

MEDICAL SCHOOL AND RESIDENCY PROGRAM
CURRICULUM RESOURCES ON DRUG ABUSE AND ADDICTION

Minimizing the Misuse of Prescription Opioids in Patients with Chronic Nonmalignant Pain

University of Massachusetts Medical School
(Massachusetts Consortium)

Jeff Baxter, M.D.

April 16, 2010



<http://www.drugabuse.gov/coe>

These curriculum resources from the NIDA Centers of Excellence for Physician Information have been posted on the NIDA Web site as a service to academic medical centers seeking scientifically accurate instructional information on substance abuse. Questions about curriculum specifics can be sent to the Centers of Excellence directly.

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Introduction and Overview

In the last decade, patient groups and accreditation agencies have advocated for improvements in pain treatment, including expanded access to opioid medications. At the same time, rates of misuse of and addiction to prescription opioids have risen dramatically. Of particular concern are the results of national surveys suggesting that the majority of patients who misuse opioid medications obtain them by way of legitimate prescriptions written either for them or for friends or family members.

Medical providers face great challenges in managing opioid medications. Opioid analgesics are very effective for decreasing many types of pain, but they carry significant risks for patients, including the possibility of cognitive impairment, respiratory depression, overdose, death, physiological tolerance, withdrawal symptoms, and addiction. Medical providers must balance the rights of patients to safe, effective treatment of pain with the responsibility to ensure these medications are prescribed appropriately, safely, and in a way that minimizes abuse and diversion of these medications.

Patients with chronic pain most commonly seek care in primary care settings, where providers often feel poorly prepared to evaluate and manage these conditions. The situation is worsened by pressures on primary care providers to see more patients in less time, and with less support, lower levels of reimbursement, and a paucity of specialty referral resources for pain treatment.

This educational module has been designed as an introduction for health professions students and primary care residents to a standardized approach to the management of patients with chronic nonmalignant pain that integrates techniques for the prevention and detection of misuse of prescription opioids. It is our hope that increasing provider knowledge and skills early in the educational process will improve patient safety and the quality of pain treatment while also decreasing the misuse and diversion of prescription opioids.

This curriculum resource is a case-study module designed for use by a faculty facilitator with small groups of health professions students or medical residents. In this module, participants care longitudinally for a single patient with a common chronic pain complaint: low back pain (LBP). The case study is structured in five sections, beginning with background information and followed by three office visits (and a separate review of lab results), which take place over the course of 9 months. Each visit begins with a medication list and a description of the patient's current condition and ends with questions for discussion. The questions are tied to the specific learning objectives for each visit.

Participants work from two sets of printed pages. The first is the learner packet, which is included here as pages 34 through 42. It contains an introduction, learning objectives, and the case study with the discussion questions. The second is a document containing 25 pages of supporting documents, including both reference materials and clinical tools completed to model what this patient's clinical chart might look like. This supporting documents section is attached at the end of this document. Participants are instructed to keep the two resources side by side as they work through this module.

There is also a one page evaluation tool that is included as page 43. We have used this simple form as a pre- and post- course evaluation. Please remember to remove the highlights from the answers before printing it for use.

This module has been piloted with 105 third-year medical students at the midpoint of the third-year curriculum, and has been reviewed by four groups of faculty comprising physicians from family medicine and internal medicine.

Key words: chronic pain; drug abuse; drug addiction; opioids; problem-based learning; substance-related disorders

Curriculum Module Overview

This module consists of:

- Three complete packets that should be kept intact in order to facilitate printing and distribution for use with learners:
 - Faculty guide, with supporting information for each of the learning objectives linked to the discussion questions
 - Learner packet, with a separate introduction and case study so the packet can be distributed to participants for review in advance of the learning session
 - Supporting documents packet with clinical tools completed to reflect what this patient's chart would look like when documentation meets current clinical guidelines, as well as other resources to support the case study. This packet is attached as a separate PDF file and should be printed and distributed with the learner module.
- Evaluation tool.
- References and Additional Readings.

Educational Objectives

- Discuss the components of the accepted standard of care for chronic nonmalignant pain.
- Describe the use of a number of clinical tools to support the management of chronic nonmalignant pain in primary care settings.
- Describe strategies for optimizing safety in the provision of opioid analgesics for chronic pain.
- Describe the approach to preventing and detecting the misuse of opioid pain medications in patients being treated for chronic pain.
- Describe the differences between physical dependence on and addiction to opioid pain medications and how to recognize addiction in chronic pain patients.

Faculty Guide

This educational module has been designed as an introduction for health professions students to the evaluation and management of chronic nonmalignant pain in primary care, with a specific focus on the prevention and detection of misuse of prescription opioids. Patients with chronic pain most commonly seek care in primary care settings, where providers often feel poorly prepared to evaluate and manage these conditions (Upshur 2006). The situation is worsened by pressures on primary care providers to see more patients in less time, and with less support, lower levels of reimbursement, and a paucity of referral resources.

Providers often feel particularly uncertain and uncomfortable with pain management involving the prescription of opioid medications. On the one hand, opioid analgesics are very effective for decreasing many types of pain, and patients have a right to safe and effective treatment of pain. On the other hand, medical providers are charged with the responsibility of ensuring opioid medications are prescribed safely and in a way that minimizes addiction to, or abuse or diversion of, this class of medications.

The goal of this module is to introduce health professions students to a standardized approach to the management of chronic nonmalignant pain that is consistent with the standards recommended by the Federation of State Medical Boards *Model Policy on the Use of Controlled Substances in the Treatment of Pain* (2004) and the treatment guidelines published by the American Pain Society (Chou R, et al. 2009). In addition, the module will demonstrate the use of some existing clinical tools for managing chronic nonmalignant pain while minimizing the misuse of opioid pain medicines.

This module is modeled on the approach to chronic pain management proposed by Gourlay et al. (2005). In this approach, the authors propose there is no way to predict with reliability who will be able to be managed safely on controlled substances for chronic pain. They therefore suggest the following: “As with universal precautions in infectious diseases, by applying the following recommendations, patient care is improved, stigma reduced, and overall risk is contained.”

1. Make a diagnosis with an appropriate differential:
 - a. Treat symptoms even when specific objective findings are absent.
 - b. Treat co-occurring disorders (e.g., depression, substance use disorders [SUDs]).
2. Assess for psychiatric conditions and SUDs.
 - a. Obtain a careful substance abuse and mental health history.
 - b. Use drug testing in a “patient-centered” manner.
3. Obtain careful, detailed, informed consent for the use of opioids.
4. Use treatment agreements outlining the goals of treatment and the responsibilities of both patients and providers.
5. Assess pain level and function both before and after each intervention.
6. Use opioids (with or without adjunctive medications) when appropriate.
7. Regularly assess pain scores and level of function.
8. Regularly assess the “four As” of pain medicine:
 - a. Analgesia
 - b. Activities of Daily Living

- c. Adverse Effects
 - d. Aberrant Drug-Taking Behaviors
9. Periodically review pain diagnosis and comorbid conditions (e.g., psych, SUDs).
 10. Document each of these components carefully and completely.
 11. Triage patients to appropriate level of care based on risk and/or on response to treatment and any problems identified during treatment. Three levels of care are discussed in this reference:
 - a. Primary care
 - b. Primary care with specialty support
 - c. Specialty care

To more effectively demonstrate how to manage chronic nonmalignant pain in a manner consistent with these guidelines, this module is structured as a case study of a patient with a chronic pain problem. At each stage of the case, the components of the “Universal Precautions” approach are modeled, either in the text of the case or through the incorporation of clinical tools that have been completed as if they were part of this patient’s medical record.

Target Audience and Setting

This module has been piloted primarily with medical students at the midpoint of their third year of medical school. It is most appropriate for health professions students who have had some firsthand experience with managing patients with pain in inpatient and outpatient settings (e.g., third- and fourth-year medical students). The learning objectives may also be appropriate for residents in primary care fields, particularly first- and second-year residents in family medicine and internal medicine. During our experience piloting this module with second-year family medicine residents, the discussion generated has been lively and valuable, but even more time was needed to work through the material due to the rich body of experiences with managing pain and opioid medications that the resident learners wanted to share and reflect on.

The module is designed for use in a small-group setting, with perhaps 8 to 10 learners, and has been piloted using both a single faculty facilitator and a team of two facilitators with each small group. Our faculty commented that having two facilitators per group improved the pace and flow of the module, because it allowed one facilitator to look ahead and plan for the next section while the other led the discussion.

Please note that in pilot testing with third-year medical students, the students often focused intently on detailed issues around pathophysiology, pharmacology, and physical examination techniques.

It is important for the facilitator to stress that, at this level, the learning objectives center on general principles. This module is designed to provide an overview of the approach to managing patients with chronic nonmalignant pain and preventing and detecting opioid misuse. Details about physical examination techniques, interventional pain procedures, alternative therapies, and prescribing guidelines for specific classes of medications are outside the scope of this module. In our home institution, these topics are covered in separate workshops offered along with this small-group module. Facilitators will need to ensure that the group continues to move through the module, glean concepts and principles rather than focusing too much time on any one topic.

Similarly, the evaluation and management of acute and subacute back pain are topics that should be covered elsewhere in the curriculum to allow the participants to focus on issues unique to chronic pain management. Participants should be instructed to review the page marked “Case Study Module: Background” prior to the session. Facilitators will begin with “Visit #1,” which takes place 4 months after this patient’s initial presentation.

Finally, please be sure to stress that these guidelines were developed for the management of chronic nonmalignant pain and do not necessarily apply to the management of cancer pain or pain at the end of life.

Structure of the Student Module

In this module, participants will care longitudinally for a single patient with a common chronic pain complaint: LBP. The case study is structured in five sections, beginning with background information and followed by three office visits (and a separate review of lab results), which take place over the course of 9 months. Each visit begins with a medication list and a description of the patient’s current condition and ends with questions for discussion. The questions are tied to the specific learning objectives for each visit.

Participants will receive two sets of printed pages. The first is a nine-page packet that includes five pages of case study. The second is a document containing 25 pages of supporting documents, including both reference materials and clinical tools completed to model what this patient’s clinical chart might look like. Please keep the two resources side by side as you work through this module.

Getting Started

We recommend a minimum of 2 hours to complete the entire module. For a group of learners with more experiences to share, or if the facilitators are less experienced at moving through case-based learning modules, 3 hours with a break incorporated will be more comfortable, as a lot of material is included. Each student should receive a copy of both the case study and the supporting documents packet. Please begin by familiarizing yourself with the student materials and the faculty guide. Consider holding a faculty development session in advance to review the module and faculty guide and to discuss the structure of and strategies for the sessions.

Using the Faculty Guide

The faculty guide is organized to follow the student case module step by step. The guide is divided into five sections, reflecting the structure of the case study and supporting documents. The guide does not contain some of the materials that are in the student module, so it may work best for each facilitator to use the guide side by side with the student module until s/he is more familiar with the material.

Each section of the faculty guide begins with a list of the learning objectives for that section, which are identical to the discussion questions in the student module. The list of objectives is followed by background information to support the discussion of each objective; the background information is numbered to match the learning objective to which it corresponds. Also, when the

discussion will require reviewing specific information in the supporting documents module, the page on which that material appears will be listed in **bold** type.

Suggestions for adapting the module to your educational setting:

- The module can be broken up and completed in multiple sessions over multiple days or weeks, depending on the time allotted for didactics at your institution. Please note that the learning objectives are not equally distributed among the sections and that it will take significantly more time to work through Visits #1 and #2.
- The pain management tools included in the module are meant to be representative of the types of tools that are available and that may be helpful in supporting the clinical care of pain patients and facilitating documentation that meets the standards set forth in the Federation of State Medical Boards *Model Policy on the Use of Controlled Substance in the Treatment of Pain* from 2004 and the American Pain Society guidelines from 2009 (Chou R, et al. 2009). By including these tools we are not endorsing the use of any specific tool. Programs with established pain treatment tools or protocols should feel free to substitute the documents used within the home institution.
- Facilitators or program sponsors may choose to prioritize some of the learning objectives over others in some or all of the sections.

Some selected strategies for facilitating the case study module:

- In order to focus on the chronic pain management issues, the acute pain presentation and first 4 months of treatment are summarized in the first page of the case study. It is reasonable to review this information briefly with the participants prior to beginning with Visit #1, but be careful not to get bogged down in discussions of the acute presentation.
- Consider starting the small group by asking the students to react to the background information included with the case study and to describe some of their experiences with managing pain. What has worked well, and what hasn't? Describe particularly challenging patient care situations.
- In the interest of time and momentum, when starting a new section (visit) in the case, consider quickly summarizing the content of the case presentation for the students, rather than having the students take the time to read it. If you have two facilitators, you can alternate this responsibility so one of you is always reading the learning objectives and ready to lead the discussion in the next section.
- Use the discussion questions at the end of each visit section—they are keyed to the objectives for the session and the material in this faculty guide.
- To improve participation, consider asking the participants to take turns responding to the discussion questions.

Optional Section for Facilitators: Background Information on Clinical Presentation

This patient's presentation suggests a common cause of low back pain (LBP): L4-L5 disk herniation with nerve root compression. This section of the faculty guide contains background information about the evaluation and treatment of LBP to help with any questions that may come up after the students have read the background section. It is expected that most of the students participating in this module will already be familiar with this approach; in order to focus more time on chronic pain management issues, try not to spend too much time discussing the initial presentation (Chou R, et al. 2007).

1. History and Physical Examination

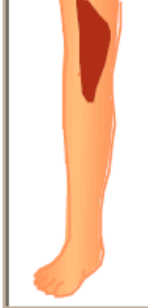

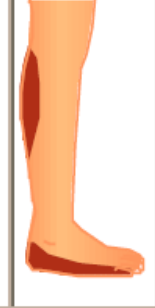
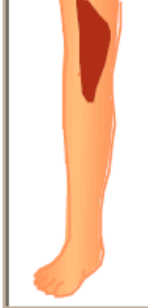

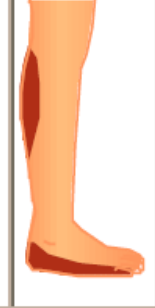
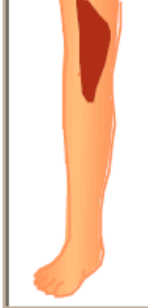

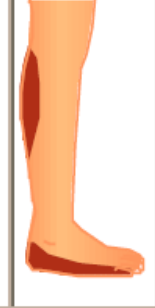
To classify this acute LBP syndrome into one of three categories:

- a. Nonspecific LBP (85%)
- b. LBP potentially associated with radiculopathy (4%) or spinal stenosis (3%)
- c. LBP associated with other specific, potentially serious causes.

2. Historical Assessment for Potential Serious Conditions

Rapidly progressing or severe neurological deficits:

- a. Motor deficits at multiple levels
- b. Fecal/urinary incontinence
- c. Urinary retention
- d. Saddle anesthesia
 - e.g., cauda equina syndrome (compression of nerve roots from lower spinal cord segments)

<u>History/physical typical for lumbar nerve root of symptomatic lumbar disc herniation and nerve root compression:</u>	<u>Physical exam findings suggestive of symptomatic lumbar disc herniation and nerve root compression:</u>															
<p>Pain originating in lumbar region extending down lateral/posterior leg on one or both sides in the following patterns:</p>	<p>Sciatica: Back and leg pain in typical lumbar nerve root distribution.</p>															
<p>Nerve root:</p>	<ul style="list-style-type: none"> • Quick test: <ul style="list-style-type: none"> – Straight leg raise, squat and stand, heel walk, and toe walk. • Straight leg raise: <ul style="list-style-type: none"> – Hip flexion with straight knee. – Reproduce symptoms between 30 and 70 degrees flexion. • Crossed straight leg raise: <ul style="list-style-type: none"> – Reproduce symptoms on one side when opposite leg is lifted. • L4 nerve root: <ul style="list-style-type: none"> – Decreased knee strength and reflexes. – <i>Squat and stand test.</i> • L5 nerve root: <ul style="list-style-type: none"> – Decreased great toe strength. – Decreased strength of dorsiflexion. – <i>Heel walk test.</i> • S1 nerve root: <ul style="list-style-type: none"> – Decreased ankle reflexes. – Decreased strength plantar flexion. – <i>Toe walk test.</i> • Consider associated sensory evaluation. 															
<table border="1" style="width: 100%; text-align: center;"> <thead> <tr> <th style="width: 33%;">L4</th> <th style="width: 33%;">L5</th> <th style="width: 33%;">S1</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> </tr> <tr> <td>Extension of quadriceps</td> <td>Dorsiflexion of great toe and foot</td> <td>Plantar flexion of great toe and foot</td> </tr> <tr> <td>Squat & rise</td> <td>Heel walking</td> <td>Walking on toes</td> </tr> <tr> <td>Knee jerk diminished</td> <td>None reliable</td> <td>Ankle jerk diminished</td> </tr> </tbody> </table>	L4	L5	S1				Extension of quadriceps	Dorsiflexion of great toe and foot	Plantar flexion of great toe and foot	Squat & rise	Heel walking	Walking on toes	Knee jerk diminished	None reliable	Ankle jerk diminished	
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Squat & rise	Heel walking	Walking on toes														
Knee jerk diminished	None reliable	Ankle jerk diminished														

- e. Findings associated with spinal stenosis (variable and unreliable):
 - Pain radiating to leg
 - Symptoms change on downhill treadmill
 - Pain relieved in sitting position
 - Age > 65
- f. Fracture of spinal column:
 - Trauma
 - Risk factors for compression fractures:
 - Age
 - Osteoporosis
 - Chronic steroids.
- g. History of cancer or symptoms associated with cancer:
 - Past cancer diagnosis
 - Unexplained weight loss
 - Age > 50
 - Prolonged symptoms
- h. Risk factors for spinal column infection:
 - Fever
 - IV drug use
 - Recent infection
 - Immunodeficiency

3. Initial Treatment

- a. For nonspecific LBP:
 - Educate patients about expected course/duration of symptoms.
 - Advise patients to stay active.
 - Educate patients about self-care options:
 - Heat
 - Lumbar supports (little evidence)
 - Consider impact of symptoms on work and other activities.
 - Role for preventive education?
 - Lifting techniques
 - Stretching exercises
 - “Back school”
- b. Adjuvant therapy:
 - Spinal manipulation
- c. Approach to acute radicular pain is similar, although little evidence/few studies are available to guide treatment in this group.

4. Initial Pharmacotherapy Emphasizes Nonopioid Options (Include discussion of side effects and toxicities.)

- a. Acetaminophen:
 - Safe, inexpensive, lower potency
 - Risk of liver enzyme elevation
- b. NSAIDs:
 - Inexpensive, higher potency

- Gastrointestinal side effects
- Renovascular side effects
- c. COX 2 inhibitors:
 - Worth mentioning increased risk cardiovascular events and removal of Bextra and Vioxx from the market, because patients may ask; preceptors may be prescribing Celebrex
- d. Muscle relaxants:
 - Variable results, low-level evidence for efficacy
 - Avoid carisoprodol (SOMA), also known by the name isopropyl meprobamate; this medication is metabolized to meprobamate, a barbiturate that was widely abused in the past and readily causes tolerance, physical dependence, and risk of seizure on withdrawal. There are many safer alternatives in this category of medications that do not carry these risks.
- e. Opioids are not absolutely contraindicated and doctors may consider use of short-acting agents for short course if:
 - There is severe, disabling pain.
 - The pain is not controlled with acetaminophen or NSAIDs.

5. *Imaging Guidelines*

(Routine imaging not recommended in nonspecific back pain.)

- a. Plain x ray:
 - Indicated for suspected compression fracture in high-risk patients:
 - Trauma or osteoporosis
 - Risks: Gonadal exposure to radiation, especially in women (equal to one CXR daily for a year)
- b. Advanced imaging: CT/MRI:
 - Does not improve outcomes
 - Incidental findings leading to additional, possibly invasive, testing
- c. Imaging should be performed in acute pain if:
 - There are severe or progressive neurological deficits.
 - Serious underlying condition is suspected.
 - MRI typically preferred over CT.

6. *Planning Follow-up*

- a. Most cases of LBP resolve within 4 weeks.
- b. Assess and respect impact on work and family responsibilities.
- c. Reassure; engage; and express concern, care, and willingness to continue to work with the patient to resolve this issue.

Subacute Back Pain

1. *Imaging in Subacute Back Pain*

- a. Used at follow-up reevaluation for signs of serious underlying conditions if signs suggest a problem
- b. Used in patients with persistent pain, radiculopathy, or stenosis for the past 4 to 8 weeks

- c. Guidelines stress imaging indicated if patient is a possible candidate for surgery or epidural steroid injection.

2. *Adjuvant Therapy in Subacute Back Pain*

- a. Intensive interdisciplinary rehabilitation (e.g., with physician; psychologist; physical, social, and vocational therapists) is really the only modality with evidence for benefit at this stage.
- b. Role for preventive education? Not much evidence.
 - Lifting techniques
 - Stretching exercises
 - “Back school”
- c. There is some evidence for other adjuvant therapies in back pain that is more chronic:
 - Acupuncture
 - Exercise therapy: Individual with supervision, stretching, and strengthening
 - Massage
 - Yoga
 - Cognitive behavioral therapy
 - Relaxation.

Visit #1: 4 Months After Initial Injury

(Page numbers correspond to pages in the Supporting Documents handout.)

Discussion Questions/Learning Objectives:

1. Discuss the definition of chronic pain, the goals of treating chronic nonmalignant pain with opioid medications, and how to establish appropriate goals and expectations with each patient (**p 2 for MRI**).
2. Describe the initial assessment and documentation procedures for treating chronic pain with opioid medications, including:
 - a. The use of an Initial Pain Assessment Tool (**pp 3–4**) to document the cardinal features of the pain complaint and the impact of the pain on the patient's functioning
 - b. The informed consent process for initiating opioids (**pp 5–6**)
 - c. The role for, and components of, a treatment agreement in the management of pain with opioid medications (**pp 7–8**)
3. Describe strategies for initiating long-acting opioids (**p 9**).
4. Discuss the use of adjuvant, nonopioid medications in patients taking chronic opioids (**p 10**).
5. Describe the psychological impact of chronic pain and the use of the PHQ-9 to assess depression (**pp 11–12**).
6. Discuss strategies for screening for SUDs in pain patients, including the use of standardized screening tools. The AUDIT and the DAST-10 are included in this packet (**pp 13-14**). The NIDA-Modified ASSIST (NMASSIST) is available online (see <http://www.drugabuse.gov/NIDAMED> .)
7. Discuss the factors associated with increased risk of abuse of opioid medications during pain treatment. The Opioid Risk Tool is included in the packet (p 15).
8. Describe how to use a statewide Prescription Drug Monitoring Program (PDMP). If it is available in your state, describe how to access it.

1. Chronic Pain: Definition and Goals of Treatment (**p 2 for MRI**)

- a. Notes on the MRI: These findings are somewhat nonspecific. One of the significant problems with imaging of the low back is that many patients with pain will have no findings, and many patients without pain will have asymptomatic findings.
- b. Definition of pain:
 - “Unpleasant sensory and emotional experience, associated with actual or threatened tissue damage, or described in terms of such.” International Association for the Study of Pain (Savage 2008).
 - Challenges in diagnosing pain:
 - No objective tests or measures (Pain is what the patient says it is.)
 - Perceived differently by different people
 - Strongly influenced by psychological and social factors
 - May coexist with mental illness and addiction
- c. Chronic nonmalignant pain definitions:
 - > 3 months? > 6 months?
 - Pain that persists beyond the usual course of an acute disease or healing of an injury or pain that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years (Federation of State Medical Board Guidelines 2004)

- Pain that is not associated with cancer or some other serious medical illness and that has continued for more than 3 to 6 months
 - Pain associated with a persistent pathologic process.
- d. Goals of using long-acting opioids (Savage 2008):
- Improve pain control throughout the day/night
 - Improve functioning
 - Provide relief of associated symptoms, such as anxiety and sleep problems
 - Decrease use of short-acting opioids, which may have higher risk of abuse due to: Rapid onset Short half-life, potentially leading to cycles of pain relief followed by rebound symptoms and/or intoxication followed by withdrawal
- e. Setting Treatment Goals and Expectations
- Treatment goals should be discussed and documented explicitly
 - Goals: decrease pain, improve function, maximize safety, minimize harm
 - Set goals that are specific, measurable, and realistic, with time lines or limits in which it would be expected that each goal would be met. Record these goals and review at each visit, tracking whether goals are being met or not.
 - “Pain free” is not a safe or realistic goal. Patients should not expect to become pain free.. Instead, the expected outcomes are decreased pain and improved function.
 - As with any medication or treatment, providers must show that the benefits outweigh the risks. Opioid treatment should be approached as a trial, As with any trial, it will require ongoing reassessment of whether or not the treatment is working, and whether or not it is sufficiently safe. If at any point the risks associated with treatment become too great, or the benefits too small, then the plan would be to stop the opioid treatment trial, just as it would be with any other treatment that is not working or is causing harm to the patient.

2. Initial Pain Assessment and Documentation

[Initial Pain Assessment Tool (pp 3–4)]

- a. Two domains covered:
- Cardinal features of the pain complaint
 - Impact of pain on patients’ lives and functioning
- b. Provides standardized format for recording cardinal features of a pain complaint:
- Just one of many different available tools
 - May be completed by MA or nurse prior to clinician visit
 - May facilitate meeting documentation standards and help standardize practice in larger offices/medical groups. This form’s major weakness is that it does not include any documentation of goal setting, which is a critical third component of pain treatment that is essential to establish at the onset of treatment in order to track whether or not the treatment is working.

[Consent for Treatment with Long-Acting Opioids (pp 5–6)]

- c. Please have participants review the model consent form provided; stop and ask them to comment. Other models are available online in public domain for use in clinical practice. This form covers the following topics (Chou R, et al. 2009):
- Diagnosis: Documentation of indication for opioids
 - Treatment of last resort; other treatments that have been tried and failed
 - Side effects/toxicities
 - Medication interactions
 - Impaired driving or other activities that put self/others at risk
 - Physical dependence
 - Addiction potential
 - Sexual side effects
 - Risk to pregnancy.

[Pain Management/Chronic Opioid Therapy Treatment Agreements (“contracts”) (pp 7–8)]

- d. For reference, see Arnold (2006).
- e. Please have participants review the model agreement provided; stop and ask them to comment.
- f. Role of agreement: it should identify:
- Responsibilities of patients
 - Office procedures
 - Safety procedures
 - Parameters for continued care.
- g. Traditional contracts or agreements are somewhat provider centered and not very patient centered. The model provided demonstrates important components of treatment and monitoring, but it expands on traditional contracts to describe commitments from both parties who are signing the contract.
- The model provided includes language reflecting what you/your practice will contribute in this therapeutic relationship:
 - Commitment to evaluate/treat pain and seek diagnosis
 - Commitment to maximize function and minimize toxicity
 - Commitment to appointments, refills, and access to provider and staff (within boundaries)
 - Monitoring to minimize risk of addiction
 - Commitment to continue treatment and avoid abandonment of patient should anything go wrong with treatment, such as toxicity, drug abuse, worsening symptoms, etc.

3. Initiating Treatment with Long-Acting Opioids (p 9 table)

- a. Initial medication selection:
- Table with common medications is included.
 - Cost and insurance coverage will often dictate choice:
 - Many new generics now available.
 - Oxycodone chosen here to facilitate discussion of urine drug screening later in the module, but consider:

- Oxycodone and hydrocodone are more commonly abused and diverted and may be better left as second or third choices.
- Morphine less commonly abused and less expensive.
- Methadone not recommended unless provider is experienced in its use. Things to consider, include:
 - 1) Long half-life: Potential for progressive medication accumulation and risk of overdose and death days to weeks after initiating dosing;
 - 2) Interactions with other medications, including risk of sedation and respiratory depression when combined with other CNS depressants and metabolic interactions at the P450 3A4 and 2D6 enzymes, potentially causing changes in blood levels of methadone and/or other prescribed medications;
 - 3) Prolongation of the QT interval;
 - 4) 700 percent increase in overdose/poisoning deaths associated with methadone between 1998 and 2006 (Eckholm 2008); and
 - 5) U.S. Food and Drug Administration (FDA) “black box” warning issued November 2006 addressing risk of overdose and QT prolongation.

b. Dosing of long-acting opioids:

- In patients—such as this one—who are taking short-acting opioids, providers can estimate level of tolerance by adding up reported cumulative daily dose of a short-acting opioid and use this as benchmark for determining the equivalent cumulative dose of long-acting medication to be given.
 - BEWARE: History is unreliable, and cross-tolerance between medications is incomplete, so most authors recommend using one-half or less of the equivalent long-acting medication.
- In nonmalignant pain, start low and increase very slowly.
- Increase dosing in small increments, weekly if needed:
 - Continue short-acting medications at lower doses and monitor use.
- Frequent follow-up until effective dose is reached.

4. Adjuvant Medications (p 10 table)

All patients being treated with opioids for chronic nonmalignant pain should be taking some form of adjuvant medication:

a. Antidepressants:

- Tricyclic antidepressants have the best data to support their use in chronic pain patients.
- SNRIs are being used in patients who cannot tolerate the side effects of tricyclics and have concurrent depression. These agents have some promise in treating pain due to noradrenergic activity, and some have won FDA indications for treating specific pain syndromes. They are not more effective than tricyclic agents, but they are significantly more expensive.
- SSRIs have not been shown to impact pain symptoms but may help alleviate depression symptoms in patients with co-occurring pain and depression.

b. Antiseizure agents are approved for use in certain types of neuropathic pain only.

5. *Psychological Aspects of Chronic Pain* (Turk 2008b)

Chronic pain can lead to significant psychological consequences for patients, including depression, poor self esteem, frustration, and loss of hope. Providers should always explore with patients their perceptions about the impact pain is having on:

- a. Ability to perform simple activities of daily living (ADLs).
- b. Work productivity and ability to maintain work and income
- c. Relationships and marriages
- d. Ability to meet role responsibilities.

Screening for depression is recommended during the initial assessment and periodically throughout treatment in patients with chronic pain.

Patient Health Questionnaire-9 (PHQ-9) (pp 11–12) :

This is a patient-completed questionnaire available for both screening for depression and monitoring a patient's response to treatment.

- a. Scores:
 - 10–14 mild depression
 - 15–19 moderate depression
 - > 20 severe depression
- b. PHQ-9 scores should decrease as a patient improves and/or responds to treatment. Some offices complete a PHQ-9 regularly to track patients' progress in depression treatment.

6. *Screening Adult Patients for Substance Use Disorders (SUDs) (pp 13–14)*

- a. All patients for whom opioids may be prescribed should be screened for SUDs early in the evaluation of pain complaints, arguably before the first prescription for opioids.
- b. Expose the students to the concept and practice of screening for SUDs using standardized instruments:
 - Provide a few examples of screening instruments (AUDIT, DAST-10, NMASSIST) rather than an exhaustive list of available tools.
- c. Discuss, model, and/or role play to demonstrate language or style that can be used to introduce the idea of screening for SUDs in a nonthreatening manner:
 - Normalize the questions:
 - “In order to help me take better care of my patients, there are some questions I ask everyone in my practice...”
 - Put the screening in a broader context:
 - “Many of my patients have expressed concern that pain medications can cause addiction...Is that something you are worried about?”
 - Ask about others first, then direct the questions back to the patient:
 - “Have any of your friends or family ever had problems controlling their use of medications? Alcohol? Drugs?”
- d. Screening tools are used for initial identification of a possible problem; they are not diagnostic and, therefore, require further investigation when the screening test is “positive.”
 - Discuss options for further investigation of a positive screening, such as further provider history and evaluation by a behavioral health or addiction treatment professional.

- e. Be sure to stress that identification of a substance-related disorder should not simply lead to excluding patients from treatment. Even when providers decide a patient may be too high risk to manage in their outpatient offices, they still have the responsibility to help the patient find resources to manage both pain and the substance-related problems.
- f. **Optional:** Discuss the challenges/successes you have encountered in your own practice in implementing the use of standardized screening tools for SUDs or any other conditions, including:
 - Time and financial pressures.
 - Organizational and structural challenges.
 - Use of nonphysician staff to perform screens.
 - The new Medicare and Medicaid codes for screening and brief counseling interventions in medical settings that have been approved and will allow physicians to bill separately for these services. Payers are gradually adopting/approving these codes around the country (see <http://www.ensuringsolutions.org>)
- g. Alcohol Screening Tool:
 - The **AUDIT** (Alcohol Use Disorder Identification Test) was developed by the World Health Organization.
 - Score ≥ 8 “positive”; significant likelihood of:
 - Hazardous or harmful drinking patterns
 - Possible diagnosis of alcohol dependence.
 - Sensitivity and specificity vary with the scoring cutoff:
 - Higher scores associated with more severe problems.
 - Administered as an interview or by having the patients complete the form on their own.
- h. Drug Abuse Screening Tool:
 - The **DAST-10** (Drug Abuse Screening Test) is a 10-item screening tool, with simple yes/no questions.
 - Score ≥ 3 is considered a “moderate level” of problems related to drug use and warrants further investigation.
 - Any single positive answer may warrant further investigation in pain patients.
 - Note that the answer for # 3 is reversed (a “yes” answer is desired to that question).
- i. NIDA Modified Alcohol, Smoking, and Substance Involvement Screening Test (NMASSIST)¹:
 - Offers web-based interactive as well as paper and pencil versions.
 - Screens for alcohol, tobacco, illicit and prescription drugs (specifically separating out prescription drugs from similar street drugs).
 - Consists of single question prescreen (lifetime use), followed by up to 7 questions depending on responses provided.

¹ Based on the ASSIST Version 3.0 developed and tested by the World Health Organization. The NMASSIST is available online: www.drugabuse.gov/NIDAMED.

- Web-based tool calculates substance involvement score automatically, provides risk level and recommended intervention.
- Substance involvement scores range from Lower Risk (0-3), Moderate Risk (4-26), to High Risk (≥ 27).

7. Factors Associated with Increased Risk for Problem Use of Opioids

Part of the “Universal Precautions” approach is to assess patients’ risk/probability of substance abuse before and during treatment and to triage patients to higher or lower structured levels of care depending on that risk/probability.

Factors associated in some studies with increased risk of abuse of medications during treatment with opioids for chronic pain are (Turk, Swanson, Gatchel 2008a):

- History of alcohol or drug abuse/addiction
- Cigarette smoking
- Younger age
- History of mood disorder, especially unipolar depression
- History of childhood sexual abuse
- Family history of substance abuse
- History of driving under the influence or drug-related legal problems.

A number of screening tools have been developed to try to help identify patients who may be at higher risk for misuse of opioid medications, and they fall into two general categories:

- Structured interviews by medical provider or trained professional
- Patient self-administered questionnaires.

The Opioid Risk Tool (Webster and Webster, 2005) (p 15):

- One of many tools currently available
- Chosen because it is simple and clearly highlights factors associated with risk of opioid misuse
- Exception: It does not include cigarette smoking
- Administered prior to initiation of opioids as an interview by the provider
- “To predict the probability of a patient displaying aberrant behaviors when prescribed opioids for chronic pain.”

Note that Webster and Webster have weighted the responses to reflect different levels of correlation between the listed risk factors and aberrant behaviors, as well as different levels of association between men and women of the risk factors with aberrant behaviors. While the authors validated the score ranges associated with risk of aberrant drug taking behaviors (0–3 low risk, 4–7 moderate risk, ≥ 8 high risk), the value of this tool may be mostly in helping providers ask about and document the presence of risk factors for medication misuse.

What to do with this information? The authors propose that “knowing which patients are at greatest risk for displaying aberrant behaviors can be useful in establishing appropriate levels of monitoring for abuse.” This approach is consistent with the “Universal Precautions” approach, which suggests not only different levels of monitoring for those with risk factors, but the possibility of triaging patients to levels of care with greater structure and/or involvement of mental health or addiction and pain specialty professionals when risk factors are present.

8. Describe how to use a statewide Prescription Drug Monitoring Program (PDMP). If it is available in your state, describe how to access it.

Source: http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm#1

What is a prescription drug monitoring program (PDMP)?

According to the National Alliance for Model State Drug Laws (NAMSDL), a PDMP is a *statewide* electronic database which collects designated data on substances dispensed in the state. The PDMP is housed by a specified statewide regulatory, administrative or law enforcement agency. The housing agency distributes data from the database to individuals who are authorized under state law to receive the information for purposes of their profession.

What are the benefits of having a PDMP?

The overview provided by NAMSDL clearly identifies the benefits of a PDMP: as a tool used by states to address prescription drug abuse, addiction and diversion, it may serve several purposes such as:

- support access to legitimate medical use of controlled substances,
- identify and deter or prevent drug abuse and diversion,
- facilitate and encourage the identification, intervention with and treatment of persons addicted to prescription drugs,
- inform public health initiatives through outlining of use and abuse trends, and
- educate individuals about PDMPs and the use, abuse and diversion of and addiction to prescription drugs

Visit #2: 4 Weeks Later

(Page numbers correspond to pages in the Supporting Documents handout.)

Discussion Questions/Learning Objectives:

1. Describe the “four As” of ongoing monitoring and care of chronic pain patients: Analgesia, Activities of Daily Living, Adverse Events, and Aberrant Drug-Taking Behaviors (**pp 17–18**).
 2. Discuss the use of the Pain Assessment and Documentation Tool (PADT™) for monitoring pain patients in clinical practice (**pp 17–18**).
 3. Discuss strategies for optimizing pain control and describe how to increase the dose of long-acting opioids more safely.
 4. List potentially “aberrant drug-taking behaviors” and which are more or less likely to be associated with drug abuse (**p 19**).
 5. Discuss the differential diagnosis of aberrant drug-taking behaviors in chronic pain patients managed with opioids.
-
1. *Ongoing Monitoring/Care of Chronic Pain Patients on Opioid Therapy* (**pp 17–18**)
Four dimensions to assess, monitor, and document; organized into “the four As” (Gourlay 2005)
 - a. **A**nalgesia: Effectiveness of medications at decreasing pain:
 - o Record levels and changes in levels using pain rating scales.
 - b. **A**ctivities of Daily Living: Has this treatment improved functioning?
 - c. **A**dverse Events: Any side effects or toxicities of the medications?
 - d. **A**berrant Drug-Taking Behavior: Signs of abuse of the medication.
 - e. Some authors have recommended the addition of a fifth “A” for **A**ffect to emphasize the importance of monitoring for depression and other mental illness during pain treatment.

For documentation purposes, it is recommended that the following additional information be obtained periodically:

- Reassessment of diagnosis and the process that was followed to make that diagnosis
- Consideration of whether further diagnostic testing or referrals are warranted
- Periodic physical examination to support diagnosis.

2. *Pain Assessment and Documentation Tool (PADT)* (**pp 17–18**)

- a. One model for a “Pain Progress Note”
- b. Clinician-directed tool that models the “four As” approach.

3. *Optimizing Pain Control*

- a. A number of things may improve overall pain control and decrease use of short-acting opioids:
 - Increase dose of long-acting opioid:
 - According to his history, the patient is taking an additional 30 mg per day of oxycodone in the short-acting form in addition to 40 mg of long-acting opioid.
 - By gradually increasing his long-acting medication, you may expect the use of the short-acting medication to decrease accordingly.

- Although oxycodone extended release is a 12-hour medication, the patient may benefit from taking the second dose earlier, perhaps right after work.
- Take medications 1 hour prior to those times if predictable to have analgesia on board, such as in the evening after work.
- Add/increase adjuvant medications and alternative therapies.
- Consider additional sleep aid.
- Add and/or schedule nonopioid medications at particularly difficult times to try to minimize opioid use:
 - In the morning before work
 - In the afternoon after work
 - Before bed
- b.** Increasing doses of long-acting opioids: start low and go slow(ly):
 - Small changes at weekly to monthly intervals.
 - Continue short-acting medications while adjusting dose of long-acting medications, but expect/plan that the number of pills and frequency of use of short-acting medications will go down as long-acting dose is optimized.

4. Aberrant Drug-Taking Behaviors (p 19)

(Adapted from Manchikanti 2008.)

- a. Aberrant drug-taking behaviors: Behaviors that look concerning, but may in reality be more or less predictive of an SUD.
- b. In this case, it is of concern that the patient is taking more short-acting medication than he is prescribed, has called in for early refills, and may be taking medications from other sources (because he is taking more than is prescribed but not getting early refills from the provider's office).
- c. Overall, however, as his medications have been increased, he has shown improvement in his pain levels and decreases in these irregularities in medication use, suggesting the behaviors may be in response to undertreated pain.

Behaviors more likely to be associated with medication abuse/addiction:

- a. Selling medications
- b. Falsification of prescription—forgery or alteration
- c. Injecting medications meant for oral use
- d. Obtaining medications from nonmedical sources
- e. Resistance to changing medications despite deterioration in function or significant negative effects
- f. Loss of control over alcohol use
- g. Use of illegal drugs or controlled substances that are not prescribed for the patient
- h. Recurrent episodes of:
 - Prescription loss or theft
 - Obtaining opioids from other providers in violation of treatment agreement
 - Increases in dosing without provider's instruction
 - Running short with medication supply and requests for early refills.

Behaviors that look aberrant but may be more a part of the process of stabilizing a patient's pain condition and less predictive of medication abuse/addiction, such as:

- a. Asking for, or even demanding, more medication

- b. Asking for specific medications
- c. Stockpiling medications during times when pain is less severe
- d. Use of the pain medications to treat other symptoms
- e. Reluctance to decrease opioid dosing once stable
- f. And, in the earlier stages of treatment:
 - Increasing medication dosing without provider instruction to do so
 - Obtaining prescriptions from sources other than the primary pain treatment provider
 - Sharing or borrowing similar medications from friends/family.

5. *Differential Diagnosis of Behaviors Suggestive of Addiction* (Savage 2002)

- a. Inadequate pain management:
 - Stable condition but inadequate pain control
 - Progressive condition/pathology
 - Tolerance to opioids.
- b. Inability to comply with treatment:
 - Cognitive impairment
 - Psychiatric conditions.
- c. Self-medication of mood, anxiety, sleep, posttraumatic stress disorder, addiction, etc.
- d. Diversion by patient or others.
- e. The risk is that some providers may prematurely discharge patients from pain treatment for failure to follow the treatment agreement and for the provider's suspicion of medication abuse without considering other possible explanations for the behaviors.
- f. For patients exhibiting these types of behaviors that could be explained by legitimate reasons other than substance abuse, it is valuable to:
 - Express concern.
 - Review the treatment agreement.
 - Increase the frequency of monitoring, especially in the early stages of treatment when the patient is first being stabilized.

Visit #2 Follow-up

(Page numbers correspond to pages in the Supporting Documents handout.)

Discussion Questions/Learning Objectives:

1. What are the two most common techniques for drug testing? What are some strengths and weaknesses of each technique?
2. If the patient is taking oxycodone, why is the opiate screen negative? Discuss challenges in testing for opioids, highlighting limitations in immunoassays for detecting semisynthetic and synthetic opioids.
3. How will you respond to the positive test for the metabolite of marijuana? Would your response be different if the test were positive for cocaine metabolites? What concerns and options do you have if a patient you are treating is using illegal drugs?
4. What if the urine the patient provided was cold? Discuss the logistics of drug testing, including prevention of sample substitution or alteration.

Urine Drug Testing in the Management of Chronic Pain (p 20):

(Sources: Gourlay 2006 and Manchikanti 2008)

1. Urine Drug Testing Techniques

There are two commonly used techniques for urine drug testing:

- Immunoassays, in which engineered antibodies bind to drug metabolites
- GCMS (gas chromatography-mass spectrometry), which is able to directly measure metabolites.

Immunoassays

- a. Quick, easy, and inexpensive. Most drug testing is by immunoassay, even in hospital labs.
- b. Immunoassays are available as dipstick or cup tests that can be “CLIA waived” and used in office practice; these often include a standard panel:
 - Opiates, cocaine, marijuana, benzodiazepines (+/- barbiturates, amphetamines).
- c. Results are based on finding a certain level of drug metabolite in the urine:
 - Cutoffs vary among labs and regulating agencies and can be quite high, meaning that patients with low levels of metabolite in their urine may be missed (i.e., increases specificity, decreases sensitivity).
- d. There is an incidence of cross-reactivity with other drugs and medications. There will be an incidence of false positives.

GCMS

- a. This technique provides direct measurement of drug or drug metabolite and can give quantitative results.
- b. Minimizes false positives, but they still occur:
 - Documented fluoroquinolones giving false positive opiates.
- c. Expensive and complicated.
- d. Available only in specialty labs.
- e. Typically used to:
 - Confirm positive screening results.
 - Resolve questions or issues of false positive screens.

- Test for substances for which immunoassays are unreliable or unavailable.

2. *Limitations of the Opiate Immunoassay in Detecting Semisynthetic and Synthetic Opioids*

- Immunoassays for “opiates” are based on finding morphine in the urine, which is the metabolite for morphine, codeine, and heroin.
 - These tests do not reliably detect synthetic and semisynthetic opioids, such as oxycodone, hydrocodone, methadone, buprenorphine, or fentanyl (**p 20, table**).
 - If a provider needs to test for the presence of synthetic and semisynthetic opioids, he/she must order specific testing for these agents and communicate with the lab to make sure that he/she is getting the type of testing needed to monitor each patient.
 - Some companies are making immunoassay tools that target some of these drugs specifically, but they are separate tests from the “opiate” screen.
- Oxycodone does not reliably show a positive on the opiate immunoassay because it is a semisynthetic opioid.
- The absence of a positive opiate screen may be seen as reassuring because it suggests there are no morphine or morphine derivatives (such as heroin) in the patient’s system; but oxycodone and/or hydrocodone metabolites at higher levels may cross-react with some opiate immunoassays, so a positive screen would not automatically indicate opioid abuse and should be confirmed with GCMS before any action is taken.

3. *Illicit Drug Use in the Pain Patient Managed with Chronic Opioids*

- The use of marijuana is a violation of the patient’s treatment agreement, but some may argue it is not grounds for changing your treatment and monitoring plan, especially as some States have adopted laws legalizing “medical” marijuana.
- Cocaine use is often seen by medical providers and society as “more serious” drug abuse, but any drug or alcohol abuse is a risk factor for misuse of opioid medications and should trigger more intensive monitoring and possibly referrals to addiction treatment or specialty pain centers.
- Responding to illicit drug use: Consider a chronic disease approach. If patients with diabetes or hypertension were doing poorly or showing signs of behaviors that could worsen their conditions, what are the ranges of possible responses?
 - Most providers would intensify treatment by increasing the frequency of visits and monitoring and by adding additional treatment modalities. The same principles apply here. This patient could be seen weekly, with weekly refills and drug screens for a while until the results are more reassuring. The provider could mandate concurrent mental health and/or substance abuse treatment.
 - Ideally, providers should be able to refer patients needing pain treatment who have co-occurring substance-related disorders to providers who specialize in that type of treatment, just as is done for patients with diabetes or hypertension that is difficult to manage. The problem is that those specialized resources are scarce or non-existent in many areas of the country.
 - Ultimately, each provider will need to make a decision about whether or not the risks of continuing treatment while a patient is using illegal drugs outweigh the benefits to the patient in terms of pain control, improved function, and productivity.

4. *Quality Control and Prevention of Falsification of Results in Urine Drug Testing*

a. “Beating the tests”:

- A cold urine sample suggests the patient may have substituted someone else’s urine for his.
- Tampering with the test can be minimized using temperature sensors, specific gravity and creatinine measurements, and by observing patients when they provide urine samples (which poses significant logistical issues in outpatient medical offices).

Frequently asked questions:

b. Can a provider determine how much of a prescribed opioid a patient is taking based on the quantitative levels detected in the urine?

- Answer: The levels of opioid metabolites in the urine depend on medication dose, half-life, and rate of metabolism, as well as physiological factors that affect urine production. Levels will vary among patients taking the same dose of the same medication and cannot be reliably used to determine how much of a prescribed medication patients are taking.

c. How long after using are drug metabolites detected in the urine? (**p 20, table**)

- Most drugs metabolites are detectable in urine for approximately 3 days.
- Marijuana metabolites may be detected for up to 30 days when the drug is used heavily/chronically.

Visit #3: 3 Months Later

(Page numbers correspond to pages in the Supporting Documents handout.)

Discussion Questions/ Learning Objectives:

1. Why is this patient feeling sick? Describe the opiate withdrawal syndrome (Clinical Opiate Withdrawal Scale [COWS] is included). (pp 22–23)
2. Is he addicted to opioid pain medications? Discuss the difference between physiological dependence, addiction, and pseudo-addiction. (p 24)
3. What are the diagnostic criteria for addiction and how would they be expressed differently in patients maintained on chronic opioids for pain? (p 24)
 - a. Discuss the DSM-IV criteria for drug abuse and dependence and the challenges in applying these criteria in chronic pain patients maintained on opioids.
 - b. List the “3 Cs” of transitioning from drug use/abuse to addiction. (p 24)
 - c. Describe behaviors suggestive of addiction in patients taking chronic opioids.
4. Discuss the challenges in managing acute pain in patients on chronic opioid therapy due to tolerance and hyperalgesia.
5. Discuss the use of an opioid equivalency table, including (p 25):
 - a. The approach to switching patients from PO to IV medications and/or between oral medications
 - b. Role/risk of incomplete cross-tolerance
 - c. Risks of using methadone and of including methadone in these tables

1. Opioid Withdrawal Syndrome (pp 22–23)

The dose of hydrocodone the patient is receiving is not equal to the dose of oxycodone he had been taking prior to the surgery, thus causing opioid withdrawal syndrome.

- a. The Clinical Opioid Withdrawal Scale (COWS) allows a somewhat objective, reliable, and reproducible way to quantify and track the severity of a patient’s withdrawal syndrome.
- b. The symptoms of opioid withdrawal have been likened to a severe influenza infection and include nausea, vomiting, diarrhea, papillary dilation, tearing, rhinorrhea, sweating, tachycardia, hypertension, muscle cramps, joint aches, piloerection, anxiety, restlessness, agitation, and tremor.
- c. Practitioners using this tool often express concern that there is very little that is truly “objective” in this scale. When examined more closely, most patients should not score above the lowest score in most of the categories without having some detectable sign or symptom.

2. Differentiating Between Addiction, Physical Dependence, and Pseudoaddiction

Definitions listed here are from the Federation of State Medical Boards *Model Policy on the Use of Opioids for the Treatment of Pain* (2004).

Addiction: Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Physical Dependence: Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction: The iatrogenic syndrome resulting from the misinterpretation of relief-seeking behaviors as though they are the drug-seeking behaviors commonly seen with addiction. The relief-seeking behaviors resolve upon institution of effective analgesic therapy.

3. Describe the DSM-IV Criteria for Drug Abuse and Dependence and Challenges in Applying These Criteria to Chronic Pain Patients (p 24)

DSM IV Substance Abuse (1/4 in 12 months)	
H	<u>H</u> azards: use despite harm/risky situations
O	<u>O</u> ccupational impairment
LE	<u>L</u> egal problems
S	<u>S</u> ocial/interpersonal consequences

DSM IV Substance Dependence (3/7 in 12 months)	
T	<u>T</u> olerance
W	<u>W</u> ithdrawal
I	<u>I</u> ntention: using more substance, or longer time than intended (loss of control)
T	<u>T</u> ime. Increased time spent obtaining, using, recovering
C	Inability to <u>C</u> ut down, unsuccessful attempts
H	Use despite <u>H</u> arm
AR	<u>A</u> ctivities <u>R</u> educed
Note that patient can meet criteria even without tolerance and/or withdrawal (physiological dependence)	

- a. Tolerance and withdrawal would not apply as criteria for addiction, because anyone taking opioids chronically will develop tolerance and experience withdrawal if the medications are abruptly discontinued.
- b. Monitor instead for the misuse of alcohol or the use of illegal drugs, and for “Aberrant Drug-Taking Behaviors” that may fall into the categories in the table below.

Recognizing Opioid Abuse and/or Addiction in Patients Taking Chronic Opioids

Components of Addiction <i>The “3 Cs”</i>	Possible Expressions in Patients on Chronic Opioids
Loss of <u>C</u> ontrol	<ol style="list-style-type: none"> 1. Reports lost/stolen medications. 2. Calls for early refills. 3. Seeks opioids from other sources. 4. Withdrawal symptoms noted at appointments.
<u>C</u> raving, preoccupation with use	<ol style="list-style-type: none"> 1. Recurring requests for increases in opioids. 2. Increasing pain despite lack of progression of disease. 3. Dismissive of nonopioid treatments.
Use despite negative <u>C</u> onsequences	<ol style="list-style-type: none"> 1. Oversedation/somnolence. 2. Decreases in activity, functioning, and/or relationships.

Adapted from:

Savage SR, et al. (June 2008). *NIDA: Addiction Science in Clinical Practice Vol. 4*
 Manchikanti L, et al. (2008). Opioids Special Issue. *Pain Physician* 11:S155-S180.
 Opioids Special Issue. *Pain Physician* 11:S155–S180.

4. Treating Acute/Postoperative Pain in Chronic Pain Patients Maintained on Opioids (Alford 2006)

Patients on chronic opioids have adapted to the medications and are **tolerant** to the effect of opioids.

- a. First, meet baseline level of physiological adaptation to opioids by providing the equivalent of the 80 to 100 mg of oxycodone taken prior to the surgery.
- b. Second, treat the new acute pain with additional medication on top of baseline medications.
- c. Tolerance:
 - Patients on chronic opioids develop tolerance to their effects.
 - These patients need increased doses of short-acting medications (not less) compared with patients not on chronic opioids who have no tolerance.
- d. Hyperalgesia:
 - Patients on chronic opioids develop hyperalgesia—increased sensitivity to painful stimuli. This is counterintuitive, but well documented in the literature.
 - These patients need increased doses of short-acting medications, and may need them earlier or in situations that may not otherwise require opioids, compared with patients not on chronic opioids who have no hyperalgesia.
- e. Take-home messages:
 - Meet the baseline opiate level of the patient (usually by continuing what he/she was on).
 - Use what you would normally use for acute pain:
 - Use medications with rapid onset and a short half-life.
 - Do not use methadone for acute pain.
 - Will likely need higher doses than patients not on chronic opioids.

5. Using the Opioid Equivalency Table (p 25)

Oxycodone long-acting formulation (40 mg) twice per day, plus the 20 mg per day of short-acting oxycodone, would mean that this patient may have needed up to 150 mg of the hydrocodone to meet his baseline opioid need.

Equianalgesic Doses of Opioid Analgesics		
Oral/Rectal Dose (mg)	Analgesic	Parenteral Dose (mg)
100	Codeine	60
-	Fentanyl	0.1
15	Hydrocodone	-
4	Hydromorphone	1.5
2	Levorphanol	1
150	Meperidine	50
10	Methadone	5
15	Morphine	5
10	Oxycodone	-

Alternatives that may have met the patient's baseline need include the following:

- a. Just continuing pre-op oxycodone.
- b. Replacing long-acting oxycodone with another long-acting oral opioid, such as extended-release morphine (see notes below).
- c. If patient could not take oral medications, then giving morphine (50 mg) by IV, in divided doses throughout the day, would have covered the baseline need.
 - If IV morphine were used, both baseline and acute pain medication needs could be covered through a PCA pump with a basal rate and allowing additional doses.
 - The use of fentanyl transdermal patches is an option as well, but they are very expensive and require advanced knowledge and experience and are therefore not recommended for discussion in this module.

Incomplete Cross-Tolerance:

- a. Factor in the potential for incomplete cross-tolerance any time a provider is switching opioid medications.
- b. It is recommended to calculate the equivalent dose, but start at half of the equivalency with the new medication, particularly when switching from one long-acting agent to another long-acting agent.
- c. Monitor for signs of overmedication (e.g., sedation) and undermedication (e.g., withdrawal, worsening pain).
 - When switching from one long-acting medication to another, allow enough short-acting medication to cover any potential shortfall in meeting the baseline opiate need, as well as enough additional medication to cover the acute pain.

d. WARNINGS ABOUT METHADONE:

- Please advise participants NOT TO USE THE ABOVE EQUIVALENCY TABLE TO DOSE METHADONE.
 - The table does not account for the accumulation of methadone with repeated dosing due to a long half-life.
 - As discussed earlier, the use of methadone in pain treatment requires advanced knowledge and experience and is therefore **not** recommended in this module.
- Methadone is a very poor choice for the treatment of acute pain due to:
 - Long delay to peak medication level (2 to 4 hours)
 - Short duration of acute pain relief compared to a long half life, leading to desire for repeat dosing and increased risk of medication accumulation, overdose, and death.

Learner Packet: Introduction and Case Study

Patients with chronic pain present a number of challenges for medical providers. Patients with chronic pain syndromes most commonly seek care in primary care settings, where providers often feel poorly prepared to evaluate and manage these conditions (Upshur 2006). The situation is worsened by pressures on primary care providers to see more patients in less time, with less support, lower levels of reimbursement, and a paucity of referral resources.

Providers often feel particularly uncertain and uncomfortable with pain management involving the prescription of opioid medications. On the one hand, opioid analgesics are very effective for decreasing many types of pain, and patients have a right to safe and effective treatment of pain. On the other hand, medical providers are charged with the responsibility of ensuring that opioid medications are prescribed safely and in a way that prevents addiction to, or abuse or diversion of, this class of medications.

The goal of this module is to introduce health professions students to a standardized approach to the management of chronic nonmalignant pain that is consistent with the standards recommended by the Federation of State Medical Boards *Model Policy on the Use of Controlled Substances for the Treatment of Pain* (2004) and the American Pain Society (Chou et al. 2009). In addition, the module will demonstrate the use of a number of existing clinical tools for managing chronic nonmalignant pain while minimizing the misuse of opioid pain medicines.

In this module, you will care longitudinally for a single patient with a common chronic pain complaint: low back pain (LBP). The case study is structured in five sections, beginning with background information and followed by three office visits (and a separate review of lab results) that take place over the course of 9 months. Each visit begins with a medication list and a description of the patient's current condition and ends with questions for discussion, which are tied to the specific learning objectives for each visit.

You will receive two sets of printed pages. The first is this packet, which includes 5 pages of case study. The second is 25 pages of supporting documents, which include clinical tools completed to model what this patient's medical chart might look like. Please keep the two resources side by side as you work through this module.

Please note that this module is designed to provide an overview of the approach to managing patients with chronic nonmalignant pain and detecting and preventing opioid misuse. Detailed discussions about many of the topics introduced, including the evaluation and management of acute back pain, will be outside the scope of this module. Also please note that pain due to malignancy and pain at the end of life are managed under substantially different principles than those described here.

Please review the page marked "Case Study Module: Background" prior to the session, as the facilitator will begin with "Visit #1," which takes place 4 months after this patient's initial presentation.

Learning Objectives:

After completing this module, participants will be able to:

- Discuss the components of the accepted standard of care for chronic nonmalignant pain.
- Describe the use of a number of clinical tools to support the management of chronic nonmalignant pain in primary care settings.
- Describe strategies for optimizing safety in the provision of opioid analgesics for chronic pain.
- Describe the approach to preventing and detecting the misuse of opioid pain medications in patients being treated for chronic pain.
- Describe the differences between physical dependence on and addiction to opioid pain medications and how to recognize addiction in chronic pain patients.

Case Study Module: Background

A 50-year-old male with a history of HTN, DM II, and elevated cholesterol presented originally reporting lower back pain. The pain came on suddenly while he was lifting furniture and was sharp and throbbing, originating in the midline and right lateral lumbar-sacral region, and extending down the lateral right leg and into the top of his foot and first toe. Pain intensity ranged from 7/10 to 10/10. The patient had been taking ibuprofen 800 mg tablets, but needed “two or three at a time” to get any relief. He has had pain like this on two occasions in the past, both following injuries sustained on his job as a construction worker.

On further history, the patient denied:

- Focal weakness or loss of sensation
- Changes in bowel or bladder function
- Direct trauma, osteoporosis, or use of corticosteroids
- Weight loss or history of cancer
- Fever, recent infection, IV drug use, or immunodeficiency

On initial physical examination, he looked uncomfortable, shifting positions in the chair frequently, sometimes preferring to stand. He was afebrile and tender to palpation lumbar-sacral region, right >> left, with muscle spasm palpated right lumbar paraspinal muscles. He had some moderate diffuse tenderness on palpation of the spine in the same region. He limped and could bend forward to about 60 degrees, but stopped there due to pain. He could squat and stand (while holding on), and toe walk, but seemed to have trouble balancing while attempting to heel walk. Strength on knee extension and plantar flexion was equal bilaterally, but he showed some decreased ability to dorsiflex his right foot. Knee and ankle reflexes were globally diminished and difficult to evaluate. Straight leg raise elicited pain on the right at 45 degrees of flexion of the right leg.

He asked when he could expect to go back to work—he gets no paid time off and worries about the financial impact on his family. He wanted an x ray of his back and asked for a prescription for Percocet. The pain had been so bad that he hadn’t been able to sleep and that is the only medicine that helped him before.

As initial treatment, you recommended cutting back the ibuprofen to safer levels, staying active, stretching, using warm compresses, and returning in a month. Because he did not have any direct trauma to his back, you recommended against the x ray. You offered him a muscle relaxant to help with the muscle spasm, and a small supply of combination codeine 30 mg/acetaminophen 300 mg tablets, warning him to take them only at night if he had trouble sleeping due to pain. You also warned him to avoid driving or operating machinery after taking them.

Visit #1: 4 Months After Initial Injury

(Page numbers correspond to pages in the Supporting Documents handout)

Current prescribed pain medication:

Medication	Dosage	Amount
<i>Ibuprofen</i>	<i>800 mg</i>	<i>1 tablet up to three times per day</i>
<i>Methocarbamol</i>	<i>750 mg</i>	<i>1–2 tablets up to three times per day</i>
<i>Codeine/acetaminophen</i>	<i>30/300 mg</i>	<i>1–2 tablets up to three times per day</i>

For the last few months you have seen this patient monthly. Because the patient returned 4 weeks after the first visit saying his pain had worsened, despite staying active and trying to do the stretching exercises you recommended, you ordered an MRI. This study showed a herniated disk with no nerve root compression (see attached result **p 2**). He has gone to physical therapy, a chiropractor, and even saw a pain specialist who gave him an epidural steroid injection, but that only helped for about a week.

Today the patient returns and is very concerned that his pain is no better. His pain varies daily depending on his activities, but is constant and still very disabling. He went for physical therapy, but says the therapist told him to stop because, due to the pain, he couldn't do most of the exercises anyway. He is now taking 8 to 10 codeine/acetaminophen tablets a day. He has been to the emergency room twice in the last month and has received various pain medications, including oxycodone and hydrocodone; he also borrowed medications from a friend when his supply ran out.

The location and nature of his pain are unchanged. The intensity decreases with taking the medications, but increases again within 3 to 4 hours. He has started to develop some numbness in the top of his right foot. He has now not worked for months and is having financial difficulties. He really needs to get back to work and asks for stronger pain medications that will last all day to help him do that. At this point, this pain has become a more chronic problem.

He denies having any history of drug abuse, but he, like his father, had problems controlling his alcohol use throughout his twenties. He no longer drinks alcohol at all, by his own choice. He has smoked one pack of cigarettes per day for more than 30 years.

Discussion Topics/Learning Objectives:

1. Discuss the definition of chronic pain, the goals of treating chronic nonmalignant pain with opioid medications, , and how to establish appropriate goals and expectations with each patient (**p 2** for MRI).
2. Describe the initial assessment and documentation procedures for treating chronic pain with opioid medications, including:
 - a. The use of an Initial Pain Assessment Tool (**pp 3–4**) to document the cardinal features of the pain complaint and the impact of the pain on the patient's functioning.
 - b. The informed consent process for initiating opioids (**pp 5–6**).
 - c. The role for, and the components of, a treatment agreement in the management of pain with opioid medications (**pp 7–8**).
3. Describe strategies for initiating long-acting opioids (**p 9**).

4. Discuss the use of adjuvant, non-opioid medications in patients taking chronic opioids (**p 10**).
5. Describe the psychological impact of chronic pain and the use of the PHQ-9 to assess depression (**pp 11–12**).
6. Discuss strategies for screening for substance use disorders (SUDs) in pain patients, including the use of standardized screening tools. The AUDIT and the DAST-10 are included in this packet (**pp 13–14**). The NIDA-Modified ASSIST (NMASSIST) is available online: **www.drugabuse.gov/NIDAMED**.
7. Discuss the factors associated with increased risk of abuse of opioid medications during pain treatment. The Opioid Risk Tool is included in the packet (**p 15**).
8. Describe how to use a statewide Prescription Drug Monitoring Program (PDMP). If it is available in your state, describe how to access it.

Visit #2: 4 Weeks Later

(Page numbers correspond to pages in the Supporting Documents handout)

Current prescribed pain medication:

Medication	Dosage	Amount
<i>Ibuprofen</i>	<i>800 mg</i>	<i>1 tablet up to three times per day</i>
<i>Methocarbamol</i>	<i>750 mg</i>	<i>1–2 tablets up to three times per day</i>
<i>Oxycodone/acetaminophen</i>	<i>5/325 mg</i>	<i>1–2 tablets up to twice per day</i>
<i>Oxycodone extended release</i>	<i>20 mg</i>	<i>1 tablet two times per day</i>
<i>Amitriptyline</i>	<i>50 mg</i>	<i>1 tablet at night</i>
<i>Magnesium hydroxide (milk of magnesia)</i>	<i>2 tablespoons</i>	<i>(30 ml) up to three times per day, as needed</i>
<i>Dietary fiber supplements</i>	<i>N/A</i>	<i>Once or twice per day</i>

At the last visit you initiated treatment with oxycodone extended release (10 mg tablets), one tablet twice per day. When the patient returned 2 weeks later, he was still quite uncomfortable, so the dose was increased to 20 mg two times each day. The patient returns today and says pain levels and everyday function have improved somewhat since starting the long-acting opioid. His pain levels now run around 4/10 at baseline, increasing to 7/10 with a lot of activity. He takes a total of six oxycodone/acetaminophen tablets per day for these pain flares. He has been taking the pain medications as prescribed and denies emergency room visits and borrowing or buying medications, although you note from the chart he did call into the office for an early refill on the oxycodone/acetaminophen about 10 days before this visit. He denies any illicit drug use, and reaffirms that he does not drink alcohol. He followed your suggestion and stores the medications in a locked box, especially because his young grandson visits often and someone in his building asked him to sell some of the medications. He has had some mild nausea and constipation, but feels alert and denies feeling sedated after dosing. He's back at work, but has accepted a light duty position with decreased pay for now.

The patient is worried today because he met with the neurosurgeon, who reviewed the MRI and EMG results with him and told him he thought surgery was needed. He is afraid of surgery, but is willing to do anything to get rid of the pain and get back to work. He received another steroid injection at the visit, which helped for about 48 hours.

Discussion Topics/ Learning Objectives:

1. Describe the “four As” of ongoing monitoring and care of chronic pain patients: Analgesia, Activities of Daily Living, Adverse Events, and Aberrant Drug-Taking Behaviors (**pp 17–18**).
2. Discuss the use of the Pain Assessment and Documentation Tool (PADT™) for monitoring pain patients in clinical practice (**pp 17–18**).
3. Discuss strategies for optimizing pain control and describe how to increase the dose of long-acting opioids more safely.
4. List “potentially aberrant drug-taking behaviors,” and which ones are more or less likely to be associated with drug abuse (**p 19**).
5. Discuss the differential diagnosis of aberrant drug-taking behaviors in chronic pain patients managed with opioids.

Visit #2: Follow-up

(Page numbers correspond to pages in the Supporting Documents handout)

At the last visit the patient gave a urine sample for drug screening. Two days later you received the following results:

Drug Screened For	Results
Opiates	negative
Cocaine	negative
Benzodiazepines	negative
Marijuana/THC	positive

Discussion Questions/Learning Objectives (p 20):

1. What are the two most common techniques for drug testing? What are some strengths and weaknesses of each technique?
2. If the patient is taking oxycodone, why is the opiate screen negative? Discuss challenges in testing for opioids, highlighting limitations in immunoassays for detecting semisynthetic and synthetic opioids.
3. How will you respond to the positive test for the metabolite of marijuana? Would your response be different if the test was positive for cocaine metabolites? What concerns and options do you have if a patient you are treating is using illegal drugs?
4. What if the urine the patient provided had been cold? Discuss the logistics of drug testing, including prevention of sample substitution or alteration.

Visit #3: 3 Months Later

(Page numbers correspond to pages in the Supporting Documents handout)

Over the previous 3 months you had gradually optimized the patient's pain control. By the time he went to surgery, his pain levels had improved, but he was still symptomatic and unable to work full time or full duty.

Current prescribed pain medication (prior to surgery):

Medication	Dosage	Amount
<i>Ibuprofen</i>	<i>800 mg</i>	<i>1 tablet up to twice per day</i>
<i>Methocarbamol</i>	<i>750 mg</i>	<i>1–2 tablets once per day</i>
<i>Oxycodone/acetaminophen</i>	<i>5/325 mg</i>	<i>1–2 tablets up to twice per day</i>
<i>Oxycodone extended release</i>	<i>40 mg</i>	<i>1 tablet twice per day</i>
<i>Amitriptyline</i>	<i>100 mg</i>	<i>1 tablet at night</i>
<i>Lactulose 15 mg/5 ml</i>	<i>10 ml</i>	<i>Twice daily as needed</i>
<i>Dietary fiber supplements</i>	<i>N/A</i>	<i>Once or twice per day</i>

You visit the patient in the hospital about 48 hours after he underwent the following:

1. Hemilaminectomy for decompression of nerve root, including partial facetectomy and proximal foraminotomy with excision of herniated intervertebral disk going into interspace lumbar left L5 with a 22 modifier for increased difficulty due to calcific disk herniation.
2. Laminectomy unilateral for decompression of cauda equina nerve foot lumbar L5 on the right.

He is awake, but complains that he is in pain, almost worse than before the surgery, and is feeling nausea, abdominal cramping, diarrhea, chills, and cramps in his legs. You notice he is sweating a little despite saying he is cold, and his pupils are dilated. He has not had any fevers, but his pulse and blood pressure have been elevated. The progress note from today says he asked for more pain medications, but the team told him the medicine they started should cover the pain and that they had changed some of his pain medications because (1) they were worried he had become addicted, and (2) the medication he was taking (long-acting oxycodone) was not allowed by the hospital formulary due to the high cost.

You check his orders, and he is currently written for hydrocodone/acetaminophen (5/500), two tablets up to every 4 hours as needed, and ibuprofen (800 mg) three times per day.

Discussion Questions/Learning Objectives:

1. Why is this patient feeling sick? Describe the opiate withdrawal syndrome (Clinical Opiate Withdrawal Scale [COWS] is included) (pp 22–23).
2. Is he addicted to opioid pain medications? Discuss the difference between physiological dependence, addiction, and pseudoaddiction (p 24).
3. What are the diagnostic criteria for addiction, and how would they be expressed differently in patients maintained on chronic opioids for pain (p 24)?
 - a. Discuss the DSM-IV criteria for drug abuse and dependence, and the challenges in applying these criteria in chronic pain patients maintained on opioids.
 - b. List the “3 Cs” of transitioning from drug use/abuse to addiction.

- c. Describe behaviors suggestive of addiction in patients taking chronic opioids.
4. Discuss the challenges in managing acute pain in patients on chronic opioid therapy due to tolerance and hyperalgesia.
5. Discuss the use of an opioid equivalency table, including (**p 25**):
 - a. The approach to switching patients from PO to IV medications and/or between oral medications
 - b. Role/risk of incomplete cross tolerance
 - c. Risks of using methadone and of including methadone in this table

Evaluation

Note: Be sure to remove the highlights from the answers as well as this sentence before distributing to learners!

Please mark “T” (True), “F” (False), or “?” (uncertain) next to each of the statements below.

- T F ?** Chronic pain is any pain that lasts for more than 12 months.
- T F ?** Chronic pain should only be treated with opioids when the specific source of the pain has been identified.
- T F ?** The goal of chronic pain treatment with opioids is to reduce but not completely eliminate pain.
- T F ?** Patients on opioid medications should not return to work.
- T F ?** In chronic pain, the initial assessment should include the measurement of the pain intensity, the patient’s functional status, and level of emotional distress.
- T F ?** Informed consent for opioids should include a discussion of the risks of sedation, overdose death, cognitive and motor impairment, and addiction.
- T F ?** Pain treatment contracts help prevent the misuse of opioid medications.
- T F ?** An MRI reliably identifies the source of pain in patients with spinal degenerative disc disease.
- T F ?** Depression is common among chronic pain patients.
- T F ?** Methadone should be the first choice of long-acting opioid medication for treating chronic pain.
- T F ?** SSRI’s help reduce pain when used in conjunction with opioid pain medications.
- T F ?** Patients with a history of drug or alcohol abuse cannot be treated safely with opioids.
- T F ?** Risk factors for misuse of opioid pain medications include a family history of substance abuse and age less than 45.
- T F ?** Provider should reassess functional status in chronic pain patients at least every third visit.
- T F ?** The emergence of aberrant drug-taking behaviors indicates that a patient has developed an addiction to opioids.
- T F ?** It is illegal to prescribe opioids to a patient who is using illegal drugs.
- T F ?** Standard drug screens are reliable tools for detecting synthetic opioids.
- T F ?** Patients may experience opioid withdrawal symptoms even if they do not have an addiction to opioids.
- T F ?** Patients taking chronic opioids will need little additional pain medication for acute pain.
- T F ?** Patients taking chronic opioids are less sensitive to acute pain due to tolerance.

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