InforMed
Continuing Medical Education
By Colibri Healthcare

State Specific Continuing Medical Education

2023 Colorado Medical Licensure Program

- **2 Hours**
  Prescribing Opioids*

ACCME ACCREDITED

*Mandatory CME Requirement

Colorado physicians (MD/DO) who prescribe opioids must complete at least two (2) hours of training on Best Practices for Opioid Prescribing

CME FOR: *AMA PRA CATEGORY 1 CREDITS™* MIPS MOC STATE LICENSURE

CO.CME.EDU

CONTENTS

2023 COLORADO

CME that counts for MOC

Participants can earn MOC points equivalent to the amount of CME credits claimed for designated activities (see page iii for further details). InforMed currently reports to the following specialty boards: the American Board of Internal Medicine (ABIM), the American Board of Anesthesiology (ABA), the American Board of Pediatrics (ABP), the American Board of Ophthalmology (ABO), the American Board of Otolaryngology–Head and Neck Surgery (ABOHNS), and the American Board of Pathology (ABPath). To be awarded MOC points, you must obtain a passing score, complete the corresponding activity evaluation, and provide required information necessary for reporting.

$55.00	$50.00
ENTIRE PROGRAM	COURSE 1

DATA REPORTING: Federal, State, and Regulatory Agencies require disclosure of data reporting to all course participants. InforMed abides by each entity's requirements for data reporting to attest compliance on your behalf. Reported data is governed by each entity's confidentiality policy. To report compliance on your behalf, it's mandatory that you must achieve a passing score and accurately fill out the learner information, activity and program evaluation, and the 90-day follow up survey. Failure to accurately provide this information may result in your data being non-reportable and subject to actions by these entities.

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Two of the nation's top healthcare education providers have joined forces with one goal in mind: to offer physicians a state-of-the-art learning experience that fulfills your state requirements and empowers you with the knowledge you need to provide the best patient care.

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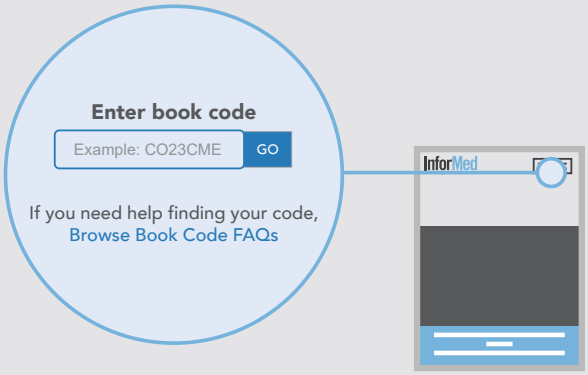
- If you already have an account created, sign in to your account with your username and password. If you do not have an account already created, you will need to create one now.
- Follow the online instructions to complete your self-assessment. Complete the purchase process to receive course credit and your certificate of completion. Please remember to complete the online evaluation.



Program Options	Code	Credits	Price
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Course 1	CO23CME-50	2	$50.00

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- Completions will be processed within 2 business days from the date it is received and certificates will be e-mailed to the address provided.
- Submissions without a valid e-mail will be mailed to the address provided.

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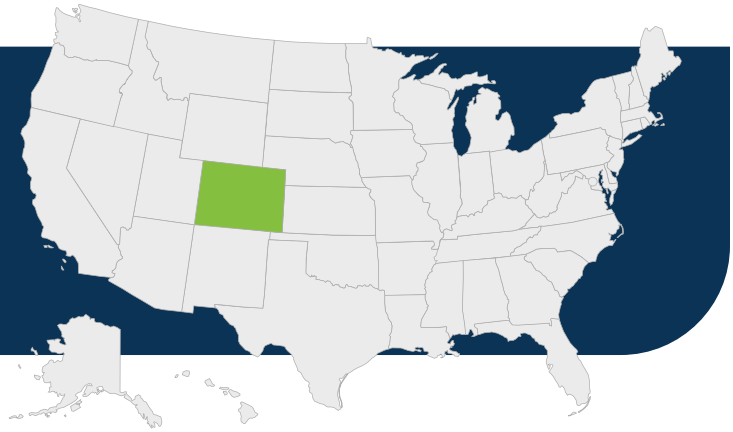
WHEN YOU NEED IT



Colorado Professional License Requirements

REQUIREMENT ON OPIOID PRESCRIBING

Every physician (MD/DO) is required to complete at least two (2) hours of training per license renewal period in order to demonstrate competency regarding the topics/areas specified in C.R.S. 12-30-114. These topics include: Best practices for opioid prescribing according to the most recent version of the division's guidelines for the safe prescribing and dispensing of opioids; recognition of substance use disorders; referral of patients with substance use disorders for treatment; and the use of the electronic prescription drug monitoring program. The current license cycle runs from 5/1/2021 to 4/30/2023.

Licensees who maintain a national board certification that requires equivalent substance use prevention training or attest that they do not prescribe opioids are exempt. For further information on this rule, visit:
https://www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=8594&fileName=3%20CCR%20713-44

What This Means for You:

Physicians (MD/DO) licensed by the state of Colorado who prescribe opioids must complete at least two (2) hours of training in prescribing opioids prior to renewal per C.R.S. 12-30-114, unless exempt.

We are a nationally accredited CME provider.
For all board-related inquiries please contact:

Colorado Medical Board
1560 Broadway, Suite 1350
Denver, CO 80202
P: (303) 894-7800

COMPLETION DEADLINE:
4/30/2023

LICENSE/TYPES
MD/DO

Disclaimer: The above information is provided by InforMed and is intended to summarize state CE/CME license requirements for informational purposes only. This is not intended as a comprehensive statement of the law on this topic, nor to be relied upon as authoritative. All information should be verified independently.

MOC/MIPS CREDIT INFORMATION

In addition to awarding *AMA PRA Category 1 Credits*™, the successful completion of enclosed activities may award the following MOC points and credit types. To be awarded MOC points, you must obtain a passing score and complete the corresponding activity evaluation.

Table 1. MOC Recognition Statements		
Successful completion of certain enclosed CME activities, which includes participation in the evaluation component, enables the participant to earn up to the amounts and credit types shown in Table 2 below. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting MOC credit.		
Board Programs		
MOCA®	**ABA**	American Board of Anesthesiology's redesigned Maintenance of Certification in Anesthesiology™ (MOCA®) program, known as MOCA 2.0®
ABIM CME MOC ACCREDITED	**ABIM**	American Board of Internal Medicine's Maintenance of Certification (MOC) program
	ABO	American Board of Ophthalmology's Maintenance of Certification (MOC) program
ABOHNS	**ABOHNS**	American Board of Otolaryngology – Head and Neck Surgery's Continuing Certification program (formerly known as MOC)
CME for ABPath CC	**ABPath**	American Board of Pathology's Continuing Certification Program
PART 2 MOC THE AMERICAN BOARD of PEDIATRICS	**ABP**	American Board of Pediatrics' Maintenance of Certification (MOC) program.

Table 2. Credits and Type Awarded							
Activity Title	***AMA PRA Category 1 Credits*™**	**ABA**	**ABIM**	**ABO**	**ABOHNS**	**ABPath**	**ABP**
Best Practices for Treating Pain with Opioid Analgesics	2 *AMA PRA Category 1 Credits*™	2 Credits LL	2 Credits MK	2 Credits LL & SA	2 Credits SA	2 Credits LL	2 Credits LL+SA
Improving Access to Care for LGBTQ Patients	2 *AMA PRA Category 1 Credits*™	2 Credits LL	2 Credits MK	2 Credits LL & SA	2 Credits SA	2 Credits LL	2 Credits LL+SA
Legend: LL = Lifelong Learning, MK = Medical Knowledge, SA = Self-Assessment, LL+SA = Lifelong Learning & Self-Assessment, PS = Patient Safety							

Table 3. CME for MIPS Statement
Completion of each accredited CME activity meets the expectations of an Accredited Safety or Quality Improvement Program (IA PSPA_28) for the Merit-based Incentive Payment Program (MIPS). Participation in this Clinical Practice Improvement Activity (CPIA) is optional for eligible providers.

BEST PRACTICES FOR TREATING PAIN WITH OPIOID ANALGESICS

COURSE DATES:	MAXIMUM CREDITS:	FORMAT:
Release Date: 10/2021 Exp. Date: 9/2024	*2 AMA PRA Category 1 Credits™*	Enduring Material (Self Study)

TARGET AUDIENCE

All health care professionals who participate in the management of patients with pain.

COURSE OBJECTIVE

To provide the fundamentals of acute and chronic pain management and a contextual framework for the safer prescribing of opioid analgesics that includes consideration of a full complement of non-opioid treatment options.

HOW TO RECEIVE CREDIT:

- Read the course materials.
- Complete the self-assessment questions at the end. A score of 70% is required.
- Return your customer information/ answer sheet, evaluation, and payment to InforMed by mail, phone, fax or complete online at program website.

LEARNING OBJECTIVES

Completion of this course will better enable the course participant to:

1. Discuss pain and comorbidity assessments as appropriate to the individual patient and pain type and duration.
2. Discuss an individualized treatment plan utilizing or considering a full range of medication and non-medication options.
3. Identify risk or presence of OUD before initiating or continuing opioid therapy for pain.
4. Recognize signs and symptoms of OUD, strategies for optimal management, and when to refer to a specialist.

ACCREDITATION STATEMENT

InforMed is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

DESIGNATION STATEMENT

InforMed designates this enduring material for a maximum of 2 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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COURSE SATISFIES

2

OPIOID PRESCRIBING

COLORADO SPECIAL DESIGNATION

This course satisfies two (2) hours on best practices for prescribing opioids.

Every physician (MD/DO) licensed by the state of Colorado who prescribes opioids is required to complete at least two (2) hours of training on best practices for prescribing opioids prior to renewal unless exempt.

DISCLOSURE OF INTEREST

In accordance with the ACCME Standards for Commercial Support of CME, InforMed implemented mechanisms, prior to the planning and implementation of this CME activity, to identify and resolve conflicts of interest for all individuals in a position to control content of this CME activity.

FACULTY/PLANNING COMMITTEE DISCLOSURE

The following faculty and/or planning committee members have indicated they have no relationship(s) with industry to disclose relative to the content of this CME activity:

- Beth Dove
- Michael Brooks

The following faculty and/or planning committee members have indicated they have relationship(s) with industry to disclose:

- Melissa B. Weimer, DO, MCR, FASAM has received honoraria from Path CCM, Inc. and CVS Health.

STAFF AND CONTENT REVIEWERS

InforMed staff, input committee and all content validation reviewers involved with this activity have reported no relevant financial relationships with commercial interests.

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The Challenge of Treating Pain

The experience of pain brings great physical and emotional suffering as well as significant societal costs. Some 50 million U.S. adults live with chronic daily pain, and 19.6 million experience high-impact pain that interferes with daily life and work.[1] Pain is even more common in military veterans, particularly those who have served in recent conflicts: 66% reported pain in the previous three months, and 9% had the most severe pain.[2] The national cost of pain is estimated at between $560 billion and $635 billion annually.[1]

Pain that is unremitting and without adequate treatment can lead to a multitude of problems for the person who suffers, including anxiety, depression, disability, unemployment, and lost income.[1] Certain populations are more vulnerable than others to developing more severe chronic pain and disability, including women, older adults, and individuals from minoritized racial and ethnic backgrounds,[3] who are also at risk for having their pain undertreated.[3] People who lack access to optimal pain care experience more complications in medical and psychiatric conditions.[1] Failure to give adequate care for pain from injury or surgery can prolong recovery times, leading to hospital readmissions and transition to chronic pain.[1]

The challenge of managing acute and chronic pain is complicated by an ongoing public health crisis related to opioid overdose, a category that includes prescription opioids, heroin, and illicitly-produced fentanyl and its analogues.[4] Numerous families have endured tragedy in the form of opioid-related overdose deaths, which doubled from more than 21,000 in 2010 to more than 42,000 in 2016.[4] As of 2019, of the approximately 71,000 drug-related overdose deaths in the United States, close to 50,000 of them involved opioids, more than 14,000 of which involved prescription opioids (Figure 1).[5] Over the past decade, the fatalities have been strongly driven by a proliferation of illicitly-produced high-potency synthetic opioids, but prescription opioids and other sedating medications, particularly benzodiazepines, also contributed to fatal overdoses.[6] In all, more than 136 Americans die every day from overdoses that involve a prescription or illicit opioid. Moreover, overdose deaths spiked during the COVID-19 pandemic, particularly deaths involving synthetic opioids.[7]

These grim statistics illustrate how important it is to keep potential public health consequences in mind when prescribing any type of controlled substance, including opioids. The economic burden of opioid misuse reaches $78.5 billion a year in healthcare, lost productivity, addiction treatment, and criminal justice costs.[8] As of 2018, more than 2 million Americans had an opioid-use disorder (OUD) involving prescription or illicit opioids. Of people age 12 or older in 2019, there were:[4]

- 1.6 million new individuals who misuse prescription pain relievers
- 949,000 new individuals who misuse prescription sedative-hypnotics
- 901,000 new individuals who misuse prescription stimulants

Many people who misuse opioids are not receiving regular medical care or prescribed opioids. Indeed, most people who are prescribed opioids for pain treatment do not misuse their medications. However, roughly 21% to 29% of patients prescribed opioids for chronic pain do misuse them, and between 8% and 12% of them develop an OUD.[9] Furthermore, an estimated 4% to 6% of people who misuse prescription opioids transition to non-prescribed opioid and/or illicit opioid use.[10-12] Approximately 75% to 80% of people who use heroin misused prescription opioids first.[10,11]

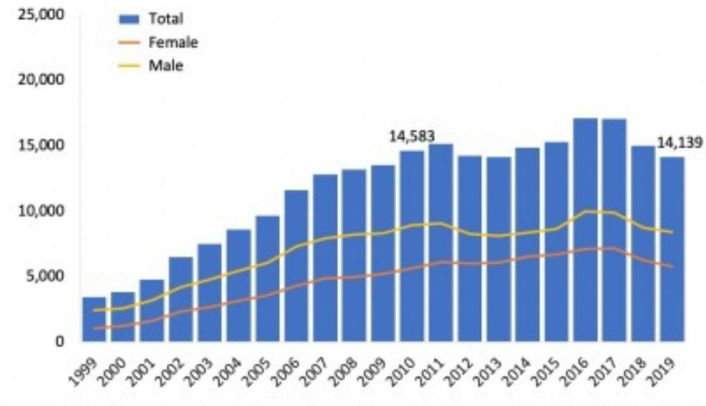
Health care practitioners (HCPs) play a key role in facilitating appropriate use of opioids and other sedating medications when prescribed for acute and chronic pain. Pain care is most effective when it combines multiple disciplines and utilizes a broad range of evidence-based pharmacologic and nonpharmacologic treatment options.[13,14] Opioids are associated with small improvements in pain and function versus placebo when used up to six months; however, evidence of longer-term effectiveness is limited, whereas increased harms from use beyond six months appear to be dose dependent.[4] Moreover, non-opioid options may bring equivalent or better patient outcomes with less risk: a comparative effectiveness review of evidence performed by the Agency for Healthcare Research and Quality found no difference in improvement in pain, function, mental health status, sleep, or depression when opioids versus non-opioid medications were used up to six months.[4]

At the same time, there is a recently recognized potential for harm in suddenly discontinuing or rapidly tapering doses in patients who have been on long-term opioids or in forcing patients who have been stable on higher doses to reduce to a set threshold dose.[1,15-17] It is also critical that HCPs recognize and optimally manage OUD when present. Distressingly few people who need treatment for substance-use disorder (SUD) are able to access it, and far more people need treatment for OUD than receive it. In 2012, the treatment gap was nearly a million people, with about 80% of opioid treatment programs nationally operating at 80% capacity or greater.[18] Solutions will include more accessibility of OUD treatment, including greater access to medications to treat OUD, and measures to prevent prescription and illicit drug misuse from developing in the first place.[19]

For acute pain and for some chronic pain, unresponsive to non-opioid therapies, opioids may form part of a customized treatment plan. A subset of patients may benefit from treatment with opioids long term, for example, during severe exacerbations of pain during the course of chronic conditions.[20] More than ever, HCPs are called on to optimize a range of available therapies and reserve opioids for when the benefits are expected to outweigh the risks and non-opioid options are inadequate.

This educational activity is built on core messages of the U.S. Food and Drug Administration's (FDA's) Blueprint for the Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS). It provides guidance on safely prescribing opioid analgesics, including all extended-release and long-acting (ER/LA) and immediate-release/short-acting (IR/SA) formulations. It is targeted to all HCPs who treat and monitor patients with pain, not prescribers alone. It stresses the importance of competence in considering and using a broad range of pharmacologic and nonpharmacologic therapeutic options for managing pain as well as in recognizing and managing OUD when indicated. The goal is to equip HCPs to recognize and manage any adverse events that may arise when a trial of potentially long-term opioids is part of a comprehensive treatment plan.

Figure 1. National Drug Overdose Deaths Involving Prescription Opioids* Among All Ages, 1999-2019[5]



*Among deaths with drug overdose as the underlying cause, the prescription opioid subcategory was determined by the following ICD-10 multiple cause-of-death codes: natural and semi-synthetic opioids (T40.2) or methadone (T40.3). Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2019 on CDC WONDER Online Database, released 12/2020.

Pain Definitions

The International Association for the Study of Pain (IASP) revised its pain definition in 2020 to better convey pain's nuances and complexities and to improve its assessment and management. The IASP defines pain as "an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage."[21] The IASP further describes pain as follows:[21]

- As a personal experience that is influenced to varying degrees by biological, psychological, and social factors
- As a separate phenomenon from nociception that cannot be inferred solely from activity in sensory neurons
- As a concept learned through the life experiences of individuals
- As an experience that should be respected
- As serving an adaptive role that may, nonetheless, have adverse effects on function and social and psychological well-being
- As existing independently of the ability to express its presence verbally, i.e., verbal description is only one of several behaviors to express pain, and inability to communicate does not negate the possibility that a human or a nonhuman animal experiences pain

There are no precise clinical markers for pain, which is experienced by the individual as a constellation of biological, psychological, and social factors that include race and ethnicity (Figure 2).[1] This biopsychosocial model is now preferred to an earlier era's biomedical model of pain care, which primarily aimed medical, procedural, and surgical treatments at a presumed biological pain generator in an attempt to fix or numb pain.[20] Given pain's complexity, it is important to perform a thorough patient evaluation so that the presumed or differential diagnosis is accurate in order to select the best therapeutic option.[1]

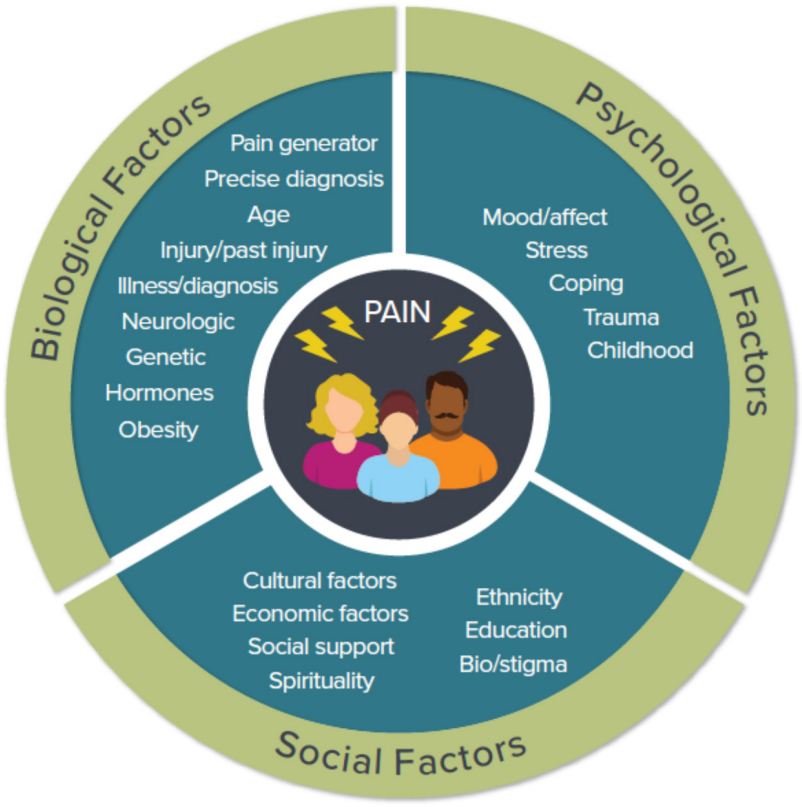
Pain is protective and essential for survival when understood as a warning signal that something has gone wrong in the body. However, when pain persists indefinitely the central nervous system (CNS) begins to sense, transmit, modulate, and interpret the pain experience differently.[14] When the nociceptors, or sensory receptors, become sensitized, they discharge more frequently. In peripheral sensitization, this state of heightened neuron excitability occurs at the site where the pain impulse originated in the body; in central sensitization, it occurs in the spinal neurons, which begin to fire spontaneously, resulting in pain that intensifies and lasts far longer than the stimulus applied.[14] Sensitization can result in hyperalgesia, where response to pain-causing stimuli is intensified, and allodynia, a pain response to stimuli that normally are not painful.[14] Therefore, the resulting pain comes not just from an injury site but from neural impulses. The pathologies created by central sensitization can persist and continue to generate pain impulses indefinitely, far outlasting pain's usefulness as a warning signal.

Pain Classifications

Pain can be categorized in several ways, including by type, duration, etiology, and pathophysiology.

- Acute pain is a physiologic response to noxious stimuli with a sudden onset and expected short duration.[1] It commonly occurs as a result of burn, trauma, musculoskeletal and neural injury, and after surgery or other procedures in the perioperative period.[1,20] Acute pain flares may also occur periodically in the course of chronic pain and medical conditions.[1] Anxiety and distress may exacerbate the acute pain experience.[22]
- Chronic pain lasts longer than normal healing and is generally diagnosed after persisting or recurring for longer than three-to-six months.[14]
  - Chronic pain's many possible causes include injuries, malignancies, chronic diseases, medical treatments or surgeries, or inflammation that appears as a result of injury or chronic disease.
  - Chronic pain may occur in the absence of a defined injury or cause.
  - Anxiety, depression, and stress are known to complicate the chronic pain experience.[1]
  - Chronic relapsing pain conditions have periods of remission and frequent relapses (e.g., various degenerative, inflammatory, immune-mediated, rheumatologic, and neurologic conditions such as multiple sclerosis [MS], trigeminal neuralgia, Parkinson's disease, complex regional pain syndrome [CRPS], porphyria, systemic lupus erythematosus, lumbar radicular pain, migraines, and cluster headaches).[1]
- Nociceptive pain is the normal response to any type of stimulus that results in tissue damage and includes visceral and somatic pain.[14] Examples of nociceptive or inflammatory pain include postoperative pain, osteoarthritis, mechanical low back pain, sickle cell crises, and pain from traumatic injuries.
  - Visceral pain is nociceptive pain that arises from the body's organs and may be cramping, throbbing, and/or vague.[14] Examples are pain related to myocardial infarction, pancreatitis, or cholecystitis.
  - Somatic pain, whether superficial or deep, is nociceptive pain that results from issues within the body's bone, joints, muscles, skin, or connective tissue; it may be localized and stabbing, aching, and/or throbbing.[14] Examples include mechanical low back pain, osteoarthritis, and muscle sprain or strain.
- Neuropathic pain results from damage to or abnormal processing of the CNS or peripheral nervous system and may be sharp, stabbing, burning, tingling, and/or numb.[14] Certain neuropathic pain conditions may be diagnosed as chronic pain before the three-month mark.[23] Examples include diabetic neuropathy, regional pain syndrome, or trigeminal neuralgia.

Figure 2. The Biopsychosocial Model of Pain[1]



- Referred pain spreads beyond the initial injury site and can have both nociceptive and neuropathic features.[14]
- Chronic pain may be primarily nociceptive or neuropathic, or have mixed nociceptive-neuropathic characteristics.

New Diagnostic Categories for Chronic Pain

Accurately diagnosing a pain condition can be challenging, particularly when the etiology or pathophysiology of the pain is not clearly understood. To systematically gather together all relevant codes for the management of chronic pain, new diagnostic categories in the International Statistical Classification of Diseases and Related Health Problems (ICD-11) take effect in January 2022.[24] These diagnostic categories are intended to assist HCPs in reaching an accurate diagnosis to better create an optimal treatment plan.

Per ICD-11, chronic pain is considered primary when pain has persisted for more than three months, is associated with significant emotional distress and/or functional disability, and is not better accounted for by another condition. Thus, in chronic primary pain, the pain is the chief complaint and disease in itself. A diagnosis of somatic symptom disorder, is not made on the basis of unexplained pain alone but requires positive psychiatric criteria. The six subgroups of chronic primary pain are:[24]

- Chronic primary pain
- Chronic widespread pain (e.g., fibromyalgia)
- Chronic primary visceral pain (e.g., irritable bowel syndrome)
- Chronic primary musculoskeletal pain (e.g., nonspecific low-back pain)
- Chronic primary headache or orofacial pain (e.g., migraine, tension-type headache, trigeminal autonomic cephalalgias)
- Chronic regional pain syndrome

Chronic pain is secondary when it may, at least initially, be a symptom of an underlying disease. A diagnosis may be made independent of biological or psychological contributors, unless another diagnosis better fits the symptoms. The six subgroups of chronic secondary pain are:

- Chronic cancer-related pain
- Chronic neuropathic pain
- Chronic secondary visceral pain
- Chronic posttraumatic and postsurgical pain
- Chronic secondary headache and orofacial pain
- Chronic secondary musculoskeletal pain

Chronic neuropathic pain is further subdivided by whether its origin is peripheral or central.[23] Peripheral neuropathic pain is caused by a lesion or disease of the peripheral somatosensory nervous and includes:[23]

- Trigeminal neuralgia is an orofacial pain condition of the trigeminal nerve with shooting, stabbing, or electric-shock-like pain that starts and ceases abruptly, and is triggered by innocuous stimuli.
- Chronic neuropathic pain after peripheral nerve injury is caused by a peripheral nerve lesion with history of nerve trauma, pain onset in temporal relation to the trauma, and pain distribution within the innervation territory.
- Painful polyneuropathy is caused by metabolic, autoimmune, familial, or infectious diseases, exposure to environmental or occupational toxins, or treatment with a neurotoxic drug (as in cancer treatment), or can be of unknown etiology.
- Postherpetic neuralgia is pain persisting for more than three months after the onset or healing of herpes zoster.
- Painful radiculopathy stems from a lesion or disease involving the cervical, thoracic, lumbar spine, or sacral nerve roots, commonly caused by degenerative spinal changes but also by numerous other injuries, infections, surgeries, procedures, or diseases.
- Other, not covered by above codes, includes carpal tunnel syndrome and disorders for which information is still insufficient to assign a precise diagnosis.

Central neuropathic pain is caused by a lesion or disease of the central somatosensory nervous system, and the pain may be spontaneous or evoked.[23] Central neuropathic pain conditions include:[23]

- Chronic central neuropathic pain associated with spinal cord injury
- Chronic central neuropathic pain associated with brain injury
- Chronic central post-stroke pain
- Chronic central neuropathic pain caused by MS
- Other, specified and unspecified

Conditions may be referenced under more than one category as with chronic painful chemotherapy-induced polyneuropathy, classed as cancer-related pain (by etiology) and also as neuropathic pain (by nature).

Although it is clinically useful to speak of chronic pain, it is important to remember that pain is a dynamic experience whose onset, maintenance, and exacerbation is not confined to set temporal categories.[25] Thus, patients who experience significant pain that lasts beyond typical healing periods or the three-month diagnostic period for chronic pain may improve with conservative measures. Conversely, some types of neuropathic pain or sudden onset pain from injury or disease does not require three months before treating the condition as chronic as the pain is likely to persist or recur indefinitely.[23] Because pain can be both a symptom and a disease, an accurate diagnosis is vital to treating the biologic source of pain when it is known and to expediting timely management of pain of uncertain origin.[25] All subtypes of chronic pain should be understood to have multiple biological, psychological, and social factors that contribute to the individual's pain experience, in keeping with the biopsychosocial framework.

Barriers to Effective Pain Care

The multimodal, multidisciplinary treatment approach is recognized as optimal for pain care; nevertheless, barriers to accessing this type of care for patients are numerous and entrenched in the health-care delivery system. It should be fully recognized that HCPs are asked to provide optimal pain care and lessen the risks from opioids in an environment that frequently provides inadequate support for practitioners and scant access for patients. A task force of health care associations convened by the American Medical Association to study and make recommendations to improve patient pain care described evidence-based care as "ensuring patients have access to the right treatment at the right time without administrative barriers or delay."[26]

Insurance barriers to providing optimal patient care are present in the policies of public and private payers and pharmacy chains as well as pharmacy benefits managers. These barriers include delays and denials from prior authorization, step therapy, treatment quantity limits, high cost-sharing, coverage limits and restrictive access for non-opioid and nonpharmacologic treatments for pain, and strict opioid limits enforced without regard to individual patient need.[26]

Barriers to the provision of nonpharmacologic therapies in particular include coverage that is absent or inadequate, unreceptive attitudes of HCPs and patients, and shortages of pain and behavioral health care specialists.[27]

An Inter-agency Task Force convened by the Department of Health and Human Services (HHS) to recommend best practices in pain care proposed several ways of addressing gaps:[1]

- Create clinical practice guidelines to better incorporate evidence-based complementary and integrative therapies into practice
- Improve insurance coverage and payment for different modalities on the basis of the best practices identified in new guidelines
- Improve coverage and payment for multidisciplinary team care coordination
- Expand access to treatment and geographical coverage via the use of telemedicine and other technological delivery methods for psychological and behavioral health interventions
- Increase the number and training of qualified practitioners in behavioral health and other evidence-based complementary and integrative disciplines
- Provide better education as well as time and financial support for primary care practitioners who give patients the sole available pain care in many parts of the country

Another barrier to pain care is the stigma in living with chronic pain, which is often cited by patients and their caregivers as a difficulty worsened by lack of objective biomarkers for pain, the invisible nature of the disease, and societal attitudes that equate acknowledging pain with weakness.[28] Compassion, empathy, and trust within a practitioner-patient relationship are key to navigating these challenges. It can help to offer education to the patient regarding the underlying disease processes of pain and to encourage them to seek help early for pain that persists beyond the expected time frame. When opioids are indicated, it is strategic to counsel patients that opioids are an appropriate part of their pain treatment plan so that the stigma of the societal opioid crisis does not interfere with appropriate treatment and good outcomes for the patient regarding opioid use.[20]

Treatment Options for Managing Pain

The HHS Inter-Agency Task Force on best practices in pain management categorizes options for pain treatment as medication, restorative, interventional, behavioral health, and complementary and integrative.[1] Medications include opioid and non-opioid pharmacologic treatments. What follows are examples of each (not an exhaustive list) and a brief discussion of the evidence base underpinning these options.

Nonpharmacologic Options for Pain

A number of evidence-based nonpharmacologic treatments are recommended, either used alone or in combination with other modalities within a treatment plan that is individualized and draws from multiple disciplines (Table 1).[1,29,30] Nonpharmacologic options should not be considered "alternatives" to opioids but are encouraged as part of a comprehensive pain plan in keeping with the evidence base, patient access to competent practitioners, and adequate insurance coverage and reimbursement.

Frequently covered modalities for chronic pain include cognitive behavioral therapy (CBT), physical therapy, certain injections, exercise, and electrical stimulation.[29] Patients may find it helpful to combine approaches that include nutritional support, healthy lifestyle changes, patient education, sleep hygiene instruction, and relaxation and visualization techniques. The noninvasive nature and low side effect profile of nonpharmacologic treatments suggest they should be used first and preferentially.

Restorative Therapies

Physical and occupational therapy are recommended for acute and chronic pain and are best combined as part of a multidisciplinary treatment plan after a thorough assessment.[1] Traction is frequently used as part of physical therapy and, although evidence that it is clinically effective is lacking, the HHS Inter-Agency Task Force suggests it should be investigated separately and considered as a treatment modality for low-back or neck pain.[1] Unfortunately, despite evidence of improved outcomes, use of these physical and occupational therapies is frequently challenged by incomplete or inconsistent reimbursement policies, and policymakers have been asked to look more closely at improving payer polices.[1]

There is high-quality evidence that therapeutic exercise improves outcomes over bed rest.[1] Principally investigated as a treatment for spinal pain, therapeutic exercise has been shown help patients function better and to help them overcome the anxiety and fear of movement that worsen pain and disability.

Transcutaneous electric nerve stimulation research is plagued by a lack of high-quality, unbiased studies, and overall evidence of efficacy is limited.[1] It has been investigated for treatment of acute low-back pain, postpartum pain, phantom limb pain, and knee osteoarthritis, and, despite limited evidence, can be considered among the safer self-care options with appropriate patient education.[1]

Massage therapy includes Swedish, shiatsu, and deep tissue or myofascial release types. A systematic review found massage can be effective in the general population for pain, anxiety, and to improve health-related quality of life compared to sham, no treatment, and active comparators.[31]

The application of cold and heat is a standard approach in relieving the symptoms of acute pain. Evidence supports use of cold therapy to reduce pain after surgery and heat wraps to relieve pain symptoms and increase function in acute low-back pain.[1]

The evidence has not been robust that therapeutic ultrasound is more effective than placebo for musculoskeletal pain conditions; however, recent findings show it can be effective in relieving knee osteoarthritis.[1] Nonrigid bracing may improve function and is unlikely to cause muscle atrophy when used for short periods.[1]

Interventional Options

Interventional pain management describes a variety of techniques that vary in terms of their invasiveness. Techniques may use image-guided technology to help diagnose and treat sources of acute and chronic pain. Such treatments may help minimize the use of oral pain medication, including opioids, but have risks as well as advantages that should be understood and discussed with patients. Low complexity interventions include:

- Trigger point injections, usually composed of an anesthetic like lidocaine, disrupt the tense bands of skeletal muscle fibers that produce pain and can be used to treat headaches, myofascial pain syndrome, and low-back pain.[1]
- Joint injections, often of corticosteroid into various joints, which are useful for inflammatory arthritis and basal joint arthritis.[1]
- Peripheral nerve injections, which are injections of local anesthetic agents or other medications by single injection or continuously by catheter, frequently delivered perioperatively and also useful for treatment or prevention of peripheral neuropathies, nerve entrapments, CRPS, headaches, pelvic pain, and sciatica.[1]

Medium complexity interventions include:

- Facet joint nerve blocks as common diagnostic and therapeutic treatments for facet-related spinal pain of the low back and neck.[1]
- Epidural steroid injections to deliver anti-inflammatory medicine to the epidural space, which are frequent treatments for back and radicular pain and have been shown to reduce need for health care visits and surgeries, although risks should be weighed and discussed with the patient.[1]
- Radio-frequency ablation, which uses needles to deliver high-voltage bursts of energy near nerves to block pain transmission and has shown promise for cervical radicular pain.[1]
- Regenerative/adult autologous stem cell therapy, which is a promising area of research for many painful conditions.[1]

Table 1. Noninvasive, Nonpharmacologic Approaches to Pain Management[1]

Restorative	Behavioral Health	Complementary and Integrative
• Physical therapy • Occupational therapy • Physiotherapy • Therapeutic exercise • Transcutaneous electric nerve stimulation • Massage therapy • Traction • Cold and heat • Therapeutic ultrasound • Bracing • Chiropracty	• Cognitive behavioral therapy • Acceptance and commitment therapy • Mindfulness-based stress reduction • Emotional awareness and expression therapy • Self-regulatory/psychophysiological approaches: • Biofeedback • Relaxation training • Hypnotherapy	• Acupuncture • Massage, manipulative therapies • Mindfulness-based stress reduction • Spirituality • Tai chi • Yoga • Reiki

- Cryoneuroablation, which uses a cryoprobe to freeze sensory nerves at the source of pain to provide long-term pain relief and may be considered for numerous intractable pain conditions that include paroxysmal trigeminal neuralgia, chest wall pain, phantom limb pain, neuroma, peripheral neuropathy, knee osteoarthritis, and neuropathic pain caused by herpes zoster.[1]
- Neuromodulation, which delivers stimulation to central or peripheral nervous system tissue and has shown efficacy in low-back and various headache disorders.[1]

High complexity interventions include:

- Spinal cord stimulators, which are devices to deliver a form of neuromodulation that has demonstrated efficacy in low-back and lower extremity pain[1]
- Intrathecal pain pumps, which can deliver opioids (and other medications) into the spinal fluid with fewer side effects and at lower doses than with oral opioids, although significant side effects such as delayed respiratory depression, granuloma formation, and opioid-induced hypogonadism can occur.[1]
- Vertebral augmentation, which uses various techniques, including injecting cement into vertebral compression fractures that are painful and refractory to treatment.[1]
- Interspinous process spacer devices, which can provide relief for patients with lumbar spinal stenosis with neuroclaudication.[1]

Behavioral Health Options

There is ample evidence that chronic pain is both associated with and complicated by psychiatric, psychological, and social factors that exert tremendous influence over the pain experience and the success of treatment.[32-34] The higher the impact of pain, the worse the disruption to the person's relationships, work, physical activity, sleep, self-care, and self-esteem.[1] Those with comorbidities that include depressive and anxiety disorders face additional challenges that complicate treatment by worsening pain and quality of life and rendering the activities of daily living more difficult. An estimated 30% of patients with chronic pain also have an anxiety disorder, such as generalized anxiety disorder, panic disorder, post-traumatic stress disorder (PTSD), and agoraphobia.[1]

Furthermore, high levels of depression and anxiety worsen pain and pain-related disability.[35] Patients with chronic pain have more disability than patients with other chronic health conditions.[1] In addition, patients with chronic pain are at increased risk for psychological distress, maladaptive coping, and physical inactivity related to fear of reinjury.[32] Behavioral therapies are valuable for helping patients cope with the psychological, cognitive, emotional, behavioral, and social aspects of pain.

Common behavioral health approaches include:

- Behavioral therapy for pain, which seeks to reduce maladaptive pain behaviors, such as fear avoidance, and increase adaptive behaviors with the goal of increasing function; it has demonstrated effectiveness (and cost-effectiveness) for reducing pain behaviors and distress and improving overall function.[1]
- CBT, which focuses on shifting cognitions and improving pain coping skills in addition to altering behavioral responses to pain; CBT is effective for a variety of pain problems (including low-back pain and fibromyalgia), helps improve self-efficacy, reduces pain catastrophizing, and improves overall functioning.[1,30,36]
- Acceptance and Commitment Therapy, which emphasizes observing and accepting thoughts and feelings, living in the present moment, and behaving according to one's values; it differs from conventional CBT in that psychological flexibility is created through accepting rather than challenging psychological and physical experiences.[1,37,38]
- Mindfulness-based stress reduction (MBSR), which stresses body awareness and training in mindfulness meditation (i.e., nonjudgmental awareness of present-moment sensations, emotions, and thoughts), typically delivered in group format; research suggests effectiveness for coping with a variety of pain conditions (including rheumatoid arthritis, low-back pain, and MS) as well as improvements in pain intensity, sleep quality, fatigue, and overall physical functioning and well-being.[1,36,39-43]
- Emotional awareness and expression therapy, which is an emotion-focused therapy for patients with a history of trauma or psychosocial adversity who suffer from centralized pain conditions; patients are taught the effect of unresolved emotional experiences on neural pathways involved in pain and how to adaptively express those emotions.[1] Research indicates a positive impact on pain intensity, pain interference, and depressive symptoms.[44]
- Self-regulatory or psychophysiological approaches, which include biofeedback, relaxation training, and hypnotherapy, help patients develop control over their physiologic and psychological responses to pain.[1]
  - Biofeedback, which provides real-time feedback about physiologic functions such as heart rate, muscle tension, skin conductance, and has evidence of effectiveness for chronic headache in adults and children.[1,45]
  - Relaxation training and hypnotherapy, which alter attentional processes and heighten physical and psychological relaxation, and have empirical support in pain management.[1]

Complementary and Integrative Health Approaches

These therapies can be overseen by licensed practitioners and trained instructors and are used as standalone treatments or in combination with a multidisciplinary plan.[1] The following treatments may be considered for acute and chronic pain, according to patient status:[1]

- Acupuncture, which involves manipulating a system of meridians where "life energy" flows by inserting needles into identified acupuncture points; with its origins in Chinese medicine, acupuncture is received by an estimated 3 million Americans each year.[46] There is growing evidence of the therapeutic value of acupuncture in pain conditions that include osteoarthritis, migraine, and low-back, neck, and knee pain; however, existing clinical practice guidelines differ in their evidence analysis and recommendations for acupuncture use.[1] Risks are minimal when performed by a licensed, experienced, well-trained practitioner using sterile needles.[1]
- Massage and manipulative therapies, including osteopathic and chiropractic treatments, which may be clinically effective for short-term relief and are recommended in consultation with primary care and pain management teams.[1] Despite the paucity of rigorous studies, the lack of detail on massage types, and the smallness of sample sizes, positive effects of massage are recognized for various pain conditions that include postoperative pain, headaches, and neck, back, and joint pain.[1,47-50]
- MBSR, which is also discussed under behavioral health approaches, and which has evidence of statistically-significant beneficial effects for low-back pain, and is shown in a meta-analysis to significantly reduce the intensity and frequency of primary headache pain.[36,51]
- Yoga, which uses stretching, breathing, and meditation and has been shown to be therapeutic in the treatment of various chronic pain conditions, particularly low-back pain.[52-55] Risks are minimal, and yoga can generally be practiced safely, especially when delivered in group settings.[1,56]
- Tai chi, which originated as a Chinese martial art and uses slow movements and meditation, and which has demonstrated long-term benefit for osteoarthritis and other musculoskeletal pain conditions.[57,58] Like yoga, it is generally safe and has the benefits of a group setting and/or availability via telehealth.[1]
- Spirituality, which encompasses a broad range of resources and practices, such as prayer and meditation, has growing evidence of benefit for people with pain.[59]

  It has long been integral to palliative and supportive care, and is gaining support as a means to help patients cope with and manage ongoing pain.[1]

Non-Opioid Pharmacologic Options for Pain

Numerous non-opioid pharmacologic therapies are available for pain, and these should be tried or considered, alone or in combination, before initiating long-term opioid therapy.[1]

Acetaminophen (ACET) is used to treat mild-to-moderate pain without inflammation. All ACET products carry an FDA-required black box warning highlighting the potential for severe liver damage and potential for allergic reactions.[60] HCPs and patients should be aware of the dose levels from all prescribed and over-the-counter medication sources to avoid exceeding the recommended daily dosage.

Nonsteroidal anti-inflammatory drugs (NSAIDs) include aspirin, ibuprofen, naproxen, and cyclooxygenase-2 (Cox-2) inhibitors and are used to treat mild-to-moderate pain and inflammation. Indications are numerous and include arthritis, bone fractures or tumors, muscle pains, headache, and acute pain caused by injury or surgery.[1] Nonselective NSAIDs are those that inhibit the activity of both COX-1 and COX-2 enzymes and can be associated with gastritis, gastric ulcers, and gastrointestinal (GI) bleeding.[1] COX-2 inhibitors have fewer GI adverse effects.[1] Risks are elevated with NSAIDs for heart attack, stroke, GI bleeding or perforation, and renal and cardiovascular abnormalities, particularly at higher doses and longer duration of use.[61]

Anticonvulsants, such as gabapentin and pregabalin, have mild-to-moderate benefit for neuropathic pain syndromes, including postherpetic neuralgia and peripheral neuropathy and are also commonly used to treat migraine and as part of a multimodal approach to treating perioperative pain.[1] Adverse effects include drowsiness, cognitive slowing,[29] and a risk of misuse, particularly in people with a history of misusing opioids.[62] Gabapentin dose should be adjusted in chronic kidney disease.

Antidepressants, including selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), and tricyclic antidepressants, are used in low doses for insomnia and neuropathic pain. Doses are typically lower for analgesia than those required to treat depression. SSRIs (e.g., fluoxetine, sertraline, citalopram, and paroxetine) have less analgesic effect compared with other antidepressant classes.[1] SNRIs (e.g., venlafaxine, duloxetine) are effective for a variety of chronic pain conditions, including musculoskeletal pain, fibromyalgia, and neuropathic pain, and are associated with less drowsiness, memory impairment, and cardiac conduction abnormalities than tricyclic antidepressants. Tricyclics (e.g., desipramine, nortriptyline, amitriptyline) are initiated at low doses and gradually titrated to effect. Depending on class, risks and adverse effects may include dry mouth, dizziness, sedation, memory impairment, orthostatic hypotension, urinary retention, cardiac conduction abnormalities, sexual dysfunction, weight gain, emotional blunting, and suicidal thoughts.[1,29] Second-generation tricyclic antidepressants (e.g., nortriptyline) tend to be better tolerated than first generation (e.g., amitriptyline). Withdrawal reactions are possible when antidepressants are suddenly stopped.

Musculoskeletal agents for pain and muscle spasm are for short-term use with sedation being a common adverse effect. Common medications used in pain treatment include baclofen, tizanidine, and cyclobenzaprine. Particular risks are notable with carisoprodol (toxicity, unclear therapeutic benefit) and benzodiazepines (SUD, respiratory depression leading to overdose) when prescribed in combination with opioids.[29] Considering the risks with carisoprodol and benzodiazepines and the availability of other agents, these medications are not recommended to treat pain from muscle spasm.[1]

Topical medications include lidocaine, ketamine, capsaicin, and anti-inflammatory drugs such as ketoprofen and diclofenac. Anti-inflammatory topicals are proven beneficial for musculoskeletal pain, as is capsaicin for neuropathic pain.[29]

Cannabis remains a Schedule I drug in the United States, defined by the Drug Enforcement Administration (DEA), as having no currently accepted medical use and a high potential for abuse.[1] Rigorous studies are lacking on the safety and efficacy of any specific cannabis product as a treatment for pain.[1] Expert views and systematic reviews[63,64] differ regarding the strength and quality of evidence for cannabis use, and the IASP does not endorse general use of cannabinoids for pain, citing lack of high-quality research. The evidence remains inconclusive to recommend the general use of cannabis for pain.

Little is known about the safety, efficacy, dose, and routes of administration of available cannabis products. Epidiolex (cannabidiol) [CBD] oral solution has been approved for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients age 2 and older.[65] (It is THC that has the primary psychoactive component of marijuana, not CBD).

Importantly, the FDA has not approved cannabis for the treatment of chronic pain.[63] However, a number of patients with pain appear to be replacing opioids with cannabis. Marijuana is legal for medical use in several states, and public interest in cannabis and cannabis-derived products for pain treatment is rising.[63] Adverse events reported with cannabis use include psychotomimetic effects, anxiety and psychosis, cognitive dysmotivational syndrome, and learning deficits in adolescents.[66] Cannabis can also have hyperemesis effects, impair driving safety, and is linked to vascular events.[66] The topic of concurrent cannabis and opioid use will be covered later in this activity.

Opioids for Pain

Opioid analgesic effects are principally achieved by the opioid binding to and activating mu, kappa, and delta receptors in the endogenous opioid system. Drugs are classified according to their action at these receptors as full agonists, mixed agonist-antagonists, or antagonists (Table 2).

Table 2. Opioid Analgesic Classifications

Type	Generic Name	Notes/Cautions
Pure agonists	Codeine Dihydrocodeine Fentanyl Hydrocodone Hydromorphone Levorphanol Meperidine* Methadone Morphine Oxycodone Oxymorphone Propoxyphene	*Meperidine not recommended for long-term treatment or in patients with renal compromise due to toxicity risks
Agonist-antagonists	Partial agonist: Buprenorphine Mixed agonist-antagonists: Butorphanol Dezocine Nalbuphine Pentazocine	May produce withdrawal if started while patient receiving full opioid agonist
Pure antagonists	Naloxone Naltrexone	Administered to reverse opioid effects
Other	Tramadol Tapentadol	Dual action mu-agonist and serotonin–norepinephrine reuptake inhibitor Dual action mu-agonist and norepinephrine reuptake inhibitor

Full mu-agonists bind selectively to the mu-opioid receptor. When an antagonist occupies the receptor, it displaces the agonist and causes opioid withdrawal. Partial agonists, such as buprenorphine, have high receptor occupancy, some antagonistic effects, and low intrinsic activity at the site. Kappa opioid receptor agonists (including levorphanol, pentazocine, and butorphanol) have been used clinically but are associated with such side effects as dysphoria and hallucinations.

Buprenorphine has a reduced potential for respiratory depression and is considered safer than full agonists such as morphine, hydrocodone, and oxycodone.[1] Buprenorphine also acts as an antagonist at the kappa receptor, which is shown to reduce anxiety, depression, and the unpleasantness of opioid withdrawal.[1] Tapentadol and tramadol have dual modes of action as agonists at the mu receptor and SNRIs.[1] Considerations with dual-mechanism opioids include lowering of seizure threshold in susceptible patients and the risk of serotonin syndrome due to concomitant serotonin activity.[20]

Opioid delivery systems include oral, buccal, sublingual, spray, intravenous, intramuscular, intrathecal, suppository, and transdermal routes.[1] Administration includes ER/LA and IR/SA formulations. IR/SA opioids typically have a rapid onset from 10 to 60 minutes and a duration of action of 2 to 4 hours. In contrast, ER/LA opioids have a relatively slow onset of action of 30 to 90 minutes and longer duration of action from 4 to 72 hours. ER/LA opioids are indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate for patients with existing opioid tolerance.

The class of ER/LA opioids are not for use "as needed," not for mild pain, and not for acute pain or pain that not expected to persist for an extended duration:[67,68]

Opioid risks, warnings, and side effects include an FDA boxed warning about the serious risks for misuse, abuse, addiction, overdose and death that apply to all IR/SA and ER/LA prescription opioids.[69] These risks are present whenever opioids are misused but apply even at prescribed doses. The labels for opioid combination products containing ACET also warn of the potential for severe liver damage.[60] An FDA boxed warning details the risks of prescribing opioids and benzodiazepines together, a combination of medications that has increased in recent years but which is associated with extreme sleepiness, respiratory depression, coma, and death.[70] In addition, patients may suffer serious harm, including serious withdrawal symptoms, uncontrolled pain, and suicide, if opioids are suddenly discontinued or tapered too rapidly.[71,72] Concomitant drugs that act as inhibitors or inducers of various cytochrome P450 enzymes can result in higher or lower than expected blood levels of some opioids. Dosages should be reduced in the presence of hepatic or renal impairment.[68]

Certain cautions apply to specific opioid types, formulations, and delivery systems. Some opioids (e.g., methadone, buprenorphine) can prolong the QTc interval. Relative potency to oral morphine is intended as a general guide with additional conversion instructions included in each product's PI.[68] ER/LA opioid tablets should be swallowed whole, never crushed, chewed, broken, cut, or dissolved. Altering them in such ways may result in rapid release and absorption of a potentially fatal dose.[67,68] When necessary, some products may be sprinkled as pellets on applesauce and swallowed without chewing. Transdermal systems and buccal films should not be cut, torn, or damaged before use. Transdermal dosage forms should not be chewed or swallowed, and exposing patches to heat may lead to fatal overdose. Possible opioid side effects include but are not limited to:[1,61]

- Lightheadedness
- Dizziness
- Sedation
- Nausea and vomiting
- Drowsiness
- Mental clouding
- Constipation
- Hormonal deficiencies
- Pruritis
- Myoclonus
- Irritability
- Respiratory depression

Opioid pharmacokinetics influence the bioavailability of the drug, the production and elimination of metabolites, and the activity of metabolic enzymes.[73] Most opioids are metabolized through the liver microsomal cytochrome P-450 (CYP) system with CYP2D6 or CYP3A4 being responsible for much metabolism of opioids and many other drugs. Certain clinical applications are relevant. Slow metabolizers of CYP2D6 may gain little benefit from codeine, for example. Opioids metabolized through the CYP450 system, including codeine, oxycodone, hydrocodone, fentanyl, tramadol, and methadone, may have heightened or reduced CYP450-associated effects with drug combinations, while morphine, oxymorphone, and hydromorphone are not as prone to such interactions.[74] Codeine and tramadol should be avoided in breastfeeding women due to risks to the infant from ultra-rapid CYP2D6 metabolism in some people.[61,75] All opioids have similar pharmacodynamics, which describe effects in the body such as binding action and location to receptors, although individual patient responses may vary.[73]

Drug-Drug interactions are possible with opioids.[68] Co-ingesting CNS-depressants that include alcohol, benzodiazepines, sedatives, hypnotics, tranquilizers, and tricyclic antidepressants can potentiate the sedation and respiratory depression caused by opioids. Alcohol can cause rapid release of ER/LA opioid formulations leading to an increased drug level. Combining opioids with monoamine oxidase inhibitors (MAOIs) can increase respiratory depression and cause serotonin syndrome with certain opioids. Opioids induce the release of antidiuretic hormone, reducing the efficacy of diuretics. Initiating CYP 3A4 inhibitors or discontinuing CYP 3A4 inducers can result in higher than expected opioid blood levels leading to overdose.

Opioid contraindications. There are some absolute contraindications for initiating a trial of long-term opioid therapy that include:[20]

- Known hypersensitivity to active ingredients or other components of opioid analgesics
- Significant respiratory depression or compromise
- Acute or severe bronchial asthma
- Known or suspected paralytic ileus and gastrointestinal obstruction
- Evidence for or history of diversion of controlled substances (e.g., forged prescriptions, pharmacy robberies, selling own prescription drugs, theft of others' drugs)

Although the combination is sometimes used, the Department of Veterans Affairs/Department of Defense (VA/DoD) practice guideline lists concomitant use of benzodiazepines as a contraindication to initiating a trial of long-term opioid therapy.[20] The Centers for Disease Control and Prevention (CDC) recommends avoiding prescribing opioids and benzodiazepines concurrently whenever possible but allows for rare instances when the combination may be indicated (e.g., severe acute pain in the presence of long-term, stable, low-dose benzodiazepine therapy).[61]

Medication errors may result from miscommunication, packaging design, confusion caused by similar drug names, and other sources. Patient counseling and education can help guard against medication errors.

Methadone for pain presents special clinical challenges due to a long and variable half-life, risk for toxicity due to accumulation in plasma concentrations during the several days necessary to achieve steady-state, and risk for cardiac toxicities due to prolongation of the QTc interval.[76-78] Methadone-related deaths have occurred in disproportionate numbers relative to the frequency with which it is prescribed for pain.[61] Methadone is only for patients whose severe pain is unrelieved by other opioids. Close monitoring is critical when initiating methadone and during dose changes, and caution is needed in patients with heart disease or taking medications with concurrent QTc interval effects. Patients should be assessed for cardiac health ahead of being prescribed methadone, and an initial ECG may be advisable, particularly if the patient has cardiac disease or risk factors. If methadone is initiated, it should be started at a very low dose (e.g., 2.5mg tid) and slowly titrated (e.g., by no more than 25%-50%, no more frequently than weekly.[76,77] In adults on relatively low previous opioid doses (e.g., <40–60 mg per day of morphine or equivalent), experts suggest a starting dose of 2.5 mg tid with initial dose increases of no more than 5 mg daily every 5 to 7 days.[79]

When switching to methadone from higher previous doses of another opioid, consider starting methadone at a dose that is 75% to 90% less than the calculated equianalgesic dose (no higher than 30 to 40 mg per day) with initial dose increases of no more than 10 mg per day every 5 to 7 days.[79] It is important to withhold methadone if there is evidence of sedation.[79] Bear in mind that pain relief from a methadone dose lasts only 4 to 8 hours, but methadone remains in the body much longer (8 to 59 hours).[78] Patients should be counseled never to exceed the prescribed dose, not to mix with alcohol or other unauthorized substances, and to take methadone doses only as scheduled, not as needed. HCPs without experience and knowledge of methadone should seek expert consultation before prescribing it.[76]

Abuse-Deterrent Opioids

The FDA defines abuse-deterrent properties as those that deter but do not prevent all abuse (i.e., misuse).[80] Common technologies incorporate physical barriers to deter crushing and chewing, chemical barriers to resist extraction in common solvents of the active ingredient for injection, or opioid antagonists to block euphoria when a pill is altered. These formulations have been suggested as a way to reduce harm from prescribed opioids. The FDA cautions that abuse may still occur by swallowing intact pills.

Data on abuse-deterrent properties are included in the Drug Abuse and Dependence section of the drug's prescribing information under 9.2 Abuse. If missing or located elsewhere, the FDA does not consider the product abuse deterrent. The label also contains information on the types of studies conducted and the routes of abuse the formulation is expected to deter (e.g., oral, intranasal, insufflation, intravenous). Thus far, 10 opioid formulations have received abuse-deterrent labeling from the FDA. Post-marketing studies for the approved formulations are in their infancy, and new deterrent formulations are continually in development.[81]

Considerations with Opioids in Special Populations:[20]

Women/Pregnant Women

Several diseases with a high burden of pain are more common in women or are sex specific. These include endometriosis, musculoskeletal and orofacial pain, fibromyalgia, migraines, and abdominal and pelvic pain.[1] Sex differences extend to the pain response itself, and recent scientific literature suggests that, compared with men, women experience more pain, are more sensitive to painful stimuli, report more intense pain, and are more likely to misuse prescription opioids, though there remain many research gaps related to women's health and pain.[1]

During pregnancy, HCPs and patients together should carefully weigh risks and benefits when making decisions about whether to initiate opioid therapy.[61]

All women should be informed of the risks of long-term opioid therapy to the developing fetus during current or potential future pregnancies, including a drug withdrawal syndrome in newborns called neonatal opioid withdrawal syndrome (NOWS).[61] An estimated 32,000 babies were born with NOWS in 2014, an five-fold increase from 2004.[82] Babies born to women who are taking opioids are at risk for birth defects (including neural tube defects, congenital heart defects, and gastroschisis), preterm delivery, poor fetal growth, and stillbirth.[61] Given the risks during pregnancy and postpartum, HCPs are encouraged to include obstetricians and gynecologists as part of the pain care management team.[1]

When caring for pregnant women who are prescribed opioids, HCPs should arrange for delivery at a facility prepared to evaluate and treat NOWS.[61] Women with SUD should be offered evidence-based treatment. In pregnant women with OUD, the risk of opioid exposure from opioids used to treat OUD should be discussed and balanced against the risk of untreated OUD, which might lead to illicit opioid use associated with outcomes such as low birth weight, preterm birth, or fetal death.[83]

Pain management guidelines in Tennessee recommend the following measures when treating women of child-bearing age:[84]

- Every woman with reproductive capacity should discuss with the HCP a method to prevent unintended pregnancy when initiated on opioids
- Agreement should be obtained to inform the HCP if the woman becomes or intends to become pregnant while prescribed opioids
- Women who plan to become pregnant should be counseled on the risks of opioid exposure to the fetus and referred to an obstetrician
- The obstetrician and HCP should work together to encourage compliance with chronic pain management and prenatal care
- All newly pregnant women should have a urine drug test administered by the appropriate women's health practitioner
- If a urine result is positive for unprescribed controlled substances or illicit drugs during a prenatal visit, the woman should have another upon admission for delivery to help identify the infant at risk for NOWS

Older adults

People who are ≥65 years require cautious opioid dosing and management as they may have numerous co-occurring medical problems with treatments that increase the risk for polypharmacy and harmful drug interactions.[77] Their risk for falls and cognitive effects with sedating medications and their sensitivity to analgesic effects are increased. In addition, prescription drug or other substance use may be difficult to spot, mimicking symptoms of common conditions such as dementia, diabetes, and depression. Initial doses should be 25–50% lower than in those who are younger.[85] The VA/DoD practice guideline suggests that tramadol has benefits in older patients because of its partial mu agonist activity and demonstrated safety profile when combined with ACET, though drug-drug interactions should be evaluated when prescribing tramadol.[20]

Children and adolescents

Evaluating the origin of the pain condition is important in the pediatric age group. If pain is not controlled, children are at risk for persistent pain as they grow to adulthood.[1] Use of multidisciplinary treatments is advised as is treatment of psychological conditions to manage difficulty coping, anxiety, and depression. It has been suggested that opioid analgesia may be indicated for certain chronic pediatric conditions; however, current guidelines generally exclude this population from treatment recommendations, and scientific investigation is scant into the indications and safety concerns with opioids for the pediatric population.[86] Accidental exposure to and ingestion of opioids can result in death.

People with renal and hepatic impairment

Extra caution and increased monitoring is necessary when initiating and titrating opioid doses in people with renal and hepatic impairment.[61] In patients with renal compromise, accumulation resulting in toxicity has been observed in case studies; therefore, it is advised to monitor for opioid toxicity and to use non-opioids when possible.[87]

People with sickle cell disease

Sickle cell disease, which affects an estimated 90,000 people in the United States, is characterized by complex acute and chronic pain symptoms.[88] The disease is particularly prevalent among African Americans. According to the HHS Inter-Agency Task Force on best pain management practices, unpredictable, episodic exacerbations of acute pain pose a challenge to patients with sickle cell disease, and this pain generally has not responded to non-opioids prior to presentation.[1] Limited access to oral opioids at home for the treatment of unplanned acute pain can result in increased use of health care services that could have been avoided. Stigma, negative practitioner attitudes, and perceived racial bias may further complicate care. Effective models of pain treatment for patients with sickle cell disease include multidisciplinary teams of practitioners with experience treating the disease.

Racial and ethnic disparities in pain care

Evidence documents disparities in health care in racial and ethnic minority populations, often related to such factors as lack of insurance or primary care access, discrimination, environmental barriers to self-management, lower likelihood of being screened for or receiving pain treatment and more.[1,20] The disparities extend to mental health care and addiction treatment where access to care is very limited for Black individuals, Indigenous individuals, and other individuals of color. There is evidence that racial and ethnic minority populations prefer seeking treatment in primary care over specialty mental health settings.[89]

Active duty military, reserve service members, and veterans

Pain management in veterans and active military members can be complex. Combat-related injuries include ballistic wounds, burns, over-pressurization, and blunt trauma.[1] In addition, complications can arise from PTSD and traumatic brain injury.[1] Delaying pain treatment can lead to acute pain becoming chronic.[90] Veterans are also at risk for death by suicide, a risk compounded when pain conditions are present. HCPS can discuss suicide risk with service members and veterans and address pain treatment as part of suicide prevention as a recognized public health approach.[1]

Medical complexities of pain care

Genetic and phenotypic variations influence how quickly or well different people metabolize opioids and other drugs.[73] Medical conditions, including kidney and liver disease, also cause variations in opioid metabolism.[73] The FDA has approved some tests, for example, one aimed at determining whether a patient is a CYP2D6 ultra-rapid metabolizer.[75] However, little data actually exist to inform the practice of pain management, and these tests are not routinely performed.[91] HPCs should be aware that genetics is one of many factors that may affect drug metabolism and responses, so patient experience with certain pain treatments or medications should be used to develop individualized treatment plans.

Definitions Related to Opioid Use and Misuse

The HHS Inter-Agency Task Force on best pain management practices endorsed a set of definitions to guide conversations and understanding of frequent terms related to opioid use and misuse.[1] These definitions are shown in Table 3.

Diversion

Most people who misuse prescription opioids are given them freely by friends or family members, though some people buy or steal them.[93] About a third of people who misuse opioids get them by prescription from one doctor.[93] Many misused opioids became available in the community because they were left over from prescriptions for acute pain.[94] It is incumbent on the HCP to remember that, although most people who are prescribed opioids for pain do not misuse them, it is possible that some people who visit a medical facility for pain are instead seeking opioids to divert for misuse or illegal sale.

Creating Pain Treatment Plans

All pain management begins with identifying the cause or causes of pain and the biopsychosocial mechanisms that contribute to its severity and associated disability.[1] An effective treatment plan is built out of a full evaluation to establish diagnosis and emphasizes individualized patient-centered care. When persistent pain pertains to a specific disease condition or patient population, HCPs are advised to seek out evidence-based practice guidelines that are relevant.[1] The patient's pain type and previous treatments should be evaluated to see if opioid therapy is likely to be effective. The HCP should consider whether medical comorbidities, such as sleep apnea, may increase risk of respiratory depression, whether other available therapies have better or equal evidence, and whether thorough patient evaluation indicates the patient is likely to adhere to the treatment plan.

Treatment plans should be revisited and adjusted frequently to ensure goals are being met and any adverse effects of therapy are addressed. The success of a pain management plan is highly dependent on the therapeutic alliance established between the patient and the HCP.

Managing Acute Pain

For acute pain, non-opioids may offer effective management and should be utilized preferentially, alone or in combination with opioids (when indicated) to increase pain control and spare opioid doses.[22] Much acute pain is manageable with rest, over-the-counter medications, or a short course of opioids and resolution of the underlying cause (e.g., trauma, surgery, illness). Objective signs of an acute, painful medical condition (e.g., bone fracture or imaging that reveals kidney stones) are examples for when opioids are likely indicated. Prompt management of acute pain is necessary to prevent progression to a chronic state.[22]

When opioids are indicated, the therapeutic goal is to prescribe the lowest dose that controls pain for a duration lasting only as long as the acute phase. Leftover pills from acute pain prescriptions may later become a chief source of diverted and misused opioids. A systematic review found that 42% to 71% of opioids obtained by surgical patients went unused.[94] Prescriptions beyond three days are usually unnecessary,[61] while more severe episodes rarely need more than 7-14 days, although there are exceptions.[61,85] Be aware that localities and states may have strict regulations governing maximum duration of prescriptions for acute pain. In nearly all cases, HCPS should not prescribe ER/LA opioids for acute pain. It is worth considering that long-term opioids typically are not recommended for nonspecific back pain, headaches, or fibromyalgia, if the HCP should see a patient experiencing acute pain flares occurring with these conditions.[20]

Table 3. Definitions Related to Opioid Use and Misuse[1]

Term	Definition
Physical dependence	• Not the same as addiction • Occurs because of physiological adaptations to chronic exposure to opioids • Withdrawal symptoms occur when medicine or opioid is suddenly reduced or stopped or when antagonist is administered • Symptoms can be mild or severe and can usually be managed medically or avoided through slow opioid taper
Tolerance	• Same dose of opioid given repeatedly produces reduced biological response • Higher dose of opioid is necessary to achieve initial level of response
Misuse	• Taking medication in a manner or dose other than as prescribed • Taking someone else's prescription, even if for a medical complaint like pain • Taking medication to feel euphoria (i.e., to get high) • Nonmedical use of prescription drugs refers to misuse
Addiction	• Primary, chronic medical disease of brain reward, motivation, memory, and related circuitry • Dysfunction in circuits leads to characteristic biological, psychological, social, and spiritual manifestations as individual pathologically pursues reward and/or relief by substance use and other behaviors • Characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and dysfunctional emotional response • Involves cycles of relapse and remission • Without treatment or recovery activities, is progressive and results in disability or premature death
*DSM-5 = Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition;[92] diagnostic criteria given later in this activity	

Be aware also that patients who seek opioids to misuse may utilize emergency departments or urgent care for this purpose. The American College of Emergency Physicians (ACEP) has identified acute low back pain and exacerbations of chronic pain as common presenting complaints in the emergency department and recommends assessing whether non-opioid therapies would be adequate pain treatment, reserving opioids for severe pain that would be unresponsive to other therapies.[95] If opioids are indicated, the ACEP recommends prescribing the lowest practical dose for the shortest duration, considering the patient's risk for opioid misuse or diversion.[95] Checking the state prescription database ahead of prescribing opioids for acute pain can help ensure the patient is receiving the appropriate quantity of opioids for the pain.[1] If pain from surgery or trauma persists beyond the expected healing period, HCPs should reevaluate the diagnosis and treatment plan.

Assessing the Risk of Transition from Acute to Chronic Pain

Most cases of chronic pain begin as acute pain, and evidence suggests that prolonged exposure to pain leads to CNS changes that can transform the experience to a chronic syndrome.[22] Studies suggest that one-third of patients have progressively worsening pain intensity postoperatively,[22] and most research on risk factors for transitioning from acute to chronic pain takes place in surgical settings. Established risk factors include younger age, female gender, catastrophizing, low socioeconomic status, preoperative pain, impaired diffuse noxious inhibitory control, type and duration of surgery, injury to specific nerves, severity of acute pain, and, possibly, prior exposure to radiation therapy and chemotherapy.[22] The high association of pain severity with subsequent chronic pain development boosts the rationale for comprehensive pain assessment and treatment in the perioperative setting.[22]

It is clear that psychological factors contribute to the pain experience overall and pose risk for chronicity. Depression after injury is an important predictor associated with reduced odds for recovery.[96] In people recovering from musculoskeletal trauma, catastrophic thinking (a psychological factor that responds to CBT) predicted pain intensity and disability at five-to-eight months post-injury.[34] Psychological interventions, following proper evaluation and diagnosis, can play a central role in reducing disability. When delivered before surgery, psychological interventions are shown to reduce postsurgical pain and opioid use[97,98] and may help prevent progression from acute to chronic pain.

A systematic literature review found support for two screening tools that may be useful in helping HCPs predict the likelihood of a transition from acute or subacute to chronic low back pain.[99] These tools are the STarT Back Screening Tool and the Örebro Musculoskeletal Pain Questionnaire, which stratify patients in into low-, medium-, and high-risk categories and were found to be valid, reliable and to have predictive value. Intense widespread pain (especially when it is increasing) and fear avoidance were found to predict the transition to chronic pain. Incorporating one of these tools or evaluating common predictors in acute pain can help HCPs identify patients at risk in order to treat them early or refer them for specialist management to prevent the trajectory to chronic pain.

Managing Cancer-Related Pain

More than 14 million cancer survivors live in the United States.[1] An estimated 40% of cancer survivors experience persistent pain as a result of treatments such as surgery, chemotherapy, and radiation therapy.[1] All HCPs who treat patients with active cancer or with cancer-related pain should assess for, recognize, and treat pain at every encounter. Remember that the CDC guideline for opioid prescribing affirms the use of opioids when benefits outweigh risks and warns against opioid tapering or discontinuation when opioid use may be warranted, such as in treatment of cancer pain or at the end of life.[72]

With cancer-related pain, HCPs are encouraged to look beyond narrow treatment choices and incorporate multimodal treatments in a multidisciplinary treatment plan.[1] Cancer survivors should be evaluated for a recurrence or secondary malignancy with any new or worsening pain symptoms.[85]

Managing Pain in Palliative Care and at End of Life

Persistent, significant pain is common in patients with a limited prognosis, such as those in hospice and palliative care environments. The goal in palliative care is to keep the patient comfortable. HCPs should assess and address pain at every encounter, using multimodal and multidisciplinary care as part of the care management plan as indicated.[1]

In end-of-life care, pain control may be balanced against meaningful priorities the patient may have such as mental alertness and maximal interactions with loved ones. Pain assessment may be challenging in the context of reduced consciousness. Signs of discomfort include more rapid breathing or heart rate. Rectal and transdermal routes can be especially valuable at the end of life when the oral route is precluded because of reduced or absent consciousness, difficulty swallowing, or to avoid nausea and vomiting.[100]

Managing Chronic Noncancer Pain

To apply best practices in chronic noncancer pain treatment, HCPs should recognize and treat pain promptly, involve patients in the pain care plan, reassess and adjust the pain care plan as needed, monitor patient progress toward treatment goals, monitor patient adherence to any treatment agreements, and document all pain management outcomes in the patient medical record.

The goals of treatment should be meaningful to the patient and contain measurable outcomes of improvement that include pain relief, functionality, quality of life, and activities of daily living.[20,61,85] Even patients with pain conditions or injuries that make complete cessation of pain unlikely can set goals such as sleeping through most nights, returning to work, walking a set distance, or participating more fully in family activities. The self-efficacy involved in collaborating on these goals can help patients gain greater control over their pain and their lives.

Choices in medications are based on pain diagnosis and severity; comorbidities as established through medical history, physical exam, relevant diagnostic procedures; patient response; and a risk-benefit assessment to increase the likelihood that benefits outweigh risks. It is important to differentiate between nociceptive and neuropathic pain and to thoroughly evaluate the patient to aid in an accurate diagnosis, identifying the generator of pain whenever possible. Neuropathic pain can be difficult to manage and generally requires a combination of pharmacologic and nonpharmacologic approaches.[23] Choices of medications for neuropathic pain that provide the most relief include anticonvulsants, antidepressants, or local anesthetics. NSAIDs are not considered effective treatments for neuropathic pain, and opioids should be reserved for patients who did not respond to other therapeutic options.[23,61]

For osteoarthritis, ACET and NSAIDs are considered first-line and second-line medications, respectively, and many guidelines recommend NSAIDs and ACET as first-line therapies for low-back pain.[61] Corticosteroid injections are generally recommended for hip and knee osteoarthritis.[101] Expert guidelines usually now recommend against ongoing opioid therapy for nonspecific back pain, headaches, and fibromyalgia.[20]

Whenever possible, nonpharmacologic therapies and self-management strategies should be optimized.[27] Noninvasive interventions in specific conditions that have sustained small improvements in pain and function for one month or longer post treatment without serious harms are shown in Table 4.[30] A trial of opioids, when indicated, should be part of a comprehensive treatment approach, typically in combination with one or more treatment modalities.[20]

Assessing Pain

A patient's initial visit for evaluation of a pain problem should include a physical exam and a patient interview to gather and document medical history and pain assessment. One should obtain a complete history of current and past substance use and misuse to include prescription drugs, illegal substances, alcohol, and tobacco. Social history is also relevant and includes employment, marital history, and family status.[77] Women should be screened for contraceptive use and pregnancy or breastfeeding status or intent.[61] Previous treatment records, including any pertinent clinical notes of treatments tried, and laboratory and imaging results should be reviewed whenever possible and retained in the current patient record.

Table 4. Noninvasive, Nonpharmacologic Treatments for Specific Pain Conditions[30]	
Pain Condition	**Treatment**
Chronic low back pain	Exercise, psychological therapies (primarily cognitive behavioral therapy), spinal manipulation, low-level laser therapy, massage, mindfulness-based stress reduction, yoga, acupuncture, multidisciplinary rehabilitation, tai chi
Chronic neck pain	Exercise, low-level laser, Alexander Technique, acupuncture
Knee osteoarthritis	Exercise, ultrasound
Hip osteoarthritis	Exercise, manual therapies
Fibromyalgia	Exercise, cognitive behavioral therapy, myofascial release massage, tai chi, qigong, acupuncture, multidisciplinary rehabilitation
Chronic tension headache	Spinal manipulation

Pain should be assessed by its severity (to include pain intensity, pain-related distress, and interference with daily activities), its temporal characteristics (to include onset, duration, whether it is continuous, has recurrent episodes with painless intervals, or is continuous with times of pain exacerbation). Psychological and social factors can contribute to the pain experience, which is why these issues should be included in the patient interview and documented in the record. Recording these factors will assist with documenting what special pain management needs a patient has as well as what level of disability.[23] Good questions to ask the patient include what relieves or increases the pain, how it affects their daily lives and functioning, and what goals they have for pain relief and improved function.

A number of evidence-based, pain assessment tools are available for clinical practice:

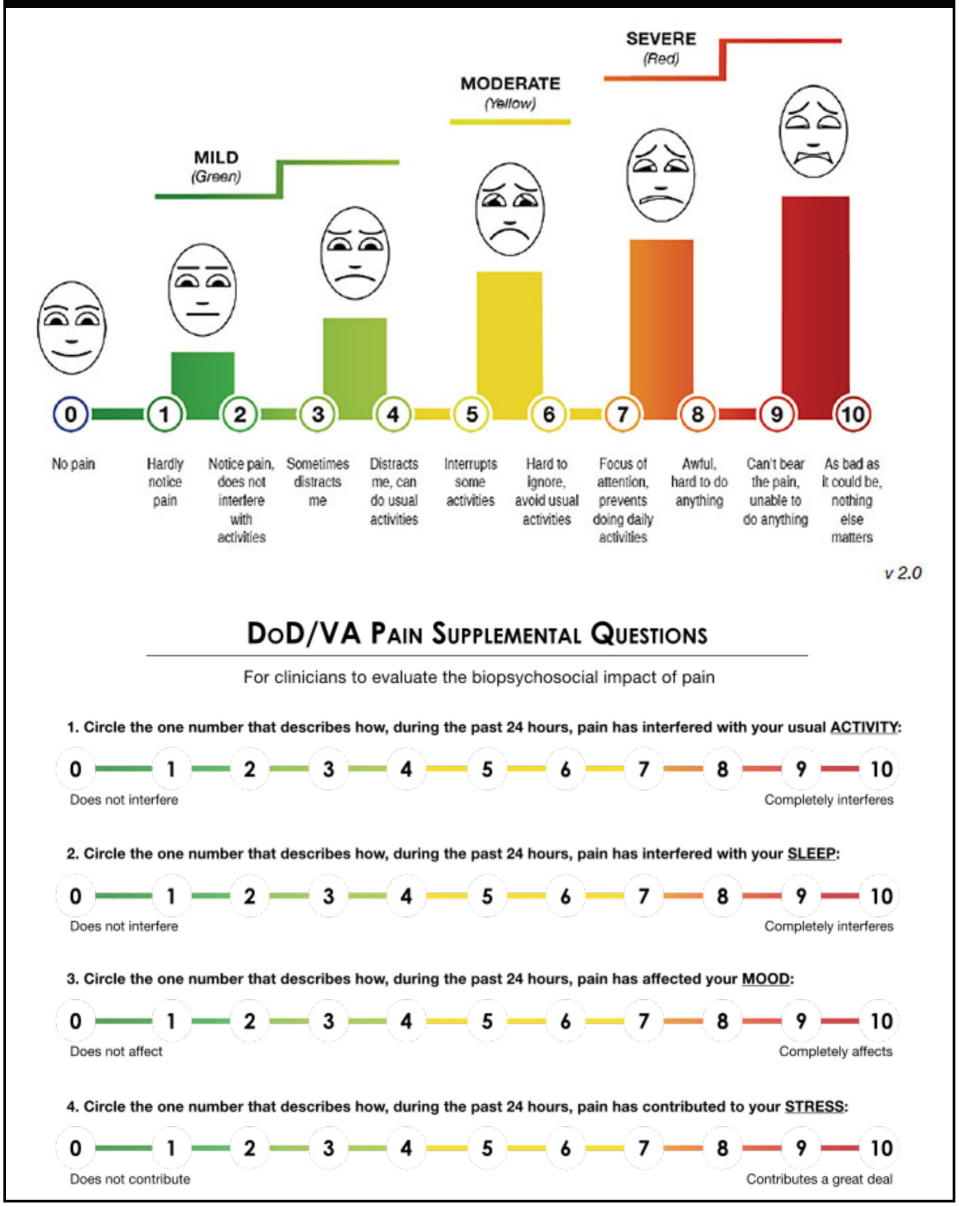
- The Visual Analogue Scale (VAS) and Numerical Rating Scale (NRS) are quick tools to measure pain severity that are sensitive, validated, and widely-used.[102]
- The Brief Pain Inventory (BPI) has good sensitivity, reliability, and validity for pain severity and interference-with-function items, including assessments of mood and sleep.[103,104]
- The Pain, Enjoyment of Life, and General Activity Scale (PEG) was created to assist management of chronic pain in primary care settings.[105] It is based on the BPI and has rating scales to measure past-week pain, pain interference, functional components, and quality of life.
- The McGill Pain Questionnaire (MPQ) assesses pain descriptors (sensory, evaluative, and affective).[102] With good validity and reliability, the MPQ is useful for helping patients describe their subjective pain experience but requires a good vocabulary when self-administered. The MPG is also available as a short form.
- The Multidimensional Pain Inventory has been validated for multiple chronic pain conditions for categorizing how well patients cope with chronic pain as adaptive, dysfunctional, or interpersonally distressed.[106,107]

Numeric pain scales, such as the VAS or NRS, have limitations in that they provide only a snapshot of the pain on a given day and do not necessarily reflect the impact of pain on the patient's life. One should also consider other clinical signs and symptoms and to make treatment decisions to further therapeutic goals meaningful to the patient rather than basing treatments solely on a pain scale number.

HCPs should also screen and monitor patients for factors associated with poor outcomes and substance abuse, such as sleep disturbance, mood disorder, and stress. HCPs are encouraged to consider use of a scale such as the Defense and Veterans Pain Rating Scale (DVPRS) (Figure 3).[1,108]

The DVPRS is a graphic tool with a numeric rating scale in which each pain level has descriptive word anchors, facial depictions of pain, and color coding that coincides with pain severity categories. The DVPRS also includes supplemental questions for general activity, sleep, mood, and level of stress. This or other numeric pain scales may be particularly useful for assessing pain in patients who have language deficits or other issues with communicating their experience of pain.

Figure 3. The Defense and Veterans Pain Rating Scale and Supplemental Questions[108]



The PEG scale can be very useful in primary care or busy practices to assess pain, functioning, and quality of life.

Assessing Mental Health

Screening tools to assess patients with pain for mental health disorders ahead of prescribing opioids include:

- Patient Health Questionnaire-2 (PHQ-2), a two-item screen for depressive disorder that leads to more detailed assessment if either item is positive.[109] The PHQ-2 is available at the following link: https://www.hiv.uw.edu/page/mental-health-screening/phq-2
- Patient Health Questionnaire-9 (PHQ-9), this nine-item screen for depressive disorder may be used initially or as a follow-up to the PHQ-2.[110] This tool and its variations are brief, reliable, valid, and easy to score. The PHQ-9 is available at the following link: https://www.hiv.uw.edu/page/mental-health-screening/phq-9
- The reliable and valid Beck Depression Inventory-II (BDI-II) is a self-report measure of depression severity.[111] This 21-item tool is available here: http://www.hpc-educ.org/Files/Danz/BDII.pdf
- Suicidal ideation is addressed by items on the PHQ-9 and BDI-II. This is an important assessment for patients with chronic pain.
- The Beck Anxiety Inventory (BAI) emphasizes somatic components of anxiety[112] and can be found here: https://www.gphealth.org/media/1087/anxiety.pdf
- The Generalized Anxiety Disorder-7 (GAD) and GAD-2 are validated and recommended to assess for generalized, panic, and social anxiety disorders, and PTSD.[61,113,114] These tools are available here: PMID: 32582485

Newer systems such as the Stanford-developed and implemented Collaborative Health Outcomes Information Registry offer more in-depth pain assessment through the use of item banks that capture many physical, psychological, and social functioning domains.[115]

Assessing Social History, Including Substance Use

Patients to be treated with opioid therapy should be screened for the risk of opioid misuse and OUD and monitored regularly. Misuse of prescription opioids is common whether from casual sharing of prescription pills, recreational or experimental use by non-patients (including adolescents), all the way up to and including development of OUD in at-risk populations. Yet clinically it is not always easy to differentiate between appropriate use of prescribed opioids and behavior that may indicate a problem. There is reason to suspect that a pattern of seeking opioids from multiple sources is a strong indicator of misuse and possible OUD.[116]

A list of behaviors suggestive of opioid misuse is shown in Table 5.[116,117]

A number of risk factors are associated with poorer outcomes in opioid therapy.[101] These factors include:[118]

- Nonfunctional status (e.g., severe physical debility) due to pain
- Exaggeration of pain
- Unclear etiology for pain
- History of rapid opioid dose escalation
- Young age (<30 years)
- Tobacco use
- Poor social support
- Personal history of SUD
- Family history of SUD
- Psychological stress
- Psychological trauma
- Psychological disease
- Psychotropic substance use
- Focus on opioids
- Sexual trauma
- History of legal problems
- History of SUD treatment
- Craving for prescription drugs
- Mood swings/disorders
- Childhood adversity, adverse childhood experiences
- Social environments that encourage illicit substance use

The HHS Inter-Agency Task Force on best practices in pain management emphasizes sleep disturbances, mood disorders, and stress as factors that put patients at risk for poorer outcomes and substance use.[1] HCPs may identify risk factors from patient and family history and current biopsychosocial evaluation.

Assessing for Risk of Overdose

Respiratory depression leading to fatal or nonfatal overdose is a chief risk with opioids. Risk factors for overdose in people taking opioids medically or nonmedically include:[119-123]

- Middle age
- History of SUD
- Comorbid mental and medical disorders
- High opioid dose (>90 mg morphine equivalents, although risk is present at any dose)
- Recent upward titration of opioids (within the first 2 weeks)
- Recent opioid rotation
- Methadone use

Table 5. Patient Behaviors Suggestive of Opioid Misuse, Diversion, Abuse, and Addiction (list not exhaustive)

Behavior Category	Behavior
Observed clinically:[116]	Over-sedated/intoxicated Opioid overdose
Laboratory findings:[116]	Abnormal (i.e., inconsistent) urine or blood screen
Unusual healthcare utilization:[116]	Reports multiple pain causes Resists therapeutic changes/alternatives Cancels/no shows pain clinic visits Has persistent/non-modifiable pain Requests refills instead of clinic visit Gets prescriptions from multiple practitioners without their coordination or knowledge
Risk factors for getting prescriptions from multiple practitioners without their coordination or knowledge:[116]	Age ≤65 Concurrent use of benzodiazepines Mood disorders Back pain Abuse of non-opioid drugs
Patient reported (primary care population):[117]	Requested early refills Increased dose on own Felt intoxicated from pain medication Purposely over-sedated oneself Used opioids for purpose other than pain relief Lost or had medication stolen Tried or succeeded in obtaining extra opioids from other doctors Used alcohol or other non-prescribed substances to relieve pain Hoarded pain medication

- Benzodiazepine use
- Antidepressant use
- Unemployment
- Use of non-prescribed illicit substances
- Recent release from jail or prison
- Recent release from substance treatment program
- Sleep apnea
- Heart or pulmonary complications (e.g., respiratory infections, asthma)
- Pain intensity

Higher dose adds risk for opioid-related overdose but other risk factors contribute, and no dose is completely safe.[124] Although the CDC guideline identified a dose limit of 90 morphine milligram equivalents (MMEs) daily after which caution is advised, another study involving 2.2 million North Carolinians did not show evidence of a distinct risk threshold and found much of the risk at higher doses to be associated with co-prescribed benzodiazepines.[122]

Evidence is strong that prescribing opioids together with benzodiazepines increases risk for overdose,[20] and evidence suggests that co-prescription of opioids and gabapentinoids also may increase overdose risk.[20]

Consider use of the Veterans Administration-developed Risk Index for Overdose or Serious Opioid-induced Respiratory Depression (RIOSORD) to assess for the risk of a serious opioid-related respiratory depression event in patients treated with medical opioids (available here: https://paindr.com/wp-content/uploads/2015/09/RIOSORD-tool.pdf). This tool showed nearly 90% predictive accuracy in a Veterans Administration case–control analysis of close to 9,000 veteran patients[125] and was subsequently validated in the commercial insurance records of a nonveteran population of approximately 18 million medical users of prescription opioids.[126]

Screening for Opioid Misuse Risk

Several screening tools are available to help HCPs detect current opioid misuse or risk that a patient may develop misuse or OUD during the course of opioid therapy. None has been associated with a high degree of predictive accuracy;[1,61] however, they are generally recommended in expert guidelines for their clinical utility (Table 6). Most of the tools in Table 6 are specific to opioid-treated patients with pain. The HHS Inter-Agency Task Force has also cited the Drug Abuse Screening Test[127] and the Alcohol Use Disorders Identification Test[128] as validated tools.[1]

HCPs should select the tool that fits best into their clinical practice, treating assessment as routine and encouraging patients to share information honestly. Even single questions, such as, "How many times in the past year have you used an illegal drug or used a prescription medication for nonmedical reasons?" can be effective means of screening for drug use if implemented consistently.[129] An answer to the single question of one or more is considered positive and was found in a primary care setting to be 100% sensitive and 73.5% specific for the detection of a drug-use disorder compared with a standardized diagnostic interview.[61,129] The information gained from screening is documented in the patient record and used to assist selection of the best treatments, including medication classes and delivery systems, to facilitate ongoing monitoring to help mitigate potential opioid misuse, and to inform whether SUD treatment and mental-health referrals are warranted.

A baseline urine drug test (UDT) should take place before opioids are prescribed or continued.[20,61,77] Usefulness of a UDT includes identifying the presence of prescribed medications as well as unauthorized prescription and illegal drugs, helping to guide clinical decisions, and serving as an alert to potential drug-drug interactions.

Immunoassay testing done at the point of care (POC) can help quickly establish whether a new patient has recently ingested illegal drugs or other opioid and prescription drugs but typically cannot isolate specific opioids.[137] If POC test results are inconsistent with medical direction, the next step is a quantitative evaluation, usually via gas chromatography/mass spectrometry (GC/MS) technology or liquid chromatography dual mass spectrometry (LC/MS/MS). These tests can detect actual drugs and their metabolites. Some laboratories offer definitive testing via LC-MS/MS that may be given as the initial test; however, most guidelines still suggest immunoassay ahead of confirmatory testing due to cost concerns.[137]

A query of the state prescription drug monitoring program (PDMP) should also take place before opioids are initiated or continued.[20,61,77] These importance checks of the patient's past and present opioid prescriptions are done at initial assessment and during the monitoring phase. PDMP data can help to identify patients who have had multiple practitioner episodes or potentially overlapping prescriptions that place them at risk of a misuse or drug interaction problem. The use of an PDMP is also aimed at stopping the spread of opioid misuse and diversion as a public health problem.

For Colorado specific PDMP information, review Appendix A at the end of this course, or visit https://dpo.colorado.gov/PDMP.

If baseline UDT and PDMP checks indicate unauthorized prescriptions or there are other signs suggestive of opioid misuse, the results should be discussed with the patient and, if OUD or another substance-use issue is suspected, treatment should be offered and/or a specialist referral can be given. More will follow on using UDT and PDMP checks for periodic monitoring during the course of opioid therapy.

BEFORE MOVING ONTO THE NEXT SECTION, PLEASE COMPLETE CASE STUDY 1 ON THE NEXT PAGE.

Table 6. Screening Tools for Risk of OUD in Opioid-Treated Patients

Tool	# of Items	Administered	Approximate Time to Complete
For Use Prior to Initiating Opioid Therapy			
Opioid Risk Tool (ORT)[130]	5	Health-care practitioner	1 min
Revised Screener and Opioid Assessment for Patients with Pain (SOAPP-R)[131]	24*	Patient	5 min
Diagnosis, Intractability, Risk, Efficacy (DIRE)[132]	7	Health-care practitioner	2 min
Pain Medication Questionnaire (PMQ)[133]	26	Patient	10 min
For Use During Opioid Therapy			
Current Opioid Misuse Measure (COMM)[134]	17	Patient	10 min
Patient Version Prescription Drug Use Questionnaire (PDUQp)[135]	31	Patient	20 min
Brief Initial Drug Screenings Not Specific to Pain Population			
CAGE-AID (Adapted to Include Drugs)[136]	4	Health-care practitioner	1 min
Drug Abuse Screening Test (DAST)[127]	10	Health-care practitioner or patient versions	5 min
Alcohol Use Disorders Identification Test[128]	10	Health-care practitioner or patient versions	5 min
*4- and 12-item SOAPP formats available			

Case Study 1

Instructions: Spend 5–10 minutes reviewing the case below and considering the questions that follow.

Jonathan, 42, presents looking anxious and in considerable pain. A year ago, while moving furniture, he experienced sudden piercing mid-low back pain that radiated down his left leg. The patient had an L4/5 microdiscectomy that appeared at first to relieve radicular symptoms, but the symptoms returned six weeks afterward. His pain intensity at rest is 6 out of 10 on the VAS, but movement brings on back spasms, which causes his pain level to spike to 9 out of 10. Walking and bending at the waist are excruciating, and he finds it hard to find a comfortable position when lying down. He reports that ACET and ibuprofen bring no relief and admits that he would like to receive an ER formulation of oxycodone because he already knows it works for the pain, having occasionally used the same prescription belonging to a friend. Jonathan is now estranged from his parents, both of whom drank to excess and used illegal drugs when he was a child. He reports a history of panic attacks and nightmares ever since his time spent serving in the armed forces. He smokes approximately 30 cigarettes a day. He has no cardiopulmonary, gastrointestinal, endocrine, or neurologic diseases.

1. **How might Jonathan's pain type, intensity, duration and treatments tried inform the creation of a treatment plan for him?**_____

2. **What mental health screening tool(s) would be helpful?**_____

3. **What risk factors for opioid misuse are present and how might they influence treatment choices?**_____

Guidelines and Regulations Governing Long-Term Opioid Therapy

If, after a risk-benefit analysis, a trial of opioid therapy for chronic pain is warranted, HCPs have access to numerous guidelines developed by professional medical societies, states, and federal agencies to assist in setting and executing treatment plans. Common recommendations include: [20,61,77,85,138]

- Start patients on the lowest effective dose
- Conduct UDT at baseline and on follow-up as appropriate
- Check PDMP at baseline and on follow-up as appropriate
- Monitor pain and treatment progress with documentation, using greater vigilance at higher doses
- Pay close attention to drug-drug and drug-disease interactions
- Recognize special risks with fentanyl patches and methadone
- Titrate slowly and cautiously
- Consider using an opioid-specific risk assessment
- Use safe and effective methods for discontinuing opioids (e.g., tapering, making appropriate referrals to substance abuse treatment or other services)

To dispense any controlled substance, including opioids, HCPs must be registered with the DEA. Be aware also that each state may have laws and regulations that govern many aspects of opioid prescribing. Each HCP should check the laws and regulations within the state of practice and take care to comply with all requirements.

Applicable state regulations are evolving rapidly and contain restrictions and directives such as:[139]

- Dose and treatment duration limits
- Expanded PDMPs and new requirements for their use
- Required continuing medical education
- Required written pain treatment agreements
- Required physical exam prior to prescribing
- Required bona fide patient-physician relationship
- Specified timing of follow-up visits and/or UDT
- Presentation of patient identification to a pharmacist prior to receiving opioids
- Medicaid plans requiring single prescriber and single pharmacy for certain high-risk patients

Whenever federal and state law conflict, the more restrictive law applies. The Prescription Drug Abuse Policy System (PDAPS), funded by the National Institute on Drug Abuse, tracks key state laws related to prescription drug abuse here: http://www.pdaps.org/.

The CDC issued has a practice guideline for using opioids to treat patients who have chronic pain and do not have an active malignancy or need palliative or end-of-life care.[61] The guideline defines long-term opioid therapy as use of opioids on most days for greater than three months. Authors of the guideline state that its strictures should not be used to deny clinically appropriate opioid therapy to patients but, rather, to help HCPs in primary care consider all treatment options with an eye to reducing inappropriate opioid use.[140]

Initiating or Continuing Long-Term Opioid Therapy

The HCP may consider a trial of long-term opioid therapy as one therapeutic option if the patient's pain is severe and ongoing or recurs frequently, diminishing function or quality of life, and is unrelieved or likely to be unrelieved by non-opioid therapies.[77] To initiate a trial or continue opioid therapy, the HCP should complete the initial exam and diagnostic procedures and assess pain, mental-health, social, substance, and opioid risk as previously described. A list of items to document in the patient record is shown in Table 7.[20,61,77,85,138,141] Medical records should be kept up-to-date and be legible so as to be easily reviewed.

Informed Consent

Patients started on opioid therapy for chronic pain should be informed of the potential risks and benefits. The most serious risk with any opioid is respiratory depression leading to death. Patients who have never taken opioids or whose medications or doses will be changed should be counseled to expect sedation or other cognitive effects.

An informed consent form should be signed by the HCP and the patient and retained in the medical record. Items recommended in informed consent include:[20,77,141]

- Potential risks and benefits of opioid therapy
- Risks of OUD, overdose, and death even at prescribed doses
- That evidence is limited for benefit of opioids in chronic noncancer pain

Table 7. Items to Perform and Document in the Patient Record When Prescribing Opioid Therapy for Chronic Pain[20,61,77,85,138,141]

1. Signed informed consent
2. Signed opioid treatment agreement(s)
3. Pain and medical history
   - Chief complaint
   - Treatments tried and patient response
   - Past laboratory, diagnostic, and imaging results
   - Comorbid conditions (e.g., medical, substance-use, psychiatric, mood, sleep)
   - Social history (e.g., employment, marital, family status, substance use)
   - Pregnancy status or intent, contraceptive use
4. Results of physical exam and new diagnostic and imaging tests
   - Review of systems
   - Pain intensity and level of functioning
   - One or more indications for opioid treatment
   - Objective disease/diagnostic markers
5. Results of opioid risk assessment prior to prescribing opioids
   - Clinical interview or any screening instruments
   - Personal history of SUD, mental health disorder
   - Family history of SUD, mental health disorder
   - Co-management or treatment referral for patients at risk for SUD
   - Treatment or referral for patients with active OUD
   - Treatment or referral for patients with undiagnosed depression, anxiety, other mental health disorders
6. Treatment goals for pain relief, function, quality of life
7. Treatments provided
   - With risk-benefit analysis after considering available nonpharmacologic and non-opioid pharmacologic op&ons
   - All medications prescribed (including the date, type, dose, and quantity)
   - All prescription orders for opioids and other controlled substances whether written or telephoned
8. Prescription of naloxone, if provided, and rationale
9. Results of ongoing monitoring toward pain management and functional goals

SUD = substance-use disorder OUD = opioid-use disorder; PDMP = prescription drug-monitoring programs; UDT = urine drug testing

- A mention of nonpharmacologic and non-opioid therapeutic options for pain treatment
- Potential short- and long-term side effects, such as cognitive impairment and constipation
- The likelihood that tolerance and physical dependence will develop
- Risks of drug interactions
- Risks of impaired motor skills affecting driving, operating machinery, and other tasks
- Signs and symptoms of overdose
- Risks when combining opioids with other CNS-depressants, including benzodiazepines and alcohol
- The importance of the patient disclosing all medications and supplements
- How to handle missed doses
- Any important product-specific risks, such as the dangers of chewing an ER formulation

Opioid Treatment Agreements

Opioid treatment agreements that spell out patient and HCP expectations and responsibilities are recommended by most opioid guidelines.[77,85] Consider including:[141]

- Treatment goals in terms of pain management, restoration of function, and safety
- Patient's responsibility for safe medication use, such as agreement not to take more than prescribed, alter pills, or combine with alcohol, unauthorized prescriptions, or illicitly-obtained drugs
- Patient's responsibility to obtain prescribed opioids from only one HCP or practice
- Patient's responsibility to fill prescriptions at only one pharmacy
- Patient's agreement to periodic UDT or other drug tests
- Instructions for secure storage and safe disposal of prescribed opioids
- HCP's prescribing policies, including handling of early refills and replacing lost or stolen medications
- Reasons for which opioid therapy may be changed or discontinued, including violation of the treatment agreement
- Statement that treatment may be discontinued without the patient's agreement
- HCPs availability policy, including responsibility to provide care for unforeseen problems and to prescribe scheduled refills
- Education that the patient should not expect complete elimination of pain
- The patient's signature

The forms for informed consent and treatment agreements may be combined into one document and adapted to the HCP's needs and preferences. Examples of informed consent and treatment agreement documents are available online from the New Hampshire Medical Society at https://www.nhms.org/Resources/Opioid-Substance-Related-Resources/Examples-of-opioid-informed-consent-agreement.

Both forms can help facilitate discussions with the patient about ongoing risks and benefits and also provide structure in case difficult conversations become necessary regarding adherence to the treatment regimen. It is advisable to have a strategy to manage opioid misuse by the patient should it occur and to know and discuss with the patient indications for which opioid therapy may be discontinued.

Managing Side Effects

HCPs should expect, prevent, and take steps to manage opioid-related adverse effects. Common opioid side effects with suggested management strategies are listed in Table 8.[77]

Managing Comorbid Disorders

Patients should have psychiatric disorders and psychological symptoms managed in the context of multidisciplinary care. Benzodiazepines may be helpful as second-line agents when used short term to treat the anxiety that arises with pain from injury or hospitalization; however, benzodiazepines are best avoided for long-term use because of their addictive potential, the increased risk for overdose, respiratory depression, and death when co-prescribed with opioids, and the blunting of cognitive and, therefore, coping skills in patients with chronic pain.[1] In 2016, the FDA announced the requirement of boxed warnings with information about serious risks of extreme sleepiness, respiratory depression, coma, and death associated with combining prescription opioids and benzodiazepines.[70]

For chronic mental-health disorders, a combination of medications indicated for the specific condition plus evidence-based psychotherapy, such as CBT, are recommended.[1] SSRIs and SNRIs (and sometimes buspirone) are medications most frequently used for generalized anxiety disorder, which often accompanies chronic pain.[1] Tricyclic antidepressants are sometimes used for panic disorder, but SSRIs, because of their lower side effect profile, are generally considered safest and most effective.[1] Recommended medications for PTSD include venlafaxine ER and prazosin.[1] When comorbid anxiety disorders are severe, psychiatric consultation to establish medication regimen is recommended.[1] In milder cases, no medication may be necessary if adequate behavioral and other nonpharmacologic treatments are helpful.

In general, opioid therapy in patients with untreated OUD is unlikely to achieve therapeutic aims, and initiating it is not recommended.[20] HCPs may consider or continue opioids for patients with chronic pain and histories of drug abuse and psychiatric issues only if they are able to implement more frequent and stringent monitoring parameters.[61]

Table 8. Common Opioid Side Effects and Suggested Management Strategies	
Side Effect	**Management**
Respiratory depression	Screen for sleep apnea Avoid sedatives, benzodiazepines, barbiturates, and alcohol
Constipation	Increase fiber and fluids; start prophylactic laxative treatment, particularly in older patients
Nausea or vomiting	Antiemetic therapy; symptoms tend to diminish
Hormonal deficiencies	Screen symptomatic patients (fatigue, sexual dysfunction
Sedation, mental clouding	Counsel as to home, work and driving safety, and concomitant CNS-depressant risks; symptoms tend to diminish
Pruritis	Treatments largely anecdotal (may include reducing dose, changing medication)
Hyperalgesia	Reduce dose or change medication

In such situations, HCPs should strongly consider consultation and co-management with a pain, mental-health, or addiction specialist or else refer the patient for specialist management.[61,77] Prescription of opioids may not be appropriate until the comorbidity has been addressed.[77]

For patients exhibiting active OUD who are already on opioids, oftentimes at high doses, HCPs should provide or refer for addiction management and treatment with medications such as buprenorphine or methadone via an opioid treatment program.[72]

Treatment of pain with full agonist opioids in patients with OUD would need a careful evaluation of the risks versus benefits to determine management. It is unlikely that a patient with OUD and pain will have adequate pain control in the absence of treatment of OUD.[20] Taper of opioids may be considered in addition to initiation of OUD treatment.

Sudden discontinuation or tapering of opioids in the absence of treatment of OUD with buprenorphine or methadone will put patients with OUD at risk for serious adverse outcomes (see subsequent sections on tapering opioids and managing OUD).[15,16,72]

Dosing and Titration Considerations

Opioids are best when used at the lowest effective dose and combined with non-medication and/or non-opioid medication modalities of treatment.[61,77] When opioids are initiated, the goal is to select the lowest effective dose for shortest duration possible to achieve therapeutic goals.[19,61] The risk of overdose increases with the dose, but the therapeutic window varies considerably from patient to patient.

Various opioid products, delivery systems, and formulations are available to maximize analgesia and minimize or prevent adverse effects. For outpatient chronic pain management, opioids are typically administrated through the oral, transmucosal, and transdermal routes. Each medication has advantages and disadvantages and safety concerns, some of which are intrinsic to all opioids and some of which are specific the route or formulation.

In pain management, IR/SA opioids, are indicated for pain severe enough to need opioid treatment and for which non-opioid treatments are ineffective or not tolerated.[69] These short-acting opioids are preferred and considered safer when initiating a therapeutic trial of opioids and are often prescribed for use as needed every 4 to 6 hours.[69,77] Commonly prescribed IR/SA opioids include morphine, hydromorphone, oxymorphone, codeine, fentanyl, hydrocodone, and oxycodone.[142] Codeine, hydrocodone, and oxycodone are also available in combination with ACET or an NSAID, which limit daily dose due to risk for liver and GI toxic effects.[142] Patients with no or limited exposure to opioids should be initiated at the lowest available dose and titrated slowly to minimize adverse effects.[77] Dual-mechanism opioids may control pain with less opioid, and opioid-sparing techniques, such as combining therapeutics should be considered.

If patients require long-term maintenance and pain is severe enough to require around-the-clock analgesia that is not adequately relieved by IR/SA opioids or other therapies, consider a transition to ER/LA opioids with scheduled dosing.[143] ER/LA opioids are primarily intended to be taken once or twice a day, are not indicated for acute pain, and are for use only in patients who are already tolerant to opioids.[68] It is critical also that HCPs be aware that all transdermal and transmucosal fentanyl and hydromorphone ER products are for use only in opioid-tolerant patients and never for acute or short-term pain.[68] Adult patients are considered opioid tolerant if they have received the following dosages of opioids (or equianalgesic dosages of other opioids) for at least one week:[61,68]

- 60 mg daily of oral morphine
- 25 mcg per hour of transdermal fentanyl
- 30 mg daily of oral oxycodone
- 8 mg daily of oral hydromorphone
- 25 mg daily of oral oxymorphone

Product information for individual formulations contain guidance on degree of opioid tolerance necessary for administration and minimum titration intervals.

IR/SA opioids are sometimes used for severe exacerbations of pain (i.e., "breakthrough pain") that occur against a background of chronic pain that is being treated with ER/LA opioids. This practice has support but is controversial in chronic noncancer pain, because the rapid-onset medications used as rescue medications may increase risk for misuse.[77]

Because patient response varies, titrating to a therapeutic dose should be individualized with close attention to efficacy, tolerability, and presence of adverse effects. The CDC recommends reassessing risk vs. benefit at ≥50 MME per day, avoiding increasing dosages to ≥90 MME per day, or carefully considering the rationale.[61] Authors of the CDC guideline subsequently clarified that the guideline does not support sudden dismissal of patients or hard limits on dosage and treatment durations.[15] These circumstances particularly affect patients who are already receiving long-term opioid therapy and who seek continuation of care after losing access elsewhere.[144] It must be reemphasized that recommended threshold doses do not remove the necessity of exercising caution at any dose or the importance of individualizing the dose.

Particular care is essential, not only during opioid dose initiation but also whenever doses are increased, changed to a different opioid, or when CNS-depressant medications are added to the regimen. Patients should be monitored carefully, particularly within 24 to 72 hours of opioid initiation or upward titration. Studies show that patients are particularly vulnerable to respiratory depression at these times.[119,120]

HCPs should consider opioid initiation a trial, discuss with the patient the risks and benefits of continuing opioid therapy beyond 90 days,[19] and, if opioids are continued, reevaluate the treatment plan at least every three months. Patients who require repeated dose escalations to achieve sufficient pain relief should be reevaluated for the cause, and the risk-to-harm benefit of long-term opioid therapy should be reconsidered.[77]

Opioid Rotation

A patient who suffers inadequate analgesia or intolerable side effects from one opioid may do better with a different opioid.[73] Because mu-agonists produce varied effects, switching a patient to a different medication may allow for pain control at a lowered dose.

Care must be taken during the switch, because tolerance to a particular opioid does not translate to tolerance to another, a concept known as incomplete cross-tolerance. Patients should be monitored especially closely during any dose or formulation changes.

Equianalgesic dosing tables, conversion charts, and calculators allow for the conversion of any opioid dose to the standard value of morphine (i.e., MME).[145] These tables have limitations because the supporting studies were conducted on single doses in patients with limited opioid exposure and did not report on dosing over time.[146] Therefore, experts have advised HCPs to use the equianalgesic dosing tables only as a starting point for opioid rotation, then reduce the dose (≥25% to 50% is advised, more with methadone) when converting to the new opioid.[77] A greater reduction is advised in patient who are older or medically frail. A 75% to 90% reduction[147] or considering the patient opioid naïve is advised for rotating to methadone followed by careful monitoring.[77] Conversions to transdermal routes of fentanyl and buprenorphine require special considerations, and HCPs should closely follow instructions in the prescribing information.

Naloxone Prescription

Naloxone can be used to save lives during overdose from a prescribed or illicit opioid, and its presence increases safety for the patient and others who live in or visit the home.[61] Strong evidence shows that providing naloxone to patients reduces opioid-related emergency-department visits.[93]

Take-home naloxone can be easily prescribed and is generally recommended for all patients who receive an opioid prescription. It is particularly recommended with the presence of opioid overdose risk factors, such as history of overdose, history of SUD, clinical depression, opioid dosages ≥50 MME/day, concurrent benzodiazepine use,[61] or with evidence of increased risk by other measures. Two easily administered products are an auto-injection device and a nasal spray that requires no assembly. Patients given naloxone should keep it available at all times.[119]

Naloxone administration can cause withdrawal symptoms, and people who have been administered it should have follow-up medical care. Laws vary by state regarding immunity for physicians or laypeople administering naloxone and can be checked here: http://www.pdaps.org/datasets/laws-regulating-administration-of-naloxone-1501695139.

Patients and their caregivers and other family members should be instructed on the signs of overdose and counseled to do the following if an opioid overdose is suspected:[148]

- Call 911 immediately
- Administer naloxone if available
- Try to keep the person awake and breathing
- Lay the person on their side to prevent choking
- Stay with the person until emergency workers arrive

Signs of an opioid overdose include:[76,148]

- Small, constricted "pinpoint pupils"
- Sedation or loss of consciousness
- Slow, shallow breathing
- Choking or gurgling sounds
- Limp body
- Pale, blue, or cold skin
- Snoring heavily and cannot be awakened
- Periods of ataxic (irregular) or other sleep-disordered breathing
- Trouble breathing
- Dizziness, confusion or heart palpitations

Periodic Monitoring of Long-Term Opioid Therapy

Follow-up with patients being treated with opioids is aimed at preventing potential misuse and tracking progress toward goals of pain control and function. Items to evaluate and document include analgesia, daily activities, adverse effects, aberrant drug-related behaviors, cognition, function, and quality of life. Similarly, patients should be reassessed for the development of tolerance and consideration of adjunctive therapies, opioid rotation, tapering, or discontinuation.[1] Tools available to assist with frequent reassessment and documentation include the Pain Assessment and Documentation Tool[149] and the COMM.[134] Ongoing periodic monitoring should incorporate checks of the PDMP and UDT.[137] When counseling patients, it is best to present UDT, PDMP data, and other monitoring measures to patients as a routine, consensual part of medical care using nonjudgmental language.

The CDC guideline states that patients on opioid therapy should be reevaluated within one-to-four weeks of initiation or dosage change and at least every three months thereafter to ensure benefits outweigh risks.[61] Monitoring measures should be ongoing with every patient prescribed opioid therapy.[20] Patients with more comorbidities or higher misuse risk require more stringent monitoring measures and more frequent follow-up than patients with less risk for harm.[19] Some expert guidance recommends using risk stratification to set clinic visit frequency and other monitoring measures as determined by patient risk category (low, moderate, or high risk) during initial screening and clinical follow-up.[77]

The recommended frequency for periodic review of PDMP data ranges from every prescription to every three months.[61] A consensus-based recommendation for UDT frequency is to test every patient at least once annually and higher-risk patients from two-to-three times annually.[137] It is very important to check local and state regulations and the recommendations of state medical boards in the area of practice, as many of these bodies set expectations for the timing and other particulars regarding UDT and PDMP checks.

Interpreting UDT results requires caution as the tests have limitations.[61] These include:[137]

- Cross-reactivity with other drugs or substances
- Potential for false positives (e.g., poppy seeds positive for opiates)
- Potential for false negatives
- Variable drug metabolism
- Laboratory error

Unexpected results, such as the absence of prescribed medications that could indicate diversion, should be discussed with the patient and documented in the record along with plans to address the results.

Reassessment of any comorbid mental health disorders is also part of ongoing opioid therapy. Tools used for initial assessment of anxiety, depression, and somatic symptoms may also be used for monitoring of these conditions and reevaluating the treatment plan.[150]

Seeking Expert Referrals

Knowing hen to seek specialist care is part of treatment with opioids. In general, the HCP should consult with a pain, addiction, or mental-health specialist or refer the patient for specialist care whenever:

- Pain continues to worsens with treatment
- OUD is suspected or identified
- Worsening of any mental health disorder is observed, including any SUD

Uncontrolled or increasing pain severity despite attempts to optimize the medication regimen and in the absence of a clear explanation is a signal that pain specialist consultation or referral is advisable.

In the presence of ongoing or severe behaviors suggestive of opioid misuse, HCPs should consider that patient may be suffering from OUD or other substance-use or mental-health disorders. When an active OUD or a recent OUD history is present, HCPs should strongly consider referral for medication treatment of addiction (unless this is provided in your clinic), specialist pain management, and/or tapering opioids and managing pain with non-opioid therapies.[61]

Criteria of an OUD are described later in this activity. Signs and symptoms seen in a clinical scenario include:[151]

- Taking opioids compulsively and long term for no legitimate medical purpose
- If pain is present, taking opioids in excess of prescription
- Obtaining opioids from unauthorized sources
- Falsifying or exaggerating medical problems to receive opioids
- Significant tolerance and physical dependence (although these may also occur in patients without OUD)
- Conditioned responses of craving that persist after cessation

Other life circumstances that may accompany OUD but are not always seen include:[151]

- Marital problems, including divorce
- Unemployment and irregular employment
- Financial insecurity
- History of drug-related crimes

SUDs involving alcohol or any other drug may threaten the success of opioid therapy and introduce safety risks. SUD should be suspected when the recurrent use of alcohol or drugs causes clinically significant impairment, including health problems, disability, and failure to meet major responsibilities at work, school, or home. The coexistence of both a mental health and an SUD is referred to as co-occurring disorders. The National Institute for Mental Health's Mental Health Information website has information about specific mental conditions and disorders as well as their symptoms: https://www.nimh.nih.gov/health/topics/. The presence of a psychiatric or substance-use condition does not mean the patient is not experiencing real pain. The many contributing factors from the biological, psychological, and social domains as well as chronic pain's adverse impact on relationships, work, sleep, function, overall health, and quality of life explain why a comprehensive approach to pain management is optimal.[14] These complexities also explain why patients often respond better to a combination of therapeutic modalities rather than a unimodal medication regimen.

Tapering

Before initiating opioid therapy, HCPs should have an exit strategy in place to humanely taper opioids whether the goal is dose reduction or to discontinue opioid therapy. Indications for discontinuing opioid therapy may include:[72]

- Failure to achieve sufficient analgesia
- Intolerable side effects
- Resolution of pain
- Development of OUD or serious misuse
- Higher doses without evidence of benefit
- Presence or warning signs of an impending serious event (e.g., confusion, sedation, slurred speech)
- Concurrent medications (e.g., benzodiazepines) that increase risk for a serious outcome
- Concurrent medical condition(s) (e.g., lung disease, sleep apnea, liver disease, kidney disease, fall risk, advanced age) that increase risk for a serious outcome
- A pattern of ongoing failure to adhere to the treatment plan to which the patient agreed

Signs of serious nonadherence that may indicate opioids are unsafe for the patient include:[77]

- Repeatedly increasing dose without HCP knowledge
- Sharing medications
- Unapproved opioid use
- Use of illicit drugs
- Obtaining opioids from unauthorized sources
- Prescription forgery
- Multiple episodes of losing prescriptions
- Polysubstance use

The CDC suggests evaluating new patients currently on >90 mg MMD daily opioid dose or whenever risks outweigh benefits for tapering protocol,[61] while the VA/DoD practice guideline recommends a comprehensive reassessment that recognizes the risks of the high dose.[20] However, one must beware of abrupt opioid discontinuation and know that treatment is individualized.[1,15-17,20] The CDC guideline is meant to advise HCPs to avoid increasing doses above 90 mg MME daily but is not meant to circumscribe individualizing treatment or to justify abrupt reduction from high doses.[72] Nor is the guideline meant to justify reducing or discontinuing opioids that may be medically indicated and when benefits outweigh risks.[72]

Patients who are candidates for taper should be treated with alternatives to opioid therapy for pain. HCPs should avoid dismissing patients from care and should ensure whenever possible that patients continue to receive coordinated care.[72] Referral should include, as indicated, treatment of OUD or management of psychiatric illnesses.[119] In an outpatient setting, taper should be done so as to avoid opioid withdrawal in physically-dependent patients. Taper may be accomplished in a detox setting if the patient is unable to reduce opioid dose.

An expert consensus guideline offered the following recommendations regarding tapering opioids:[20]

- Evaluate comorbidities, the patient's psychological condition, and other relevant factors before beginning the taper
- Educate the patient and family about the taper protocol
- Manage withdrawal symptoms (e.g., nausea, diarrhea, muscle pain, myoclonus) using non-opioid analgesics and adjuvant agents
- For complicated withdrawal symptoms, refer the patient to a pain specialist or chemical dependency center
- Refer for counseling or other support during the taper if there are significant behavioral issues

Diversion of opioids or other controlled substances is a contraindication for continuing opioid therapy.[20] With confirmed diversion, the best practice is to monitor for withdrawal symptoms, offering necessary support and treatment of SUD, if present.[20]

There is no one established taper rate that will work best for every patient.[1,15-17,20] Certain characteristics will influence the recommended speed of tapering. These include opioid dose, duration of therapy, type of opioid formulation, and co-occurring psychiatric, medical, and substance-use conditions.[20] Various rates have been studied or recommended by experts:

- The CDC recommended 10% per week reduction as a starting point.[152]
- A more recent HHS guide suggested individualized tapering plans that range from slower tapers of 10% per month (or slower) to faster tapers of 10% per week until 30% of the original dose is reached, followed by 10% weekly reductions of the remaining dose.[72]
- The VA/DoD practice guideline suggests 5% to 20% reduction every four weeks, individualizing according to patient need (e.g., some patients may need or tolerate a faster taper when risks are too high, while patients on high doses require a very slow taper).[20]
- The HHS guide allows for rapid tapers (e.g., over two-to-three weeks) when risks of continuing the opioid outweigh the risks of a rapid taper (e.g., in the case of a severe adverse event such as overdose) and further warns that ultrarapid detoxification under anesthesia is associated with substantial risks and should not be used[72]

A principle to remember is that slow tapers may require several months or years and are more appropriate than faster tapers for patients who have been receiving prolonged opioid therapy.[72] Rapid reduction of opioid doses should occur only if there is imminent danger to the patient from continuing doses (such as an overdose event at the current dose, medical complications, or dangerous behaviors such as injecting opioids), or in cases in which it is discovered the individual is obtaining pills to divert.[61,144]

Tapering works best when it is collaborative between the HCP and the patient, when tapering is slow and careful, when support and close monitoring are offered, and when comorbidities such as depression, anxiety, and insomnia are concurrently addressed.[144] It is helpful to slow or to pause and restart tapering at times. There are serious risks to noncollaborative tapering in patients who have been prescribed opioids for a long period and have physical dependence, including acute withdrawal, pain exacerbation, anxiety, depression, suicidal ideation, self-harm, ruptured trust, and patients seeking opioids from high-risk sources.[72] Include patients in discussions of taper planning and take time to gain patient buy-in to the plan whenever safety allows.

It is of paramount importance to address opioid withdrawal symptoms (Table 9).[144] Early withdrawal symptoms (e.g., diarrhea and cramping, anxiety, restlessness, sweating, yawning, muscle aches) usually resolve after 5-10 days but can take longer.[72] Other post-acute withdrawal symptoms (e.g., dysphoria, insomnia, irritability) can take weeks or months to resolve.[72] Recommended oral medications to manage withdrawal symptoms (particularly for faster tapers) include alpha-2 agonists for autonomic symptoms such as sweating and tachycardia and symptomatic medications for muscle aches, insomnia, nausea, cramping, and diarrhea.[72]

Table 9. Common Opioid Withdrawal Symptoms[144]	
Physical symptoms	Tremor Diaphoresis Agitation Insomnia Myoclonus Diffuse pain/hyperalgesia Hyperthermia Hypertension Cramping/diarrhea Pupillary dilation Piloerection Release of stress hormones Pain increase
Affective symptoms	Dysphoria Anhedonia Anxiety Depression Hopelessness/suicidal ideation

Follow-up and behavioral health support is very important during tapering. HCPs should acknowledge patient fears of pain, stigma, withdrawal, and abandonment while reassuring them that many patients have improved function after tapering, although the pain might be worse at first.[72,93] This is a time to collaborate with mental-health and other specialists and to watch closely for signs of OUD, anxiety, depression, and suicidal ideation. At least weekly follow-up has been used in successful tapers.[72]

Buprenorphine or Slow Taper in Select Patients

In some patients on long-term opioid therapy, even on higher-than-recommended doses, with demonstrated benefit and no evident adverse effects, aberrant behavior, or major risks, taper may not be the best course of action.[144] Reports of harms after involuntary opioid discontinuation include overdoses, termination of care, emergent hospital or emergency department visits, and suicidal ideation or behavior.[144] Though other patient factors may also contribute to these behaviors, opioid stoppage in such patients, particularly when abrupt or nonconsensual, may put them at risk for poor outcomes.[144]

Patients with worsened pain and function despite high daily opioid doses may exhibit a poor response to taper, whether or not OUD criteria are met, and may benefit from transitioning to buprenorphine.[72] Buccal and cutaneous patches of low-dose buprenorphine are FDA-approved for the treatment of pain, and buprenorphine/naloxone has been used off-label as an analgesic for chronic pain.[144] Buprenorphine has safety advantages over full mu agonists because respiratory depression tends to plateau as dose increases, and it is also less subject to dose escalation. Use of buprenorphine/naloxone to treat OUD no longer requires specific training, but a waiver from the Drug Enforcement Administration (DEA) is required to prescribe it. Practitioners are encouraged to receive training prior to use and there are new, short trainings that are freely available (see the following link: https://elearning.asam.org/products/buprenorphine-mini-course-building-on-federal-prescribing-guidance#tab-product_tab_overview.)

Transitioning from a full agonist opioid to the partial opioid agonist of buprenorphine requires careful attention to timing and may best be accomplished with consulting with an HCP experienced in its use. See the following link for support: https://pcssnow.org/.

Check the prescribing information for safe induction practice,[153] and consider the following safety principles with buprenorphine analgesia treatment as endorsed by an expert panel:[144]

- Buprenorphine may produce acute opioid withdrawal in patients on full mu agonists
- Patients discontinue all opioids the night before initiation (time depending on duration of action)
- After mild withdrawal is present, initiate 2-4 mg (repeated at two-hour intervals, if well tolerated, until withdrawal symptoms resolve)
- Typically, 4-8 mg will be needed the first day
- Reevaluate on day two and increase dose if needed
- Total dose given on day two can then be prescribed as the daily dose
- Unlike treatment for OUD, buprenorphine for analgesia should be given in three-to-four daily doses

Other patients with poor pain control and function who do not tolerate taper well may do better with a very slow taper over many months or even years.[144] Tapering decision points are shown in the following flow chart with the reminder that follow-up timing should be frequent and individualized (Figure 4).[72] Patients who continue on high-dose or otherwise high-risk regimens should be monitored, provided with overdose education and naloxone, and periodically encouraged toward appropriate therapeutic changes.[72]

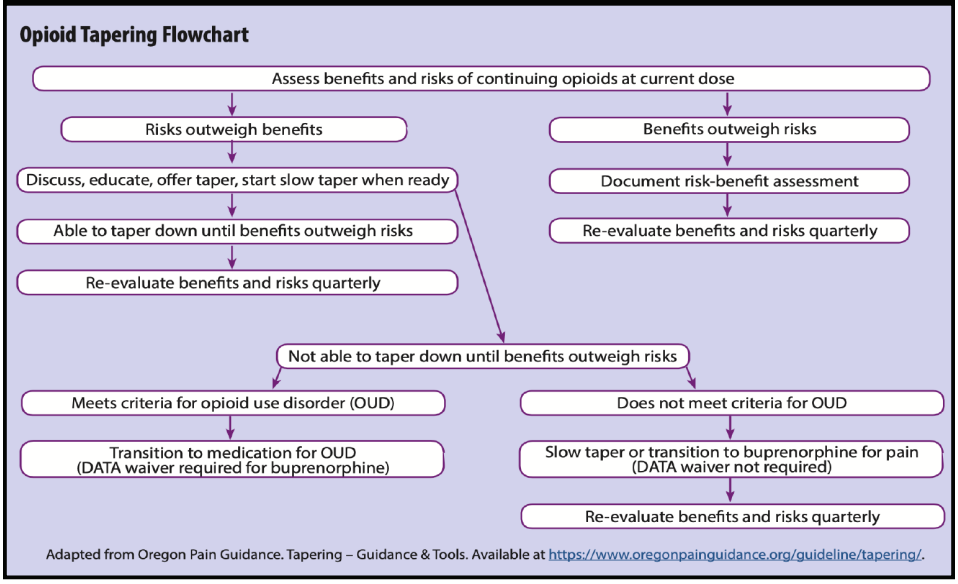
BEFORE MOVING ONTO THE NEXT SECTION, PLEASE COMPLETE CASE STUDY 2 ON THE NEXT PAGE.

Managing OUD

Methadone and buprenorphine are used to treat OUD, a process known as medication treatment for OUD (MOUD) when combined with behavioral therapy.[69] Buprenorphine works by suppressing and reducing opioid cravings. Methadone reduces cravings and withdrawal and also blunts the effects of opioids. Buprenorphine is widely used and encouraged for treating patients with OUD.[1,18] One reason is buprenorphine's antagonistic action at the kappa receptor, as this effect is associated with reducing opioid withdrawal symptoms along with helping to attenuate anxiety and depression.[1]

HCPs should treat OUD with buprenorphine/naloxone if authorized by the DEA Drug Addiction Treatment Act of 2000 waiver or should refer the patient for addiction treatment.[144] Recent practice guidelines released by the Substance Abuse and Mental Health Services Administration within HHS are available here: https://www.samhsa.gov/newsroom/press-announcements/202104270930. Approaching OUD as a chronic illness can help patients to stabilize, achieve remission of symptoms, and establish and maintain recovery.[18]

Figure 4.



Adapted from Oregon Pain Guidance. Tapering – Guidance & Tools. Available at https://www.oregonpainguidance.org/guideline/tapering/.

Case Study 2

Instructions: Spend 5–10 minutes reviewing the case below and considering the questions that follow.

Giorgio, 62, has a long history of chronic pain in his back from degenerative disc disease. He has had three surgeries and tried trigger point injections and multiple medication regimens that include NSAIDs and gabapentinoids before being prescribed oxycodone for pain. He began to request higher oxycodone doses, citing difficulty sleeping and inability to function. He began to visit the clinic without an appointment, demanding opioids and behaving in an agitated and aggressive manner toward clinic staff. He was transitioned to methadone at 30 mg daily. The methadone relieved his pain at first but analgesia began to wane and his dose was increased until it reached 120 mg daily. As his pain continued to worsen, his HCP refused to raise his methadone dose any higher. Giorgio has a history of depression but does not take antidepressants. He can no longer work because of the pain, which he describes as at least a constant 9/10 on the numerical pain score. He is restless and finds it difficult to sit still during examination. A routine UDT turned up evidence of methamphetamine. During follow-up of the result, he admits to seeking out the street drug and also to procuring a few doses of heroin. He has a history of alcohol-use disorder that was in remission for many years but admits to recent relapse.

1. **What opioid risk factors and clinical signs and symptoms can be observed in Giorgio?**_____

2. **How might the Opioid Tapering Flowchart shown Figure 4 be used to evaluate and treat this patient?**_____

3. **What type of specialty referral is advisable for Giorgio?**_____

Patients with OUD should have access to mental health services, medical care, and addiction counseling to supplement treatment with medication.[18] Individualized psychosocial supports may include supportive counseling, recovery coaching, recovery support services, and other services that may be needed by particular patients.

Patients who present with or develop OUD or mental health disorders or both and who also have persistent pain require multidisciplinary care.[1] Patients with co-occurring pain and OUD should be offered MOUD.[18,19]

For any population with trouble accessing treatment for OUD, including poorer urban areas and rural areas with limited treatment options, expanding the number of qualified HCPs able to treat OUD with buprenorphine in an office-based setting leads to more ready diagnosis and treatment.

Because OUD medication is best combined with evidence-based psychological and behavioral therapies, the growing popularity and feasibility of accessing telehealth sessions is another possible means of expanding access to currently underserved communities.

Opioids and Concurrent Cannabis

Some patients who are taking opioids for pain are also using cannabis concurrently. However, synthesis of the data has been incomplete to guide clinical choices, and the short- and long-term health and safety effects have remained elusive. There are some data suggesting those who take medical cannabis are similar demographically to those who use cannabis recreationally.[154]

A prospective cohort study of patients with musculoskeletal pain who are also on a stable dose of opioids was conducted to compare those who endorsed past-month cannabis for pain to those who denied any cannabis or illicit drug use.[155] Of 17% who endorsed past-month cannabis use for pain, 31% had a current medical cannabis card, and 66% reported that cannabis was helpful for reducing pain. Those who used cannabis for pain had higher rates of nicotine use, risk for prescription opioid misuse, and hazardous opioid use. No difference between groups were found in opioid dose, pain intensity, pain interference, or depression severity.

The most common route of administration is smoking, despite risks of pulmonary effects. Some evidence suggests vaporization may be safer in this regard, although other research notes similar exposure as smoking to carbon monoxide and other respiratory toxins.[156] Other delivery options including edibles and extracts.

Patients may develop cannabis-use disorder (CUD) and be unable to stop use on their own even though it is interfering with their health and function. Signs of CUD include:[155]

- Using a larger quantity or over a longer duration than intended
- Unsuccessful attempts to limit or quit
- Significant amounts of time spent obtaining cannabis
- Cravings
- School or occupational impairment
- Social or interpersonal impairment
- Reduction of social, occupational, or recreational activities
- Recurrent use in physically harmful situations
- Continued use despite recurrent physical or psychological harms
- Tolerance
- Withdrawal

Because some patients who are taking opioids will elect to use cannabis, HCPs should be aware of certain clinical recommendations:[156]

- Keep current with relevant federal, state, and institutional policies and laws
- Establish goals of care for cannabis use
- Screen for signs of misuse, CUD, and diversion
- Counsel patients on harms and risks on the basis of symptoms, condition, and comorbidities
- Advise on routes of administration using current evidence base
- Continually monitor similarly to opioids (informed consent, written agreement, regular follow-up, functional status, considering periodic urine testing, symptom severity, and use of other medications or substances)
- Monitor for other harms, including car accidents and falls
- Advise on discontinuation or referral to CUD treatment if pain relief and function goals are not being met without harm

Although not specific to pain therapy, useful measures to screen for CUD include:

- Single question: How often in the past year did you use marijuana (never, less than monthly, monthly, weekly, daily or almost daily)[155]
- The 8-item Cannabis Use Disorders Identification Test-Revised (CUDIT-R)[157]
- Comprehensive Marijuana Motives Measure[158]

The Basics of Addiction Medicine

Definitions and terms used to discuss addiction have evolved over time. Certain phrasing that is potentially stigmatizing has fallen out of usage, and more accurate terminology has been introduced. For example, patients with SUD, including OUD, should not be referred to as "addicts." The disease of OUD is diagnosed using DSM-5 criteria (Table 10).[92] A minimum of two-to-three criteria are required for a mild SUD diagnosis, while four-to-five is moderate, and six or more is severe;[92,151] OUD is specified if opioids are the substance of use. Addiction, while not a DSM-5 diagnosis, is a frequently used term and typically describes severe SUD. The presence of tolerance and physical dependence does not necessarily mean that an OUD has developed, particularly if the medication is taken as prescribed.

The rewarding effects of drugs occur through dopamine stimulation in the mesolimbic system of the brain.[159] When a drug stimulates the brain's mu opioid receptors, cells in the ventral tegmental area release dopamine into the nucleus accumbens, causing pleasurable feelings.[159] The pharmacokinetics and lipophilicity of the drug and its route of administration influence the speed and amount of dopamine released and thus the degree of reward experienced by the individual. Intravenous and inhalational use speeds onset more than oral ingestion. However, ER/LA opioids can be altered by the individual to produce a rapid onset of action by crushing, chewing, or dissolving in liquids, for example.[68]

Repeated ingestion stimulates the brain's reward system. At the same time, the brain creates conditioned associations and lasting memories that associate reward with environmental cues of drug use. Normally, inhibitory feedback from the prefrontal cortex helps most individuals overcome drives to obtain pleasure through unsafe actions.[159] However, prefrontal cortex inhibitory cues are compromised in people with addictions, and drug use behaviors are driven by a complex combination of both positive and negative reinforcements. Positive reinforcements include the individual's pleasure from using the substance and negative reinforcements include the desire to prevent withdrawal. As tolerance and dependence develop, more drug is necessary to obtain the same reward and prevent withdrawal. The locus coeruleus area of the brain plays an important role in the production or suppression of withdrawal symptoms. When an OUD is present, the compulsion to use opioids repeatedly goes beyond the reward drive. As changes in the brain develop, the person's experience of pleasure diminishes and they engage in the compulsive drug use despite adverse consequences that characterizes OUD.[159]

Conclusions

All HCPs who treat pain with the use of opioids need up-to-date competencies to manage potential opioid-related harms. This includes a familiarity with the full complement of nonpharmacologic and pharmacologic options to create an individualized treatment plan, reserving opioids for when other strategies are not effective.

An optimal multimodal approach to pain management consists of using treatments from one or more clinical disciplines incorporated into comprehensive plan.[1]

For select patients who benefit from opioids long term, HCPs should reduce risk and optimize benefits by patient education, screening of high-risk patients for OUD, continuous monitoring, combining treatments with non-opioid options when indicated, referral and co-management of comorbid conditions, and an exit strategy to ensure careful tapering when indicated. It is important for patient outcomes and for regulatory and legal requirements to document every aspect of opioid therapy within the medical record and to follow all federal, state, and local regulations regarding opioid therapy. HCPs should know the signs and symptoms of OUD and be prepare to treat or refer for treatment with the understanding that medications for OUD are essential to save lives.

Table 10. Criteria for Opioid-Use Disorders from the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition[92]

A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12-month period:
• Opioids are often taken in larger amounts or over a longer period of time than was intended
• There is a persistent desire or unsuccessful efforts to cut down or control opioid use
• A great deal of time is spent in activities to obtain the opioid, use the opioid, or recover from its effects
• Craving, or a strong desire or urge to use opioids
• Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home
• Continued opioid use despite having persistent or recurrent social or interpersonal problems caused by or exacerbated by the effects of opioids
• Important social, occupational, or recreational activities are given up or reduced because of opioid use
• Recurrent opioid use in situations in which it is physically hazardous
• Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that's likely to have been caused or exacerbated by the substance
• Tolerance,* as defined by either of the following: a. A need for markedly increased amounts of opioids to achieve intoxication or desired effect b. A markedly diminished effect with continued use of the same amount of an opioid
• Withdrawal,* as manifested by either of the following: a. The characteristic opioid withdrawal syndrome b. The same—or a closely related—substance is taken to relieve or avoid withdrawal symptoms
*This criterion is not met for individuals taking opioids solely under appropriate medical supervision. Severity: mild = 2–3 symptoms; moderate = 4–5 symptoms; severe = 6 or more symptoms.

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Appendix A: Colorado Guidelines for the Safe Prescribing and Dispensing of Opioids

Revised: 3/14/2019

EXECUTIVE SUMMARY

Prescribers and dispensers have an obligation to effectively manage pain and improve function while reducing opioid-related adverse outcomes. To assist healthcare professionals in discharging this duty, the Boards have adopted this Policy to ensure consistent, evidence-based guidance for all Colorado prescribers and dispensers in their treatment of patients 18 years of age and older suffering from acute, subacute or chronic, non-cancer pain. For the purpose of this Policy, the terms "chronic pain" or "chronic non-cancer pain" refer to pain that lasts longer than 90 days or beyond the time of normal tissue healing and is non-terminal. It does not include conditions such as cancer, scleroderma, multiple sclerosis, muscular dystrophy, rheumatoid arthritis or other conditions that may require palliative or end-of-life care.

Overview of Recommendations

Prior to Prescribing or Dispensing Opioids

- Develop and Maintain Competence
- Diagnose and Evaluate Patient
- Consider Alternatives to Opioids
- Collaborate with the Healthcare Team
- Patient Education
- Develop an Exit Strategy

When Prescribing or Dispensing Opioids

- Verify a patient–provider relationship
- Prescribing Safeguards
  - **Dosage**- When prescribing a dosage above 50 mme/day, STOP: 1) Ensure the patient's condition warrants the higher dose; 2) Ensure the benefits of a higher dose outweigh the risks; and, 3) Ensure additional risk mitigation strategies are in place.
  - **Formulation**- When prescribing a long-acting or extended relief formulation, STOP: 1) Ensure the patient's condition warrants this formulation; 2)Ensure the benefits of this formulation outweigh the risks; 3) Consider concurrent medications that my potentiate the effects of the formulation; 4) Ensure the patient has been treated with immediate release opioids for at least one week prior to prescribing or dispensing this formulation; and, 5) Ensure additional risk mitigation strategies are in place.
  - **Duration-**
    - When treating acute, non-traumatic or non-surgical pain, STOP: 1) Ensure the amount of medication prescribed or dispensed does not exceed the expected duration of the pain, typically 3-7 days, and complies with Colorado law. When prescribing opioids for subacute pain and the treatment of chronic, non-cancer pain STOP: 1) Reassess pain and function within 30 days of initiating therapy to ensure a clear benefit; and, 2) Ensure the benefits of continued opioid therapy outweigh the risks.
    - If the opioid treatment exceeds 90 days for chronic, non-cancer pain, STOP: 1) Ensure the patient continues to show clinical improvement with opioid therapy; 2) Ensure the benefits of continued opioid therapy outweighs the risk; and 3) Ensure additional risk mitigation strategies are in place.

Risk Mitigations Strategies

- Tools and Trials
- Referral to Pain Management Specialist
- Monitoring and Treatment Agreements
- Concurrent Naloxone Prescribing
- Patient Education

Discontinuing Opioid Therapy Treatment for Opioid Use Disorder

BEFORE PRESCRIBING OR DISPENSING

Develop and Maintain Competence

Prescribers, including prescribers who dispense, must maintain competence to assess and treat pain to improve function. This includes understanding current, evidenced-based practices and using other resources and tools related to opioid prescribing and dispensing. Pharmacists must maintain competence in the appropriateness of therapy. Prescribers and dispensers should incorporate education courses specific to pain management and opioid prescribing and/or dispensing practices into their maintenance of competence plan.

See Appendix A.1 on page 43 for a list of resources, courses and tools for developing and maintaining competence.

Diagnose and Evaluate

The decision to prescribe or dispense opioid medication to patients may be made only after a proper diagnosis and complete evaluation, which should include an assessment of the pain, functionality and risk, and review of relevant PDMP data. These safeguards should be used prior to initiating treatment for both acute[1] and chronic, non-cancer pain.

1. Diagnose

Prescribers should establish a diagnosis and legitimate medical purpose appropriate for the initiation of treatment for pain management including opioid therapy through a history, physical exam, and/or laboratory, imaging or other studies. A bona fide provider-patient relationship must exist.

2. Assess Risk

Prescribers should conduct a risk assessment prior to prescribing opioids, periodically during continuation of opioid therapy, and before increasing dosage or the addition of other medications or upon learning of any factors that may lead to adverse outcomes. Risk assessment is defined as the identification of factors that may lead to adverse outcomes that may include:

- Patient and family history of substance use (drugs including prescription medications, alcohol and marijuana);
- History of opioid use through both patient history and the PDMP;
- Overdose history;
- Patient medication history (among other reasons, this is taken to avoid unsafe combinations of opioids with sedative-hypnotics, benzodiazepines, barbiturates, muscle relaxants, other opioids or to determine other drug-drug interactions) through patient history, PDMP, and Urine Drug Screen, as indicated;
- Mental health/psychological conditions and history;
- Insomnia or other sleep disorders;
- Abuse history including physical, emotional or sexual[13];
- Pregnancy or current family planning for women of reproductive age[14];
- Health conditions that could aggravate adverse reactions (including COPD, CHF, sleep disordered breathing, including sleep apnea, obesity, age < 18 years or > 65 years, or history of renal or hepatic dysfunction);[4] and
- Prescribers and dispensers should observe the patient for any aberrant drug-related behavior and follow-up appropriately if such behavior is exhibited. See the Appendix for a description of aberrant drug-related behaviors.

If the assessment identifies risk factors, prescribers should first opt for non-opioid treatment options. If the benefits of opioid therapy outweigh the identified risks, the prescriber should proceed with caution, ensuring safeguards, as detailed below, are in place prior to the initiation of opioid therapy.

See Appendix A.1 for additional resources related to assessment, including resources for alcohol and substance use screening and guidelines for treating patients with risk factors.

3. Assess Pain

Prescriber should assess the patient's pain prior to treatment. This assessment should also be completed periodically during continuation of opioid therapy and before increasing dosage, changing formulation or the addition of other medications in order to document the trajectory of the treatment.

An appropriate pain assessment should include an evaluation of the patient's pain for the:

- Nature and intensity;
- Type;
- Pattern/frequency;
- Duration;
- Past and current treatments;
- Underlying or co-morbid disorders or conditions; and
- Impact on physical and psychological functioning.

4. Assess Function

Functional assessment is critical in the management of pain. Functional ability has been found to be a more reliable measure in the evaluation of treatment and is essential for establishing agreed upon functional goals.

Prescribers should assess the patient's functional ability prior to treatment. This assessment should also be completed periodically during opioid therapy and before increasing dosage, changing formulation or the addition of other medications.

See Appendix A.1 for Functional Assessment Tools.

5. Psychological Assessment

In instances where the risk assessment identifies a mental health or psychological condition, the prescriber should consider referring the patient to a mental health provider for a psychological or cognitive behavioral assessment.

6. Review PDMP

Prescribers and dispensers should access the PDMP and review the patient profile prior to making a determination regarding the initiation of opioid therapy. Prescribers and dispensers should also review the patient's PDMP profile prior to each instance in which opioids are prescribed, refilled or dispensed. Prescribers and Dispensers may want to consider reviewing the patient's pet or animal profile if there is a concern for diversion of veterinary prescriptions.

Further, prescribers and dispensers must follow the statutory mandates of Senate Bill 18-022, Clinical Practice for Opioid Prescribing, which requires prescribers to check the PDMP prior to a second fill of any opioid in certain circumstances.

Consider Alternatives to Opioid Therapy

Not all pain conditions require opioid treatment. The first step in reducing the misuse and abuse of opioids is to avoid prescribing opioids when non-pharmacologic or non-opioid pharmacologic treatments are effective in addressing the patient's pain and function. This applies not only to chronic, non-cancer pain, but also, acute pain. Studies have shown that opioid treatment for acute pain has been associated with long-term opioid use[5] and that physical dependence on opioids is an expected physiological response for patients using opioids for more than a few days.[6]

The decision to prescribe or dispense opioids should be made only after careful consideration of the benefits and risks of all treatment options. Other treatment options may include, but are not limited to, the following:

- Non-opioid Pharmacologics such as acetaminophen, alpha-acting agents, anticonvulsants, antidepressants, nonsteroidal anti-inflammatory drugs (NSAIDS), muscle relaxants, or topical lidocaine; and
- Non-pharmacologic treatments such as acupuncture, complementary alternative medicine, cognitive behavioral therapy, dry needling, exercise therapy, massage therapy, physical therapy, occupational therapy, osteopathic manipulation, regenerative therapy, trigger point or interventional/ targeted injections, electrical stimulation, biofeedback, radio frequency ablation or interventional pain management procedures.

If opioids are used, they should be combined with non-pharmacologic therapy and non-opioid pharmacologic therapy, as appropriate.

Collaborate with the Healthcare Team

Prescribers and dispensers should collaborate with members of the healthcare team, including mental and behavioral health providers and addiction and pain management specialists, to prevent under-prescribing, over-prescribing, misuse and abuse of opioids. See the Appendix for additional resources.

Patient Education

A decision to initiate opioid therapy should be a shared decision between the patient and the prescriber. Prescribers should educate patients regarding all treatment options for the management of pain, ensuring the patient is provided with, and understands, the necessary information to make informed decisions. Prescribers should provide this information in a format suited to the particular patient, taking into account the patient's learning style, literacy, culture, language and physiological barriers.

When providing information, prescribers and dispensers should emphasize key points, speak slowly and avoid medical jargon. Prescribers and dispensers should review any handouts or materials with the patient prior to providing them to the patient, using resources as supplement to, rather than substitute for, one-on-one patient education. Prescribers and dispensers should include family members in patient education whenever possible.

Patient education relating to pain management should include the risks and realistic benefits of each therapeutic option. Risks of opioid use may include, but are not limited to, overdose, misuse, diversion, addiction, physical dependence and tolerance, interactions with other medications or substances, and death. When alerted to these risk factors, patients can make more informed decisions about their treatment options. For example, some patients have reduced, discontinued or forgone opioids when alerted to the risk factors.

Prescribers should also ensure patients are provided with information on dose, administration, side effects, effects of opioids on the safe operation of a motor vehicle or heavy machinery, potential medication or substance interactions, risks to family members who may come into contact with the drug, and the safe use, storage, and disposal of opioids. See the Appendix for resources on safe disposal.

Pharmacists should offer to review information with the patient about dose, side effects, medication or substance interactions, risks, disposal, and other applicable topics.

Establish an Exit Strategy

Prior to initiating opioid therapy, prescribers should develop a longitudinal treatment plan for the management of the patient's pain. This plan should be established with the patient, particularly as it relates to how treatment effectiveness will be established and setting realistic goals for pain and function.

This plan should highlight how and when opioid therapy will be discontinued, linking the discontinuation of the therapy to the achievement of functional goals. The prescriber should further ensure the patient is aware that opioid therapy should be discontinued, absent clinically significant improvement in pain and function or when the risks of opioid therapy outweigh the benefits.

This plan is also an opportunity for the prescriber to detail the responsibilities of the patient and the prescriber in the management of the patient's pain.

WHEN PRESCRIBING OR DISPENSING

Verify a provider-patient relationship

A bona fide provider-patient relationship must exist. The prescriber or dispenser should verify the patient's identification prior to prescribing or dispensing opioids to a new or unknown patient.

For pharmacists, this includes exercising judgment and conducting research (such as use of the PDMP or communication with the prescriber or relevant pharmacies) when the prescription order is:

- For a new or unknown patient;
- For a weekend or late day prescription;
- Issued far from the location of the pharmacy or patient's residential address; or,
- Denied by another pharmacist.

Prescribing Safeguards

Prescribers should ensure the dose, quantity, and refills for prescription opioids are appropriate to improve the function and condition of the patient, at the lowest effective dose and quantity, in order to avoid over-prescribing opioids.

Factors that have been associated with adverse outcomes include: 1) opioid doses greater than 50 morphine milligram equivalents per day; 2) long–acting or extended relief formulations; and, 3) treatment exceeding 3 to 7 days for acute pain and 90 days for chronic, non-cancer pain. Risk mitigation strategies have been found to reduce these risks.

Dosage

When initiating and throughout continuing opioid therapy, prescribers should prescribe the lowest effective dosage. Opioid doses greater than 50 morphine milligram equivalents (MME) per day is a dosage that the Boards and the Centers for Disease Control[7] agree is more likely dangerous for the average adult (chances for unintended death are higher) over which prescribers should use clinical judgment, invoke additional risk mitigation strategies, consult a specialist or refer the patient to a specialist. Pharmacists and dispensers should exercise greater caution in such instances.

When determining dosage, prescribers should consider patient medications including, but not limited to, benzodiazepines, that are known to potentiate the effects of opioids and health conditions that may affect that patient's ability to process and excrete the drug. In addition, prescribers should exercise caution when determining dosage using dose calculators, particularly when prescribing methadone.[8] See the Appendix for additional resources regarding dose calculators.

Formulation

Long-acting or extended relief opioids increase the risk of overdose in opioid naïve patients.[9] In addition, patients who begin opioid therapy with long-acting opioids are over 4 times more likely to use opioids long term than patients who begin opioid therapy with immediate release formulations.[10] Prescribers should not prescribe long-acting or extended relief opioid formulations for the treatment of acute pain, subacute pain or when initiating opioid therapy for chronic, non-cancer pain.

Long-acting or extended relief opioids should be reserved for severe, continuous pain and should be considered for only those patients who have received immediate release opioids for at least one week.[11] When prescribing long-acting or extended relief opioids, the prescriber should consider patient medications, including concurrent use of immediate relief opioids, which may potentiate the effects of the opioid and health conditions that may affect that patient's ability to process and excrete the drug.

- Providers should exercise caution when prescribing or dispensing transdermal fentanyl or methadone.

See Appendix A.1 for information regarding methadone.

Duration

Long-term opioid use often begins with treatment of acute pain. When treating acute pain, prescribers should prescribe only the amount of medication needed for the expected duration of the pain. In most instances of non-traumatic or non-surgical pain, three days or less is sufficient, while more than seven days is rarely necessary.[12] Prescribers must also be aware of the statutory limitations, in certain circumstances, on prescribing opioids for pain that has not been treated with an opioid over the previous twelve months as set forth in Senate Bill 18-022, Clinical Practice for Opioid Prescribing.

For longer-term opioid therapy for subacute pain[13] and the treatment of chronic, non-cancer pain, prescribers should note that contextual evidence suggests that patients who do not experience pain relief from opioids at 30 days are unlikely to experience relief at six months.[13] Prescribers should reassess pain and function within 30 days of initiating therapy to minimize the risks of long-term opioid use for those patients receiving no clear benefit from opioid therapy.

Continuing opioid therapy for over 90 days substantially increases the risk for opioid use disorder.[14] As such, treatment for chronic non-cancer pain exceeding 90 days should be re-evaluated, assessing both the effectiveness of the therapy as measured by attainment of functional goals and weighing the benefits of the therapy against the risks to the patient.

In those instances in which the benefits continue to outweigh the risks and the patient continues to show clinical improvement after 90 days of opioid therapy, prescribers and dispensers should implement additional risk mitigation strategies, if not already in place, as detailed below.

RISK MITIGATION STRATEGIES

Tools and Trials

Prior to issuing prescriptions that are outliers to the dosage, formulation and duration guidelines, described herein, for chronic, non-cancer pain, prescribers should determine whether the opioid therapy has resulted in clinically significant improvement in pain and function and that the benefits of the therapy outweigh the risks to the patient. Opioid trials may assist in this determination.

Referral to Pain Management Specialist

Prior to issuing prescriptions that are outliers to the dosage, formulation or duration guidelines, as described herein, for chronic, non-cancer pain, prescribers should consult with, or consider referral of the patient to, a pain management specialist. Such consultation or referral should also be considered for those patients at risk for respiratory depression, suicide or overdose and any patient concurrently prescribed medications such as benzodiazepines that are known to potentiate the effects of opioids.

Monitoring

Opioid therapy for chronic, non-cancer pain requires regular monitoring by the prescriber. Monitoring should include:

- Reassessment of the patient's pain, function, and risk;
- Rebalancing of the risks and benefits of continued opioid therapy;
- Rechecking the PDMP, and,
- Conducting random and/or routine pill counts or drug screening according to the prescriber's clinical assessment.

These monitoring tools and others should be documented in a treatment agreement signed by the patient, described more below. Prescribers should not increase an initial opioid dosage without reassessing the patient's pain, function and risk, rechecking the PDMP and rebalancing the risks and benefits of continued opioid therapy.

Treatment Agreements

Prescribers should utilize treatment agreements (also commonly referred to as a plan or contract). Treatment agreements should incorporate information from the patient's longitudinal treatment plan including, the agreed upon pain and function goals, the responsibilities of the patient and the prescriber in the management of the patient's pain and the discontinuation plan. The agreement should also address the risks and benefits of opioid therapy and address alternative treatment options. Treatment agreements should address risk mitigation strategies that may include, but are not limited to:

- Prescribing and Dispensing Controls (single prescriber, single pharmacy for refills);
- Random or routine drug testing;
- Restrictions on alcohol and/or illicit drug use;
- Random or routine pill counts;
- Storage, disposal, and diversion precautions (including detailed precautions related to adolescents and/or children and visitors to the home); and,
- Disclosure of alternative therapies.

Treatment agreements should also address the process and reasons for changing or discontinuing the treatment plan, the reassessment schedule and referral to a specialist for pain management or suspected opioid use disorder.

Prescribers should ensure the patient has a clear understanding of the treatment agreement using the patient education techniques previously discussed and by documenting the patient's understanding in the medical record or through the patient's signature on the treatment plan.

See Appendix A.1 for resources on sample agreements.

Concurrent Naloxone Prescriptions

Opioid overdose deaths may be preventable by the timely administration of naloxone. Several studies indicate that home naloxone programs are effective in decreasing overdose mortality and have a low rate of adverse events.[15] Prescribers and dispensers should consider concurrent naloxone prescriptions for those patients at risk for respiratory depression, suicide or overdose and any patient concurrently prescribed medications such as benzodiazepines that are known to potentiate the effects of opioids. In addition, concurrent naloxone prescriptions should be considered for patients receiving any prescription outlier for dosage, formulation or duration.

Naloxone rescue prescriptions should be accompanied by patient and family member education regarding signs of overdose, administration of naloxone and activation of emergency medical services.

Patient Education

In addition to educating the patient prior to initiating opioid therapy, prescribers should incorporate patient education into each patient's evaluation during opioid treatment. Education is particularly important prior to increasing dosage, extending treatment, changing formulations, upon learning of new factors that may lead to adverse outcomes and any change in the risk/benefit balance.

Prescribers should regularly re-educate patients regarding risks, benefits, side effects, alternative treatments, diversion and the safe use, and the storage and disposal of opioids.

Pharmacists should offer to re-review information with the patient about risks, disposal, and other applicable topics with each refill.

DISCONTINUING OPIOID THERAPY

The prescriber should consider discontinuing opioid therapy when:

- The underlying painful condition is resolved;
- Intolerable side effects emerge;
- The analgesic effect is inadequate;
- The patient's quality of life fails to improve;
- Functioning fails to improve or deteriorates;
- The risks of treatment outweigh the benefits;
- The patient overdoses;
- The patient demonstrates suicidality;
- Non-compliance with the treatment plan;
- The prescriber suspects diversion; or
- The prescriber suspects opioid misuse or abuse.

The prescriber discontinuing opioid therapy should employ a safe, structured tapering regimen through the prescriber or an addiction or pain specialist. There is a risk of patients turning to street drugs or alcohol abuse if tapering is too rapid or is completed without appropriate support. See the Appendix for resources addressing tapering.

TREATMENT FOR OPIOID USE DISORDER

Opioid use disorder is defined as a problematic pattern of opioid use leading to clinically significant impairment or distress, manifested by at least two defined criteria occurring within one year.[17] Studies estimate that 2.1 million people in the United States suffer from substance abuse disorders related to prescription opioids.[18] Medically Assisted Treatment ("MAT") in combination with cognitive behavioral therapy has been shown to reduce relapse in patients with opioid use disorder. [19]

The identification of an opioid use disorder is an opportunity for the prescriber to collaborate with the patient to improve their safety and increase the likelihood of successful opioid use disorder treatment. Prescribers suspecting opioid use disorder should discuss their concerns with the patient and identify treatment resources for the patient.

Because treatment need is often not met with sufficient MAT resources, prescribers should consider undergoing training and obtaining a waiver from the Substance Abuse and Mental Health Services Administration ("SAMHSA") to provide buprenorphine to treat opioid use disorder in an office setting. (See the Appendix for resources related to MAT and obtaining a waiver from SAMHSA).

APPENDIX A.1

PDMP

Colorado Prescription Drug Monitoring Program (PDMP):
https://www.colorado.gov/dora-pdmp

Please note, pursuant to SB-1746, Access to Prescription Drug Monitoring Program, authorized use of the PDMP was expanded effective April 6, 2017, to include the following:

- Prescribers are authorized to query the PDMP about a current patient, regardless of intent to prescribe controlled substance, thus making the PDMP an even more useful tool for health professionals in their clinical decision-making for patients;
- Veterinarians are authorized to query the PDMP about a current client if the veterinarian has a reasonable basis to suspect the client has committed drug abuse or has mistreated an animal; and
- Pharmacists are authorized to query the PDMP about a current patient for whom the pharmacist is dispensing any prescription drug, rather than only patients receiving controlled substances.

Appendix A: Colorado Guidelines for the Safe Prescribing and Dispensing of Opioids

Revised: 3/14/2019

Please note, pursuant to SB18-022, Clinical Practice for Opioid Prescribing, statutory limitations have been placed on the prescribing of opioids for pain that has not been treated with opioids in the previous 12 months.

Preventing diversion through appropriate disposal

In order to prevent diversion, providers should provide information regarding appropriate disposal, including the following:

- Securing unused prescription opioids until such time they can be safely disposed. Specifically, ensure that prescription opioids are not readily accessible to other family members (including adolescents and/or children) or visitors to the home.
- Take-back events are preferable to flushing prescriptions down the toilet or throwing them in the trash. Only some medications may be flushed down the toilet. See the FDA's guidelines for a list of medications that may be flushed: www.fda.gov
- Utilize take-back events and permanent drop box locations www.colorado.gov/pacific/cdphe/colorado-medication-take-back-program
- Utilize DEA disposal guidelines if take-back or drop boxes are unavailable. Those guidelines include:
    - Take the drugs out of their original containers and mix them with an undesirable substance, such as used coffee grounds or kitty litter; then put them in a sealable bag, empty can, or other container to prevent the medication from leaking out of a garbage bag;
    - Before throwing out a medicine container, tell the patient to scratch out all identifying information on the prescription label to protect their identity and personal health information; and
- Educate patients that prescriptions are patient specific. Patients may not share prescription opioids with friends, family or others and may pose serious health risks, including death.
- Use activated charcoal absorption technologies to inactivate unused medications or used fentanyl patches.

Record keeping

Prescribers who treat patients with opioids should maintain accurate and complete medical records according to the requirements set forth by their licensing board.

The medical record should include, but is not limited to, the following:

- Copies of the signed informed consent and treatment agreement;
- The patient's medical history;
- Results of the physical examination and all laboratory tests;
- Results of the risk assessment, including results of any screening instruments used;
- A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity);
- Instructions to the patient, including discussions of risks and benefits with the patient and any significant others;
- Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement;
- Notes on evaluations by and consultations with specialists;
- Results of queries to the state PDMP;
- Any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors. These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers; and,
- Authorization for release of information to other treatment providers.

Discontinuing/tapering opioid therapy

Weaning from opioids can be done safely by slowly tapering the opioid dose and taking into account several factors related to risk, symptom, and alternatives.

Opioid Taper Plan and Calculator:

- "Interagency Guidelines on Opioid Dosing for Chronic Non-Cancer Pain" State of Washington Agency Medical Directors Group. 2010 Online: www.agencymeddirectors.wa.gov
- Pocket Guide: Tapering Opioids for Chronic Pain www.cdc.gov/drugoverdose/pdf/clinical_pocket_guide_tapering-a.pdf
- Tapering Long-Term opioid Therapy in Chronic Noncancer Pain www.mayoclinicproceedings.org/article/S0025-6196(15)00303-1/fulltext

Withdrawal Symptoms Assessment:

"Clinical Opiate Withdrawal Scale" The National Alliance for Advocates for Buprenorphine Treatment. Online at: www.naabt.org

Aberrant drug-related behavior

Prescribers and dispensers should use clinical judgment when aberrant drug-related behaviors are observed. Such behavior should be reported to the proper authorities and/or healthcare team as appropriate.

Aberrant drug-related behaviors broadly range from hoarding medications to have an extra dose during times of more severe pain to felonious acts such as selling medication.

These are any medication-related behaviors that depart from strict adherence to a prescribed therapeutic plan of care.

Prescribers and dispensers should observe, monitor and take enhanced precautionary measures when a patient presents aberrant drug-related behaviors such as:

- Requesting early and/or repeated refills;
- Presents at or from an emergency department seeking high quantities of a prescription;
- Denied by other prescribers or dispensers;
- Presents what is suspected to be a forged, altered or counterfeit prescription;
- Forging prescriptions;
- Stealing or borrowing drugs;
- Frequently losing prescriptions;
- Aggressive demand for opioids;
- Injecting oral/topical opioids;
- Unsanctioned use of opioids;
- Unsanctioned dose escalation;
- Concurrent use of illicit drugs;
- Positive drug screen;
- Obtaining opioids from multiple prescribers;
- Obtaining multiple veterinary prescriptions for opioids for the patient's animal(s); or,
- Recurring emergency department visits for chronic pain management[20]

Prescribers and dispensers should be alert for subjective behaviors such as being nervous, overly talkative, agitated, emotionally volatile, and evasive, as these may be signs of a psychological condition that may be considered in a treatment plan or could suggest drug misuse.[21]

Practitioner Considerations

Healthcare team:

Consider that the patient may be receiving opioids from another prescriber. Contact the patient's healthcare team when appropriate which may include the following:

- Physician;
- Specialist (pain, addiction, etc.);
- Dentist;

- Optometrist;
- Advanced Practice Nurse (APN);
- Podiatrist;
- Physician assistant;
- Mental and Behavioral Health Providers;
- Pharmacists;
- Area emergency rooms and urgent care clinics;
- Surrounding (within 5 miles) or historical pharmacies; and
- Veterinarian[22]

Authorities:

- If the prescriber or dispenser suspects illegal activity, the matter should be referred to the Drug Enforcement Agency (DEA) and local law enforcement.
- If a prescriber or dispenser suspect illegal activity on behalf of another prescriber or dispenser, at a minimum, the matter should be reported to the appropriate licensing board.

Prescribers and dispensers should be aware that:

- There is no legal obligation to prescribe or dispense a prescription; and,
- Colorado law strongly encourages prescribers and dispensers of opiate antagonists "to educate persons receiving the opiate antagonist on the use of an opiate antagonist for overdose, including but not limited to instructions concerning risk factors for overdose, recognition of overdose, calling emergency medical services, rescue breathing and administration of an opiate antagonist." (Section 18-1-712(3) (b), C.R.S.)

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22. Patients may be obtaining opioids through the diversion of a veterinary prescription for an animal.

BEST PRACTICES FOR TREATING PAIN WITH OPIOID ANALGESICS

Self-Assessment

Choose the best possible answer for each question and mark your answers on the self-assessment answer sheet at the end of this book. There is a required score of 70% or better to receive a certificate of completion.

1. **What is one way to reduce the stigma for patients living with chronic pain?**
   A. Counseling patients in whom opioids are indicated that opioids are appropriate for them.
   B. Urging patients to self-manage moderate-to-severe pain.
   C. Optimizing use of non-steroidal anti-inflammatory drugs.
   D. Ensuring that individuals from minoritized racial and ethnic backgrounds have greater access to opioid therapy.

2. **Gabapentin has mild-to-moderate benefit in the treatment of:**
   A. Insomnia that commonly accompanies chronic pain.
   B. Short-term inflammation associated with acute pain caused by injury or surgery.
   C. Muscle spasm in low-back pain as an alternative to more sedating medications.
   D. Neuropathic pain syndromes.

3. **Spinal manipulation has demonstrated improvements in pain and function when used:**
   A. In combination with opioids in pain lasting longer than 3 months.
   B. For chronic tension headache.
   C. For fibromyalgia.
   D. In patients with chronic neck pain and concomitant opioid-use disorder (OUD).

4. **Which is a true statement about factors to record in the patient record?**
   A. Psychological and social factors should be included as these can contribute to the pain experience.
   B. Objective clinical markers for pain must be present before pain treatment is given.
   C. The primary objective of pain treatment is to document a reduction in the patient's self-reported pain scale number.
   D. Diagnosis of chronic pain is made if pain is continuous.

5. **Which of the following tools assess pain, pain interference, functional components, and quality of life, and was created to assess management of chronic pain in primary care settings?**
   A. McGill Pain Questionnaire (MPQ).
   B. Pain, Enjoyment of Life, and General Activity Scale (PEG).
   C. Revised Screener and Opioid Assessment for Patients with Pain (SOAPP-R).
   D. The Visual Analogue Scale (VAS) combined with the Numerical Rating Scale (NRS).

6. **Which is a true statement about screening patients for potential opioid misuse?**
   A. Only the Drug Abuse Screening Test has been associated with a high degree of predictive accuracy.
   B. Brief screening tools are regarded to have clinical utility in diagnosing OUD.
   C. Single screening questions may be used.
   D. There is no evidence to support screening for risk ahead of opioid prescription.

7. **Patients who are already being prescribed opioids for chronic pain who exhibit an active OUD should be:**
   A. Discontinued immediately from opioids and treated with nonpharmacologic pain therapies.
   B. Engaged in collaborative taper and treated or referred for treatment with medications to manage OUD.
   C. Tapered rapidly from opioid doses and encouraged to seek psychiatric counseling.
   D. Rotated to a dual-mechanism opioid with less misuse potential and sent for detoxification from high-dose opioids.

8. **Which of the following is an example of an opioid-related risk factor appropriately influencing a treatment choice?**
   A. Pain duration lasting longer than 6 months is a contraindication for carisoprodol co-prescribed with opioids.
   B. Patients without previous exposure should be initiated at the lowest possible dose of an extended-release opioid and titrated slowly to minimize adverse effects.
   C. Cardiac toxicities due to QTc prolongation suggest morphine should be carefully evaluated or should not be used.
   D. Take-home naloxone is advised in the presence of concurrent benzodiazepines.

9. **One sign of an active OUD is:**
   A. Craving that persists after cessation.
   B. Combining opioids with alcohol.
   C. Persistent failure of analgesia despite optimal doses.
   D. Chronic insomnia with opioid therapy for pain.

10. **Which of the following statements is true regarding a diagnosis of OUD using DSM-5 criteria?**
   A. A minimum of four criteria are required for a mild OUD diagnosis.
   B. The preferred term for problematic opioid usage that does not meet criteria for OUD is “abuse”.
   C. The presence of tolerance and physical dependence does not necessarily mean that an OUD has developed.
   D. Patients cannot develop an OUD if they take medication as prescribed.

NOTES

IMPROVING ACCESS TO CARE FOR LGBTQ PATIENTS

COURSE DATES:	MAXIMUM CREDITS:	FORMAT:
Release Date: 3/2022 Exp. Date: 2/2025	*2 AMA PRA Category 1 Credit*™	Enduring Material (Self Study)

TARGET AUDIENCE

This course is designed for all physicians (MD/DOs), physician assistants, and nurse practitioners.

HOW TO RECEIVE CREDIT:

- Read the course materials.
- Complete the self-assessment questions at the end. A score of 70% is required.
- Return your customer information/ answer sheet, evaluation, and payment to InforMed by mail, phone, fax or complete online at program website.

COURSE OBJECTIVE

The purpose of this course is to help improve care and health outcomes of the LGBTQ population by recognizing the existing disparities and increased health risks present in this population. This course will examine system and provider/client barriers to equality in healthcare.

LEARNING OBJECTIVES

Completion of this course will better enable the course participant to:

1. Discuss concepts regarding healthcare disparities of the LGBTQ population.
2. Identify strategies to improve healthcare access of the LGBTQ population.
3. Describe health risks within the LGBTQ community resulting from healthcare disparities.
4. Identify strategies to improve health outcomes in the LGBTQ community.

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Introduction

People who identify as lesbian, gay, bisexual, transgender, or queer (LGBTQ) come from all walks of life, including people of all races and ethnicities, all ages, all socioeconomic statuses, and from all geographic regions. The Centers for Disease Control and Prevention (CDC) and many professional organizations assert that the perspectives and needs of LGBTQ people should be routinely considered in all medically related interactions to improve overall health and eliminate health disparities.[1]

To have productive and health-promoting interactions with LGBTQ patients, clinicians need to recognize the differences among sexual orientation, gender identity, and gender role, understand the health disparities faced by people who identify as LGBTQ, be able to identify specific health risks, and ensure they create a welcoming environment for all people. The purpose of this course is to discuss the disparities in healthcare and increased health risks that exist in the LGBTQ population; identify system, provider, and client barriers; and examine ways to provide better care. In addition, this CME learning activity is designed to improve the care and health of LGBTQ patients by educating providers on the perspectives and needs of LGBTQ patients as well as ways to improve practices, office settings, policies, and staff training to make them welcoming and supportive for everyone. The author would like to emphasize there is no single definition of the LGBTQ community. Instead, just as any other group or community, the LGBTQ community is made up of a group of individuals from a variety of racial/ethnic backgrounds, cultures, incomes, religions, and many other characteristics, resulting in unique diverse groups of individuals.[2] Stigma is a commonly shared experience among the groups.

A Note About Acronyms

This learning activity uses LGBTQ as the acronym for discussing the entire range of sexual orientation, gender, and sexual behavior, with the acknowledgement that there are some variations not captured explicitly by the terms "Lesbian," "Gay," "Bisexual," "Transexual," and "Queer." ("Queer" and "genderqueer" are non-pejorative terms describing people whose sexual orientation is not exclusively heterosexual or homosexual.) LGBTQ is the acronym currently used by the Human Rights Campaign, the Gay and Lesbian Medical Association, and many (but not all) other organizations focused on sexual minority/gender non-conforming individuals. Still, language and usage are constantly changing. In the future, variations that attempt to be more inclusive such as LGBTQ+ or LGBTQ* may become more standard.

To date, the available research has mainly focused on lesbian, gay, and bisexual individuals with limited information on transgendered individuals. Findings vary among different sources, primarily because of differing methodologies for data collection.[1] Sexual orientation is a multidimensional construct that consists of sexual identity, sexual and romantic attraction, and sexual behavior. Sexual orientation describes a person's identity in relation to the gender(s) that they are attracted to and how they act on that attraction. This orientation includes heterosexuality (attraction to the opposite sex), homosexuality (attraction to the same sex), bisexuality (attraction to both male and female sexes), pansexuality (attraction to all sexes), and asexuality (no attraction to any sex).[3]

Similar to sexual orientation, significant changes have occurred over time in the scientific understanding of gender. Gender is a ubiquitous and multi-faceted social category. When discussing the concept of gender, scientists distinguish between biological sex, gender identity, and gender expression. Though one's biological sex, gender identity, and gender expression are distinct constructs, society expects that they will align. For most individuals this is true – that is, most individuals who are assigned female at birth identify as girls or women and adopt a feminine gender expression, while most individuals who are assigned male at birth identify as boys or men and adopt a masculine gender expression.[4] However, for some individuals, these constructs do not align. The term transgender refers to individuals whose gender identity is not consistent with their sex assigned at birth. The terms gender nonconforming or gender incongruence refer to individuals whose gender expression does not conform to the stereotypical norms in their culture for any assigned sex at birth.[3,5] Infants' biological sex is labeled at birth, almost always based solely on external genital appearance; this label given at birth is referred to as one's assigned sex at birth.

Sex assigned at birth helps to determine health risk factors and the need for screening, particularly if there are remaining natal organs (i.e., breasts, ovaries, testes).[6] Gender identity refers to a person's deeply felt, inherent sense of being. A person can identify as a girl, a woman, or female; a boy, a man, or male; a blend of male or female; or an alternative gender. Gender expression refers to the ways a person communicates their gender within a given culture, such as clothing choices and communication patterns. A person's gender expression, the ways in which a person demonstrates their gender, including naming conventions, social presentation, and pronouns, and often aligns with gender identity.[5]

In the past, diverse sexual orientation has been considered pathologic or a medical condition in need of treatment. The first edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-I) listed homosexuality as a sociopathic disorder. Homosexuality was not removed as a diagnostic category until 1973 when the American Psychiatric Association (APA) decided that homosexuality did not fit the criteria of mental disorder. However, until 1987, the APA continued to include a diagnostic category for individuals who were unhappy with their sexual orientation, which supported the development of conversion therapies.[7]

Since that time, many organizations, including the American Medical Association, the American Academy of Pediatrics, and the American Counseling Association, have issued statements condemning conversion therapy and supporting gender-affirming care.

Furthermore, scientists and clinicians now understand that identifying with a gender that does not align with sex assigned at birth, as well as a gender expression that varies from that which is stereotypical for one's gender or sex assigned at birth, is not inherently pathological.[4] However, people may experience distress associated with discordance between their gender identity and their body or sex assigned at birth (i.e., gender dysphoria) as well as distress associated with negative social attitudes and discrimination. This shift in the understanding of gender identities and expressions was reflected in the replacement of the category "Gender Identity Disorder" with "Gender Dysphoria" in the 5th edition of the *Diagnostic and Statistical Manual of Mental Disorders*.[8] The diagnosis of Gender Dysphoria, which is marked in children and adolescents by clinically significant distress associated with the discordance between biological sex and gender identity that disrupts school or social functioning, depathologizes diverse gender identities and expressions. This newer definition focuses instead on the potential psychosocial challenges associated with gender diversity.

Sexual orientation questions are included in 11 federal surveys and, of these, seven also have an inquiry regarding gender identity.[9] Gender identity questions were added to the National Health Interview Survey (NHIS), a principal source of US population health, beginning in 2013,[3] and in the National Survey on Drug Use Abuse and Health (NSDUH) in 2015. It is important for healthcare providers to understand the differences between gender identity, sexual orientation, and sex assigned at birth and how these factors are important.

The 2020 census was the first census that included a question specifically about same-sex relationships. Optional answers included opposite OR same-sex husband/wife/spouse and opposite OR same-sex unmarried partner.[10] Use of census data assists in determining federal funding to states. In 2015, $175 million in funding for Housing Opportunities for Persons with AIDs, $312 billion for Medicaid, and $71 billion in money for food stamps was received through census data.[11] LGBTQ people are among those most likely to rely on these programs, and under-representation may affect financial assistance.[11] Unfortunately, a single question is unable to reflect this diverse population.

Epidemiology

The most accurate and current information about LGBTQ demographics is based on independent polling and survey organizations. The most recent large-scale survey was a 2021 Gallup report based on interviews with a random sample of approximately 15,000 U.S. adults, which showed that the proportion of American adults identifying as LGBTQ increased to 5.6% from 4.5% in 2017. Millennials (born 1981-1996) and Generation Z (born 1997-2002) are more likely to identify as bisexual compared to lesbian, gay, transgender, or other.[12]

As the general population ages, the number of older LGBTQ adults will increase as well. By 2030, there will be an estimated 2 million to 6 million LGBTQ adults ≥65 of age in the United States (vs. an estimated 1 million to 2.8 million in 2000), approximately 120,000 of whom are projected to be living in nursing homes.[13] These individuals will have distinct healthcare needs and face well-documented health-related disparities including disability, poor mental health, smoking, and increased alcohol consumption. In addition, older lesbians have a higher risk of developing metabolic syndromes and cardiovascular disease (CVD). Older transgender adults are at significantly higher risk of poor physical health, disability, depression, and perceived stress compared with cis-gender patients.[13,14]

Risk Identification

To identify risk, healthcare providers need to see, talk to, and examine patients. This point sounds obvious, but there are many barriers that may prevent this examination and communication from occurring. One of the most common barriers in caring for LGBTQ people is the lack of provider training and experience in caring for sexual minority persons.[15,16] This lack of training may cause a fear of missing or doing something wrong or result in inadvertently doing or saying something offensive.

Provider implicit bias can also prevent risk identification in the LGBTQ population. Bias can stem from religious or cultural backgrounds, fear of the unknown or unfamiliar,[16,17] and preconceived ideas from media representation. If the healthcare community in general or individual caregivers have a preconceived concept of gender as male or female, sexual orientation as based on gender at birth, or sexual activity as between heterosexual individuals, and do not venture from this idea, information will be missed that may affect the health of an individual. Provider discomfort with inquiry into sexual orientation, gender identity, and sexual activity may inhibit an open discussion on sexual risk factors. There also may be a lack of awareness of the risks of LGBTQ patients or a desire to remain impartial and avoid cultural discussions.[18] In both cases, providers may potentially miss important information.

In examining disparities in healthcare, it is crucial to consider patient factors such as access to care. Is the population (or person) able to receive care? There are a variety of factors that can affect the ability to access care, including the following: insurance coverage or the financial means to pay for care; ability to access the care, which can relate to location, transportation, finances, and/or desire; and locating a qualified provider one feels comfortable with, which may vary according to culture, gender, race, and sexual identity to name a few. Additional difficulties can arise in small tight-knit communities and rural areas where decreased access to care, lower incomes, and lack of public transportation may already exist.[19] Transgender people in particular report difficulty finding gender-affirming healthcare.[20,21]

While these examples are mainly interpersonal/relational, there are also system/institutional barriers. Smith and Turell[22] identified several themes in their study, including substandard care, lack of determinants for quality care, heteronormativity in forms, extra documentation for partner participation in care, geographic barriers to LGBTQ-friendly care, and inadequate insurance. Under the Winsor & Obergefell ruling, federal and state employees with same-sex married spouses are guaranteed the same benefits as heterosexual married couples.[2] However, 45% of the LGBTQ population lives in states that do not have LGBTQ-inclusive insurance protection.[23]

Healthy People Goals

A goal of Healthy People 2020 was to increase the health, safety, and well-being of LGBTQ people.[24] Progress has focused on population-based data systems to increase their collection on Healthy People objectives, or recommendations for LGBTQ or states and territories to increase their data collection in the Behavioral Risk Factor Surveillance System.[25] Additional important goals are to increase the quantity and uniformity of data collected on transgender individuals. The inclusion of sexual orientation and gender identity questions on health history forms is an excellent beginning to open discussions in the healthcare setting.

LGBTQ objectives for Healthy People 2030 fall under the major goal of improving the health, well-being, and safety of LGBTQ people.[26] The objectives are then classified under the following categories: adolescents, drug and alcohol use, mental health, infrastructure, and sexually transmitted infections. Within these categories, there are a variety of objectives including reducing bullying, illicit drug use, and increasing the number of entities collecting data on LGBTQ health.[25] The focus of the adolescent objectives is to reduce bullying, both in-person and cyberbullying. The 2019 Youth Risk Surveillance Survey found that 32% of adolescents who identify as a member of a sexual minority group report they were bullied at school and 26.6% report being cyberbullied. Almost twice as many students who are lesbian, gay, or bisexual compared to their heterosexual peers reported missing school because of concerns for their personal safety.[27]

Accessing or Avoiding Healthcare

Quality of care is important for all patients and providers and is paramount to achieving positive outcomes. Part of the healthcare experience results from the patient-provider relationship along with the general experience of the patient in the healthcare setting, whether clinic, hospital, or community. A qualitative study by Smith and Turell[22] examined the differences in expressed needs of different groups (lesbian, trans woman, gay, and HIV+ gay men) seeking healthcare in the LGBTQ community. Participants had a wide range of feelings on topics and several areas of agreement.

Terms to Avoid

These terms may have been used in the past but are now considered outdated and may be offensive. In addition, while patients may use these terms, when in doubt, the provider should ask the patient which terms they prefer.

Unacceptable	Acceptable
Berdache (to describe gender non-conforming indigenous people)	Two-spirit
Gender reassignment surgery	Gender assignment surgery
Homosexual	Gay or lesbian
Intersex/hermaphrodite	Disorders of sex development
Sex change	Gender affirmation surgery
Sexual preference	Sexual orientation
Transgendered/a transgender	Transgender

First, there were differences regarding identity disclosure to providers, with the HIV+ group noting the importance of informing the clinician on their positive status. Levels of comfort on disclosure varied from no concern "for the straight people's discomfort"[22(p643)] to great concern about how one's healthcare would be affected by disclosure and how the information would be stored and shared.[22] Participants also shared that they experienced lapses in confidentiality such as using incorrect pronouns, physician sharing HIV+ status with family at bedside rounds after surgery, and other situations that eroded patient trust.

Although this study has several limitations, including small sample size (n=26) and exclusion of persons of color/trans men, similar findings were identified in other studies.[2,28,29] Participants also perceived discomfort and heteronormative expectations of healthcare professionals. These examples ranged from unfamiliarity with terms of address, lack of knowledge of LGBTQ health needs, too much focus on sexual health, and implicit bias such as assuming that a woman needed birth control because she is sexually active, that a lesbian's partner is her "husband," or that gays or lesbians do not have children. Participants also identified overt discrimination, homophobia, and transphobias and discussed being made to feel like a "freak" by staff and providers through refusal of care, excessive use of personal protective equipment inappropriate for the situation, and putting the LGBTQ person on display.[22,28] Overall, findings revealed general heteronormativity in healthcare, lack of knowledge of LGBTQ healthcare needs, and microaggressions or phobias of clinicians and staff. These experiences led to patients feeling stressed and stigmatized.[22]

Nondiscrimination in Access to Healthcare

The Affordable Care Act (ACA) implemented in 2010 and the expansion of Medicaid in 2014 increased the rate of LGBTQ adults who have insurance. In states that have adopted the expansion, 8% are uninsured and 25% have Medicaid compared to states that did not adopt the expansion where rates are 20% uninsured and 13% have Medicaid.[21,30] The ACA set nondiscrimination protections for LGBTQ people, which included prohibition of discrimination or refusal of care based on sexual orientation and gender identification in any ACA health plan as well as any health program receiving federal funds (including Medicare and Medicaid).[21] These protections and the removal of limits on chronic or pre-existing conditions mean an increase in access to care. However, there are still problems for transgender individuals, especially people of color, desiring transition-related care. A Center for American Progress study[21] found that 43% of transgender individuals and 48% of transgender people of color were denied transition surgery, with 38% of transgender individuals and 52% of transgender people of color being denied hormone therapy for transition.[21]

A note about conversion therapy

Conversion therapy—the effort to change an individual's sexual orientation, gender identity, or gender expression—is not supported by credible evidence and has been disavowed by behavioral health experts and associations. Conversion therapy perpetuates outdated views of gender roles and identities as well as the negative stereotype that being a sexual or gender minority or identifying as LGBTQ is an abnormal aspect of human development. Most importantly, it may put young people at risk of serious harm.[31]

Importance of History

Health disparities and unidentified risks exist for many reasons, including poverty, inadequate access to healthcare, environmental threats, and individual factors. One important potentially unrecognized weakness is obtaining the appropriate health history in a nonjudgmental manner. Each provider should act as a concerned practitioner, looking out for the well-being of each patient. Providers should ask open-ended questions, encourage patients to share important information about potentially risky behaviors, and listen in a nonjudgmental manner.

While a provider may be aware that certain patients are lesbian or gay, or that certain heterosexual patients have high-risk sexual practices, social discomfort regarding the topics may lead to avoidance. It is important for a provider to talk openly and objectively with these patients about potential risk factors. In addition, health history forms may contain presumptive language about sexual partners. Staff members may exhibit a bias based on a patient's appearance or way of speaking. A patient's perception of bias may lead to a reluctance to discuss symptoms or may even cause them to avoid seeking additional care. This could lead to missed opportunities for screening, consideration, diagnosis and treatment of potential disease processes.

Evidence-Based Practice

A 2017 national survey showed that LGBTQ patients experienced discrimination in healthcare settings because of their sexual orientation, and this discrimination keeps them from seeking care or may lead to trouble finding care if turned away.[32] This study demonstrates the discrimination that still exists against the LGBTQ population and the need to educate healthcare providers to mitigate such disparity.

No Judgment

The National LGBTQIA+ Health Education Center has published suggestions for improving healthcare environments for LGBTQ patients.[33] One suggestion includes posting a nondiscrimination policy, signed by the staff, in plain view of patients. A nondiscrimination policy helps ensure commitment to an environment in which all people are valued and respected and provides an opportunity for staff members to examine their own beliefs and assumptions about race, age, sex, gender, and marital relationships. Another suggestion is to provide an area to display local LGBTQ resource information.

Using an intake form that allows a patient to provide personal information in a nonjudgmental manner will set the tone for quality patient-provider interactions. The inclusion of domestic partnership under the "relationship status" of a history form as well as options for transgender individuals, such as male-female or female-male, may help patients feel more comfortable sharing this information. Additional suggestions include providing more inclusive options for screening questions, using open-ended questions, and using the term "partner" rather than "spouse."

It is dangerous to assume how others may behave. When a provider believes a particular person, group, or community has a characteristic or action, they risk overlooking potential conditions. Asking the patient about their definition of behavior, sexual activities, language, or terminology helps prevent misperceptions that endanger health. An example may be a person who does not consider themselves in terms of sexual orientation, that is, they do not identify as heterosexual, homosexual, bisexual or asexual, and may have sexual partners of both genders; Providers should avoid assuming that a lesbian, or her female partner, has never had intercourse with a male or has never been pregnant. Focus on questions about anatomy and behavior to gain information about potential health risks and opportunities for health promotion.

Obtaining a sexual history—questions to consider and use[6]:

- Are you sexually active?
- With whom do you have sex?
- What parts of your body do you use when having sex?
- What do you do to practice safe sex?

To obtain pertinent health-related information, it is important to ensure confidentiality and gather a complete sexual history during a nonjudgmental discussion. This sexual history form should be used with all patients in the healthcare practice. If staff members are obtaining this information, practitioners should display a privacy statement in the office and/or provide such a policy to patients. Ensuring privacy is important and should be guaranteed for everyone.

Many forms used today assume heterosexual and monogamous behavior. Changing the form to include gender rather than sex, and providing the options "male," "female," "transgender," or "both" to questions about recent sexual partners, recognizes that alternative relational patterns exist. This use of an inclusive form provides patients with the opportunity to provide accurate information.

Creating a welcoming environment

LGBTQ patients often assess a clinical practice for clues to help determine what information they feel comfortable sharing with a healthcare provider.

The following are among the measures that can promote a more welcoming environment and encourage patients who are LGBTQ to access care:

- Post a rainbow flag, pink triangle, unisex bathroom signs, or other LGBTQ-friendly symbols or stickers.
- Exhibit posters showing racially and ethnically diverse same-sex couples, transgender people, or posters from nonprofit LGBTQ or HIV organizations.
- Display brochures (multilingual when appropriate) about LGBTQ health concerns.
- Distribute or visibly post a nondiscrimination statement stating that equal care will be provided to all patients, regardless of age, race, ethnicity, physical ability or attributes, religion, sexual orientation, or gender identity/ expression.
- Display magazines or newsletters about and for LGBTQ and HIV-positive individuals.
- When possible, diversify staff. Hire openly lesbian, gay, bisexual, and/or transgender staff, who can provide valuable knowledge and perspectives about serving LGBTQ patients, as well as help patients feel comfortable. Ensure non-discrimination statements are included in job postings.
- Review and consider rooming and visitation policies to ensure they are inclusive.
- Physicians communicate an impression of their practice and can set a positive tone with patient
- intake forms. These inclusive forms can help patients feel more comfortable and open about their sexual orientation or gender identity/expression.
- Ensure that clinic staff is aware of the process for responding and reporting discrimination.
- The following ideas may improve the inclusivity of forms and help clinicians with in-person discussions:
- Intake forms and electronic medical records/ patient portals should include questions about sexual orientation, gender identity, and sex assigned at birth.
    - Use neutral terms on forms such as "relationship status" instead of "marital status."
    - Avoid referring to questions as "female only" or "male only" and instead leave a box for "not applicable."
- Ensuring that gender options include "transgender" and "nonbinary" allows for people to choose the option that most applies to them and offers an initial sign of acceptance. It may also be helpful to include a body map for patients to identify anatomic elements of their bodies. There should also be a space about how they would like to be referred to including asking about preferred pronouns.
- Train front desk staff to avoid assumptions about identity and teach techniques to clarify ambiguity in a patient-centered way. Front desk staff should not make assumptions about patients' gender or sexual identity or the gender of their spouses/ partners, and they should use gender-neutral terms whenever possible. When it is unclear or a staff member is unsure, she or he should ask the patient how they would like to be addressed. By anticipating the event where there may be a discordance between names/ genders on official identifications or insurance forms and what a patient is currently using, staff members can more effectively address the situation. Another strategy might be adding a name/identity reconciliation box or form. This strategy is particularly relevant for transgender patients in the process of transitioning from one gender identity to another.
- Clinicians can encourage openness by explaining that patient-provider discussions are confidential and that they, the clinicians, need complete and accurate information to provide optimum and appropriate medical care.
- Developing and distributing a written confidentiality statement will encourage people who identify as LGBTQ and other patients to disclose information pertinent to their health. The statement should be prominently displayed and distributed to each patient.

Consider careful communication: Clinicians should always ask patients how they identify and wish to be addressed. Patients may use words that are considered derogatory like "dyke" to describe themselves. Although individuals might have reclaimed the terms for themselves, they are not appropriate for use by healthcare providers. The key is to follow the patient's lead about self-description while exploring how this self-description relates to their current and potential medical needs. For example, avoid using the term "gay" with a patient even if they have indicated a same-sex or same gender sexual partner because if the patient has not indicated a particular identity or has indicated a sexual orientation other than gay, using this term may cause alienation and mistrust that can interfere with the patient-provider relationship. Therefore, clinicians need to elicit and understand all three aspects of sexual orientation: attraction, self-described identity and behavior, as well as gender identity.

Respect transgender patients by making sure all office staff are trained to use their preferred pronouns and names. Clearly indicate this information in their medical record for easy reference for future visits. Traditional personal pronouns are based on a binary she/he framework. An inclusive approach to addressing both gender nonconforming and transgender patients is to use non-binary personal pronouns. An optimal approach is to first provide your own personal pronouns and then ask patients how they would like to be called. For transgender patients, their answers may include pronouns such as "they," "ze" (pronounced "zee"), or "xe (also pronounced "zee"). Some clinicians may be challenged using a pronoun that they learned in English classes as a plural now as a singular noun. However, this accommodation may improve rapport with patients.

Tips for clinical encounters:

- Don't make assumptions about a patient's body or behavior based on their initial visual presentation.
- Get in the habit of assessing preferred pronouns at every visit. The most common format used is to introduce yourself and state your preference, as in "I'm Dr. Jones, and I use the pronouns she/her; how about you?"
- Understand that discussing genitals or sex may be very sensitive, stressful, or possibly traumatic for certain patients. Therefore, always ask permission before any physical contact and clearly explain all processes, tests, or examinations before they are done. For more information, visit the National LGBTQIA+ Health Education Center at www.lgbtqiahealtheducation.org .

> Clinical consideration: Used the wrong pronoun or name? Overheard your staff? A simple apology and dedication to do better may make the difference in your patient staying with your practice or not. "I'm sorry I used the incorrect pronoun. I did not intend to be disrespectful."

BEFORE MOVING ONTO THE NEXT SECTION, PLEASE COMPLETE CASE STUDY 1 ON THE NEXT PAGE.

Health Risks for LGBTQ Patients

LGBTQ patients have the same risk factors as any patient, but they also have risk factors and healthcare disparities that require special consideration. Healthy People 2020 targeted health disparities for elimination among LGBTQ people.[34] Research showed that negative health outcomes of LGBTQ individuals are often related to stigma, discrimination, and denial of human rights.[34] Eliminating disparities and improving LGBTQ health are important in contributing to increased longevity, decreased expenditure for healthcare, reduced disease transmission, and increased physical and mental wellness.[34]

Case Study 1 - Part 1

Instructions: Please read through the case study below and consider the questions that follow, then do the same for Part 2.

Sam had been searching for a primary care provider for months. He wanted to find someone who would treat him like a person, not a freak. In the previous primary care clinic where he received care, he overheard a front desk person commenting it was a shame that such a pretty girl was going to be a male. Fortunately, that was a different place, and he was now away at graduate school in a liberal arts college with a Campus Pride Index of 4.5. Someone in the resource center recommended this office, and he had a few things he hoped to find once he arrived. Sam called to inquire and received a package of information electronically that already gave him some comfort. Instead of the questions Sam had normally seen, these forms had options for gender that included transgender and relationship questions that did not assume married or single but allowed for partnered.

1. **From the information in the case study, how does Sam identify?**

2. **What type of barrier to care did Sam experience in his previous primary care practice?**

Discussion for Question 1: Gender identity is a personal feeling or idea that one has of themselves. One may choose to express their gender identity through the way they dress, behave, and mannerisms they use. They may also select pronouns they feel express who they are. The most identified genders are male, female, intersex, non-binary, trans, and non-conforming. Gender identity may or may not conform to assigned sex at birth. At birth Sam was identified as female according to anatomy and now identifies as male and is referring to himself as "he." Gender transition occurs when a person begins to live their gender identity. This transition is different for each individual and may include changing clothing, appearance, name, pronoun, identification, and for some, may include hormone therapy and/or surgery.

Discussion for Question 2: Multiple barriers can affect a person's access to healthcare. Relational or interpersonal interactions and system or institutional functions can present barriers impeding or serving as a discouragement for individuals needing or desiring healthcare. Sam purposefully left a previous healthcare provider because of insensitivity and bias from an employee who commented on his male identification. This is an example of a personal or relational barrier that created a stressful situation for Sam and resulted from the bias of another person. The experience of stigma is common among LGBTQ people and is a cause for stress and avoidance of healthcare. Insensitivity and/or discomfort of providers and office staff and occasionally refusal of care are also in this personal/relational category. System or institutional barriers are issues like transportation, distance, access to appropriate care, insurance restrictions, and assumed heteronormativity.

Case Study 1 - Part 2

Sam entered the office and scanned the waiting room/reception area. There were several areas for literature around the room, with one section dedicated to sexual minorities. The receptionist greeted Sam, and he handed her his previously filled out forms. The receptionist asked for a preferred first name and pronoun. Sam felt relieved that he could tell the office his preferred pronouns were he/him/his because the legal-name-change paperwork was not finalized. He grabbed a brochure and had a seat to wait for his appointment. In about 10 minutes, he heard someone call his name and he stood to walk in the back. After having his height and weight measured, he was led to an exam room. The nurse introduced herself, and Sam noticed a framed print on the wall titled "We Promise." The nurse saw him looking at it and explained the people who worked here felt very strongly that each person deserved respect and privacy for who they were and what they believed, and that everyone signed it. She asked a few questions and then handed him a form, saying they have all adult patients complete it and that the nurse practitioner would go over it with him. He turned it over and saw it was a sexual history form.

3. **What are some methods the office used to provide a welcoming environment for LGBTQ people?**

Discussion for Question 3: This office provided a section in the waiting room for literature relating to local resources and information for LGBTQ individuals. The intake form included preferred gender and pronoun, which was reinforced by the receptionist. Instead of asking only for marital status, it included additional options. In the exam room there was a nondiscrimination policy statement signed by employees, which showed their support for all individuals. Finally, the use of a sexual history form to be reviewed with a provider serves as a starting point for a discussion related to sexual practices and assists with risk identification. There are additional methods including displaying sexual minority couples, displaying a rainbow flag or sticker, providing a gender-neutral toilet facility, and listing your office on the Gay and Lesbian Medical Association (GLMA) directory.

Equality in healthcare has not yet been achieved, but what has been accomplished is an increase in sexual orientation and gender identification data collection.[35] This information will assist in identifying disparity, increasing recognition of the need to obtain unbiased social and sexual histories, and increasing provider education related to sexual minorities and social determinants of health to increase the potential for culturally competent care.[34]

Social Stressors and Mental Health

Social stressors contribute to increased rates of mental health issues, suicide, substance abuse, obesity, and victimization in this population. Chronic stress resulting from stigma, discrimination, and prejudice in the social environment has been referred to as minority stress and is a topic of interest in sexual minority individuals.[35] One frequently used framework for understanding the factors involved in the health disparities experienced by members of the LGBTQ community is the minority stress model.[37] Meyer[37] identifies the processes of minority stress, as related to LGBTQ populations, as having distal to proximal factors. These factors include experiencing external objective stressors, expecting such events to take place and the vigilance this expectation entails, and internalizing negative attitudes. Individual response to stressors varies as do stress-relieving factors. Many minority groups respond with group solidarity, which serves to support the morale and protect individuals from adverse stressors.[37] When a person does not have access to group-level resources, it can lead to increased stress and alienation.

Mental health issues are prevalent among LGBTQ people of all ages. Much of the risk for mental health conditions is thought to result from discrimination, bullying, violence, and loss of support. LGB identified youth were more than eight times more likely to have attempted suicide if their family rejected them than LGB peers with low or no level of family rejection.[38] LGB individuals have a two-to-six-time higher lifetime risk of suicide and/or depression.[39] A 2015 US study on transgender individuals found that 81.7% contemplated suicide and 40.4% had attempted suicide at some point.[39] In addition to risk factors common to the non-transgender public, elevated risks of suicidal thoughts and attempts were more likely among transgender people who report heavy substance use, have poor general health, have a disability, or have experienced recent homelessness or an arrest.[39]

In addition to stress and mental health issues, people who identify as LGBTQ are at risk for misuse of tobacco, alcohol, and other substances. In 2016, the Centers for Disease Control and Prevention (CDC) reported that 20.5% of LGB adults smoked compared to 15.3% of heterosexual adults.[40] This report means that about one LGB adult in five is a person who smokes. While limited information exists on transgender tobacco use, it is reported to be higher than among the general population.[40] Although actual substance abuse rates are unknown, the Substance Abuse and Mental Health Services Administration (SAMHSA) reports rates of 20% to 30% vs. 9% for the general population.[41] In 2019, 7.6 million LGB adults > 18 had a mental health or substance use disorder. That figure is a 20.5% increase from 2018.[42]

Although, historically, intimate partner violence has not been widely recognized or reported among the LGBTQ population, studies show that it is experienced as frequently or more frequently by LBGTQ individuals compared to those who identify as cis-gender.[43] Clinicians should include gender-neutral screening tools, such as the Partner Violence Screen, and be prepared with appropriate resources for positive screening results.[6] Violence against transgender people, especially transgender women of color, continues to occur in the United States. People who identify as transgender are 2.2 times more likely to experience physical IPV and 2.5 times more likely to experience sexual IPV compared to those who identify as cisgender.[44] Social stigmatization and other factors may lead to an under-reporting of acts of violence committed against transgender people.[44]

Findings from several studies illustrate the seriousness of criminal and interpersonal violence in transgender communities.

- The Human Rights Campaign began tracking fatal violence against transgender people in 2013. In 2020, 44 transgender or gender non-conforming people were killed. In November of 2021, 47 fatalities had already been recorded.[45]
- In 2016, the National Coalition of Anti-Violence Programs received information on 1,036
- incidents of hate violence from 12 antiviolence organizations across the United States. The information showed 21% self-identified as transgender women and 5% as transgender men.[46] Despite the known risk, 13 states do not have hate crime laws that cover sexual orientation or gender identity, and four states and three US territories do not have hate crime laws at all. In addition, only 12 states require hate crime training for law enforcement that includes crimes based on sexual orientation or gender identity.[47] Moreover, 20 states and five territories do not require hate crime data collection,[47]suggesting that the true crime numbers are higher.

Medical Risk Factors

Although cardiovascular deaths have declined since 2010 in the US, there remain significant differences in cardiovascular death rates based on race, sex, and income.[48,49] Caceres and colleagues[50] found that sexual minority persons experienced a higher prevalence of elevated cardiovascular (CVD) risk because of largely modifiable conditions than their heterosexual peers. For women, these risks included tobacco, alcohol, and illicit drug use, mental health issues, and elevated body mass index. For men, the risks were tobacco use, illicit drug use, and poor mental health.[50]

Repeat exposure to interpersonal stress (discrimination, family rejection, expectation of stigma), general stress (financial, life adversity, childhood trauma), and the potential for additional physical stress from hormone or antiretroviral treatments, combined with risks of tobacco, illicit drugs, excess alcohol, and elevated BMI, are believed to increase CVD risk. These findings were based on subjective data rather than physical markers and show the need for further research. According to Caceres and colleagues,[49] cardiovascular health research in sexual minorities has not been prioritized because of other health concerns such as HIV/AIDS and substance use.

In 2018, there were 37,968 new diagnoses of HIV in the US and its territories, with 69% being among gay and bisexual men.[51] A 2019 systematic review found 14% of transgender women have HIV, with 44% of these individuals identifying as African American, 26% as Hispanic/Latino, and 7% as White transgender women.[52] Sixty-four percent of new cases of HIV are among men who have sex with men (MSM), ages 13 to 34, with higher representation in African American and Hispanic/Latino groups. Use of pre-exposure prophylaxis is lower among these two racial/ethnic groups than among White MSM.[51] Sexually transmitted infections (STIs) are also more prevalent among MSM, with more than 8 in 10 new cases of gonorrhea and primary and secondary syphilis, 10% of new hepatitis A, and 20% of new hepatitis B cases are found in this group.[2]

Lesbian and bisexual women are less likely to obtain routine care, are more likely to be overweight or obese, and less likely to receive screening mammography.[6,53,54] Lack of insurance or lack of knowledge about cervical cancer risk may contribute to the fact that only 74.6% of lesbian women obtain cervical screening compared to 83.3% of heterosexual and 77.9% of bisexual women.[54] As a group, lesbian and bisexual women have breast cancer risks from a higher BMI, higher frequency of nulliparity, socioeconomic disparity, delay in care, and potential lack of provider relationship, which should spur a conversation about screening mammogram before age 50.[56] When considering screening for cancer, clinicians should remember the maxim "screen what you have" in addition to considering surgical history and use of hormones to ensure thorough screening.[6]

Caring for LBGTQ Youth

In the 1960s, Kohlberg hypothesized that gender-related development begins in infancy and continues progressively throughout childhood following three key concepts: gender constancy, gender consistency, and gender identity. On average, children develop gender constancy – stability across time in the identification of their gender – between ages 3 to 4 and gender consistency – recognition that gender remains the same across situations – between ages 4 to 7.[57,58]

The development of gender identity appears to be the result of a complex interplay between biological, environmental, and psychological factors.[5,59]

The period during which gender identity is clarified and solidified is unclear. There is no single trajectory of gender identity development for gender minority children. Some gender non-conforming children experience significant distress, currently termed gender dysphoria. Signs of gender dysphoria may emerge as early as the preschool years. One study found that nearly all transgender men and women experienced gender dysphoria by age 7. Furthermore, most participants continued to experience gender dysphoria without treatment until their adult years.[60] However, gender incongruence in early childhood is variable whereas adolescents experience a more constant identity.[61]

Health concerns of LGBTQ youth

Given the caveat that this group is understudied, especially through prospective longitudinal studies, it appears that gender diverse children who come to clinical attention, on average, have poorer relationships with parents and peers, experience high rates of mistreatment from peers, and are at increased risk of physical and sexual abuse in childhood, as compared to their gender conforming peers.[31,62,63] Compared with the general population, LGBTQ youth are at a higher risk for a wide variety of health concerns: substance use, STIs, cancers, CVD, obesity, bullying, isolation, rejection, anxiety, depression, and suicide.[1] It is difficult to tease out cause and effect in these associations. They also often receive lower quality of care because of stigma, lack of awareness among healthcare providers, and insensitivity to their unique needs. Twenty-nine percent of LGBTQ youth reported they had attempted suicide at least once in the previous year vs. 6% of heterosexual youth. In 2014, young gay and bisexual men accounted for 8 out of 10 HIV diagnoses among youth.[1]

Changing Mindsets

Healthcare providers must be caring and open in a non-biased way to provide an equal level of care for all patients. Sensing negativity may cause patients to withhold important information about sexual identity or avoid returning for follow-up care. It is important that personal belief systems are mutually exclusive of the healthcare relationships with all patients, including LGBTQ patients, to avoid influencing the interaction and quality of the healthcare provided. Although research and public advocacy groups cluster LGBTQ patients into categories, variances exist among each group, as do potential ethnic and familial risk factors. These factors compound the serious nature of LGBTQ health risks.

Healthcare professionals traditionally receive minimal education about the LGBTQ population's needs. The National LGBTQIA+ Health Education Center[33] has published resources and maintains a website with webinars and learning modules. Knowledge of basic terms and definitions will assist in establishing a mutual understanding and increasing communication with LGBTQ people.[64-66] Previous studies have demonstrated that healthcare providers felt their medical education was inadequate in regards to issues specific to patients who identify as LGBTQ.[67,68] Calls have gone out to reform undergraduate and graduate medical education to better prepare clinicians to address the health of this population and decrease the documented health disparities.[69,70] In addition, new curricula are available for medical residency and training programs to provide formal education about appropriate care for LGBTQ patients.[71]

Clinician Consideration

Clinicians should ensure that they keep up to date with the concerns and needs of the LGBTQ population through continuing education opportunities. Continuing education with a focus on human sexuality, sexual minorities, and specific aspects of LGBTQ healthcare can increase knowledge and provider/staff comfort, as well as decrease bias.

In addition to self-education and national guidelines, healthcare providers and their patients benefit from identifying specialty providers familiar with LGBTQ concerns and risks and knowledge of local LGBTQ-friendly resources. Displaying sensitivity to the healthcare needs of all patients is an important step in decreasing healthcare disparity in the United States.

Healthcare Preferences

Martos and colleagues[72] examined qualitative data from Lifestyle Interviews of LGB persons in three age cohorts from the Generations Study, looking for influences on healthcare preferences in the population. Findings centered on themes of stigma, expertise, identity, service type, and access. Stigma was the factor that most influenced participants' preferences and communication with providers. Martos and colleagues[72] defined stigma as "real or perceived negative social attitudes directed toward participants about one or more of their identities". Findings showed that stigma influenced participants' communication with their providers and varied from concern over one's own comfort to comfort of both provider and participant. Although avoiding stigma was a high priority, there were many different ideas on how to achieve this goal in the healthcare experience. They included a desire for an LGB-provider/venue, or a provider of a particular gender, to no concern at all if the provider was comfortable with the patient's sexuality. Expertise was also a priority, and providers were frequently selected based on their specific skills. Barriers in access to healthcare were varied by age groups and insurance coverage. A frustration for many was the additional cost for utilization of a provider outside the network or the compromise between preferences such as skill set or "queer friendly."[72]

Cultural Differences

The concept of understanding and demonstrating respect in interactions with individuals from different cultures has long been labeled "cultural competency". But, more recently, the term "cultural humility" is being favored over cultural competency. Can one every really be competent in a culture other than their own? And, if you are not culturally competent, are you then, in fact, culturally incompetent? Still, many bureaucratic agencies continue to promote "cultural competency" in their educational considerations for members of healthcare fields. In contrast, cultural humility emphasizes a continuum of education, self-evaluation, self-critique and improvement in our interactions with communities that are different from our own, rather than the "either or" implication of cultural competency.[73] The following section will explore both cultural competency and humility.

Cultural competence in healthcare is understood as the ability to provide care to people from diverse backgrounds and adapting or designing that care to meet their social, cultural, and linguistic needs.[74] To achieve cultural competence in healthcare systems, there must be policies in place along with training and education to change behaviors at the systems and personal levels. For systems, there may be the provision of language assistance or a cultural specialist that is part of the care team and interacts in the community. Benefits to these changes are social, such as promoting inclusion, increasing community participation in their health, and increased trust. Health benefits include improved preventive care, fewer missed appointments, and reduced disparity.

There are several stages in cultural competency: blindness (ignorance), awareness (you know you do not know), knowledge (you see differences and accept the person and their beliefs), and skills (gain ability to interact with different cultures).[75] Cultural competence develops in stages with individuals moving through stages at various rates with the assistance of education, training, commitment, and practice.[75] While cultural competency training can be beneficial, there is a concern of forming assumptions and stereotypes,[75] and no one person manifests all expectations of their culture.

Cultural humility involves a personal commitment to self-evaluation and critique to focus on improving relationships.[76] The benefit to cultural humility is a focus on individuals, getting to know a person's health goals, fears, and expectations, allowing for person-centered care. Cultural humility also calls for self-reflection of one's thoughts and biases, allowing for an equal provider-patient relationship and not requiring specific courses.

Regardless of the method, identification of one's feeling as they encounter someone with a different lifestyle or experiences is important in both cultural competence and humility.

Culturally affirming care seeks to support, validate, and honor the culture of the individual while recognizing current and historical oppression experienced by members of that culture.[77]

People who are transgender or gender diverse have expressed difficulty in finding culturally affirming medical care, especially in rural areas. Both healthcare providers and community members have identified the need for improved data collection and gender-inclusive intake forms, signage, and education of providers.[20] One study introduced an intervention over the course of one year to train staff at federally qualified health centers on culturally affirming practices, increase the collection of sexual orientation and gender identify information, and improve targeted screening. Post-intervention, the percentage of sites collecting sexual orientation and gender identity information had increased from 13.5% to 50.8%. Screening practices also indicated improvement. The authors note, however, that some of the centers felt the staff needed more training in culturally affirming care to better collect data and perform screening.[78]

Treatment Recommendations

This course has discussed some of the general recommendations for creating a welcoming, nonjudgmental environment and incorporating intake and sexual history forms that provide more inclusive and open-ended questions. The Gay and Lesbian Medical Association recommends discussing patient confidentiality and developing a written statement to explain how their information is protected, how it remains confidential, who can access it, and what circumstances may require sharing of information. The preventive care topics are no different than for any client and, as always, we must take the time to determine which is a specific risk for each patient. Each new patient visit should assess sexual risk, safety related to lifestyle (e.g., seatbelts, firearms, sunblock), domestic violence, and substance use.[79]

As many as 45% of lesbian and bisexual women are not out to their providers, which reinforces the need to obtain a nonjudgmental sexual history and reinforces the need for confidentiality. Social and behavioral risk factors include stress and failure to seek care, being overweight, as well as smoking and substance use.[79] Completing screening for substance use, interpersonal violence, depression, and anxiety are important to identify these possible risks. Consideration should be given for breast cancer screening at age 40 in women who are nulliparous or experienced early menarche, and in those with a positive family history. Do not assume a lesbian or bisexual woman does not plan to have children. Pap smears should be completed on all individuals with a uterus, including HPV testing at the recommended intervals, since transmission of HPV can occur among WSW. Additional screening and health concerns should be age-appropriate and focused on the actual behaviors of each client.

Gay and bisexual men should receive the same screenings as any male (i.e., colon, prostate, and testicular cancers; coronary artery disease) with consideration for the increased risk of anal HPV, anal cancer, domestic violence, mental health issues, and substance use.[79]

Healthcare for transgender individuals has been lacking in much of the US because of the insufficient number of healthcare providers with adequate training, because of discrimination, or negative behaviors experienced during healthcare utilization, and insufficient insurance or ability to pay for care.[80,81] Screening should be based on anatomy and behaviors that are present. Cervical and prostate screenings, for anyone with a cervix or prostate respectively, should be conducted at recommended intervals for trans and cisgender individuals. Transgender men may experience anxiety or distress during pelvic examinations, and healthcare providers should be sensitive to this possible reaction and attempt to maximize comfort during the examination.[81] Likewise, mammography is recommended for trans men who have not undergone chest reconstruction. Desire for birth control and fertility should also be discussed without assumptions by the provider.[81]

Recommendations

There are several additional suggestions in the literature to decrease disparity and improve access to care among LGBTQ persons. Although there has been some increase in acceptance of sexual minority individuals, there is still much work needed to reduce the health disparities and identify risks:

Seek resources for continuing education. An increase in knowledge and understanding on topics of concern for the LGBTQ population improves patient outcomes.

Effective communication. Using correct pronouns will increase a patient's comfort level. Do not gossip or joke about any patient. Encourage coworkers in their communication with patients. If you are uncertain, avoid the use of gender-related terms until you have confirmed this information with the patient. Apologize if you make an error and if there is a discrepancy with names or records. Ask what the name on the insurance card is or if the chart may have a different name. Confirm identity with date of birth.

Increase data collection on transgender individuals. As previously mentioned, there is minimal data available, lack of provider knowledge, and hesitancy to disclose this information to others. Four focus groups, with self-identified transgender individuals, explored the feasibility of asking about transgender identity in the Current Population Survey sponsored jointly by the U.S. Census Bureau and the U.S. Bureau of Labor Statistics (BLS).[9] Feedback revealed some concerns about accuracy of responses since answers may be made by household proxy and because it would be difficult to create adequate response options to capture group diversity.[9] General recommendations were to develop and test a variety of questions to test with other trans focus groups.

Address one's own bias. Explicit bias is conscious; the person is aware of their feelings, which may be expressed in words or actions. Implicit bias is unconscious and can reflexively interfere with assessments, decision-making, and provider-patient relationships.[82] Both explicit (conscious) and implicit (unconscious) bias should not be in healthcare. The former will take significant time and effort to overcome. Implicit bias must be uncovered and identified by the individual who must then desire to change their thoughts and behavior.[81] Several versions of the Implicit Association Test[82] can be accessed online (https://implicit.harvard.edu/implicit_/takeatest.html). Consider taking the Sexuality IAT, Transgender IAT, and Race IAT to assist with your self-evaluation.

Use of screening tools and guidelines. Guidelines and screening tools exist for general wellness in primary care practice and for specialty diagnosis in multiple settings. Additional research is needed to provide consistent care and optimize outcomes for our LGBTQ clients, including adequately developed guidelines that are evaluated and revised as information is updated.

BEFORE MOVING ONTO THE NEXT SECTION, PLEASE COMPLETE CASE STUDY 2 ON THE NEXT PAGE.

Resources

Many online sites provide education and CME credit related to sexual minority healthcare. The following list represents just a few of the hundreds of available resources. You can search by state and even locally to determine what is in your area

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The National LGBTQQ+ Health Education Center (https://www.lgbtqiahealtheducation.org/resources/) provides free publications, videos, webinars, and learning modules, many with continuing education credits, on multiple topics including providing inclusive healthcare, understanding disparities, and understanding health needs among others.

The CDC (https://www.cdc.gov/stophivtogether/hiv-prevention/) provides a variety of healthcare provider trainings along with some clinical care protocols and resources for HIV prevention and treatment.

The American College of Obstetricians and Gynecologists (https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2012/05/healthcare-for-lesbians-and-bisexual-women) provides recommendations for the healthcare of lesbian and bisexual women.

Case Study 2

Instructions: Please read through the case study below and consider the questions that follow.

(ANSWER KEY AND RATIONALE IS DISPLAYED AT THE BOTTOM OF THIS EXERCISE)

A new patient has presented to your primary care practice. Sarah M. is a 55 YO female without any known past medical history. You notice on her intake form that she is in a long-term, monogamous relationship with her female partner, Melissa, for 23 years. Sarah admits she has not seen a physician "in probably 25 years." She is not taking any medications or supplements. Sarah has a BMI of 34 and her vital signs are:

HR= 78 RR= 16 BP 155/92 T=98.8 F.

Sarah reports she did have a miscarriage at age 24 but no additional pregnancies. She states her periods had been regular until she completed menopause more than 3 years ago.

1. **Based on this limited information, you recognize that**
   a. Sarah does not require any specific gynecologic care since she is not sexually active with men.
   b. Sarah has a lowered risk for breast cancer compared to a heterosexual woman.
   c. Sarah may have been hesitant to seek medical care over the past several years because of negative interactions with healthcare professionals.
   d. Sarah should attempt to lower her BMI with weight loss supplements.

2. **Based on this limited information, you believe Sarah could be at risk for**
   a. Breast Cancer
   b. Metabolic disease
   c. Cervical cancer
   d. All of the above

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1. *Answer: C - Rationale: It is important that healthcare professionals recognize that a large number of individuals within the LGBTQ community have experienced negative interactions within the healthcare system. These negative interactions may result from explicit or implicit bias.*

2. *Answer: D - Rationale: Sarah has not received any medical care in more than 20 years. Based on her age, lack of prior screening and elevated BMI, she is at risk for all of the above disease processes. In fact, she has an elevated blood pressure at this visit, which could represent an indication of metabolic dysfunction.*

The Gay and Lesbian Medical Association: Health Professionals Advancing LGBTQ Equality (http://www.glma.org/index.cfm?fuseaction=Page.viewPage&pageId=534), founded in 1988 for physicians and medical students, is now open to members of other health specialties including nurses. Their mission is to ensure health equality for all sexual minority individuals.

On their resource page, there are links for both patients and providers. They also have free webinars and continuing education related to quality healthcare for LGBTQ people and assorted publications.

Familia es familia (https://www.familiaesfamilia.org/) provides information and links to topics such as family issues, immigration, school, community, discrimination, transgender, same-sex relationships, and student resources for LGBTQ individuals. Many of these are in Spanish and English.

The Safe Zone Project (https://thesafezoneproject.com/resources/) provides training resources in creating LGBTQ/Ally training and many other links to a variety of topics related to sexual minorities.

Campus Pride Index (https://www.campusprideindex.org/contactus/index) launched in 2007 and provides an assessment of colleges on eight LGBTQ-friendly aspects including safety, housing support, academic and student life, counseling and health, institutional support and commitment, and recruitment.

The Trevor Project (https://www.thetrevorproject.org/about/), founded in 1988, provides crisis intervention and suicide prevention 24/7 to LGBTQQ people under the age of 25. In addition to online and telephone service, individuals can chat confidentially via instant messenger or text a counselor any day any time. Text START to 678-678.

HealthSherpa (https://blog.healthsherpa.com/lgbtq-healthcare-resources/) helps individuals find quality, affordable health coverage under the Affordable Care Act. There are also links for people to become involved in political activism.

U.S. Office of Special Counsel (https://osc.gov/Pages/SearchResults.aspx?k=sexual%20discrimination) provides guidelines and factsheets related to complaints of employment-related discrimination in the federal workforce based on sexual orientation or gender.

The National Center for Transgender Equality (https://transequality.org/) was founded by transgender activists who desired to see policy changes. The site has multiple resources along with an FAQ section, issues relevant to transgender people and their advocates, legal rights information, and self-help guides.

Glossary

Unless otherwise stated, definitions are from New Jersey Institute of Technology.[65]

Ally: A person who supports and respects sexual diversity and acts to challenge homophobic or heterosexist remarks.

Cisgender: A person whose biological sex matches their gender identity.

Gender expression: The way a person presents and behaves.

Gender identity: How one perceives oneself (man, woman, or otherwise); this gender identity is internal and cannot be seen by others.

Healthcare disparity: Inequitable differences in healthcare resulting from differences in insurance coverage, access and availability of care, and quality of care received, leading to disparities (differences) in health and/or outcomes.

Healthcare provider: A person who is licensed, certified, registered, or otherwise authorized by the law of a state to provide healthcare in the ordinary course of business or practice of a profession.[83]

Heteronormativity: The assumption that all individuals are heterosexual or that heterosexuality is superior.

HIV+ (Human immunodeficiency virus positive): Having tested positive for a viral infection that affects CD4 cells, transmitted by contact with blood and body fluids infected with HIV.[84]

LGBTQ: Lesbian, gay, bisexual, transgender, queer (also may include additional Q for questioning).

MSM: Men who have sex with men.

Non-binary ("NB" or "enby"): a person who does not identify with gender binary of male or female.[85]

Pansexual: Person who is emotionally, physically, romantically, and/or sexually attracted to people regardless of those people's gender identity.

Queer: Individuals with non-normative gender identity, sexual orientation, or sexual anatomy (a term that has been used as a slur).

Sex assigned at birth: Determined by physical genital anatomy.

Sexual minority: "Those who identify as lesbian, gay, bisexual, or transgender or reported same-sex attraction."[50]

Transgender: Term for those whose gender identity does not match that assigned to their physical sex; may or may not use hormones or have had gender confirmation surgery.[86]

Transman FtM/F2M: Transgender person who lives as a male but was assigned female gender at birth.[87]

Transwoman MtF/M2F: Transgender person who lives today as a female but was assigned male gender at birth.[87]

Transition: The period of time during which a person begins to live according to their gender identity. This time frame varies by individual and may or may not include changes in clothing, appearance, identification, hormone therapy, and gender confirmation surgery.[87]

WSW: Women who have sex with women.

Ze: Non-gender pronoun used instead of "she" or "he"; ze (subject), hir (object), hirs (possessive pronoun), hirself (reflexive). Pronounced zee.[88]

Conclusion

As summarized in this learning activity, LGBTQ patients, in addition to having the same basic health needs as the general population, experience health disparities and barriers related to sexual orientation and/or gender identity or expression. LGBTQ health disparities exist throughout all age groups.

Youth have higher rates of homelessness, suicide, and mental health issues than their heterosexual peers. Many avoid or delay care or receive inappropriate or inferior care because of perceived or real homophobia, biphobia, transphobia, and discrimination by health care providers and institutions. Fear of and experiences with discrimination and stigma influence the decision whether to seek healthcare. Insurance coverage, cost, and lack of knowledgeable and experienced providers can cause a delay in seeking care.

Health care providers can take meaningful, positive steps to promote the health of their LGBTQ patients by examining their practices, offices, policies and staff training for ways to improve access to quality health care for LGBTQ people and by following the recommendations made in this activity. This course discussed methods to create a welcoming environment with a focus on primary care. Healthcare professionals can still identify ways to create a more inclusive environment and address instances of outright bias observed or encountered. Change is reliant on the identification of a situation in need of a different outcome.

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IMPROVING ACCESS TO CARE FOR LGBTQ PATIENTS

Self-Assessment

Choose the best possible answer for each question and mark your answers on the self-assessment answer sheet at the end of this book. There is a required score of 70% or better to receive a certificate of completion.

11. When obtaining a sexual history on all patients, it is important to do which of the following?
- A. Avoid uncomfortable topics.
- B. Limit discussion to the patient's current status.
- C. Ensure confidentiality and remain nonjudgmental.
- D. Obtain only if the visit pertains to reproductive matters.

12. Which of the following is a recommendation for decreasing bias related to LGBTQ healthcare needs?
- A. Continuing education with a focus on sexual minorities.
- B. Increased exposure to LGBTQ individuals.
- C. Asking questions related to human sexuality.
- D. Assume all individuals are LGBTQ.

13. Using an intake form that allows a patient to provide personal information in a nonjudgmental manner can do which of the following?
- A. Avoid uncomfortable topics during the patient encounter.
- B. Limit work for office staff.
- C. Set the tone for provider-patient relationships.
- D. Encourage them to refer other patients.

14. The National LGBTQ Health Education Center suggests posting which of the following?
- A. Nondiscrimination policy.
- B. Welcome sign.
- C. Statement of purpose.
- D. HIPPA facts.

15. A national survey in 2017 revealed which of the following?
- A. Discrimination kept LGBTQ people from seeking care.
- B. Discrimination may result in LGBTQ patients having trouble finding care if turned away.
- C. Discrimination in healthcare still exists for those in the LGBTQ community.
- D. All of the above.

16. Improved health outcomes are a direct result of which of the following?
- A. Confrontation regarding unacceptable behaviors.
- B. Avoidance of sexual topics for discussion when uncomfortable.
- C. Risk identification, behavior modification, continued surveillance.
- D. Limiting time spent in waiting rooms.

17. A health disparity:
- A. Is a difference in health status, resulting from a form of disadvantage.
- B. May be based on race, gender, immigrant status, disability, or sexual orientation.
- C. May be overcome through education and understanding of healthcare providers.
- D. Is all of the above.

18. Which of the following correctly defines health disparities?
- A. Differences in healthcare providers' approaches to patient care.
- B. Differing responses to a specific treatment among various patients.
- C. Patients suffering from multiple disease processes.
- D. Differences in health status of populations often as a result of some form of disadvantage.

19. In addition to common health risk factors, LGBTQ patients may experience social stressors contributing to all of the following EXCEPT:
- A. Mental health issues.
- B. Suicide.
- C. Substance abuse.
- D. Motor vehicle accidents.

20. One way to avoid negatively influencing the interaction and quality of healthcare provided is to:
- A. Exclude personal belief systems from healthcare relationships.
- B. Treat everyone differently.
- C. Limit patient visits to only one topic for evaluation.
- D. Avoid uncomfortable or difficult patient situations.

NOTES

NOTES

NOTES

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Shade circles like this: ● Final exam questions are located at the end of each chapter.

Best Practices for Treating Pain with Opioid Analgesics

	A	B	C	D
1	○	○	○	○
2	○	○	○	○
3	○	○	○	○
4	○	○	○	○
5	○	○	○	○
6	○	○	○	○
7	○	○	○	○
8	○	○	○	○
9	○	○	○	○
10	○	○	○	○

Improving Access to Care for LGBTQ Patients

	A	B	C	D
11	○	○	○	○
12	○	○	○	○
13	○	○	○	○
14	○	○	○	○
15	○	○	○	○
16	○	○	○	○
17	○	○	○	○
18	○	○	○	○
19	○	○	○	○
20	○	○	○	○

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LEARNER RECORDS: EVALUATION

You must complete the program evaluation and applicable activity evaluation(s) in order to earn *AMA PRA Category 1 Credits*™, MOC points, or participation in MIPS. For each of the objectives determine if the activity increased your:

A Competence B Performance C Outcome D No Change

COURSE 1 - BEST PRACTICES FOR TREATING PAIN WITH OPIOID ANALGESICS:

		A	B	C	D
1.	Identify and employ a full range of therapeutic options when developing a pain treatment plan..	○	○	○	○
2.	Screen patients for presence or risk of OUD, assess and manage patients who demonstrate signs of OUD, or refer if necessary	○	○	○	○

3. Please identify a specific change, if any, you will make in your practice related to safe prescribing of opioid analgesics.

_____

_____

4. What do you see as a barrier to making these changes?

_____

_____

COURSE 2 - IMPROVING ACCESS TO CARE FOR LGBTQ PATIENTS:

		A	B	C	D
5.	Implement strategies to improve healthcare access of the LGBTQ population	○	○	○	○
6.	Apply strategies to address health risks in the LGBTQ community.	○	○	○	○

7. Please identify a specific change, if any, you will make in your practice related to caring for LGBTQ patients.

_____

_____

8. What do you see as a barrier to making these changes?

_____

_____

OVERALL PROGRAM:

		Yes	No	If no, please explain:
9.	The program was balanced, objective & scientifically valid	○	○	_____
10.	Do you feel the program was scientifically sound & free of commercial bias or influence?	○	○	_____

11. How can this program be improved?_____

_____

12. Based on your educational needs, please provide us with suggestions for future program topics & formats._____

_____

13. For which activities would you like to use your participation as a clinical practice improvement activity (CPIA) for MIPS?

○ Course 1 ○ Course 2 ○ None

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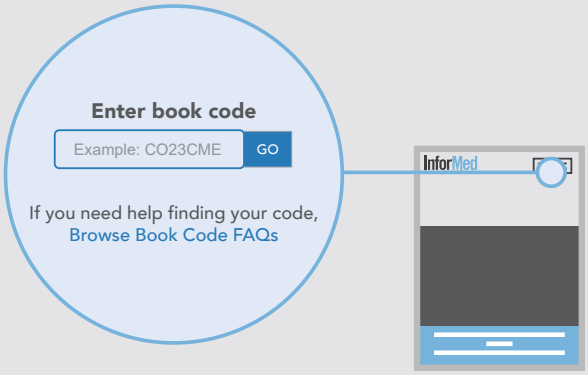

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