

Safe and Effective Prescription of Controlled Substances

Prescription Authority



Objectives

1. Describe the emotional and financial burden of treating chronic pain in the United States
2. Identify the risk factors of opiate misuse and abuse.
3. Compare and contrast schedule I, II, III, IV, and V substances.
4. Compare and contrast morphine, fentanyl, hydrocodone and tramadol.
5. Identify strategies for assessing and monitoring controlled substances
6. Compare and contrast physical dependence, psychological dependence, and addiction.
7. Summarize how to perform an assessment, and evaluation of substance abuse and addiction disorder
8. List the universal precautions for prescribing control substances
9. Describe ways to prevent prescription substance Illegal use and abuse

Purpose

The purpose of this continuing education is to provide health care providers with an overview of the current nationally vetted pain management, opioid-prescribing standards, and safe and effective prescription of controlled substances. A further aim is to present techniques and recommendations based on best practice experiences so that health care providers can assimilate them into practice for safe opioid prescribing and for protection of their own practice should they become the subject of a regulatory investigation.

Introduction

The ARNP is authorized to prescribed controlled substances in accordance with certain State Laws [State law chart: Nurse Practitioner Prescriptive Authority | AMA](#) The protocols must be signed by the ARNP and supervising physican/s and have a current date. Prescribing controlled substance vary from state to state. Currently there are 37 states that have working prescription drug monitoring programs in place for health care providers. The most common reason for prescribing controlled substances is for pain. Parselis-Kelly, Cook, and Kaufman (2008), illustrates that prescribing controlled substances for pain is the most common reason that people seek medical attention. Pain can also be associated with a wide range of surgical procedures, injuries, and diseases.

According to the American Academy of Pain and Medicine, (2016) Millions of individuals suffer from acute or chronic pain every year and the effects of pain exact a tremendous cost on our country in health care costs, rehabilitation and lost worker productivity, as well as the emotional and financial burden it places on patients and their families. In addition, the Institute of Medicine (2011) reports that pain is a significant public health problem that costs society at least \$560-\$635 billion annually, an amount equal to about \$2,000.00 for everyone living in the U.S. This includes the total incremental cost of health care due to pain ranging from \$261 to \$300 billion and \$297-\$336 billion due to lost productivity (based on days of work missed, hours of work lost, and lower wages). The prescribing of a controlled substance for patients with severe pain can lead abuse potential and the likelihood of causing dependence.

Opioid Misuse

According to the National Institute of Health (NIH) (2014) opioids are medications that relieve pain. Opioids reduce the intensity of pain signals reaching the brain and affect those brain areas controlling emotion, which diminishes the effects of a painful stimulus. The medications that falls under the classification of Opioids are as follows:

Phenanthrene Opioids	Nonphenanthrene Opioids
Codeine, and related drugs	Piperidine derivatives:
Hydrocodone (e.g., Vicodin)	Fentanyl
Hydromorphone	Meperidine
Morphine (e.g., Kadian, Avinza)	Sufentanil
Oxycodone (e.g., OxyContin, Percocet)	Other:
Oxymorphone	Buprenorphine
	Methadone
	Tramadol

Opioid misuse, divergence, and overdose are public health problems in the United States (Hudspeth, 2016). According to the United States Department of Health and Human Services, (2013) every year the death toll increases due to abuse of opioids. Evidence supports that more people use opioids for nonmedical reasons and become addicted. American Society of Addiction



Medicine (2015) illustrates that there is an increasing numbers of patients are seen in emergency departments with some level of opioid misuse. Outpatient clinics report increased numbers of patients seeking pain medications for multiple issues. More hospitals offer inpatient pain services to manage complex patients who are admitted for surgical or other interventions and who also have substance-abuse issues (Braden, Russo, and Fan, 2019).

Opioids have the potential to provide analgesia and improve function. These benefits must be weighed against the potential risks including: misuse, addiction, physical dependence, tolerance, overdose, abuse by others, drug-to-drug and drug-to-disease interactions. Opioid misuse and abuse is a major public health problem and it affects 34.2 million Americans over the age of 12 (SAMHSA, 2012). According to the Center for Disease Control, in the United States, 46 people die each day from an overdose of prescription painkillers. In 2012, health care providers wrote 259 million prescriptions for painkillers (Center for Disease Control, 2014). Two times as many painkiller prescriptions are written in the United States as in Canada.

Evidence shows that > 50% of opioid prescriptions are written by primary care providers, including certified nurse practitioners (CNPs (Breuer, Cruciani, and Portenoy, 2010). Opioid prescribing is complex and both professional organizations and regulatory authorities have demonstrated interest in formulating prescribing standards and implementing safeguards to protect patients and the public from misuse and adverse outcomes.

Control Substances

A controlled substance is a drug, compound, preparation, mixture, or substance contained in Schedule I, II, III, IV, or V. This list is updated annually and substances are put into their



schedules based on the substances current medical use, abuse potential and likelihood of causing dependence when abused. Controlled substances are laced with risks. Understanding the risks of controlled substances is critical for proper prescribing. The prescriber who understands the medications and how to prescribe them properly will provide better and safer care for their patients.

Control Substances Schedule I-V	
<p>The Controlled Substance Act regulates five classes of medications: anabolic steroids, depressants, hallucinogens, narcotics and stimulants. Each class has different properties and substances in each class typically produce similar effects. Most controlled substances alter mood, feeling or thought due to their effect on the central nervous system. Medications likely to produce euphoria are more likely to be abused, but medications may be abused to aid in sleep, reduce pain, reduce anxiety, reduce depression and improve energy.</p> <p>Complete list of Control Substances Schedule I-V can be found 812. Schedules of controlled substances</p>	
Schedule I	<ul style="list-style-type: none"> a. The drug or other substance has a high potential for abuse. b. The drug or other substance has no currently accepted medical use in treatment in the United States. c. There is a lack of accepted safety for use of the drug or other substance under medical supervision. <p>Substances in this class include: heroin, marijuana, 3, 4-methylenedioxymethamphetamine ("Ecstasy") and lysergic acid diethylamide (LSD).</p>
Schedule II Schedule IIN	<ul style="list-style-type: none"> a. The drug or other substance has a high potential for abuse. b. The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. c. Abuse of the drug or other substances may lead to severe psychological or physical dependence. <p>Schedule II narcotics includes: oxycodone (OxyContin, Percocet), fentanyl (Sublimaze, Duragesic), methadone (Dolophine), hydromorphone (Dilaudid), morphine, opium, and codeine.</p> <p>Examples of Schedule IIN stimulants include: methylphenidate (Ritalin) and amphetamine (Dexedrine, Adderall).</p>

<p>Schedule III Schedule IIIN</p>	<ul style="list-style-type: none"> a. The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II. b. The drug or other substance has a currently accepted medical use in treatment in the United States. c. Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence. <p>Examples of medications in this class include: buprenorphine (Suboxone) and products that have less than 90 milligrams of codeine per dosage unit such as Tylenol with Codeine.</p> <p>Medications that are considered Schedule IIIN include: anabolic steroids such as Depo-Testosterone and ketamine.</p>
<p>Schedule IV</p>	<ul style="list-style-type: none"> a. The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III. b. The drug or other substance has a currently accepted medical use in treatment in the United States. c. Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III. <p>Examples of medications in this class include: benzodiazepines, midazolam (Versed), modafinil (Provigil) and carisoprodol (Soma).</p>
<p>Schedule V</p>	<ul style="list-style-type: none"> a. The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV. b. The drug or other substance has a currently accepted medical use in treatment in the United States. c. Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV. <p>Examples of medications in this class include cough preparations that contain less than 200 milligrams of codeine per 100 milliliters or per 100 grams such as Robitussin AC, lacosamide (Vimpat), and pregabalin (Lyrica).</p>

Strategies for Assessing and Monitoring Controlled Substances

Controlled substances (CSs) are powerful agents (Brown, and Kaplan, 2011). Brown, and Kaplan, (2011) Further illustrates that when prescribed carefully CSs can have a significant positive impact on quality of life, pain function, mood, and sleep. When prescribed inappropriately, CSs use can be physically, emotionally, and socially harmful. Therefore, it is important for the advance practice registered nurse to be knowledgeable, competent, and astute prescriber of controlled substances. The management of controlled substances originally started with regulation through legislative actions.

CSs are drugs regulated by the Federal Controlled Substance Act (CSA) of 1970 and have been determined to be at higher risk for abuse and diversion than other drugs. One of the main purposes of the CSA, was to establish a list of Schedules, into which each drug and medication is classified, in order to control their manufacture and distribution. While opioid analgesics make up a substantial number of controlled substances, there are various other drugs that are also classified into the different categories, including anabolic steroids, stimulants, hallucinogens, and depressants. It is critical to correctly define terms by the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine to determine if CSs are being misused.

Definitions

Abuse - Drug abuse occurs with any use of an illegal drug, or the intentional self-administration of a medication for nonmedical purpose such as altering one's state of consciousness (Chou et al., 2009, p 130).

Physical Dependence - is a state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist (American Academy of Pain Medicine, American Pain Society, & American Society of Addiction Medicine, 2001). Patients may display withdrawal symptoms such as anxiety, tachycardia, hypertension, diaphoresis, a volatile mood, or dysphoria after the rapid discontinuation of the substance.

Psychological Dependence-is the perceived need for the substance. It makes the person feel as though they cannot function if they do not have the substance. Psychological dependence often kicks in after physical dependence wears off. It typically lasts much longer than physical dependence and often is a strong contributing factor to relapse.

Addiction - is a primary, chronic disease of the brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. This is an individual pathologically pursuing reward and/or relief by substance use and other behaviors. At this point there is typically a loss of control regarding drug use. The drug is continued despite serious medical and/or social

consequences. Tolerance, increasing doses of the medication needed to produce an equivalent effect, is typically seen by the time addiction is present. Physical dependence can occur without addiction. Individuals who take chronic pain medication may be dependent on the medication, but not addicted.

Addiction is a major concern in those taking opioids. When prescribing opioids it is important to determine who is likely to participate in aberrant drug related behaviors. This may occur in those with major depression, psychotropic medication use, younger age or those with a family or personal history of drug or alcohol misuse (Boscarino, Rukstalis, Hoffman, Han, Erlich, Gerhard, & Steward, 2010). Those at high risk for addiction should likely be managed in concert with a specialist (Sehgal, Manchikanti, & Smith, 2012).

Aberrant behaviors - may include abuse, misuse or addiction. Examples of aberrant drug related behaviors include: requests for early refills, not taking medications as prescribed, failure to keep appointments, visits in distress, frequent reports of lost medication, using multiple prescribers, positive urine drug test for illicit substances, altering prescriptions, resistance to referrals, resistance to providing prior medical records, resistance to change in therapy, increasing the dose without telling the prescriber, or requests for specific drugs.

Habituation - is considered a less intense attachment that occurs in response to drugs which never produce compulsive craving, yet their pharmacologic action is found desirable to some individuals who readily form a habit of administration (Savage 2008).

Pseudoaddiction - “The iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management” (Weissman & Haddox, 1989).



Substance Use - “a maladaptive pattern of drug use behavior leading to significant impairment or distress, such as failure to fulfill major role obligations at home, work or in school. To meet DSM-IV criteria, this must be demonstrated for at least 12 months” (Savage, 2008, p. 10).

Tolerance - “a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug’s effects over time” (American Academy of Pain Medicine, American Pain Society, & American Society of Addiction Medicine, 2001).

Assessment of Substance Use and Addiction Disorder

Unfortunately, for the reason that CSs are classified as CSs they are more likely to be taken in ways that are beyond that which they are intended. Because of the staggering statistic on the use it is important for the health care provider to be able to identify those people at risk of developing a problem and understand their role in managing their care. A range of screening and assessment tools can be used to determine CSs dependency. One example is the ICD 10 classification for dependency. The ICD 10 classification for dependency indicates that three or more of the following should be present when measuring the severity of dependence:

1. A strong desire or sense of compulsion to take the substance;
2. Difficulties in controlling substance-taking behavior in terms of its onset, end or levels of use;
3. The substance is often taken in larger amounts or over a longer period than was intended;
4. Any unsuccessful effort or a persistent desire to cut down or control substance use;

5. Increased amounts of time needed to obtain or take the substance or recover from its effects; also progressive neglect of alternative pleasures or interests;
6. Persisting with substance use despite evidence of overtly harmful consequences.

Physical Assessment

Assessment instruments assist in gathering consistent information, clarifying and elaborating on information obtained through the patient history and physical examination, and establishing a baseline against which patient progress can be monitored. The health care provider might notice acute symptoms such as anxiety, agitation and tremor when performing a physical assessment of a patient abusing controlled substances. A *multidimensional* approach to assessment ensures that the variety of factors that impinge on an individual's substance abuse (pattern, and history of use; signs and symptoms of use; and consequences of use) are considered when evaluating individual patient problems and recommending treatment (Institute of Medicine, 2009).

Drug Abuse and Misuse

The key to drug abuse and misuse is early intervention. Early intervention will result in excellent outcomes. Addiction is a “chronic, relapsing brain disease”, which has implications not only as an individual health problem, but also as a public health problem. It impacts the drug abuser and the community on a physical, mental, psychological and social level (Qureshi, Al-Ghamdy, & Al-Habeeb, 2000). A primary, chronic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. The disease is often progressive and fatal. It is characterized by continuous or periodic impaired control over drinking, preoccupation with the drug, and use of the drug despite adverse consequences and

distortions in thinking, most notably denial. Nearly half of all individuals diagnosed with substance abuse or disorder also have co-occurring mental health issues (samhsa.org).

Health care providers play a pivotal role with identifying “red flags” for example, nasal inflammation, perforation or bleeding, unexplained bruises, needle marks, enlarged liver, hepatitis, cirrhosis, and withdrawal symptoms. The use of Screening, Brief Intervention, & Referral to treatment (SBIRT) is a science-based, preventive care approach used to identify people at high risk for unhealthy illicit drug use. SBIRT should be used to identify at risk patients. When at risk patients are identify counseling and referral should be initiated promptly.

Using the Universal Precautions for Prescribing Control Substances

1. Make a diagnosis, identify treatable causes of pain.
2. Perform a psychological assessment including risk of addictive disorders.
3. Discuss urine drug testing with all patients.
4. Informed consent: benefits and risks of treatment.
5. Verbal or written treatment agreement reviewing the expectations and obligations of both the prescriber and the patient.
6. Emphasize that opioid therapy is initially a therapeutic trial based on clinical goals.
7. Have a rational plan for appropriate use of opioid therapy and adjunctive medications
8. Regular reassessment of pain score and level of function Corro- borate with third parties if possible.
9. Regularly assess the “5 A’s” of pain medicine
 - a. Analgesia
 - b. Activity

- c. Adverse effects
 - d. Aberrant behavior
 - e. Affect
10. Periodically review the patient's diagnosis and comorbid conditions, including addictive disorders.
11. Documentation of initial and ongoing assessments (Gourlay et al., 2005).

Prevention of Prescription Substance Illegal Use and Abuse

Prescription drug monitoring programs (PDMPs), state-run electronic databases are used to track the prescribing and dispensing of controlled prescription drugs to patients. PDMPs are also important tools for preventing and identifying prescription drug misuse. While research regarding the impact of these programs is currently mixed, the use of PDMPs in some states has been associated with lower rates of opioid prescribing and overdose, though issues of best practices, ease of use, and interoperability remain to be resolved (Rasubala, Pernapati, Velasquez, Burk, and Ren, 2015; Johnson, Paulozzi, Porucznik, Mack, and Herter, 2014).

In 2015, the federal government launched an initiative directed toward reducing opioid misuse and overdose, in part by promoting more cautious and responsible prescribing of opioid and CSs medications. In line with these efforts, in 2016 the Centers for Disease Control and Prevention (CDC) published its CDC Guideline for Prescribing Opioids for Chronic Pain to establish clinical standards for balancing the benefits and risks of chronic opioid treatment (Dowell, Haegerich, & Chou, 2016). Preventing or stopping nonmedical use of prescription drugs is an important part of patient care. However, certain patients can benefit from prescription

stimulants, sedatives, or opioid pain relievers. Therefore, physicians should balance the legitimate medical needs of patients with the potential risk for misuse and related harms.

The Model policy for the use of controlled substances for the treatment of pain was adopted in 1998 and updated in 2004 by the Federation of State Medical Boards with the goal of promoting consistency in state medical board policy. As of March 2008, 32 states have adopted the Policy in whole or in part (Pain & Policy Studies Group, 2008, p. 15). Healthcare providers that adhere to these guidelines when prescribing CSs can assistance in the prevention of prescription substance illegal use and abuse.

Model Policy For The Use of Controlled Substances For The Treatment of Pain	
Guideline #1	Evaluation of the patient Health history and physical exam must be obtained and documented in the medical record, along with the medical indication for treatment with a controlled substance (CS).
Guideline #2	Treatment plan A written treatment plan should state objectives that will determine treatment success, such as pain relief, improved physical and psychosocial function.
Guideline #3	Informed consent and agreement for treatment Discuss risks and benefits of use of CSs. Prescriptions should be from one provider and one pharmacy when possible. Consider use of a written agreement.
Guideline #4	Periodic Review Periodically review the course of pain treatment for progress or lack of progress toward treatment goals.
Guideline #5	Consultation Refer the patient for additional evaluation and treatment in order to reach treatment objectives. Special attention should be given to those patients at risk for medication misuse, abuse, or diversion.
Guideline #6	Health Records Keep accurate records to include the above-listed items. In addition, records should include medications prescribed, instructions, treatment agreements.
Guideline #7	Compliance with Controlled Substances Laws and Regulations The provider must be licensed and comply with applicable federal and state regulations. (Advanced Practice Registered Nurse as a Prescriber, edited by Marie Annette Brown, and Louise Kaplan, Wiley, 2011).

Monitoring the Use of Controlled Substances

Monitoring the use of control substance by the patient requires several steps by the health care provider. According to the American College of Preventive Medicine, (2011) studies have shown that frequent and ongoing monitoring of the use of controlled substances decreases the risk of illicit drug use and drug abuse. These steps includes:

- a. Control of the Drug- The health care provider is in control of regulating how much medication to dispense and is responsible for writing the dose and schedule of how often the patient takes the drug on the prescription.
- b. Monitor Refills- The health care provider all with other members of the health care team (pharmacist) should monitor the number of refills that the patient uses, as well as the number of refills the patient attempts to make (even if more refills are not allowed).
- c. Documentation – Documentation is an essential step in recording a completed assessment of the patient and the reasons for the type and amount of drug prescribed. Documentation should include:
 1. Conversations regarding the control substance prescribes.
 2. Any adverse reaction the prompts additional or alternative prescriptions for control substances
 3. How often refills being requested by the patient
 4. Documentation of education provided to the patient regarding medication.
 5. Purpose of the medication and its use.

6. If a patient uses controlled substances inappropriately or develops a drug addiction, the healthcare provider is required to report the situation to the appropriate authorities.
7. In Florida If you prescribe Control substances for “chronic non-malignant pain” then you must register as “Designated control substances Prescribing Practitioner” through the MQA Online Services website. Under “My Dashboard” scroll down to “Manage My License” and in the dropdown with your license no. “Choose Activity” and click on “Controlled Substance Prescribing”. Follow the prompt “Controlled Substance Prescribing” and you’ll see the statute language listed. Click on the box and answer yes or no. (You can upload your new protocol here as well whether you’re prescribing for chronic pain or not.) [Florida Nurse Practitioner Network](#)

Summary

According to the United States Department of Justice Office of Diversion Control (2016) currently, there are 37 states that have working prescription drug monitoring programs in place. Each individual states have prescription drug monitoring programs in place that assist with supervising patient use of medications and controlled substances. Programs may vary from state to state therefore, it is imperative for health care provider to be familiar with the programs by administrative, regulatory, or law enforcement agencies within the state government. The state programs are designed to decrease the risk of drug abuse by identifying signs that patients are



misusing drugs or developing symptoms of addiction, supporting the access to legal prescription controlled substances to better prevent illicit drug use, encouraging the identification and treatment of people who have become addicted to controlled substances, and educating the public and communities at large about the dangers of prescription drug abuse and the purposes of the drug monitoring program.

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