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Responsible Controlled-Substance Prescribing

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LEARNING OBJECTIVES

- Define opioid abuse and addiction.
- Explain how opioid abuse presents in the healthcare setting.
- Identify patient factors that increase the risk for development of opioid use disorder.
- Demonstrate effective teaching techniques for patients using or requiring opioids for pain control.
- Design a pain management strategy for a patient that minimizes risk of opioid misuse and addresses the need to control pain.
- Assess patient behaviors that would prompt referral to a professional for substance addiction and abuse.

INTRODUCTION

A perfect storm of challenges led to America's opioid crisis, which continues to claim the lives of about 130 Americans each day.[1] The origins of the opioid epidemic are both complex and multifactorial. In 2018, the federal government declared a nationwide public health emergency to curb the opioid epidemic. Yet, despite a public outcry, opioid overdose rates are rapidly accelerating. According the Centers for Disease Control and Prevention (CDC), about 40% of opioid-related deaths can be attributed to prescriptions of opioids.[1] Some populations are more affected than others. For example, the black community has experienced the largest surge in opioid overdose deaths among any racial and ethnic group.[2] Because of the highly addictive nature of opiates/opioids and their dangerous side effects, there appears to be a concerted effort by commercial health plans, pharmacy benefit managers, Centers for Medicare and Medicaid Services (CMS), and policy makers to decrease the use of opioid prescriptions. But has the national campaign on combating the opioid epidemic resulted in changing prescriber behavior? Despite growing awareness and several abuse-prevention initiatives, opioid prescriptions have not substantially declined from their peaks and remain one of the most prescribed drug class in the United States.[3] This chapter provides effective strategies that promote responsible and conscientious controlled substance prescribing in the clinical setting.

BACKGROUND

The management of patients with acute and chronic nonmalignant pain represents a real challenge for practicing clinicians. The chronic use of opioids now carries an "addiction-related" stigma and concerns about efficacy and safety of opiates have been called into question. Overprescribing of opioids and opiates by clinicians in various disciplines remains a serious public health concern and a major contributor to the opioid epidemic. The largest prescribers of controlled substances are primary care clinicians. According to the 2013 Medicare Part D prescription drug coverage claims, family practice doctors issued slightly over

15 million prescriptions, while internal medicine physicians issued 12.8 million.[4] Excessive opioid prescribing may be in part due to significant limitations in medical education curricula and residency training around addiction and aberrant opioid use behavior.[5] Opioids are highly addictive, and the risk of long-term opioid use increases with subsequent prescriptions. For example, a second opioid prescription doubles the risk that a patient will continue to use opioids up to a year later.[6] Consequently, among patients taking a prescribed opioid for 90 days; at least 50% will still be taking opioids at 5 years.[7] In addition, opioid use can be a gateway toward substance use disorders, such as heroin addiction. Research showed that out of the estimated 2.4 million people who developed substance used disorders, nearly half a million suffer from heroin abuse.[8] Therefore, clinicians should consider adopting policies for opioid prescription during pain management that closely align with the current CDC guidelines. In addition, improving pain through effective communication strategies is critical when initiating opioid or nonopioid therapy.

OPIOID PRESCRIBING: ACUTE PAIN MANAGEMENT

The causes of acute pain are multifactorial and include surgery, infection, soft tissue injury, fractures, dental, and joint pain. When addressing pain symptoms, clinicians should solicit a thorough patient history, pain characteristics, quality of the pain, comorbidities that may exacerbate the pain, clinical efficacy of prior pain therapy, and any current *controlled substance agreement* with a prescribing clinician. The major goals in managing any pain are to provide sufficient analgesia to relieve pain and improve function. For example, patients with acute musculoskeletal pain from strains, sprains, contusions, dislocations, and simple fractures, unless contraindicated, can be treated with a short duration of acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs) alone or in combination. See Chapter 22 for a discussion of acetaminophen and NSAIDs. In addition, overprescribing of controlled substances for acute pain may have far reaching legal implications.[9]

A synopsis of the literature shows that NSAIDs reduce concurrent opioid requirements and shorten hospital length of stay.[10] Furthermore, acetaminophen (Tylenol®) and NSAIDS have been shown to have good efficacy in improving both pain and function without interfering with fracture healing.[11,12] In one study of 60 patients with ankle fractures, researchers concluded that those who used nonopioid medication reported less pain than those who used opioids.[13] But if opioids are needed to address acute pain, clinicians should review a patient's prescribing history through a Prescription Drug Monitoring Program (PDMP) system prior to prescribing an opioid.[14] The CDC recommends that clinicians prescribe the lowest effective dose of immediate-release-opioids for 3 days for most patients and up to 7 days for patients with nontraumatic pain unrelated to major surgery.[14] Interestingly, major nationwide retail chains and health maintenance organizations (HMO) in the United States, such as Walmart, Sam's Club, and Kaiser Permanente have aligned their pharmacy policies to coincide with the CDC recommendations and now restrict initial acute opioid prescriptions to no more than a 7-day supply. This trend will eventually be seen in other pharmacy corporations as time goes on and more clinicians are adopting these recommendations.

OPIOID PRESCRIBING: CHRONIC PAIN MANAGEMENT

Nonmalignant chronic pain is classified as persistent or recurrent pain lasting longer than 3 months.[15] According to the American Pain Foundation, nearly 50 million Americans are afflicted with chronic pain. The four most common causes of chronic pain include headaches, back, joint, and nerve pain.[16,17] Patients using long-term opioids to address chronic pain may report worsening pain as compared to those using other pain management modalities.[18] The utility of opioid therapy in chronic pain remains controversial. The CDC has issued guidelines to clinicians recommending nonopioid and nonpharmacologic treatments as the preferred treatment options for chronic pain.[14] Clinicians should be cautious in considering opioid analgesics for mechanical back pain, hip and knee arthritis.[19,20] Research clearly demonstrates that chronic opioid consumption prior to total joint arthroplasty has been associated with worse outcomes, such as readmission, infection, stiffness, and aseptic revision.[21,22] In addition, studies have demonstrated that long-term opioid use for chronic pain was associated with higher healthcare utilization, lower activity levels, and worsening of the pain.[23,24] Furthermore, persistent use of controlled substances, especially schedule II agents, or the commonly prescribed tramadol (schedule IV), is a substantial risk factor for fracture nonunion.[25] Tramadol may also precipitate seizures and/or hyponatremia, especially in elderly patients.

Amid these growing concerns, the mainstay of nonmalignant chronic pain management should consist of nonopioid alternatives such as topical analgesics (e.g., diclofenac cream, capsaicin), acetaminophen, antispasmodics, targeted peripheral topical analgesic patches (e.g., lidocaine 5%), trigger-point injections, and NSAIDs.[14] Research seems to suggest that opioids are no more effective than acetaminophen in addressing chronic back and symptomatic osteoarthritis.[26] It should be noted that NSAIDs can cause dyspepsia and even peptic ulcer disease (see Chapter 22 for a discussion of NSAID prescribing). Additional nonpharmacologic approaches such as physical therapy (PT), home exercise programs, cognitive behavioral therapy, and sleep hygiene can also aid in the reduction of chronic pain. Lastly, patients for whom these and other nonopioid alternatives are ineffective should be referred to a pain management specialist for consideration of other modalities such as opioids, spinal cord and peripheral nerve stimulation, nerve blocks, and radiofrequency denervation.[27,28]

CONTROLLED-SUBSTANCE PRESCRIBING: SAFETY IMPROVEMENT

Clinicians should avoid concurrent benzodiazepine and opioid prescribing as this elevates the risk of overdose. Patients requiring opioid therapy beyond 90-mg morphine equivalents should receive naloxone (opioid antagonist) to combat potential unintended consequences of opioid treatment.[14] Also, it is important to avoid prescribing opiate medications to a patient who has a signed *controlled substance agreement* with another prescriber. Patients who have signed such agreements have consented to having their pain relief needs met by one clinician (e.g., pain management specialist). Additionally, clinicians should exercise caution when prescribing opioid therapy to patients taking cannabinoids as it is unknown whether these products alter plasma opioid levels.

STRATEGIES TO MITIGATE CONTROLLED-SUBSTANCE MISUSE

Research shows that 52% of Americans misused prescription drugs in 2017, which is unchanged from 2016.[29] Opioid misuse often occurs when prescription opioids are shared, stolen, obtained illegally, or sold for a profit. In addition, combining opioids with medications used to treat anxiety or sleep can also contribute to misuse and lead to respiratory depression. Furthermore, opioid misuse is associated with an increased risk of infectious disease transmission such as HIV and Hepatitis C.[30]

There are various evidence-based strategies that clinicians can employ to prevent controlled substance misuse. One such strategy discussed earlier is the use of PDMPs. The PDMPs are state-run electronic databases used to combat opioid misuse by tracking the prescribing and dispensing of opioids. PDMPs differ in scope and design, for example, some PDMPs share data using prescriber "report cards," while others do not. The research on the impact of PDMPs is mixed, but in one study, the use of PDMPs in some states has been associated reductions in opioid use among Medicare beneficiaries compared with states that do not have the program.[31] Certain states such as California require mandatory review of a PDMP before subsequently prescribing a controlled substance and every 4 months for patients with uninterrupted use of opioids for chronic pain.

The second strategy in preventing opioid misuse is patient education. Prescribers should inform patients about correct opioid usage, potential dangers of nonrecreational medication sharing, "doctor shopping," and mixing opioids with other drugs to enhance psychoactive effects. Additionally, to reduce diversion of controlled substances, patients should be counselled on proper storage and disposal of unused opioid medications. A third strategy involves increasing access to medication-assisted treatment (MAT) for those presenting with opioid use disorder. MAT is part of a comprehensive multimodal treatment consisting of medications, counseling and behavioral therapies to address substance use disorders to curb opioid overdose rates. Clinicians should be familiar with how to identify opioid use disorder (as defined by the criteria of the *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition). Clinicians should have protocols in place for when to refer patients for MAT. These and other prevention strategies may mitigate opioid misuse.[14]

IMPROVING PAIN MANAGEMENT THROUGH EFFECTIVE COMMUNICATION

Communication about pain and opioids can be quite challenging in today's healthcare environment. Clinicians may find it difficult to understand the individual pain needs of their patients and negotiate a plan of care. Patients and healthcare clinicians have differing goals, opinions, and biases concerning treatment options.[32] A

2017 study found that a majority (60,8%) of prescribers surveyed did not feel confident managing patients with chronic pain.[33]

Patients afflicted by acute or chronic pain should be treated with the upmost respect and never demonized or classified as drug seekers, especially during difficult encounters. Mitigating potential or challenging encounters when treating chronic pain patients requires effective communication, which has been linked to better patient outcomes, improved ability to manage pain, and reduction in disability and opioid use.[34,35] In addition, effective and empathic communication can improve pain and anxiety in patients with acute and chronic pain syndrome.[35] Patients should have an active part in shared decision-making concerning their pain relief needs.

Effective communication may include nonverbal strategies. Clinicians should pay attention to social cues, such as altered facial expressions or body posture, coping skills, and how patients react to their pain. When negotiating chronic pain syndromes, clinicians should focus treatment strategies on maintaining an acceptable quality of life for their patients. This involves a clinical assessment of the patient's psychological and physical health. Patients with chronic nonmalignant pain should be assessed and treated for concurrent psychiatric disorders, which can exacerbate and influence the expression of pain. In addition, patients with mental health problems may not always follow their treatment plans. Taking time to engage the chronic pain patient should lead to a healthy dialogue that improves treatment adherence. A multimodal treatment plan with ongoing follow-up is needed to improve chronic pain syndromes and health outcomes.

In light of the ongoing opioid crisis, it is important to communicate and educate patients on the risks, benefits, and alternatives of opioid and nonopioid therapies. The benefits of nonopioid therapy as a first-line option in addressing acute and chronic pain have been supported by the literatures. However, in some cases, a patient may require opioids for legitimate medical purposes and therefore, clinicians should identify and address any implicit or explicit biases they may hold regarding the use of prescription opioids. **Box 9.1** provides several strategies that can be used to facilitate empathic communication regarding pain symptoms and treatment plans.

These and other strategies can help prevent under treatment of pain while improving physical and psychological outcomes. In addition, effective communication is the key to providing safe, satisfactory, high-quality healthcare.

BOX 9.1
STRATEGIES TO FACILITATE EMPATHIC COMMUNICATION REGARDING PAIN

Use empathic statements, such as:

- "I would be just as frustrated as you."
- "I understand this isn't easy."
- "We're going to work on this together."
- "We can make gradual changes and see what works for you."
- "We may not need to make abrupt or drastic changes at this time."

Consider your nonverbal communication, such as:

- Making eye contact
- Having appropriate, caring facial expressions
- Using a caring tone and pace
- Being mindful of your body posture

Source: Centers for Disease Control. Module 3. Communicating with Patients-Applying CDC's Guideline for Prescribing Opioids. March 26, 2020. https://www.cdc.gov/drugoverdose/training/communicating/; Centers for Disease Control and Prevention. Wide-ranging Online Data for Epidemiologic Research (WONDER). National Center for Health Statistics. 2017. http://wonder.cdc.gov

CONCLUSION

Responsible controlled substances prescribing should be an expectation for all prescribers. Systemic opioid analgesics should only be used when indicated. Alternative therapies should always be considered in cases of acute and noncancer chronic pain. There is little evidence to support the use of opioids in the treatment of osteoarthritis, simple fractures, strains, sprains, contusions, or dislocations. Moreover, the use of opioids to treat patients with chronic noncancer pain remains controversial due to concerns about efficacy and safety. If opioids are required to treat nonterminal pain conditions, the lowest effective dose of immediate-release opioids should be given for a short duration. Given the vast array of pharmacologic and nonpharmacological treatments on the market, it is important for clinicians to individualize pain treatment to the specific needs of their patients. This starts with effective communication strategies along with an honest assessment of the needs of the patient in addressing their acute and chronic pain based on the best practices and available evidence. The opioid-centric model of pain delivery has fallen out of favor. Prescribers should rethink how to best optimize communication and pain management strategies that improve the quality of patient care without jeopardizing pain treatment.

CASE EXEMPLAR: Patient with Traumatic Injury

MF is a 25-year-old graduate student who was involved in a motorcycle accident 2 days ago and sustained several injuries. He presented with the left femur fracture, multiple rib fractures bilaterally, and burst spine fractures at T4 and T5 levels. Upon arrival to the ED, his pain was 9/10 and marginally controlled with hydromorphone 1 mg every hour as needed. He had an episode of desaturation while in the ED; therefore, he was admitted to the ICU.

Past Medical History

- Significant for asthma since the age of 5

Family History

- Noncontributory

Social History

- Social alcohol use
- No tobacco use
- Occasional use of marijuana (legal in his state)
- Denies any other illicit drug use
- Occupation: Teaching assistant in the laboratory at the local pharmacy school

Physical Examination

- Blood pressure: 150/95; pulse: 95; respiration rate 18; temperature: 97.7°F
- Well-developed, well-nourished male in moderate distress due to pain
- Respiratory effort is reduced due to pain associated with rib fractures
- Examination is benign except for decreased mobility due to injuries

Labs

- Within normal limits,
- Blood alcohol: 0.24 mg/dL
- Urine: positive for methamphetamines and cannabinoids

Assessment

- A diagnosis of multiple fractures is made, and orthopedic surgery is planned to fix the injuries to the spine and left femur.
- Patient is complaining of severe pain "all over"; rates pain at 9/10. He describes pain as throbbing, sharp, with significant back spasm.
- Trauma surgeon started the patient on morphine by patient-controlled analgesia (PCA) with the following settings:
  - Morphine PCA dose, 2 mg
  - Lockout interval: 15 minutes
  - Maximum: Four doses/hour
  - Additional doses of morphine 4 mg were administered four times in the past 24 hours in response to the patient's loud complaints

Discussion Questions

1. What are the potential factors that may have contributed to the desaturation episode in the ED?
2. MF will more than likely become a patient with chronic pain after this incident. How should his chronic pain be managed after discharge? What are some strategies to mitigate the risk of opioid misuse?
3. What drug–drug interactions should a clinician avoid while considering an opioid as a pain reliever for this patient?
4. To proactively treat potential overdose of opioids, what medication should also be prescribed when opioids are prescribed or have escalated to this level?
5. What patient communication strategies should a clinician implement to optimize outcomes?

CASE EXEMPLAR: Patient with Osteoarthritis

SI is a 55-year-old female with advanced osteoarthritis of the right knee and left hip. She has mild osteoporosis as seen on plain films during evaluation of her joint pains. In years past, she was a competitive bodybuilder, but she has been unable to exercise because of her pain. She is contemplating total joint arthroplasty, initially for the hip and eventually for the knee. She ambulates with a cane.

Past Medical History

- Osteoarthritis
- Osteoporosis
- Hypothyroidism
- Depression
- Breast augmentation with abdominoplasty, complicated by prolonged post-operative pain
- Bunionectomy, complicated by prolonged postoperative pain
- Bilateral carpal tunnel release

Medications

- Levothyroxine, 100 mcg once daily
- Gabapentin, 600 mg TID
- Hydrocodone, 7.5 mg/acetaminophen 325 mg one to two tablets TID to QID
- Celecoxib, 400 mg once daily
- Bupropion, 300 mg once daily
- Calcium, vitamin D, multivitamins

Social History

- Smoker, half pack per day
- Alcohol, two to three glasses of wine per day
- Employed in retail; recently resigned because she could not climb the stairs to get to the time clock
- Married

Physical Examination

- Well-developed, well-nourished female in no distress
- Height: 66 inches; weight: 162 lbs.; blood pressure: 142/96; pulse: 80; respiration rate: 16; temperature 98.6°F
- Knee with palpable osteophytic spurs, 1+ effusion, decreased range of motion

Labs and Imaging

- Blood count, electrolytes, coagulation studies, rheumatoid studies negative
- X-ray shows extensive degenerative joint disease of the knee with narrowing, subchondral cysts, osteophytic spurs

Discussion Questions

1. Assess SI's risks related to her upcoming surgery.
2. Assess SI's risks for opioid dependence and abuse.
3. What can be done preoperatively to reduce SI's risks of opioid dependence postoperatively?

CLINICAL PEARLS

- When addressing pain symptoms, clinicians should solicit a thorough patient history, pain characteristics, quality of the pain, comorbidities that may exacerbate the pain, clinical efficacy of prior pain therapy, and a current *controlled substance agreement* with a prescribing clinician. The CDC recommends that clinicians prescribe the lowest effective dose of immediate-release-opioids for 3 days for most patients and up to 7 days for patients with non-traumatic pain unrelated to major surgery.
- Nonmalignant chronic pain is classified as persistent or recurrent pain lasting longer than 3 months.
- Chronic opioid use before or after major surgery is a risk factor for adverse surgical outcomes.
- A multimodal treatment plan with ongoing follow-up is needed to improve chronic pain syndromes and health outcomes.

KEY TAKEAWAYS

- The largest group of prescribers of controlled substances are primary care clinicians.
- If opioids are needed to address acute pain, clinicians should review a patient's prescribing history through a PDMP system prior to prescribing an opioid.
- The mainstay of nonmalignant chronic pain management should consist of nonopioid alternatives such as topical analgesics, acetaminophen, antispasmodics, targeted peripheral topical analgesic patches, trigger-point injections, and NSAIDs.
- When negotiating chronic pain syndromes, clinicians should focus treatment strategies on maintaining an acceptable quality of life for their patients, including a clinical assessment of the patient's psychological and physical health.

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