Best Nursing Practices: Care of Patients Prescribed Opioids for the Treatment of Pain

3 Contact Hours

Release Date: 2/22/2016 **Expiration Date: 2/22/2019**

Audience

The audience for this course is any registered or advanced practice nurse responsible for prescribing or managing patients who may be prescribed opioids for the treatment of pain.

Purpose statement

Historically, prescribers limited the use of opioids for pain management solely to patients with acute or cancer-related pain. However, recent studies indicate that many types of pain are undertreated. To potentially bridge this therapy gap, the use of opioids for the treatment of nonterminal pain is on the upswing. This course covers the changes in opioid use as well as provides details for the assessment and care of those taking opioids for non-cancer pain.

Learning objectives

- Describe six pain-related components of an initial patient evaluation.
- Describe two tools for patient risk assessment.
- Describe three advantages of creating written patient/provider opioid agreements.
- Explain the value of function-based treatment goals over pain-relief goals.
- Describe four key steps to take prior to initiating treatment with an opioid pain medication.
- Explain why special care must be taken with extended-release/long-acting (ER/LA) opioid formulations.
- Explain two reasons that methadone must be used with particular caution.
- Describe two ways to potentially address unpleasant or intolerable opioid side effects.
- Explain three potential benefits of using prescription drug monitoring programs (PDMPs).

How to receive credit

- Read the entire course online or in print which requires a 3-hour commitment of time.
- Depending on your state requirements you will asked to complete either:
  - An affirmation that you have completed the educational activity.
  - A mandatory test (a passing score of 70 percent is required). Test questions link content to learning objectives as a method to enhance individualized learning and material retention.
- Provide required personal information and payment information.
- Complete the mandatory Self-Assessment and Course Evaluation.
- Print your Certificate of Completion.

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Bradley Gillespie, PharmD, trained as a clinical pharmacist, has practiced in an industrial setting for the past 20+ years. His initial role was a Clinical Pharmacology and Biopharmaceutics reviewer at FDA, followed by 15 years of leading Early Development programs in the pharma/biotech/ nutritional industries. Currently, he supports efforts at the National Institutes of Health to develop therapeutics for rare and neglected disease. In addition to his industrial focus, he remains a registered pharmacist and operates a medical writing business, with a focus on developing health professional continuing education programs.

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Introduction

Historically, prescribers limited the use of opioids for pain management solely to patients with acute or cancer-related pain. However, recent studies indicate that many types of pain are undertreated. To potentially bridge this therapy gap, the use of opioids for the treatment of nonterminal pain is on the upswing [1]. This shift does not come without controversy as considerable debate continues regarding the appropriate use of these potent, and potentially addictive medications [2]. This increase in opioid prescriptions is staggering: in 1991, approximately 76 million opioid prescriptions were written in the United States; but by 2013, this figure jumped to nearly 207 million. The United States (U.S.) is the world's largest consumer of these medications, cornering nearly 100% of the global hydrocodone demand, and 81% of the demand for oxycodone [3].

Of the estimated 24.6 million U.S. citizens (i.e., 9.4% of the population 12 and older), suffering from substance abuse, approximately 1.9 million people abuse or are dependent on prescription opioid drugs. Addiction occurs in every state, county, and socio-economic or ethnic groups [4]. Possibly relating to this surge in the use of prescription narcotics, each day 44 people in the U.S. will die of a prescription opioid overdose [5].

Opioids, far more than any other medications, are highly correlated with risks of abuse, misuse, and diversion from intended use. In an attempt to counter these growing adverse events, both the pharmaceutical industry and the government have taken steps to address this public health issue. In 2005 the U.S. Food and Drug Administration (FDA) developed three guidance documents that outlined risk management approaches for drug products. The four cornerstones of the approaches included:

1. Characterization of each drug product's risk/benefit profile;
2. Development and implementation of each drug product's usage guidelines to optimize benefits while minimizing risks;
3. Evaluations of items (1) and (2) coupled with a reassessment of the risk/benefit relationship; and
4. Active adjustments, as needed, to the established risk management tools to optimize the risk/benefit profile. These guidelines were codified into law in 2007 with the passage of the fda amendments act. The law officially established the requirements for risk evaluation and mitigation strategies (rems) for all drugs with potential safety issues. While the rems are required training for prescribers and pharmacists, they should also be included in the training requirements of nurses involved in the care of patients receiving opioid medications [6].

In 2012, FDA published a REMS specific to the use of extended-release and long-acting opioids. This document encourages prescribers to consider the following prior to ordering opioids for their patients:

- **Educate**: Complete a REMS-compliant educational program geared to your discipline.
- **Counsel patients**: Ensure that the risks, safe use, secure storage and disposal of the medications are understood every time these drugs are prescribed.
- **Medication guides**: Ensure that every patient is provided and understands a comprehensive medication guide with each prescription refill [7].

In addition to REMS, a variety of risk management strategies are used by governments, healthcare organizations, and pharmaceutical companies to minimize prescription opioid risk, and most importantly, their potential for abuse, addiction, and diversion [6].

This continuing education program is designed to characterize the best practices for the use of prescription opioid medications intended for treating chronic pain, within the constraints emphasized by the FDA. It will also characterize other strategies to combat the misuse of prescription medications. This program will provide nurses with a solid foundation for responsible opioid use and include vigilant monitoring designed to identify misuse.

Critical terminology

Chronic pain lasts longer than six months. Such pain can range in intensity from mild to excruciating, and can occur episodically or continuously. Such discomfort can be inconvenient to incapacitating. Chronic pain can affect patients physically and emotionally.

The most common sources of chronic pain include headaches, joint pain, injury-associated pain, and backaches. Chronic conditions can lead to generalized muscle or nerve pain [8].

Pain disorders, exclusive of cancer or end of life pain, are often referred to collectively as chronic non-cancer pain (CNCP).

Although many clinicians may quickly turn to opioids for the treatment of CNCP, it is critical to recognize that opioids are only one

weapon in the pain management toolbox. In fact, not all patients are good candidates for opioid medications, either due to the nature of their condition, their comorbidities, or their potential for medication abuse. However, if used properly, opioids can be a very useful component in pain management. Clinicians need to carefully balance the potential benefits against the significant risks associated with opioid use and potential abuse.

Critical concepts

Nurses whose patients suffer from CNCP must be keenly aware of the need to balance pain relief with the many risks associated with the use of opioid analgesics. One term used to describe this intricate balancing act is pharmacovigilance (PV). Pharmacovigilance is defined by the World Health Organization (WHO) as the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or other drug-related problems [9].

Pharmacovigilance need not be complex or burdensome, but rather be based on a commonsense approach not unlike those used for most any other category of medication. The concern with opioids is their potential danger coupled with their high demand by recreational drug users and criminal organizations. Optimal CNCP therapy requires establishment of a middle ground between appropriate pain relief and prevention of abuse and diversion, considered in light of unrelieved pain. In addition to the many comorbidities to consider, clinicians must also be especially vigilant for concomitant usage with other medications or products such as alcohol or sedatives which cause respiratory depression.

In 2016, the Centers for Disease Control (CDC) issued a draft guidance describing the appropriate use of opioid pain medications. A number of elements were explored and a few common themes are presented below:

- Need for a thorough physical examination including pain, past medical history, and family/social histories.
- Possible urine drug toxicology testing if abuse is suspected.
- Consideration of alternative treatment options prior to the prescription of opioids.
- Initial dosage levels at the lowest effective dose.
- Implementation of pain treatment agreements.
- Comprehensive monitoring and documentation of pain and treatment progress, i.e., the higher the dose, the greater the level of vigilance.
- Implementation of safe and effective methods for opioid discontinuation (e.g., dose tapering or medication-assisted treatment, as required) [10].

The continuing education program is designed to detail how to implement these general guidelines in a realistic approach in line with the time and budgetary constraints that govern contemporary nursing practice. Important considerations will be reinforced using realistic case studies to best illustrate key concepts.

Nursing consideration: There is a large, unmet need for the safe and effective use of opioid analgesics. As such, the employment of prescription opioids is widespread and likely increasing. At the frontline in patient contact and communication opportunities, nurses are in an ideal position to ensure appropriate narcotic usage.

Appropriate prescription opioid use; Step 1: Assessing patients for opioid therapy

In order to effectively determine the appropriateness of an opioid medication for the treatment of CNCP, it is critical that both the patient's condition and their potential for misusing or abusing the medication are fully characterized. Specifically, it is critical that healthcare professionals complete a comprehensive physical, medical, and social history and include an assessment of substance abuse and consideration of any special population requirements. A thorough pain assessment must also be conducted which includes the patient's chief complaint and a history of the present illness. Diligent nurses will look beyond the specific complaint and holistically evaluate the broader mental, cultural, and socioeconomic contexts in which the chief complaint is embedded.

Nurses are uniquely qualified to contribute to this critical evaluation. Prior to a physical examination, typically nurses will obtain a thorough medical history, with a focus on the chief complaint. A good medical history assessment is a test of both the nurses' knowledge and communication skills. The specific questions to be asked will depend on the specifics of the patient, but nonetheless, general frameworks exist to cover most eventualities. In addition to asking the most appropriate questions, organizing the findings is critical. Finally, depending on the mental state and reliability of the patient, a collateral history from a friend, relative or caregiver may be required [11].

A comprehensive evaluation of a patient in pain usually requires moving beyond the typical list of questions asked during a general history. It may be possible to gather this information before an in-person visit by using paper or online questionnaires. In most cases where pain is the chief complaint, it is appropriate to begin a conversation by asking about the pain, but then it is usually best to review the broader context and impact of that pain.

When conducting an initial evaluation, clinicians should be alert for signs that a patient is minimizing his or her pain. This may result from a variety of psychological or emotional factors. For example, some patients may worry that they will be labeled as a "complainer" if they mention pain, or that their health care provider will suspect that they are addicted if they ask about opioid pain medications. Other patients may underreport pain because they fear that pain medications will dull their cognitive abilities, lead to addiction, or produce undesirable side effects. Clinicians should be empathic, supportive and honest, neither promising too much nor removing all hope, when evaluating a patient in chronic pain.

It is critical to gain as much information as possible about the specific complaint of pain. The SOCRATES acronym is a useful tool to remember key points to be collected when taking a pain history. Its use is illustrated by asking the following questions when assessing a complaint of pain:

- Site: Where exactly is the pain?
- Onset: When did it start? Was it constant/intermittent? Was it gradual/sudden?
- Character: What is the pain like, e.g., sharp, burning, tight?
- Radiation: Does the pain radiate/move anywhere?
- Associations: Is there anything else associated with the pain, e.g., sweating, vomiting?
- Time course: Does it follow any time pattern? How long does it last?
- Exacerbating/relieving factors: Does anything make it better or worse?
- Severity: How severe is the pain (consider using the 1-10 scale) [12]?

These questions must be asked and the responses evaluated in light of the philosophy offered by Goodwin and Bajwa, "Pain is what the patient says it is." It should never be inferred that pain is "all in a patient's head." Psychological factors may be important in a patient's experience of pain, and the importance of such factors should be taken seriously and incorporated into the overall treatment plan [12].

Psychosocial evaluation

Pain affects every aspect of a patient's life. Therefore, it is vital to evaluate the ways pain may be impacting, or may be affected by, psychosocial elements of a patient's life. Clinicians must be alert for signs of depression or anxiety, which are very common in patients suffering from chronic

pain. Be particularly alert for suicidal thoughts, since the risk of suicide is roughly doubled for patients with chronic pain. Due to the potential for misuse and abuse, medical histories collected in preparation for opioid prescribing must also include a complete psychosocial history evaluation. Key points that must be covered include:

- Childhood history including sexual, physical abuse, and abandonment issues.
- Educational history.
- Family history including disability and addictions.
- Marital history as well as any other significant adulthood events.
- Legal history, including both criminal and civil litigation.
- Employment and military history.
- Psychological dysfunction.
- Current interpersonal relationships, support, and living situation [13].

Some freely-accessible instruments for gathering a psychosocial history are available [see, for example, the Depression Anxiety & Positive Outlook Scale (http://www.dapos.org) or the Patient Health Questionnaire PHQ Screeners (http://www.phqscreeners. com)]. Referral to a mental-health professional is warranted if the clinician's judgment suggests that the patient has active psychological issues beyond his or her expertise. Clinicians should also probe for ways in which pain may be affecting the patient's family system, work, or social activities. Pain can seriously erode these spheres of life, and evaluating these challenges and addressing them during treatment (for instance by referral to a vocational counselor or social worker) is just as important as treating the more immediate medical issues that may be contributing to chronic pain.

Evaluating patients for risk of opioid dependence or abuse

Whenever a clinician considers treating pain with a controlled substance, the risk of misuse or diversion is always a possibility, no matter how remote, and must be assessed. Exactly whom to suspect, and when to be proactive in investigating risk factors is an area of great debate as there are no convincing data available that support a strategy of focusing on any one specific population parameter or setting. As a result, clinicians must be vigilant with all patients.

In patients treated with opioids for chronic pain, addiction is rare in the absence of a prior self- or family history of alcohol or drug abuse. With this in mind, investigators have attempted to validate instruments to objectively separate potential opioid abusers from patients who are at low risk. One example is the Screening Instrument for Substance Abuse Potential (SISAP), which was designed to identify individuals with a possible substance abuse history based on the National Alcohol and Drug Use Survey. A total of five questions were obtained from the survey that identified with a history of drug and/or alcohol abuse. This instrument was shown to correctly identify 91% of substance abusers with a very low rate of false negatives. It is hypothesized that the use of such tools could improve pain management by guiding appropriate opioid use to include the more vigorous monitoring of patients at greatest risk of abuse [14].

SISAP was one of the original screening tools developed to formally assess a patient's risk of developing an opioid abuse problem. Subsequently, a number of tools have been developed and validated. Many of these instruments are appropriate for routine clinical use. A key ease of use attribute is that they are relatively brief and can be easily implemented. In Table 1, potential tools are listed. In order to be listed, they must have relatively good content and be at least partially validated for assessing patient risk for opioid misuse or abuse. It is critical to note that although these tools may be helpful adjuncts to clinical judgement, no single tool has been widely endorsed or thoroughly validated.

Table 1. Tools for opioid patient risk assessments

Tool	Use	Who administers?	Length	Access
Current Opioid Misuse Measure (COMM)	Monitor for misuse by patients currently on long-term opioid therapy.	Patient self-reports.	17 items	http://www.inflexxion.com/COMM/
Diagnosis, Intractability, Risk, Efficacy (DIRE)	Screen for risk of opioid addiction.	Clinician.	7 items	Belgrade, M.J., et al (2006) *J Pain*. 7:671-681
Opioid Risk Tool (ORT)	Screen for risk of opioid addiction.	Clinician, or patient self-reports.	5 yes/no questions	http://www.opioidrisk.com/node/887
Screener and Opioid Assessment for Patients with Pain, Version 1 and Revised (SOAPP, and SOAPP-R)	Screen for risk of opioid addiction.	Patient self-reports.	24 items	http://www.inflexxion.com/SOAPP/

Some studies have also shown that younger age, and the presence of psychiatric conditions are also associated with aberrant drug-related behaviors. In evaluating patients with chronic pain for risk of addiction or signs that they may be abusing a controlled substance, it may be helpful to consider the sets of characteristics listed in Table 2 [15].

Table 2. Characteristics of chronic pain patients versus addicted patients

Chronic pain patient	Addicted patient
Medication use is well-controlled.	Medication use is out of control.
Medication use improves quality of life.	Medication use impairs quality of life.
Wants to decrease medication use if adverse events develop.	Medication use continues or increases despite the incidence of adverse events.
Is concerned about the physical problem being treated with the drug.	Is unaware or in denial about any problems that develop as a result of drug treatment.
Follows the practitioner-patient agreement for the use of the opioid.	Does not follow the opioid agreement.
May have leftover medication.	Does not have left over medication.
	Loses prescriptions.
	Always has a story about why more drug is required.

Physical examination

The physical examination conducted as part of the initial patient screening contains all of the elements common to contemporary practice, with a few areas that should be emphasized due the unique nature of opioid prescriptions. Themes to be evaluated include:

- A rigorous evaluation of the patient's nervous system.
- An assessment of allodynia (pain from stimulation that would not normally evoke pain, such as light touch).
- Hyperalgesia (amplified pain response to stimulation that would normally evoke only mild pain).
- Pain insensitivity, also known as congenital analgesia, is one or more rare conditions in which a person cannot feel (and has never felt) physical pain.
- A sensory examination that could include response to light touch, light pressure, pinpricks, cold, or vibrations [16].

It may be useful to employ a visual analog scale (VAS) to characterize the level of pain experienced by the patient. An example (Figure 1) is provided below, with a range between zero (no pain) and ten (worst pain imaginable) in centimeters (cm) [17]:

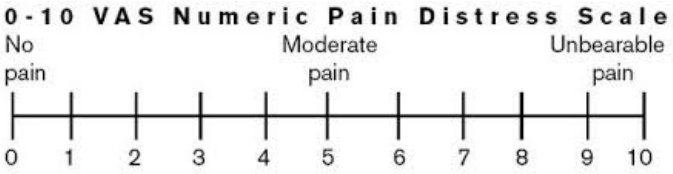

Figure 1. Visual Analog Scale of Pain.

In the case of pain assessment in children, it may be useful to employ an age-appropriate instrument, such as that provided in Figure 2 [18]:

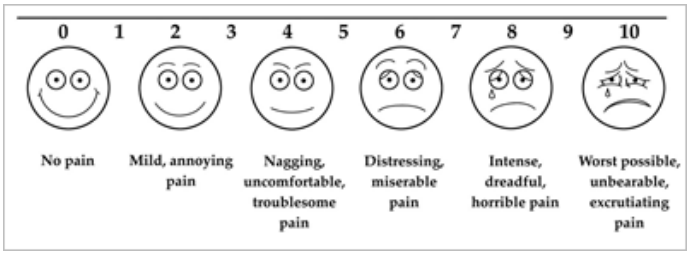

Figure 2. Age-appropriate pain assessment.

The process is the same for whichever VAS assessment tool is employed. A pain VAS is usually self-completed by the patient. He or she (s/he) is asked to draw a line perpendicular to the VAS line best representing their pain intensity. By measuring the distance between the "no pain" reference point and the patient's mark in millimeters (mm), a pain score ranging from 0-100 is derived. The higher the score, the greater the perception of pain magnitude. The general recommendations based on pain VAS scores in postsurgical patients are as follows: 0 - 4 mm, no pain; 5 - 44mm, mild pain; 45 - 74mm, moderate pain; and 75 - 100mm, severe pain [19].

Nursing consideration: Determining each patients' candidacy for appropriate opioid usage requires extensive effort from the entire healthcare team. Nonetheless, the important bond present between nurses and their patients leaves them well-positioned to actively contribute to the process.

An ideal approach to summarizing the role of proactive nursing is to illustrate key concepts in relevant case studies. The case presented below covers the highlights of an initial presentation and assessment of a patient as a candidate for opioid pain control.

Opioid therapy case study: Initial presentation and assessment

Matt Davidson, age 69 years, is a retired, male high school physical education teacher. He has come to his primary care physician for his annual physical. He has a history of hypertension, osteoarthritis, and prostate cancer, for which he was treated two years ago with a combination of external beam radiation and chemotherapy. His PSA is now near zero, and he has no signs of disease, although he continues to be troubled by mild urinary incontinence and erectile dysfunction. On this visit, Mr. Davidson complains of joint pain, as well as a burning, tingling pain in his hands and feet, and asks if anything can be done for it.

A full evaluation of the patient's pain leads to a dual diagnosis of osteoarthritis and peripheral neuropathy secondary to chemotherapy. Specific questions from the nurse can be used to optimize Mr. Davidson's treatment plan.

Appropriate assessment questions and responses:

Q. Please rate your current pain levels on a scale of 1-10. Also describe any side effects that could be related to the current treatment.
A. He rates his pain as a 7 or 8 on the ten-point scale. Additionally, he describes the occurrence of heartburn.

Q. What are your current medications for pain?
A. Ibuprofen: 800-1200 mg, daily.

Q. How is your pain affecting your life? Is it preventing you from engaging in any of your normal activities?
A. He reports disturbed sleep, which he says makes him more irritable during the day. He also says he no longer plays tennis, that walking has begun to hurt, and it is becoming difficult to use the computer keyboard.

This information is used to create a treatment plan with the functional goals of: reducing night time awakenings to no more than once per night; walking daily at least one mile without pain; and using the computer without pain. A return to tennis is left as a possible goal if less strenuous goals are achieved first. An extended-release oxycodone product is prescribed, as well as a prophylactic laxative (to counter the known opioid side effect of constipation). The patient is given printed information about the safe use, storage, and disposal of opioid medications.

Written agreements; Step 2: Written documentation of all aspects of a patient's care

Professional documentation of treatment

Written documentation of all aspects of a patient's care, including assessments, informed consent, treatment plans, and provider/patient agreements are a vital part of opioid prescription "best practices." Such documentation provides a transparent and enduring record of a clinician's rationale for a particular treatment, provides a basis for ongoing monitoring, and, if needed, modifications of a treatment plan. Clinicians must decide for themselves how thoroughly, and how frequently, their documentation of a patient's treatment should be. Regardless of the approach, records should have documentation of patient pain and function using objective measures. Further, there are a number of items that should be considered for documentation.

Key components include:

- Histories demonstrating consistent improvements in pain and function offer a solid rationale for increases in opiate doses.
- All histories of substance abuse must be recorded including past treatment successes and failures.
- Documentation of collaboration with a substance abuse professional is required for any patients with ongoing substance abuse issues that are receiving opiates.
- All prescriptions, especially psycho-active drugs, and drugs with the potential for abuse must be documented.
- The medical necessity of drugs like benzodiazepine, or carisoprodol, etc. must be clearly recorded.
- It is critical to include the morphine equivalent dose (MED) in the permanent patient records.

- Every prescription written must include the dose, and the number dispensed must be charted.
- Prescriptions should be written with the objective of avoiding the necessity to refill prescriptions outside a clinic visit.
- Notes should have documentation of screening for depression, e.g. "In the past month have you felt overwhelmed?"
- All side effects must be documented, especially in patients receiving high dose narcotics.
- Documented histories of constipation, worsening sleep apnea, impairment of operation of equipment or vehicles.
- Complete documentation of red flags, e.g. early refills, self-dose escalation, "lost scripts," missed, appointments, signs of substance abuse, violated past care agreements.
- Documentation of urine toxicology screens.

Prior to issuing any opioid medications, treatment expectations should be clearly outlined in a treatment plan (frequency of visits, who can prescribe, etc.). Furthermore, the consequences of violating the treatment plan need to be prospectively determined. Best practice elements for pain treatment agreements include:

- Medications will not be refilled early.
- Refills require a clinic visit, by appointment.
- No urgent requests, i.e., appointments for refills must be requested at least two days in advance.
- Lost or stolen prescriptions or medications cannot be refilled.
- Failure to follow these policies may result in discontinuation of pain medications.
- Regularly scheduled urine toxicology screens should occur often, e.g., at the first visit, then at random intervals 2-3 times/year or more if the patient has a history of substance abuse) [20].

Patient-provider agreement

Provider/patient agreements have many potential advantages including:

- Allowing treatment to start on a note of mutual respect and partnership.
- Enhancing transparency.
- Engaging patients in a collaborative education and decision making process.
- Helping to set functional goals and clarifying the clinician's and patient's roles and responsibilities in attaining these goals.
- Documenting acceptance of treatment risks and benefits.
- Documenting informed consent.
- Helping avoid misunderstandings that may occur over long treatment time periods.
- Providing a foundation for subsequent decisions about changes in medications or termination of treatment.

To be effective, the specifics of treatment must be clearly characterized and explained using a specific approach tailored to the individual patient and their family or caregiver. This may require the provision of agreements in multiple languages. All agreements should be written at the sixth- to seventh grade education level, or lower. Translators may need to be provided for speakers of other languages to ensure patient understanding and effective informed consent. A patient who does not fully understand the potential risks and benefits of a treatment cannot be truly "informed" as required by the legal and ethical guidelines for medical practice. Time must be allowed for patients to ask questions, and for prescribers to ensure patients understand what they are being told. It is critical to ensure that none of language used could be interpreted as coercive. Thus, agreements should avoid:

- Putting all burden on the patient rather than sharing it between patient and clinician.
- Framing the agreement in terms of punishments for possible future crimes or difficulties.
- Using language that is stigmatizing, dominating, or pejorative.
- Using coercion in any way.
- Imposing limitations for the clinician's convenience without clear and substantial benefit for the patient.
- Insisting on behaviors unrelated to actual use of medications.
- Using the term "fired" to describe termination of treatment.
- Threatening abandonment or suggesting that patients will not have continued access to non-opioid pain relieving treatments if opioids are terminated.

Patient-provider agreements are in wide usage, and come highly recommended for long-term opioid therapy. Although the literature does not demonstrate the quantitative efficacy of such agreements, the 2012 FDA blueprint for opioid prescriber education suggests the adoption of a patient-provider agreement in such situations [21]. A number of samples of patient-provider agreements are available in the public domain including the following, issued by the National Institute on Drug Abuse: https://www.drugabuse.gov/sites/default/files/files/SamplePatientAgreementForms.pdf.

Although the term "agreement" is generally perceived as being more patient-friendly than the word "contract," clinicians should understand, that from a legal standpoint, any written or oral agreement between a prescriber and a patient may be considered a binding "contract." Clinicians should ensure that the terms in any agreement are understood by the patient, and are acceptable, attainable, and consistent with high quality practice.

Some, or all, of the tasks related to documentation may be efficiently managed by properly trained nursing personnel.

Nursing consideration: In addition to collecting a plethora of patient-specific data, thorough and comprehensive documentation is key to treatment success. A nurse's close patient relationship places them in an ideal position to make this key contribution to safe and effective use of opioids in all types of patients.

Informed consent; Step 3: Ensuring that each patient is fully apprised of the risks and benefits of opioid therapy for the treatment of pain

Informed consent is a fundamental part of planning for any treatment, but it is critically important in long-term opioid therapy, given the potential risks of such therapy. At its best, consent also fortifies the clinician/patient relationship.

Fortunately, the great majority of patients who are prescribed opioids experience limited and reversible adverse events and rarely develop addiction. Nonetheless, a subset of all populations will encounter significant difficulties including protracted adverse events, misuse, abuse and addiction. All of these issues may result in morbidity and/or mortality. Informed consent is an important consideration prior to prescribing opioids [22].

The American Medical Association (AMA) has taken a firm position and states that proper informed consent is a crucial communication tool between the patient and the prescriber. The AMA guidelines suggest that the minimum essential elements of informed consent include:

- The patient's full diagnosis.
- The nature and purpose of the proposed opioid treatment plan.
- A complete listing of the potential risks and benefits of the therapy.
- All available alternative treatments including their risks and benefits.
- Risks and benefits of not receiving treatment.

A current example of an informed consent to be discussed with the patient, and signed prior to the issuance of any opioids can be found at http://www.painmed.org/files/consent-for-chronic-opioid-therapy.pdf.

Nursing consideration: While the prescriber has the ultimate responsibility for obtaining informed consent, the process of fully explaining all elements of the informed consent often fall to the nurse. As such, it is critical that nurses involved in providing opioid informed consent are well versed on the pros and cons of pain therapy.

Treatment plans; Step 4: Development of a patient-specific safe and efficacious treatment roadmap

As soon as a patient has been determined suitable for opioid therapy and informed consent is obtained, a comprehensive, written plan must be developed specific for the individual patient. In order to quantify the success of the program, a concise statement of goals must be included in the plan. Typically, a chronic pain patient will be asked to rate his or her pain on a scale of one to ten as described in the physical examination portion above. But this subjective approach may be flawed; every patient has different pain thresholds. One person's seven could be interpreted as a three by another. At the same time, even with a significant quantitative easing of pain, if the patient is still confined to his or her bed by their pain, this may not be a clinical success [23].

A more realistic approach may employ a function-based strategy. Using this method, efficacy is not measured as a patient's progress in achieving pain relief, but rather by his or her ability to objectively achieve better functions. Potential post-therapeutic goals could include the ability to go to work, walking, enhanced sleeping, or simply improved social interactions. Possible functional scales could include one or two activities with minimal impact, e.g., non-grossly affect work enjoyment, and largely jeopardized undertakings, e.g., pain-free walking, with intermediate steps interspersed [23]. As with the pain scales, functional scales would be rated on a scale of one to ten, with one being the least affected and ten as the most affected.

Function-based goals offer two key advantages for managing opioid use in patients with chronic pain:

- Prescribing decisions (or decisions to terminate treatment) are based on outcomes that can be objectively demonstrated to both clinician and patient (and, possibly, to the patient's family).
- Individual differences in pain tolerance become secondary to the setting and monitoring of treatment goals since subjectively perceived levels of pain are not the primary focus in determining functionality.

Such assessment can be a valuable tool in identifying an opioid-addicted patient. The basis of this characterization is that addiction often leads to decreased function, counter to what one would expect in the case of appropriate opioid use.

If such a function-based approach can be used, progress can be documented independently of subjective swings in reported pain. Of course, it is critical to note that progress may not be measured in days. Rather, gains may be incremental and occur over the course of months or years, and some patients who begin showing solid progress may plateau. In these cases, re-assessment should be considered. It may be beneficial to begin with more easily achievable goals, to be replaced with more difficult goals after initial successes. This approach can be much more motivating than a plan resulting in early treatment failure. Some potential examples of functional goals are illustrated in Table 3 [24].

Table 3. Evidence and functional goals

Functional goal	Evidence
Begin physical therapy.	Letter from physical therapist.
Sleeping in bed instead of a lounge chair.	Reported by family member or friend*.
Participation in a pain support group.	Letter from the group leader.
Increased daily living activities.	Reported by family member or friend*.
Ability to walk around the block.	Self-report, pedometer readings, or written log.
Increased social activities.	Reported by family member or friend*.
Return to work.	Pay stubs or letter from employer.
Daily exercise.	Reported by family member or friend*.
**When another person is involved, explicit permission from the patient is required, and should be documented in writing whenever possible.*	

It must be explicitly clear in the patient-provider agreement that obtaining evidence of these functional goals is the sole responsibility of the patient. If for whatever reason the patient is unable to achieve or document progress, as outlined in the treatment plan, an adjustment may be indicated.

While the assessment of treatment goals is highlighted by setting functional goals, there are a number of other "nuts and bolts" to consider when developing an effective treatment plan. First, the treatment plan must be an effective collaboration between the patient and his or her clinician. In addition to the goals being realistic and measurable, they must be effectively tailored to be meaningful to the individual. For example, the discussion could begin with a simple question, "What do you hope to achieve through treatment?"

Like with most patient/provider documents, patients should be reminded of the potential risks and benefits of therapy, even after obtainment of informed consent. The realities of tolerance and physical dependence cannot be overly emphasized. A key component is also a description of how treatment might be terminated. It is critical to discuss the conditions that could lead to discontinuation of therapy. Opioids are not curative, and have no standard duration of treatment. Termination may be required for many reasons, including:

- Healing or resolution of a specific pathology underlying the pain.
- The experience of intolerable side effects.
- Lack of adequate response to a medication in terms of either pain relief or functional improvement.
- Evidence of non-medical or inappropriate use of the medication(s).

If inappropriate use of a prescription medication is discovered, treatment usually must be suspended, although provisions should be in place for the continuation of some kind of pain treatment and/or referral to other professionals or members of a pain management team. Some clinicians may be willing and able to continue a regimen of opioid therapy even after the discovery of aberrant behavior, if conducted with intensified monitoring, patient counseling, and careful documentation. This heightened level of vigilance and risk management may exceed the abilities and resources of the average

prescriber. In such cases, referral to a provider with specialized skills or experience in dealing with high-risk patients may be prudent.

Nursing consideration: Development of a solid treatment plan can be time consuming as the success and utility of such a plan requires a significant investment in patient contact time. Without the intimacy that can be established in such a relationship, a meaningful and realistic plan will be difficult or even impossible to develop. The typical nurse-patient relationship is ideal for this sort of communication.

Case study: Treatment hits a roadblock

Mr. Davidson returns for a follow-up after two weeks. He reports that his arthritis pain has become only slightly better, and that he is still experiencing the burning/tingling pain in his hands and feet. He has not achieved any of his functional goals. Upon questioning, he reveals that he has not been taking the opioid medication as frequently as prescribed because he "doesn't want to become an addict."

Appropriate assessment and action: The common patient fear of addiction should be allayed with careful, compassionate education that explains the differences between addiction and tolerance and communicates the key idea that proper use of an opioid may improve functioning and quality of life. The prescription for the extended release/long acting opioid is continued, and a prescription for a 10mg extended-release gabapentin is added.

Which opioid; Step 5: Which is the optimum therapeutic for your patient?

In 1682 Sydenham said, "Among the remedies which it has pleased Almighty God to give to man to relieve his sufferings, none is so universal and so efficacious as opium." This is still true hundreds of years later. Opioids, as a class, comprise many specific agents available in a wide range of formulations. A given patient might be appropriate for extended release/long acting (ER/LA) therapy only, short-acting only, or a combination of an ER/LA opioid with a short-acting opioid for breakthrough pain [25].

Short-acting oral opioids typically have a rapid effect (15-30 minutes), but may take longer to achieve peak efficacy due to the time required to pass the blood brain barrier. Generally speaking, elimination half-lives average three to four hours, offering a relatively narrow duration of action. As a result, they are best used for acute, intermittent or breakthrough pain (pain occurring against a background of constant pain). Fentanyl may be the fastest acting opioid of all. Combination products couple an opioid with a non-opioid analgesic, usually for use in patients with moderate pain [25].

Single-agent immediate release products are made using a variety of opioids such as codeine, morphine, hydromorphone and oxymorphone. Combination products typically combine a nonsteroidal anti-inflammatory drug and an opioid. Examples of the narcotics employed include codeine or hydrocodone combined with either aspirin, or more commonly, acetaminophen [26]. In 2014, the FDA made a recommendation that prescribers discontinue the use of combination products containing more than 325mg of acetaminophen per dosage unit. This decision is based on data suggesting that the increased risks of liver damage associated with larger doses of acetaminophen are not outweighed by any initial efficacy benefits [27].

ER/LA opioid formulations are purposely engineered to control the release of drug in such a way as to provide relatively consistent and prolonged drug levels in the blood. The resultant lower maximum and higher minimum concentrations should provide more effective pain relief. The onset of action is typically slower than that of immediate release products (perhaps 30-90 minutes), but offer a much longer duration of action (4 to 72 hours). These potent products are typically reserved for patients suffering from constant pain [28].

Prescribers should educate themselves regarding the general characteristics, toxicities, and drug interactions common to opioid products. Respiratory depression is the most serious adverse effect of opioids; it can be immediately life threatening. The risk of respiratory depression or respiratory arrest is higher in patients with an upper respiratory infection, asthma or other respiratory problems. Constipation is the most common long-term side effect but can often be managed with laxatives or stool softeners. Drug-drug interaction profiles are product specific. As such, the knowledge of particular opioid-drug interactions allows for the safer administration of opioid analgesics. In general, central nervous system depressants (sedatives, hypnotics, tranquilizers, tricyclic antidepressants, and alcohol) can have a potentiating effect on opiate-derived sedation and respiratory depression. Methadone can be an effective opioid, but it must be prescribed carefully and with a full knowledge of its highly variable pharmacokinetics and pharmacodynamics. Due to their enhanced duration of action, prescribers of ER/LA opioids must be even more mindful of these considerations. For detailed information on current ER/LA opioid analgesics, see the FDA Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting Opioids [29].

Nursing consideration: Although nurses are not responsible for ultimate prescribing conditions, a solid familiarization of product selection considerations will allow the nurse to collect much of the information needed to guide proper product choices as well as providing optimum side effect monitoring.

Initiating therapy, Step 6: How to best begin treatment

Prior to beginning treatment in patients with opioids, after a complete patient-specific assessment, it must be confirmed that they are responsible candidates for treatment via proper documentation of past therapy and a solid treatment plan. Components of a comprehensive treatment plan are discussed in detail in Step 3, above. Initial treatment should be conducted as a trial to determine if the proposed regimen can safely and efficaciously treat your patient. Such a trial could range in duration from a few days to several months [30]. A decision to continue opioid therapy after an appropriate trial should be based on careful review of the trial outcomes including:

- Progress toward meeting therapeutic goals.
- Changes in functional status.
- Presence and nature of opioid-related adverse effects.
- Changes in the underlying pain condition.
- Changes in medical or psychiatric comorbidities.
- Degree of opioid tolerance in the patient.
- Identification of altered or aberrant behaviors, misuse, or diversion.

It may not always be possible to safely prescribe after a single office visit, requiring repeat visits. It is also critical to always consider consultations and/or referrals if the patient appears to be beyond the scope of your practice or comfort level [30].

Nursing consideration: In addition to a nurse's critical role in selecting appropriate patients, and proper opioid therapeutic choices, nurses are in an optimum position to monitor safety and efficacy, especially immediately after the initiation of therapy.

Dose titration; Step 7: Getting to the right dose for the right patient

Patients who are opioid-naïve or have modest previous opioid exposure should be started at a low dose of a short-acting opioid and titrated slowly upward to decrease the risk of opioid-related adverse effects. If it is unclear if a patient has recently been using opioids (either prescribed or non-prescribed), the clinician should assume that the patient is opioid-naïve (i.e., not tolerant) and proceed as if opioid-naïve.

While some clinicians may initiate treatment with immediate release opioids, others will begin with an ER/LA product. Analgesic efficacy can be established after approximately 24 hours for immediate release opioids or in two to three days when ER/LA products are used. All opioids used during a 24-hour time period should be totaled to obtain the total daily dose (TDD). The TDD can be divided by the dosing interval to obtain a new dose level. The "end of dose" pain should also be considered. If full pain relief is obtained, but unreasonable adverse events have developed, the dose should be reduced to find a level that can be tolerated. Doses should not be adjusted more frequently than every 24 hours. If patients are stabilized on immediate release opioids, the use of an equivalent ER/LA product can be considered when appropriate. Such decisions can only be made after an assessment for opioid tolerance is established. While a slower titration strategy may be appropriate in older, frail patients, a more aggressive titration could be in order in cases of severe pain [31].

It is critical to note that although low-dose, short-acting opioids may offer the greatest safety for initiating opioid therapy, clinicians must recognize that short-acting opioids are not intrinsically safer than other formulations, and must stress to their patients the importance of strict adherence to prescribed doses/administration.

In a variety of clinical settings, nurses play an important role in pain assessment and opioid dose titration. Nursing knowledge surveys have revealed that information deficits may contribute to an under-treatment of pain. It is thought that in some cases, nurses are more influenced by patient behavior than the patient's self-report of pain. Survey results revealed a tendency of nurses' personal opinions to influence opioid dosing rather than recorded assessments [32]. Based on these findings, it is clear that nurses should maximize their understanding of opioid use to best serve their patients.

Nursing consideration: Dose titration is highly subjective and requires close monitoring and individualization. Since nurses often have the greatest level of patient contact, as in other parts of the opioid use process, they are ideally placed to optimize dose titration.

Abuse-deterrent formulations; Step 8: Keeping your patient safe

The previously cited abuse of prescription drugs has spurred the development of novel drug formulations designed for resistance to various methods of tampering and misuse. Current technologies intend to make the product not active unless taken as directed. For example, one class of deterrent formulation includes an opioid antagonist within the dosage form. If the dosage is crushed, the antagonist is released, rendering the opioid inactive. Thus, if such an ER/LA product was ground and inhaled, it would remain inactive in the respiratory tract. Another method is to use an inactive pro-drug formulation that is not activated unless subjected to gastric conditions. Another strategy is to change the physical structure of the dosage making it difficult or impossible to liquefy or concentrate the opioid.

Abuse-deterrent opioid formulations, of course, do not prevent users from simply consuming too much of a medication.

Development of any of these approaches is proving to be elusive and are mainly untested in the general population [33].

Case study: Progress
At the next scheduled follow-up visit, Mr. Davidson reports reduced pain and improved functioning. He says his pain is now 3-4 on a 10-point scale. He can now walk his dog twice daily, and is using the computer without pain. He says his sleep has improved as well. Mr. Davidson asks for a higher dose of the opioid "to see if I can get the pain down to zero."

Appropriate assessment and action: Although seemingly reasonable, it is explained to Mr. Davidson that, in fact, "zero pain" is an unrealistic goal for anyone, and that increasing the dose to achieve that goal would likely incur a range of side effects that would erode his overall quality of life.

Periodic review and monitoring; Step 9: Maintaining a good thing

If a trial of an opioid medication is deemed successful and opioid therapy is continued, periodic review and monitoring should be performed for the duration of treatment. Ensuring adherence to the prescribed treatment can be quite difficult, yet is crucial to good outcomes. Opioid therapy is often complex and complicated by legal, social, pharmacologic, and psychologic factors. Unless these issues can be overcome, safe and effective therapy may be impossible to achieve. Improved use surveillance and drug monitoring is key [34].

All patients receiving opioid therapy need to be assessed regularly. Routine monitoring is imperative, since risks and benefits rarely remain stable. Additionally, changing circumstances may trigger earlier assessment. The tests performed, questions asked, and evaluations made should be tailored to the patient as guided by clinical judgment. At a minimum, monitoring should include a documentation of pain intensity and level of function, progress towards the achievement of goals, adherence to therapy, and presence of adverse events. Clinicians must be vigilant towards the detection of aberrant drug-related behaviors, substance abuse, and any psychological changes. Elements of opioid therapy review and monitoring are not largely different than the tools used during initial assessment [35].

Patients with chronic pain receiving a steady dose of an opioid medication may experience episodes of pain that "breakthrough" the analgesic effects of the steady-state drug level. Close monitoring of breakthrough episodes is key to helping patients reduce pain and facilitate functioning.

By definition, breakthrough pain is a transient increase in pain of moderate to severe intensity occurring in the background of persistent pain that has been controlled. It is critical to distinguish true breakthrough pain from uncontrolled persistent pain. Breakthrough pain is episodic, with no persistent pain between flare-ups. Breakthrough pain must also be distinguished from end-of-dose failure, which can often be managed by increasing the frequency of the medication. Authentic breakthrough pain typically presents 1-4 times per day, but a patient could go days between episodes, then experience a day with eight attacks [36].

Patient pain diaries can be useful to help track breakthrough episodes and spot correlations between the episodes and variables in the patient's life. If specific triggers are identified, this may provide opportunities for changes that will reduce the prevalence of breakthrough episodes without need to increase reliance on medication. Non-opioid methods of dealing with breakthrough pain (e.g., cold or warmth, massage, yoga, acupuncture, meditation, or electrical stimulation) could be considered prior to any increases in opioid medication. As with the management of the underlying chronic

pain condition, clinicians should use an agreed-upon set of functional goals as a way to monitor, and if necessary, adjust, the use of as-needed opioid medications for breakthrough pain.

Patients who have previously engaged in aberrant drug-related behaviors or are otherwise at high risk of abuse should be required to submit to periodic urine drug screens to confirm adherence to the treatment plan. Drug testing must be conducted in a consensual manner as a part of the treatment plan with the understanding that it is key to patient success. Benefits of testing include:

- Serving as a deterrent to inappropriate use.
- Providing objective evidence of abstinence from drugs of abuse.
- Monitoring response to treatment.
- Assisting with a diagnosis.
- Helping patients allay concerns by family members, employers, or law-enforcement.
- Demonstrating to regulatory authorities a clinician's dedication to monitoring "best practices."

In the context of family practice settings, unobserved urine collection is usually an acceptable procedure for drug testing. Clinicians, however, should be aware of the many ways in which urine specimens can be adulterated. Clinicians charged with interpreting test results should be familiar with the metabolites associated with each opioid that may be detected in urine, since the appearance of a metabolite can be misleading. A patient prescribed codeine, for example, may test positive for morphine because morphine is a metabolite of codeine. Similar misunderstandings may occur for patients prescribed hydrocodone who appear positive for hydromorphone or oxycodone and oxymorphone (see Table 4).

While quarterly or twice yearly assessments may be adequate for most patients, high-risk patients must undergo more frequent or intense monitoring. For the highest risk patients, weekly checks may be indicated. Regardless of frequency, regular, consistent checks are critical to success [35].

As part of routine practice, clinicians who prescribe opioids should perform medication reconciliation at each patient visit. The American Medical Association defines "medication reconciliation" as "…making sense of a patient's medications and resolving conflicts between different sources of information to minimize harm and maximize therapeutic effects [37]."

Although clinical patient care is a solid approach to monitoring appropriate opioid use, prescribers should also take advantage of prescription drug monitoring programs (PDMP) when available. A PDMP is a statewide electronic database designed to collect data on substances dispensed. Information contained in the database can be distributed to individuals who are authorized to receive it for the purposes of their profession. A PDMP offers a variety of benefits including:

- Support access to legitimate medical use of controlled substances.
- Identify and deter or prevent drug abuse and diversion.
- Facilitate and encourage the identification of, intervention with, and treatment of persons addicted to prescription drugs.
- Inform public health initiatives through outlining of use and abuse trends.
- Educate individuals about PDMPs and the use, abuse and diversion of and addiction to opioids.

Case study: A caution light

After 3 weeks, a message has been received stating that a young woman has called requesting an early refill of Mr. Davidson's opioid "because he's suffering."

Appropriate assessment and action: This message rightly raises suspicions. The clinician first accesses her state's Prescription Drug Monitoring Program to see if Mr. Davidson might be acquiring prescriptions from another provider. He is not, and nothing appears unusual. The prescriber then calls Mr. Davidson directly. Mr. Davidson confirms that he did ask his granddaughter to call for the prescription because he was having increased pain after playing tennis for an hour. Mr. Davidson is advised to temporarily use an OTC NSAID (ibuprofen, not more than 600 mg, three times per day) and is asked to return for an in-person visit within a week. At that visit, a range of non-pharmacological strategies are reviewed to provide additional pain relief (i.e. post-exercise cold/warm treatments; exercises to improve flexibility; massage; and the use of an elbow brace to be used for tennis).

What to watch for; Step 10: Opioid side effects

Many patients treated with an opioid will experience side effects, the most common of which are constipation (very common) and nausea. Unfortunately, these side effects are challenging to manage, and tolerance to these frequently do not develop. In some cases, these may be so adverse as to warrant opioid discontinuation, contributing to inadequate analgesia. Proactive treatment for constipation is typically indicated. Other common side effects include sedation, dizziness, vomiting, physical dependence, tolerance, and respiratory depression. Less frequently observed side effects of opioid use are delayed gastric emptying, hyperalgesia (increased sensitivity to pain), immunologic and/or hormonal dysfunction, muscle rigidity and myoclonus (spasmodic jerky contractions of groups of muscles) [38]. Unlike constipation and nausea, tolerance to many side effects can occur, becoming less troublesome over time.

A variety of approaches are being explored in an attempt to mitigate these troubling side effects. Some patients can benefit from changing the opioid or the route of administration used. Proper screening, education, and pre-emptive treatment will minimize bad outcomes and enhance efficacy in many cases.

Opioids and pregnancy

A prominent team of obstetric researchers determined that maternal opioid treatment in the early phases of pregnancy was associated with a variety of birth effects that are important contributors to infant morbidity and mortality. It is critical to consider the background rate of such maladies. For example, it was found that the prevalence of hypoplastic left heart syndrome was about 2.5 times higher in women taking opioids compared to those that were not. It is also important to consider that the incidence in mothers with opioid therapy was only 5.8 out of 10,000 women compared to a baseline event rate of 2.4 out of 10,000 women. Since neither event rate is relatively high (less than 0.06% chance in women taking opioids), it is critical that clinicians weigh potential benefits versus risks on an individual patient basis [39].

If opioids are used in pregnant women, opioid withdrawal issues are to be expected in the infant if the mother becomes opioid dependent.

Driving and work safety

Prior to the onset of any therapy, patients need to advised that cognitive impairment may occur. This must be included in their informed consent. Patients can expect a variety of changes in cognitive function including:

- Somnolence.
- Fatigue.
- Dizziness.
- Decreased ability to concentrate.
- Slowed motor performance.
- Slowed reflexes.
- Impaired coordination.

Any of these can impact a patient's ability to drive or work safely, with increased incidence at the initiation of therapy. Some recent studies suggest that driving ability may be less impaired in patients dependent on chronic opioid treatment. Nonetheless, impairment should be assumed in patients receiving opioids and should be considered when determining what a patient can safely accomplish [40].

Clinicians should be aware that certain professions (i.e., school bus drivers and pilots) may be subject to restrictions in the use of opioid medications. Clinicians should check with their state medical society or the Federation of State Medical Boards to obtain up-to-date information in this regard.

Screening for endocrine function

While it has become evident that estrogen plays a role in the female pain experience, less attention has been paid to the role of testosterone in either sex. Opioid therapy is associated with changes in testosterone levels. Since testosterone plays critical roles in both males and females, it is important that clinicians be aware of potential endocrine change issues as well as possible hormone replacement strategies. A recent publication detailed a survey showing that sex hormone determinations are rarely carried out in pain treatment centers [41].

Both male and female patients on long-term opioid therapy are at risk for hypogonadism, thus the endocrine function of all patients should be assessed at the start of long-term opioid therapy and at least annually thereafter. The symptoms of hypogonadism in both genders may include fatigue, mood changes, decreased libido, loss of muscle mass, and osteoporosis. Although there are insufficient data to recommend routine endocrine screening of asymptomatic patients, current guidelines recommend such testing for patients exhibiting any of the aforementioned signs and symptoms.

Nursing consideration: Like most every aspect of opioid therapy, clinical monitoring is highly subjective, and benefits from the formation of a close and trusting bond between the patient and nurse. All communications must be direct, honest, and caring. Since nurses often have the greatest level of patient contact, they should ideally optimize this beneficial contact.

Opioid rotation; Step 11: Best balance to optimize treatment

"Opioid rotation" means switching from one opioid to another in order to better balance analgesia and side effects. Rotation may be needed because of a lack of efficacy (often related to tolerance), bothersome or unacceptable side effects, increased dosing that exceeds the recommended limits of the current opioid (e.g., dose limitations of co-compounded acetaminophen), or an inability to absorb the medication in its present form (e.g., if there is a change in the patient's ability to swallow, switch to a formulation that can be absorbed by a different route, such as transdermal). The initial step is to select a new drug at a starting dose designed to minimize risks while retaining the level of efficacy obtained with the former drug product. Relevant estimates of analgesic interchangeability have been outlined using "equianalgesic dose tables," which have been modified only slightly in the past several decades [42]. A good example of such a table generated by Stanford University School of Medicine can be found at https://palliative.stanford.edu/opioid-conversion/equivalency-table/.

Because of the large number of variables involved in how any opioid will affect any given patient, opioid rotation must be approached cautiously, particularly when converting from an immediate-release formulation to an ER/LA product. As a result, an equivalent dose table must be used carefully as a high degree of variation has been found across the various charts and online calculator tools, potentially accounting for some overdoses and fatalities. The optimal dose for a specific patient must be determined by careful titration and appropriate monitoring. In some cases, because of the potential risk of harm while rotating from one chronic opioid regimen to another, it may be wise to initially use lower doses of an ER/LA opioid than what might be suggested by equianalgesic charts and at the same time, temporarily liberalizing, as needed, the use of a short-acting opioid. This would then be followed by gradual titration of the LA opioid to the point where the as-needed short-acting opioid is incrementally reduced, until no longer necessary.

Non-adherence patients; Step 11: How to manage non-compliant patients

Patients who begin to exhibit aberrant drug-related behaviors or nonadherence to a prescription should be monitored more strictly than compliant patients. It is critical to not rush to judgement, though, and move methodically as you assess the situation. The management of chronic pain can be difficult. Putting a patient on the defensive can adversely impact their treatment, but an important distinction must be drawn between addiction and pseudo-addiction. Chronic pain sufferers seeking increased dosages of opioids may not be addicted (marked by loss of control, compulsion, etc.), and the pseudo-addicted may demonstrate concerning behavior, such as demands on clinicians, procurement of opioids from more than one prescriber, or hoarding medications. If non-adherence is suspected, clinicians should rely on extra close observation, testing, and the inclusion of other healthcare professionals including psychiatrists or drug addiction specialists. Finally, a reliance on the prospective treatment plan will ensure that therapy is following the agreed upon course [43].

Possible reasons to keep in mind during assessment for nonadherence include:

- Inadequate pain relief.
- Misunderstanding of the prescription specifics.
- Misunderstandings related to lack of fluency with English.
- Attempts to "stretch" a medication in order to save money.
- Cultural or familial pressure not to take a medication.
- Stigma about taking a pain medication.
- Overmedication and fears about addiction.
- Misunderstanding of a prescription by a caregiver who has taken responsibility for daily apportioning of medications.
- Confusion between two medications that look very similar to each other.

Nursing consideration: When it comes to managing patient non-adherence to opioid therapy, solid relationship building is key to success. A proper investigation and assessment of the situation may be time consuming and frustrating. Due to the many demands placed on prescribers, they may be unable to adequately conduct this task. Nurses may find themselves in an ideal space to work with the patients to fully characterize any issues with their treatment, and provide productive advice to the ultimate prescriber.

Case study: Stable improvement

After a slight dose adjustment of the gabapentin, Mr. Davidson reports continued functional progress and acceptable levels of pain. He has increased his level of physical activity and reports that his mood and general health is better as a result. He says he would like to try to taper down his use of the opioid.

Appropriate assessment and action: This is a treatment success; the health care team should be gratified. In this case, Mr. Davidson is given clear and specific instructions for how to taper his dosage of opioids to the lowest effective dosage level.

Treatment termination; Step 12: Safely halting opioid therapy

Reasons for the discontinuation of an opioid analgesic can include: the healing of or recovery from an injury, medical procedure, or condition; intolerable side effects; lack of response; or discovery of misuse of medications. Regardless of the reason, termination should be accomplished so as to minimize unpleasant or dangerous withdrawal symptoms by tapering the opioid medication slowly, or by carefully changing to a new formulation.

Tapering, or detoxifying patients after chronic opioid use is complex and needs to be monitored in order to minimize withdrawal symptoms. Sadly, very little clinical guidance is available to guide proper tapering strategies. In some cases, it may be beneficial to consult with an addiction specialist for help when designing an approach to treatment discontinuation [44].

In general, a slower taper will produce fewer unpleasant symptoms of withdrawal. As an alternative to termination, a clinician may choose to continue opioid treatment with intensified monitoring, counseling, and careful documentation if it is deemed in the best interest of the patient. This requires deliberate consideration and a well-documented risk management plan that addresses the greater resources necessary for opioid continuation following evidence of misuse. If termination of the provider/patient relationship is deemed necessary, clinicians must ensure that the patient is transferred to the care of another provider, and see that the patient has adequate medications to avoid unnecessary risk from uncontrolled or potentially dangerous withdrawal. Practitioners can be held accountable for patient abandonment if medical care is discontinued without justification or adequate provision for subsequent care.

Methadone; Step 13: High potential + elevated risks = controversy

Methadone, a synthetic opioid, was originally used as an analgesic in the 1940s. Beginning in the 1960s, methadone was re-purposed as a maintenance drug for use in the treatment of opioid addiction. Currently, it is employed for both indications. While specialized training and DEA registration is required for the treatment of addiction, it can be prescribed for pain by any provider authorized to prescribe Schedule II controlled substances. Over the past few decades, methadone sales have risen sharply, largely for use outside of the narcotic treatment arena. Coupled with the increase in the use of methadone for pain, questions of its safety have also been on the rise. Although methadone accounts for less than five percent of opioid prescriptions, it has been linked to one-third of opioid-related deaths [45].

There is a disconnect between the half-life of methadone in the blood and the duration of analgesia that it provides. While its plasma half-life ranges from 8 to 60 hours, the duration of methadone analgesia is 6 to 12 hours. In practice, pain relief may end long before the drug is eliminated from the body, leading to re-dosing, and potentially dangerous systemic accumulations. Furthermore, methadone is metabolized by several different enzyme systems, subjecting it to multiple potential drug-drug interactions. Due to both of these liabilities, prescribers must exercise great caution when utilizing methadone [46].

Methadone's long duration of action, coupled with its low price is likely contributing to the upsurge in its use for the treatment of chronic pain. In addition to the complications described previously, the use of methadone is complicated by its interaction with cigarette smoking (which increases the rate of its metabolism), and alcohol (which can augment its toxicity in addition to also increasing the rate of its metabolism).

While methadone is not commonly employed as a first-line opioid, it could be beneficial in opioid-naïve patients. Due to its slow onset and long duration of effect, it may help avoid some of the reward behaviors common to fast-acting opioids. The APS/AAPM guidelines recommend a starting dose in most opioid-naive patients of 2.5 mg every eight hours, with dose increases occurring no more frequently than weekly. It is nearly impossible to determine an equivalent dose of methadone based on morphine dosing. Although a 10mg dose of methadone is an approximate analgesic to 15mg of morphine, the required methadone dose will decrease over time. Therefore, the lowest possible dose titration should be followed in opioid-tolerant patients. Most available narcotic equivalence tables are based on single doses. Due to its potential accumulation, relying on these charts for chronic methadone dosing can result in a substantial overdose that may not become apparent for several days [47].

Nursing considerations: Because the risk of overdose is particularly acute with methadone, patients should be educated about these risks and counseled to use methadone exactly as prescribed. They should also be warned about the dangers of co-administering other respiratory depressants.

In 2006, the FDA issued an alert warning that methadone can cause serious cardiac conduction disturbances, including QT-interval prolongation and Torsades de Pointes, a potentially fatal ventricular arrhythmia. It appears that methadone-related corrected QT (QTc) interval prolongation and cardiac arrhythmias can occur at any dose, but are more likely at higher doses, or with concomitant use of drugs that interact with methadone or that themselves prolong QTc. Although uncommon, the cardiac arrhythmias that can be induced by methadone are potentially lethal if not detected. The cardiac health of patients who are candidates for methadone should be assessed, with particular attention paid to any history of heart disease or arrhythmias. An initial ECG may be advisable prior to starting methadone, particularly if a patient has a specific cardiac disease, or cardiac risk factors, or is taking agents that may interact with methadone [48].

Clearly, there are liabilities associated with the use of methadone. At the same time, it has potentially favorable attributes as an analgesic. Appropriate use of methadone in patients with chronic pain demands a clear characterization of the patient followed by a thorough risk-benefit assessment.

Safe storage and disposal of opioid medications; Step 14: Proper opioid logistics

It is well established that many abusers of prescription drugs obtain them from family and friends. Therefore, appropriate medication and disposal is an effective strategy in preventing potential abuse. Prior to receiving opioids, patients should be informed of these facts and provided key steps for safely maintaining their medications including information regarding take-back programs for un-needed medications [49].

If possible, opioid pain medications should be stored in a locked cabinet or other secure storage unit. Storage areas should be cool, dry, and out of direct sunlight. Remind patients not to store medications in their car, to keep medications in the original containers, and to avoid storing medications in the refrigerator or freezer unless specifically directed to do so by a healthcare provider or pharmacist.

A variety of approaches are available for home disposal of unused medications. Examples include mixing the drugs with unappealing substances, such as coffee grounds or used cat litter. Such mixes should be sealed in plastic bags prior to placing them in the garbage. It is critical that pills should not be crushed, and never flushed down a drain or toilet. Additional details can be found on the Massachusetts Medical Society website [50].

Many communities sponsor take-back days for un-used medications. The U.S. Drug Enforcement Agency (DEA) regularly sponsors such programs. Details on upcoming events can be found on their website [51].

Nursing consideration: In addition to limiting the quantity of opioid medications administered, nurses can play a critical role in preventing their misuse by keeping patients aware of the proper methods and resources available for medication storage and disposal.

Managing an overdose; Step 15: Keys to keeping your patient alive

An opioid overdose is a potentially lethal condition resulting from some combination of prescribing practice, failure to appreciate patient risks of medication misuse, drug administration errors, or simply abuse. In addition to the commonly known issue of respiratory depression, overdose can also have life-threatening toxic effects on multiple organ systems. It is key to recognize that the duration of action varies between products. As such, overdose treatment must reflect these differences [52].

It is critical to note that respiratory depression typically takes some time to develop. As a result, there will be early warning signs of overdose including:

- Intoxicated behavior – confusion, slurred speech, stumbling.
- Feeling dizzy or faint.
- Acting drowsy or groggy.
- Unusual snoring, gasping, or snorting during sleep.
- Difficulty waking up from sleep or staying awake.

Patients and their caregivers should be counseled to immediately call 911 or an emergency service if they observe any of these warning signs. If a person has stopped breathing, artificial respiration/cardio-pulmonary resuscitation (CPR, including rescue breathing) should be begun immediately and continued until emergency help arrives.

Naloxone; Step 16: A pharmacologic approach to reversing opioid overdose

Naloxone is a pharmacologic antidote that can be used to treat opioid overdose. It acts by binding to opioid receptors with a greater affinity than an opioid, displacing the opioid, and making it inactive. Administered properly, naloxone can reverse all signs and symptoms of opioid intoxication, and it can be administered using a variety of dosage forms including parenteral, intra-nasal, or by pulmonary inhalation [53].

Intranasal naloxone is becoming more and more readily available on an over the counter (OTC) basis. As of October, 2015, OTC naloxone was legally available in 14 states, with many others considering legislation to allow this practice [53].

While discussing the suitability of naloxone for OTC use, the U.S. Food and Drug Administration grappled with a number of issues unique to this problem, e.g., the issue of self-selection. The current OTC paradigm states that a patient deciding to use an OTC drug would self-select to treat their symptoms, but the use of naloxone would be unique in that the patient choosing to administer the drug would not be the patient receiving it. Data were required to demonstrate that the individual administering naloxone can properly diagnose an opioid overdose and that such administration is appropriate [54].

If available, patients might be considered for naloxone OTC therapy if they:

- Receive prescriptions of more than 50mg of morphine equivalent/day.
- Are being rotated from one opioid to another when there may be incomplete cross-tolerance.
- Are opioid naïve and have been prescribed methadone or are rotated from another opioid to methadone.
- Are released after emergency medical care involving opioid intoxication or poisoning.
- Have a suspected history of substance abuse, dependence, or nonmedical opioid use.
- Have known or suspected concurrent heavy alcohol use.
- Have a respiratory infection or illness.
- May have difficulty accessing emergency medical services.

Patient education; Step 17: What do you need to teach your patient?

Thorough patient education about the safe use, storage, and disposal of opioid medications is an essential part of opioid prescribing "best practices." This education can be partially integrated into standard patient/provider agreements or informed consent documents. As with other patient-directed materials, education must be provided in a language and at a reading level (typically 6th-7th grade) appropriate for a clinician's patient population.

Safe use of opioid medications means that patients carefully follow clinician instructions, including special directions about timing of doses, and whether to administer the medication with food or without. Clinicians should be mindful of any patient physical limitations (e.g., poor eyesight) that could interfere with the accurate and timely administration of prescribed opioids.

Key educational topics include:

- Read the prescription container label each time to check dosage.
- Never use medicines after expiration date.
- Never share medicines with others.
- Do not take a pain medicine with alcohol or other sedatives.
- Do not take a pain medicine to promote sleep.
- Never break, chew, or crush medicines, particularly ER/LA opioid medications.
- For transdermal products, external heat, fever, and exertion can increase absorption, leading to a potentially fatal overdose.
- Transdermal products with metal foil backings are not safe for use in MRI scanners.
- Do not use transdermal products if they are broken or torn.

Generalities of opioid safe use as well as a comprehensive listing of opioid ER/LA product-specific information can be found in the August 2015 FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics [55].

Conclusions: Tying it all together

This educational program has summarized "best practices" for the responsible use of opioid pain medications for chronic non-cancer pain, with an emphasis on nursing roles. Clinicians face the competing demands of relieving pain while minimizing potential harm to both patients and society. The steps and procedures described in this program provide a structure by which clinicians can achieve these twin goals without incurring undue burdens of time or energy.

Pharmacovigilance simply means that prescribers apply basic principles of prudent medicine to the needs of patients in pain. And, because the evidence base for current guidelines remains sub-optimal, clinicians retain a great deal of latitude in deciding how that vigilance is best deployed on a day-today basis. The treatment of pain is a dynamic and evolving field, and clinicians should periodically refresh their knowledge through reading, attending seminars/courses, or by taking additional CME courses.

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BEST NURSING PRACTICES: CARE OF PATIENTS PRESCRIBED OPIOIDS FOR THE TREATMENT OF PAIN

Self Evaluation Exercises

Select the best answer for each question and check your answers at the bottom of the page.
You do not need to submit this self-evaluation exercise with your participant sheet.

1. In 2012, FDA published a REMS specific to the use of extended-release and long-acting opioids. This document encourages prescribers to consider which of the following prior to ordering opioids for their patients:
   a. Educate: Complete a REMS-compliant educational program geared to your discipline.
   b. Plan an exit strategy to ensure safe opioid termination prior to initiating dosing.
   c. Make sure that all caregivers have provided informed consent.
   d. Ensure that all patients receiving opioids have reached the age of majority.
2. Prior to initiation of opioid therapy, clinical professionals need to complete which of the following assessments?
   a. A comprehensive clinical laboratory workup.
   b. Cardiac evaluation.
   c. Intelligence testing.
   d. A thorough pain assessment.
3. A nurse trained to characterize and identify an opioid addicted patient might note which of the following regarding the addicted patient?
   a. Their medication use clearly improves the patient's quality of life.
   b. If adverse events are observed, the patient wants to increase medication use.
   c. The patient is greatly concerned about the physical problem being treated.
   d. The patient is aware of problems that could develop as a result of drug treatment.
4. "Best practices" for pain treatment contracts contain which of the following elements?
   a. Medications are to be refilled at the patient's discretion.
   b. All urine toxicology screens will be prospectively scheduled.
   c. Lost or stolen opioid prescriptions must be re-written with 48 hours.
   d. Refills require a clinic visit by appointment.
5. Function-based goals offer key advantages for managing opioid use in patients with chronic pain. Examples of such advantages include which of the following?
   a. Functional goals are purely subjective.
   b. Perceived levels of pain are the sole focus in determining functionality.
   c. Prescribing decisions are based on outcomes that can be objectively demonstrated to both clinician and patient.
   d. The attainment of function-based goals is totally independent of states of addiction.
6. Short-acting opioids are most appropriate and commonly used for which of the following conditions?
   a. Cancer pain.
   b. Breakthrough pain.
   c. Neuropathic pain.
   d. Terminal pain.
7. Of the following tools, which one can help patients identify triggers of breakthrough pain?
   a. Paper or electronic pain diary.
   b. Pill box organizers.
   c. Portable EEG monitors.
   d. Automated systems for sending patients reminders to take their medications.
8. A Prescription Drug Monitoring Program (PDMP) is a statewide electronic database designed to collect data on substances dispensed. Information contained within the database can be distributed to individuals who are authorized to receive it for the purposes of their profession. A PDMP offers a variety of benefits including which of the following:
   a. Individual pharmacy brand versus generic dispensing patterns.
   b. Restriction of access to legitimate medical use of controlled substances.
   c. Ability to identify and deter or prevent drug abuse and diversion.
   d. Provide Pharmacy Benefit Managers with critical opioid prescribing patterns.
9. If non-adherence to proper opioid therapy is suspected, clinicians should rely on extra close observation, testing, and the inclusion of other healthcare professionals including psychiatrists or drug addiction specialists. Possible issues to keep in mind during assessment for nonadherence include:
   a. Adequate pain relief.
   b. Complete understanding of the specifics of the opioid prescription and treatment plan.
   c. Pride in taking a pain medication.
   d. Cultural or familial pressure to not take a medication.
10. When providing education to your patients receiving opioid medications, it is important to stress that it can be particularly unsafe to combine opioids with which of the following other medicines?
    a. Stimulant medications.
    b. SSRI antidepressants.
    c. Benzodiazepines or barbiturates.
    d. Anti-hypertensive medications.

Answers:	1.A 2.D 3.B 4.D 5.C 6.B 7.A 8.C 9.D 10.C