to result from the secondary inhalation of marijuana smoke or eating food derived from hemp seed
     - A positive UDT for cocaine as a result of drinking tea derived from coca leaves is rare. The sale of products that contain any level of cocaine is illegal under Drug Enforcement Agency regulations
   - Detection times of common drugs of misuse[42]:

Drug	Approximate retention time
Amphetamines	**48 hours**
Barbiturates	**24 hours:** short acting (eg, secobarbital) **2–3 weeks:** long acting (eg, phenobarbital)
Benzodiazepines	**3 days:** ingestion of therapeutic dose **Up to 6 weeks:** for extended usage (ie, 1+ years)
Cannabinoids	**5 days:** moderate smoker (4 times/week) **10 days:** heavy smoker (daily) **20–28 days:** chronic smoker
Cocaine (metabolized)	**2–4 days**
Ethanol	**2–4 days**
Methadone	**~30 days**
Opiates	**2 days**
Phencyclidine	**8 days:** acute use **Up to 30 days:** chronic use (average of 14 days)
Propoxyphene	**6–48 hours**

Gourlay, DL, Heit HA. Universal precautions revisited: managing the inherited pain patient. *Pain Med*. 2009;10(S2):S115-S123. Copyright © American Academy of Pain Medicine.

2) Opioid risk tool (ORT)[24]

Item	Mark each box that applies	Item score if female	Item score if male
1. Family history of substance abuse			
Alcohol	☐	1	3
Illegal drugs	☐	2	3
Prescription drugs	☐	4	4
2. Personal history of substance abuse			
Alcohol	☐	3	3
Illegal drugs	☐	4	4
Prescription drugs	☐	5	5
3. Age (mark box if 16–45)	☐	1	1
4. History of preadolescent sexual abuse	☐	3	0
5. Psychological disease			
Attention-deficit disorder, obsessive-compulsive disorder, bipolar, schizophrenia	☐	2	2
Depression	☐	1	1
Total			
Total score risk category Low risk: 0–3 Moderate risk: 4–7 High risk: ≥8			

Webster LR, Webster RM. Predicting aberrant behaviors in opioid-treated patients: preliminary validation of the Opioid Risk Tool. *Pain Med*. 2005;6:432-442.

CONTINUED ON NEXT PAGE

3) Diagnosis, Intractability, Risk, Efficacy (DIRE) risk assessment tool[35]

Score	Factor	Explanation
	Diagnosis	1= Benign chronic condition with minimal objective findings or no definite medical diagnosis. Examples: fibromyalgia, migraine headaches, nonspecific back pain 2= Slowly progressive condition concordant with moderate pain or fixed condition with moderate objective findings. Examples: failed back surgery syndrome, back pain with moderate degenerative changes, neuropathic pain 3= Advanced condition concordant with severe pain with objective findings. Examples: severe ischemic vascular disease, advanced neuropathy, severe spinal stenosis
	Intractability	1= Few therapies have been tried and the patient takes a passive role in his or her pain management process 2= Most customary treatments have been tried but the patient is not fully engaged in the pain management process or barriers prevent (insurance, transportation, medical illness) participation 3= Patient fully engaged in a spectrum of appropriate treatments but with inadequate response
	Risk	(R= Total of P+C+R+S from below)
	Psychological	1= Serious personality dysfunction or mental illness interfering with care. Example: personality disorder, severe affective disorder, significant personality issues 2= Personality or mental health interferes moderately. Examples: depression or anxiety disorder
	Chemical health	1= Active or very recent use of illicit drugs, excessive alcohol, or prescription drug abuse 2= Uses medications to cope with stress or a history of chemical dependence in remission 3= No chemical dependency history. Not drug-focused or chemically reliant
	Reliability	1= History of numerous problems: medication misuse, missed appointments, rarely follows through 2= Occasional difficulties with compliance but generally reliable 3= Highly reliable patient with meds, appointments, and treatment
	Social support	1= Life in chaos. Little family support and few close relationships. Loss of most normal life roles 2= Reduction in some relationships and life roles 3= Supportive family/close relationships. Involved in work or school and no social isolation
	Efficacy score	1= Poor function or minimal pain relief despite moderate to high doses 2= Moderate benefit with function improved in a number of ways (or insufficient info; hasn't tried opioids yet or very low doses or too short of a trial) 3= Good improvement in pain, function, and quality of life with stable doses over time
_____ Total score **Score 7–13:** Not a suitable candidate for long-term opioid analgesia **Score 14–21:** Good candidate for long-term opioid analgesia		

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