InforMed
Continuing Medical Education
By Colibri Healthcare

Florida Continuing Medical Education

2024 Florida

Medical Licensure Program

2 HOURS

BOARD-APPROVED
Controlled Substances/Opioids
SATISFIES BOARD-APPROVED CONTROLLED SUBSTANCE PRESCRIBING REQUIREMENT

2 HOURS

Medical Errors
SATISFIES MEDICAL ERROR REQUIREMENT

2 HOURS

Intimate Partner Violence
SATISFIES DOMESTIC VIOLENCE REQUIREMENT

6 TOTAL
AMA PRA Category 1 Credits™

Need to complete the ***DEA's new one-time MATE requirement?*** See page i for more details.

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

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CONTENTS

2024 FLORIDA

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.

$50.00	$40.00
ENTIRE PROGRAM	COURSES 1 & 2

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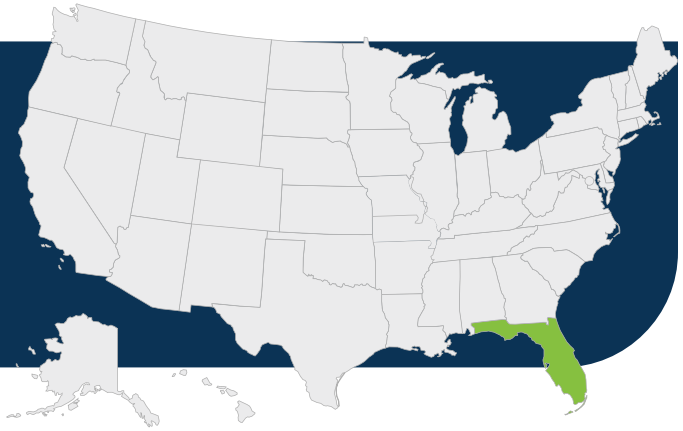
- Completions will be processed within 2 business days from the date it is received and certificates will be e-mailed to the address provided.
- Submissions without a valid e-mail will be mailed to the address provided.

By fax

- Fill out the answer sheet and evaluation found in the back of this booklet. Please include credit card information and e-mail address. Fax to **1-800-647-1356**.
- All completions will be processed within 2 business days of receipt and certificates will be e-mailed to the address provided.
- Submissions without a valid e-mail will be mailed to the address provided.

INFORMED TRACKS WHAT YOU NEED, WHEN YOU NEED IT



Florida Professional License Requirements

MANDATORY CONTROLLED SUBSTANCES CME

All physicians (MD/DO) that have a current DEA registration to prescribe controlled substances must complete a board-approved two (2) hour course on prescribing **controlled substances/opioids**.

MANDATORY MEDICAL ERRORS CME

As a condition of biennial renewal the State Board of Medicine requires each person licensed as a physician (MD) to complete two (2) hours relating to prevention of **medical errors** which includes a study of root cause analysis, error reduction and prevention, and patient safety.

MANDATORY DOMESTIC VIOLENCE CME

As part of every third biennial renewal period, all licensees shall complete two (2) hours of training in **domestic violence.**

GENERAL PHYSICIAN CME REQUIREMENTS

Every physician licensed pursuant to Chapter 458, F.S., shall be required to complete 40 hours of continuing medical education courses approved by the Board in the 24 months preceding each biennial renewal period as established by the Department. All of the above mandatory CME requirements may be included in the total general hours required for renewal.

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

Department of Health
Board of Medicine
4052 Bald Cypress Way
Bin C-03
Tallahassee, FL 32399-3253
P: (850) 245-4131
F: 850-488-0596

LICENSE RENEWAL DATE:

1/31/2024

Provider Reports CE/CME to cebroker

ELECTRONIC TRACKING OF CE

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
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**	**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 SA	2 Credits LL	2 Credits LL+SA
Medical Errors and the United States Healthcare System	2 *AMA PRA Category 1 Credits*™	2 Credits LL	2 Credits MK	2 Credits SA	2 Credits LL	2 Credits LL+SA
Intimate Partner Violence: Compassionate Care, Effective Assessment	2 *AMA PRA Category 1 Credits*™	2 Credits LL	2 Credits MK	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.

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

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.

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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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.

COURSE SATISFIES

SPECIAL BOARD APPROVAL

This activity is approved by the Florida Boards of Medicine and Osteopathic Medicine and satisfies the mandatory educational requirement on controlled substances/opioids.

CE Broker Provider #: 50-25874

The Florida Boards of Medicine and Osteopathic Medicine require all physicians (MD/DO) with a current DEA registration to complete a minimum of two (2) hours of CME on controlled substances/opioids through a board approved course.

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.

DISCLAIMER

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]

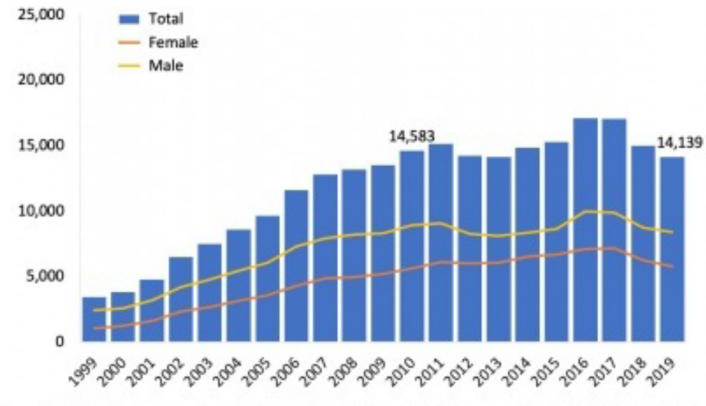
Health care practitioners (HCPs) play a key role in facilitating appropriate use of opioids and other sedating medications when prescribed for acute and chronic pain. Pain care is most effective when it combines multiple disciplines and utilizes a broad range of evidence-based pharmacologic and nonpharmacologic 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]

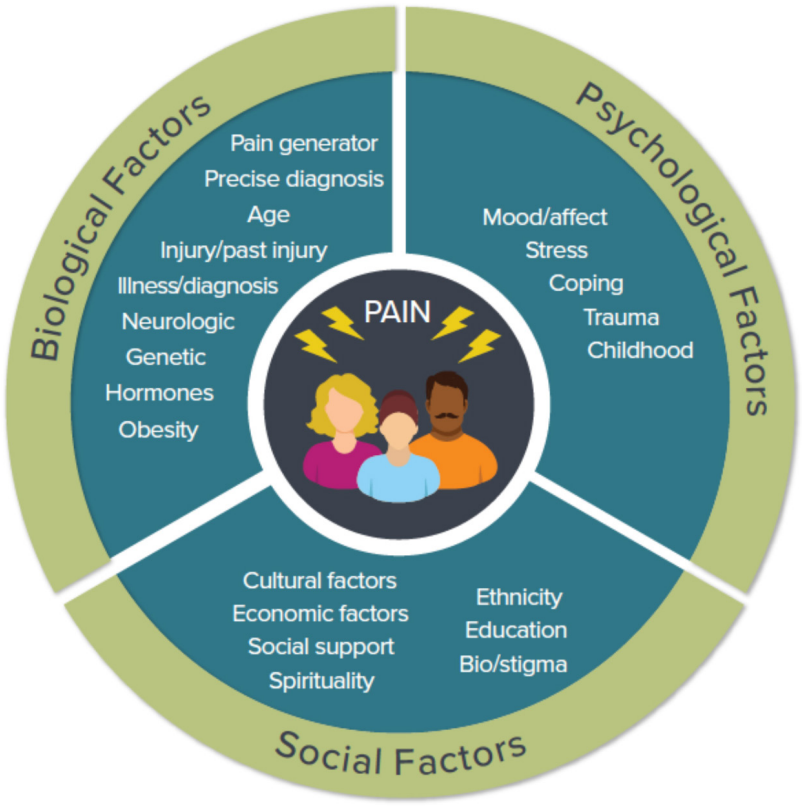
Pain is protective and essential for survival when understood as a warning signal that something has gone wrong in the body. However, when pain persists indefinitely the central nervous system (CNS) begins to sense, transmit, modulate, and interpret the pain experience differently.[14] When the nociceptors, 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.

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
Opioid-use disorder	• A problematic pattern of opioid use leading to clinically significant impairment or distress • Defined by 11 criteria in the DSM-5* over a 12-month period • Previously classified as "opioid abuse" or "opioid dependence" in DSM-4 • Severe opioid-use disorder also referred to as "opioid addiction"

*DSM-5 = Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition;[92] diagnostic criteria given later in this activity

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]

In 2018, Florida passed the Controlled Substances Bill, which limits a prescription of a Schedule II opioid to alleviate acute pain to a 3-day supply, codifying the CDC guideline for the treatment of acute pain.

However, a health care practitioner may prescribe up to a 7-day supply if the physician determines it is medically necessary, indicates "acute pain exception" on the prescription, and documents the justification for deviating from the 3-day supply limit in the patient's medical record. The bill defines acute pain as the normal, predicted, physiological, and time limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness. For information on new legislative updates related to controlled substances, see the "Updates to Florida Controlled Substances Regulations" at the end of this monograph.

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]

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

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.

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.

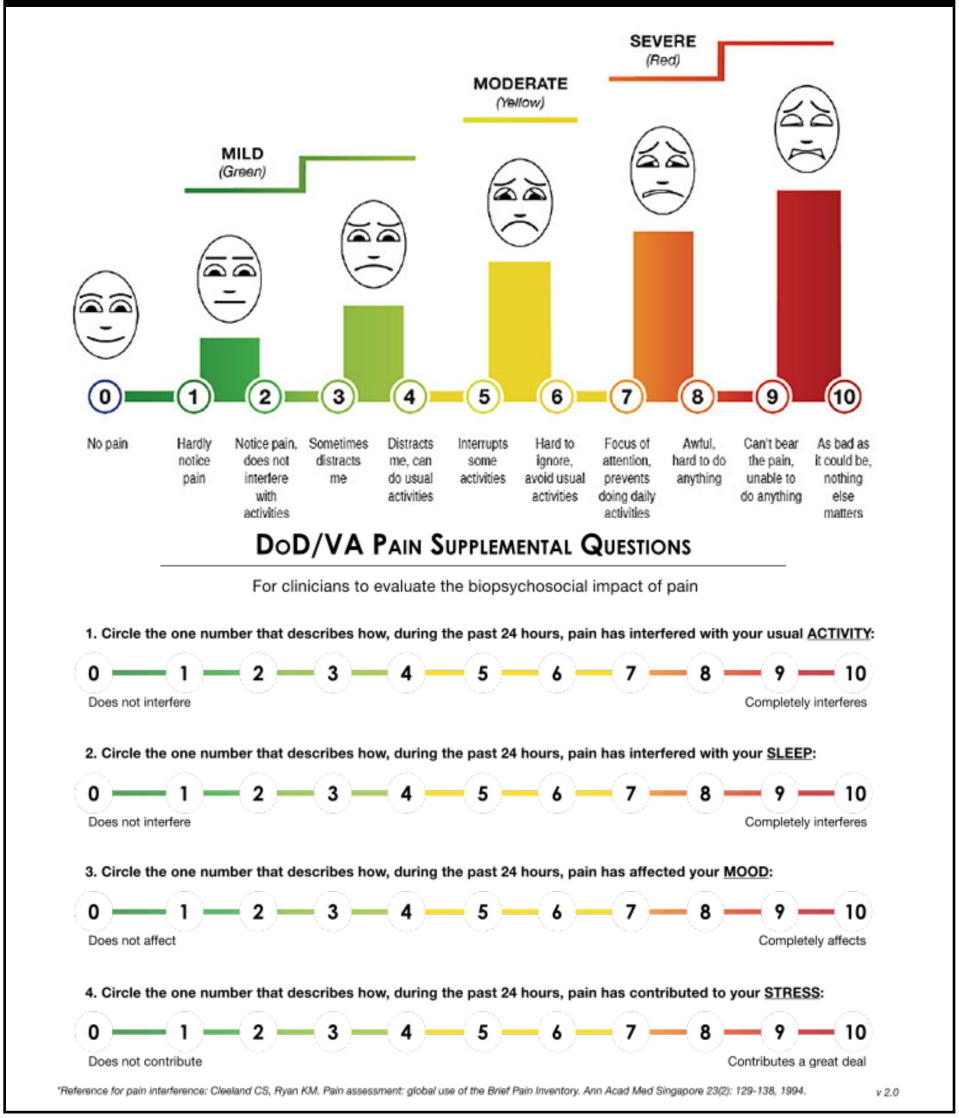
A number of evidence-based, pain assessment tools are available for clinical practice:

- 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]

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

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

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
- 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.

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			

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.

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.

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?**_____

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

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
- 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.

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 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] 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]

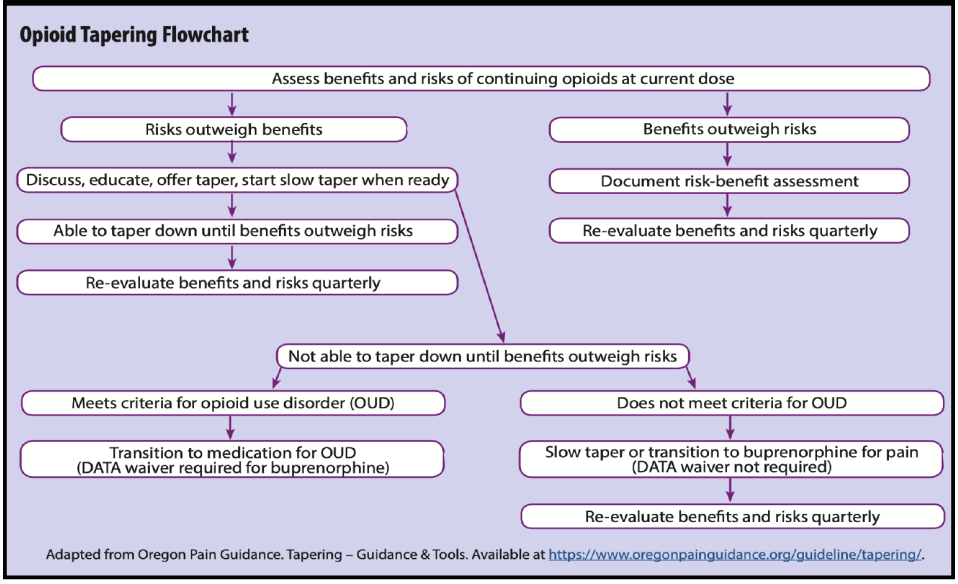
BEFORE MOVING ONTO THE NEXT SECTION, PLEASE COMPLETE CASE STUDY 2 ON THE NEXT PAGE.

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]

Updates to Florida Controlled Substances Regulation

House Bill 831 Electronic Prescribing

This bill was signed into law by Governor DeSantis with an effective date of January 1, 2020. The bill provides important new requirements for prescribers to generate and transmit all prescriptions electronically upon licensure renewal or by July 1, 2021, whichever is earlier.

The law requires prescribers to generate and transmit all prescription electronically, unless:

- The practitioner and the dispenser are the same entity;
- The prescription cannot be transmitted electronically under the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT Standard;
- The practitioner has been issued a waiver by the department, not to exceed 1 year, due to demonstrated economic hardship, technology limitations that are not reasonably within the control of the practitioner, or another exceptional circumstance demonstrated by the practitioners;
- The practitioner reasonably determines that it would be impractical for the patient in question to obtain a medicinal drug prescribed by electronic prescription in a timely manner and such delay would adversely impact the patient's medical condition;
- The practitioner is prescribing a drug under a research protocol;
- The prescription is for a drug for which the federal Food and Drug Administration requires the prescription to contain elements that may not be included in electronic prescribing;
- The prescription is issued to an individual receiving hospice care or who is a resident of a nursing home facility; or
- The practitioner determines that it is in the best interest of the patient, or the patient determines that it is in his or her own best interest to compare prescription drug prices among area pharmacies. The practitioner must document such determination in the patient's medical record.

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.*

House Bill 743 Non-opioid Alternatives

The bill revises these requirements for certain health care practitioners to inform patient or patient's representative of nonopioid alternatives before prescribing or ordering an opioid drug by:

- Requiring that the pamphlet provided to the patient be printed: the pamphlet can be downloaded at: http://www.floridahealth.gov/programs-and-services/non-opioid-pain-management/_documents/alternatives-facts-8.5x11-eng.pdf
- Authorizing a health care practitioner to discuss non-opioid alternatives with, and provide the pamphlet to, the patient's representative rather than the patient;
- Removing the requirement to address non-opioid alternatives when a drug is dispensed or administered; and
- Exempting hospice services and care provided in a hospital critical care unit or emergency department from the requirement to discuss non-opioid alternatives with a patient
- Document the nonopioid alternatives considered in the patient's record

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.

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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.

MEDICAL ERRORS AND THE UNITED STATES HEALTHCARE SYSTEM

COURSE DATES:	MAXIMUM CREDITS:	FORMAT:
Release Date: 5/2022 Exp. Date 4/2025	*2 AMA PRA Category 1 Credits™*	Enduring Material (Self Study)

TARGET AUDIENCE

This course is designed for physicians (MD/DO) and all other health care professionals.

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 update physicians on the continuing impacts and challenges of medical errors for the healthcare system in the United States and to provide strategies to address root causes of these errors.

LEARNING OBJECTIVES

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

1. Review terminology and categories of medical errors.
2. Understand how to conduct a root cause analysis to identify and correct errors.
3. Identify factors that contribute to medical error occurrence.
4. Describe strategies for reducing common medical errors.

ACCREDITATION STATEMENT

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COURSE SATISFIES

2

PREVENTION OF MEDICAL ERRORS

SPECIAL DESIGNATION

This course fulfills two (2) hours related to prevention of medical errors.

CE Broker Provider #50-25874

The Florida Board of Medicine requires physicians (MD) to complete a minimum of two (2) hours of CME on prevention of medical errors as a condition of each biennial renewal.

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DISCLAIMER

INTRODUCTION

Medical errors are an under-recognized cause of death in the United States. Error rates are significantly higher in the United States compared with other developed countries such as Canada, Australia, New Zealand, Germany, and the United Kingdom.[1] Patient safety experts at Johns Hopkins analyzed medical death rates over an 8-year period and estimated that >250,000 deaths each year are due to medical error in the United States (Figure 1).[2] This statistic makes medical errors the third highest cause of death in the United States, accounting for 10% of all deaths.[2] Unfortunately, the way that the Centers for Disease Control and Prevention collects national health statistics fails to classify medical errors separately on death certificates. Because medical errors are not listed, they do not get the public attention given to other leading causes of death such as cancer and heart disease.[2]

Medical errors increase personal and institutional financial burdens, adding an estimated $20 billion to US healthcare costs annually.[3] Beyond the emotional toll on the patient, medical errors have substantial negative effects on the mental and emotional well-being of the providers who are involved.[4] These negative effects include guilt, shame, anxiety, fear, depression, posttraumatic stress disorder and suicidality.[4]

Although improvement has occurred in specific areas, significant challenges remain. For example:

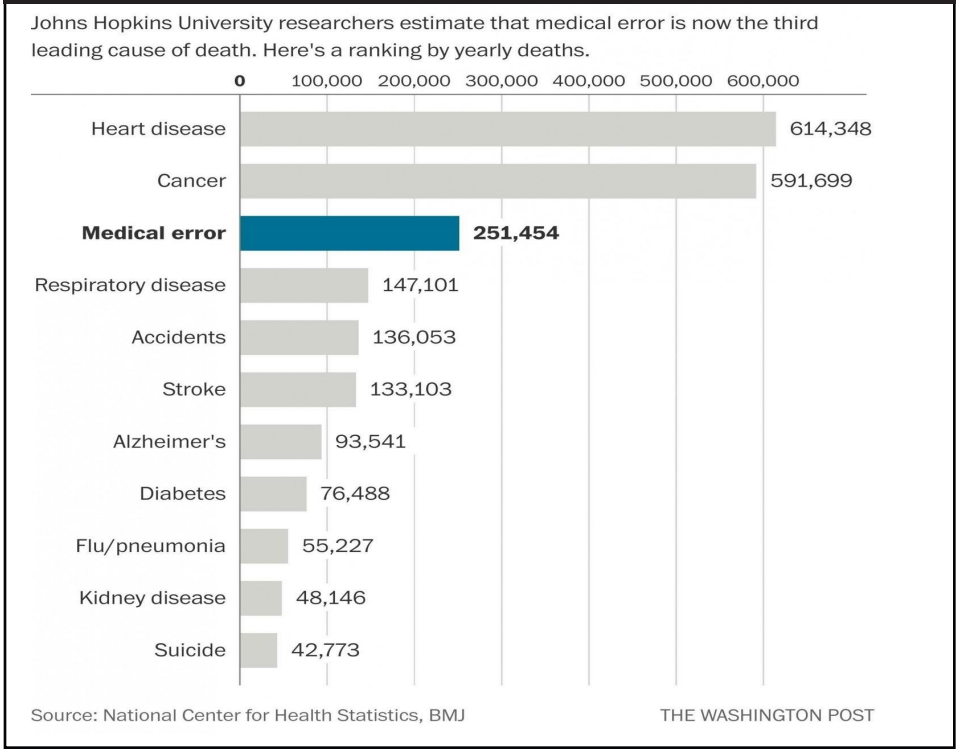
- One in two surgeries involved a medication error and/or an adverse drug event.[5]
- Approximately 5% of all adult Americans experience a diagnostic error in outpatient settings every year.[6]
- An estimated 29% of Medicare patients in rehabilitation hospital stays experienced an adverse event and half of these were considered preventable, which is similar to findings regarding adverse events in hospitals and skilled nursing facilities (27% and 33%, respectively.[7]
- An assessment of the frequency and types of errors identified by patients who read open ambulatory visit notes found 20% of patients who read a note reported finding a mistake and 40% perceived the mistake as serious. Among patient-reported very serious errors, the most common characterizations were mistakes in diagnoses, medical history, medications, physical examination, test results, notes on the wrong patient, and left vs right side.[8]

Medical Error or Unintended Consequence?

The term medical error captures all the unintended events that occur during a patient's care cycle. These can be as innocent as the wrong doctor's name placed into a chart, or a missed dose of medication that has no consequences to the patient. Some medical errors are discovered before any harm occurs, and some are so benign they go completely unnoticed.[9]

Some clinicians believe that the term medical error is excessively negative, antagonistic, and perpetuates a culture of blame. Many experts suggest the term medical error should not be used at all, because, for example, an adverse medication event could be an unintended consequence of a therapeutic intervention. However, adverse patient outcomes may occur because of medical errors and to delete the term obscures the goal of preventing and managing its causes and effects.[10]

Figure 1. Death in the United States



Regardless of the nomenclature, medical errors typically occur from the convergence of multiple contributing factors. Public and legislative intolerance for medical errors typically illustrates a lack of understanding that some errors may not be preventable with current technology or the resources available to the practitioner.[11]

The trend is for patient safety experts to focus on improving the safety of healthcare systems to reduce the probability of errors and mitigate their effects rather than focus on an individual's actions. Medical errors represent an opportunity for constructive changes and improved education in healthcare delivery.[11]

TERMINOLOGY

Medical error is defined as harm to a patient that results from either.[12, 13]

- The failure of a planned action to be completed as intended or
- The use of a wrong plan to achieve an objective.

Medical error can be associated with failures in medical practice, products, procedures, and/or systems. Medical error requires two critical parts: harm and whether the harm or error could have been prevented.[12]

Other terms related to medical error include.[12-14]

- *Safety:* Freedom from accidental injury.
- *Adverse drug event:* Injury resulting from the use of a drug caused by an adverse drug reaction, a medication error, or an overdose. An adverse drug event frequently necessitates discontinuation of the drug and potentially administering an antagonist.
- *Adverse drug reaction:* Unavoidable, appreciably noxious, or unpleasant reaction that occurs during the normal, proper use of a medical product. Some drug reactions may be minor and temporary; others have the potential to be permanent and serious.
- *Medication errors:* Errors that occurs due to mistakes made in the processes of the drug's prescribing, transcribing, dispensing, administering, or monitoring.
- *Near-miss:* Error that is detected and corrected before harm can be done.
- *Sentinel event:* Unexpected occurrence involving death or serious physical or psychological injury, or the risk of death or such an injury. A sentinel event indicates the need for immediate investigation and response. The terms "sentinel event" and "error" are not synonymous; not all sentinel events occur because of an error, and not all errors result in sentinel events.
- *Root Cause Analysis:* Root cause analysis is a process for identifying factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event.
  - A root cause analysis focuses primarily on systems and processes, not on individual performance.

- The analysis progresses from special causes in clinical processes to common causes in organizational processes and systems and identifies potential improvements in these processes or systems.
- The goal is to decrease the likelihood of such events in the future by implementing strategies to prevent the event from occurring again.

CATEGORIES OF MEDICAL ERRORS

Many preventable adverse events can be associated with more than one type of medical error. Although there are many different ways to categorize medical error, and categories may overlap, the following classifications are common.

- *Misdiagnosis/Diagnostic errors:* Diagnosis errors are errors that occur when a diagnosis is missed, wrong, or delayed.[15] Preventing medical misdiagnosis is a recognized national public health priority.[16] In their landmark 2015 report Improving Diagnosis in Healthcare, the National Academy of Medicine (NAM) stated that "most people will experience at least one diagnostic error in their lifetime, sometimes with devastating consequences."[17]Diagnostic error rates in real-world practice are not known, but a commonly cited estimate is that 10–15% of all diagnoses are incorrect.[16] A 2021 review article found that missed vascular events, infections, and cancers account for 75% of serious harms from diagnostic errors and 15 diseases account for nearly half of all serious misdiagnoses.[16]
- *Systems or process errors:* Systems or process errors involve predictable human failings in the context of poorly designed systems.[18]
- *Active errors:* Active errors nearly always involve frontline staff members and occur at the point of contact between a human and some part of a larger system.[18]
- *Latent errors:* Sometimes referred to as "accidents waiting to happen," latent errors involve failures of organization or design (e.g., systems and processes) that allow active errors to cause harm.[18]
- *Medication errors:* Medication errors are "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer."[19] The FDA receives approximately 100,000 reports each year associated with suspected medication error. These reports come from drug manufacturers, healthcare professional, and consumers through MedWatch, the Agency's safety information and adverse event reporting program.[20]
- *Infection-related errors:* According to the U.S. Centers for Disease Control and Prevention (CDC) on any particular day, approximately one in 25 patients has at least one healthcare associated infection.[21] The main types of infection include: pneumonia (22%), surgical site infections (22%), gastrointestinal infections (17%), and device associated infections, which include central line infections, catheter-associated UTI, and ventilator-associated pneumonia (26%).[22] It is impossible to estimate the percentage of hospital acquired infections that are avoidable, but evidence shows that many of these infections can and should be prevented. For example, failure to conform to hand hygiene standards can lead to preventable infections.[21]
- *Surgical errors:* Wrong-site, wrong-procedure, wrong-patient errors should never occur and indicate serious safety problems within an organization. Recent studies show that these types of errors occur in about one of 112,000 surgical procedures or that an individual hospital would experience such an error every five to 10 years. However, these data sets only include procedures in the operating room. If procedures performed in other settings, such as ambulatory surgery centers, were to be included, the rate of such errors may be significantly higher.[23]
- *Pharmacy errors:* Pharmacy errors can involve such issues as the preparation or processing of a prescription or giving incorrect directions to patients. Researchers at a tertiary care medical center in Houston, Texas, recently monitored 1,887,751 medication orders, 92 medication error events, and 50 pharmacists. They determined that the overall error rate was 4.87 errors per 100,000 verified orders. Pharmacy errors were associated with workload, work environment, and number of pharmacists per shift. Factors such as the type of pharmacy degree, age, experience, and the number of years at an institution may also influence the error rate.[24]
- *Laboratory errors:* Errors made in the laboratory can be technical, procedural, or the result of poor communication. The ECRI Institute evaluated 2,420 mistakes that occurred between 2011 and mid-2013. Only 4% of reported potentially harmful errors occurred in the laboratory itself. Nearly 75% of mistakes occurred in the pre-analytic stage, defined as the time frame in which tests are selected and ordered, specimens are identified and transported, and patients are prepared. Such mistakes were more likely to be linked to labels that had the wrong patient's name, the wrong specimen ordered, and incomplete or missing information. The other 22% occurred in the post-analytic stage, when results were interpreted, reported, or stored.[25]

BEFORE MOVING ONTO THE NEXT SECTION, PLEASE REVIEW THE 5 MOST MISDIAGNOSED CONDITIONS ON THE NEXT PAGE.

ROOT CAUSE FACTORS THAT CONTRIBUTE TO MEDICAL ERRORS

The causes and prevention of medical errors are the focus of considerable academic and professional attention. For accreditation purposes, the Joint Commission requires that healthcare institutions have a comprehensive process for the systematic analysis of sentinel events.[26] Reporting of sentinel events by accredited organizations is voluntary, and it is estimated that less than 2% of all sentinel events that occur in healthcare are reported to The Joint Commission. The most frequently reported sentinel events in 2020 were fall (n=170), unintended retention of a foreign object (n=106); suicide (n=81); delay in treatment (n=76); wrong side-surgery (n=68); assault/rape/sexual assault (n=47); fire (n=30); clinical alarm response (n=27); self-harm (n=24); and medication management (n=24).[27] The Office of Quality and Patient Safety at The Joint Commission works with organizations reporting sentinel events to identify contributing factors and actions the organization can take to reduce risk.[27]

The root cause analysis (RCA) process is one of the most commonly used tools by institutions to optimize patient care and enact measures to mitigate adverse events. RCA is primarily based on system-level process. The RCA starts with a designated team that reviews and identifies required changes at the systemic level, improving performance and reducing the likelihood of another sentinel event. Failure to perform an RCA within 45 days of the occurrence of a sentinel event may result in the healthcare institution being placed on an 'accreditation watch,' which is public information. Repeat violations may result in an onsite review by the Joint Commission that may jeopardize accreditation. The Joint Commission has created a framework and series of 24 questions to aid in organizing an RCA. This framework is recommended to be used as a general template when preparing the RCA report that will eventually be submitted to the Joint Commission after thorough evaluation.[26]

The 24-question framework recommended by the Joint Commission considers a variety of situational factors that may have contributed to a sentinel event. This includes examining the systematic process, human factors, equipment malfunctions, environmental factors, uncontrollable external factors, organizational factors, staffing and qualifications, contingency plans, performance expectations, informational disruptions, communication, environmental risks, training, and technology (Table 1, see pg. 35).[26]

Prevention strategies typically address the three most common causes of medical errors: communication, planning and knowledge, and systemic or institutional failure.

THE 5 MOST MISDIAGNOSED CONDITIONS

Cancer-Related Issues: Early and accurate diagnosis of cancer is important to optimize patient outcomes in terms of local disease control, overall survival, and health-related quality of life.[1] Cancers detected before they metastasize are easier to treat and associated with better outcomes and survival rates. For example, lung cancer diagnosed at the localized stage has a relative 5-year survival rate of 57% compared with 7% when found at the distant or metastatic stage.[2] A recent review found that the highest cancer misdiagnosis rate was for lung cancer at 22.5%, while the lowest misdiagnosis rate was for prostate cancer at 2.4%.[3]

Misdiagnosis of lung cancer can result from failure of the provider to recognize symptoms, such as shortness of breath and coughing up blood, that often overlap with other common conditions, including pneumonia, asthma, chronic obstructive pulmonary disease, acid reflux, and tuberculosis.[4] Additionally, approximately 90% of missed lung cancer cases occur on chest X-ray . Although CT is much more sensitive than chest radiography, lung cancer can still be missed. In these cases, observer error, lesion characteristics, and technical defects are the main causes of missed lung cancer.[5]

Misdiagnosis Rates for Cancer[3]	
Lung	2.5%
Melanoma	13.6%
Colorectal	9.6%
Breast	8.9%
Prostate	2.4%
Total Cancers	1.1%

Neurologic-Related Issues: Misdiagnosis in patients with neurologic symptoms associated with conditions such as multiple sclerosis (MS), epilepsy, Bell's palsy, dementia, and migraine, may result in ineffective and potentially toxic treatment. Misdiagnosis of MS may expose patients to the adverse effects of disease-modifying agents with no chance of benefit while misdiagnosis of epilepsy may expose patients to the risks of antiepileptic drugs and potential loss of a driving license or job. In addition, as occurs with misdiagnosis in other conditions, misdiagnosis fails to address symptoms, delays appropriate therapy, and may result in a worse prognosis.[6]

MS is often misdiagnosed because it remains a clinical diagnosis that relies on appropriate interpretation of radiologic data in patients with an appropriate history and neurologic examination. In a study[7] of patients misdiagnosed with MS, alternate diagnoses included migraine alone or in combination with other diagnoses 22%, fibromyalgia 15%, nonspecific or nonlocalizing neurologic symptoms with abnormal MRI 12%, conversion or psychogenic disorders 11%, and neuromyelitis optica spectrum disorder 6%. Duration of misdiagnosis was 10 years or longer in 33% of patients and an earlier opportunity to make a correct diagnosis was identified for 72%. In addition, 70% of patients received disease-modifying therapy and 31% experienced unnecessary morbidity because of the misdiagnosis.[7]

Cardiac-Related Issues: Despite significant advances in the diagnosis and treatment of cardiac conditions, misdiagnosis remains a concern. Although heart disease is often considered a man's disease, almost as many women as men die of heart disease each year in the US.[8] Heart disease is the leading cause of death in women, responsible for 1 in every 4 deaths. But almost two-thirds of women who die suddenly from heart disease had no previous symptoms. Diagnosis of an impending heart attack in a woman may be more difficult than in men, because women often show different early signs and symptoms.[9] A study of closed medical malpractice claims involving undiagnosed heart disease in women from 2011 to 2015, found that in 70% of claims the patient died when her heart condition was not correctly diagnosed and 28% had heart muscle damage from myocardial infarction.[9]

The diagnosis of heart failure can be easily missed due to similar symptoms with other conditions especially respiratory diseases. A recent review found that the rate of misdiagnosis of heart failure ranged from 16.1% in the hospital setting to 68.5% when a general practitioner referred patients to a specialist setting. The most common cause for misdiagnosis in this study was chronic obstructive pulmonary disease.[10]

Surgical Complications: Wrong side surgery/wrong patient surgeries are considered sentinel events by the NQF to describe a significant adverse medical error that should never take place. In Pennsylvania, during the period of 2015-2019, there was an average of 1.42 wrong-site surgeries reported each week or 368 wrong side surgery events during a period of 260 weeks.[11] Four of the most common errors in spinal surgery include operating on the wrong patient, doing the wrong procedure performing wrong level surgery, and/or performing wrong side surgery.[12]

A retained surgical sharp (RSS) is a never event and defined as a lost sharp (needle, blade, instrument, guide wire, metal fragment) that is not recovered prior to the patient leaving the operating room. A "near-miss" sharp (NMS) is an intraoperative event where there is a lost surgical sharp that is recovered prior to the patient leaving the operating room. A recent, large-scale national survey-based study estimated the incidence of these events.[13] Most of each respondent group reported 1–5 lost sharp events over the last year: 91.7% of surgeons; 75.5% of anesthesiologists; 80.5% of nurses/ technologists. Unlike previous estimates that lost sharp objects are rare events, data from this survey suggest a higher incidence of 2.7 events per 10,000 surgeries or approximately 1 event per every 3800 surgeries.

Surgical site infection, which is defined by the CDC as infection related to an operative procedure that occurs at or near the surgical incision within 30 days of the procedure, or within 90 days if prosthetic material is implanted at surgery, is among the most common preventable complication after surgery. Surgical site infections occur in 2% to 4% of all patients undergoing inpatient surgical procedures. Although most infections are treatable with antibiotics, they remain a significant cause of morbidity and mortality after surgery. They are the leading cause of readmissions to the hospital following surgery, and approximately 3% of patients who contract an infection will die as a consequence. Although infections are less common following ambulatory surgery than after inpatient procedures, they are also a frequent source of morbidity.[14]

Urologic-Related Issues: Urologic conditions that are misdiagnosed range from urinary tract infection (UTI) and asymptomatic bacteremia,[15, 16] to interstitial cystitis/bladder pain syndrome,[17] to stress urinary incontinence,[18] to spontaneous rupture of the urinary bladder.[19] A study[15] of women who presented to an urban academic emergency department with genitourinary symptoms or diagnosed genitourinary infection found that 57% were treated for a UTI, without performing a urine culture. In addition, 14 of 22 women who were later found to have a sexually transmitted disease were misdiagnosed with a UTI. Although UTIs are common in hospitalized patients, many patients with asymptomatic bacteremia are misdiagnosed with UTI. In one study, approximately 30% of patients received antimicrobials within 48 hours prior to urine culture.[16] Some cases of misdiagnosis have severe consequences as is the case of spontaneous rupture of the urinary bladder, which is a rare and often life-threatening condition. The common misdiagnoses reported in a literature review included acute abdomen, inflammatory digestive disease, bladder tumor or inflammation, and renal failure.[19]

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Table 1. 24 Analysis Questions from the Joint Commission Framework for Root Cause Analysis and Corrective Actions.[27]

1. What was the intended process flow?	13. Did staff performance during the event meet expectations?
2. Were there any steps in the process that did not occur as intended?	14. To what degree was all the necessary information available when needed? Accurate? Complete? Ambiguous?
3. What human factors were relevant to the outcome?	15. To what degree is communication among participants adequate?
4. How did the equipment performance affect the outcome?	16. Was this the appropriate physical environment for the processes being carried out?
5. What controllable environmental affected the outcome?	17. What systems are in place to identify environmental risks?
6. What uncontrollable external factors influenced the outcome?	18. What emergency and failure-mode responses have been planned and tested?
7. Were there any other factors that directly influenced this outcome?	19. How does the organization's culture support risk reduction?
8. What are the other areas in the healthcare organization where this could happen?	20. What are the barriers to communication of potential risk factors?
9. Was staff properly qualified and currently competent for their responsibilities?	21. How does leadership address the continuum of patient safety events, including close calls, adverse events, and unsafe, hazardous conditions?
10. How did actual staffing compare with ideal level?	22. How can orientation and in-service training be improved?
11. What is the plan for dealing with staffing contingencies?	23. Was available technology used as intended?
12. Were such contingencies a factor in this event?	24. How might technology be introduced or redesigned to reduce risks in the future?

Communication

Accurate communication is vital for diagnosing, treating, dispensing and administering medications, maintaining patient safety, following policies and procedures, and ensuring treatment instructions are carefully followed. Communication errors can be verbal or written and occur in every part of the care delivery process. Breakdowns in communication are one of the leading causes of medical errors. The Joint Commission reports that, according to an RCA of over 4,000 adverse events, 70% were caused by communication breakdowns.[28] Such breakdowns can include inadequate patient handoffs, interpersonal communication failures, and reluctance to admit a lack of knowledge or failure to seek clarification.

Planning and Knowledge

Planning and knowledge failures can encompass virtually every aspect of care delivery, and the different types of errors that can be caused by failure in planning and knowledge are almost limitless.[12, 13] It is therefore essential healthcare professionals work together to establish the most effective plan of care for each patient to ensure that all members of the healthcare team have the necessary knowledge and skills to implement the plan of care, and to evaluate the effectiveness and safety of the plan as it is implemented.

Systemic or Institutional Failures

The Institute of Medicine (IOM) reports medical errors are more often due to poor systems than negligent practitioners. System failures involve poor planning and execution, inappropriate or absent policies and procedures, failure to procure and maintain equipment, failure to hire and retain staff, failure to maintain safe staffing levels, failure to monitor care, and failure to recognize errors and correct the conditions that caused the errors.[12, 13] While systemic failures in communication, infection control, and medication prescribing, dispensing, and administration have contributed considerably to medical error, entrenched healthcare traditions (e.g., using blame and shame, closing ranks, and strategies that minimize legal liability) have played a major role in discouraging disclosure necessary to reduce the risk of medical error.

Personal behavior is in one sense the least changeable aspect of medical error prevention. Healthcare professionals are not motivated to disclose medical error if policies and procedures focus on punishment rather than timely reporting and prevention. While individuals bear responsibility for their actions when a medical error occurs, the traditional blame and shame culture of healthcare is counterproductive if the goal is reducing error. First, it discourages voluntary reporting; second, it does not assess whether there was a system contribution to the error; and third, it focuses on assigning blame and punishment, not on why the error occurred, or on error prevention.[12 13]

Some suggest healthcare medical error reporting would be more effective if modeled on alternative reporting systems, such as those used in the aviation industry, which has a very high level of safety. Aviation reporting guidelines do not absolve individuals of responsibility and punishment for errors, but instead treat each incident as a complex event with many possible causes and contributing factors.[12, 13]

Root Cause Analysis of Adverse Events Reports From Emergency Departments in the Veterans Health Administration

The ED is an important area to focus improvement efforts because it serves as the initial point of care for a majority of the population. Since 1997, the number of ED visits per year in the United States has increased by 23%, which amounts to a total of 141.4 million individuals using emergency care services in 2014, more than half of which are for nonurgent reasons. In addition, a large variety and number of conditions are treated, which make errors more likely. Because 70% of errors in the ED are preventable, the IOM identified the ED as a prime area for patient safety improvement.[29]

A recent retrospective study used RCA reports of adverse events occurring in Veterans Health Administration EDs to understand the range of events that were happening and to determine the primary causes of these events as well as actions to prevent them.[28] Safety reports from EDs from Veterans Health Administration medical centers across the nation for a two-year period (2015–2016) were coded by event type, root cause, and recommended actions. The most common adverse events were as follows: delays in care (26.4%), elopements (n14.6%), suicide attempts and deaths by suicide (10.4%), inappropriate discharges (10.4%), and errors in following procedures (9.7%). The most common root cause categories leading to adverse events were knowledge/educational deficits (11.4%), policies/procedures needing improvement (11.1%), and lack of standardized policies/procedures (9.4%).[29]

Overall, 44.4% of cases were associated with no injury, 22.2% with moderate injury resulting in increased length of stay, 17.4% with major injury resulting in permanent injuries, and 16.0% resulted in catastrophic injury or death (Figure 2).[29]

The authors noted that identifying the most severe ED adverse events and their preceding causes permits the development of action plans aligned to address root causes and the prioritization of action plan implementation.[29]

ADDRESSING ROOT CAUSES: STRATEGIES FOR REDUCING COMMON MEDICAL ERRORS

Human error is inevitable. Although we cannot eliminate human error, we can better measure the problem to design safer systems mitigating its frequency, visibility , and consequences. Strategies to reduce death from medical care should include three steps: 1. Making errors more visible when they occur so their effects can be intercepted. 2. Having remedies at hand to rescue patients. 3. Making errors less frequent by following principles that take human limitations into account (Figure 3).[30]

The identification of errors needs to become more transparent. There needs to be standardized data collection and evaluation of the root cause of each error. Punishment is not helpful as it leads to the nondisclosure of errors or risk of error. Both individuals and hospital systems have unique responsibilities in the reduction of medical errors.[30]

Figure 2. Injury Severity of all RCA Cases

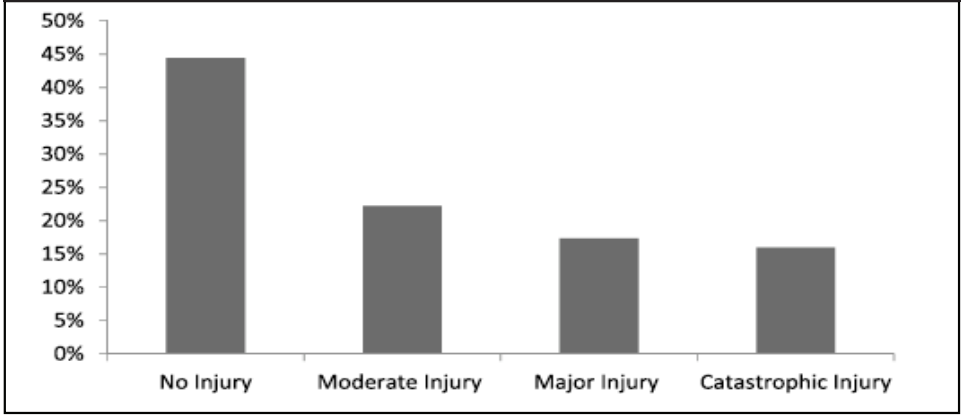
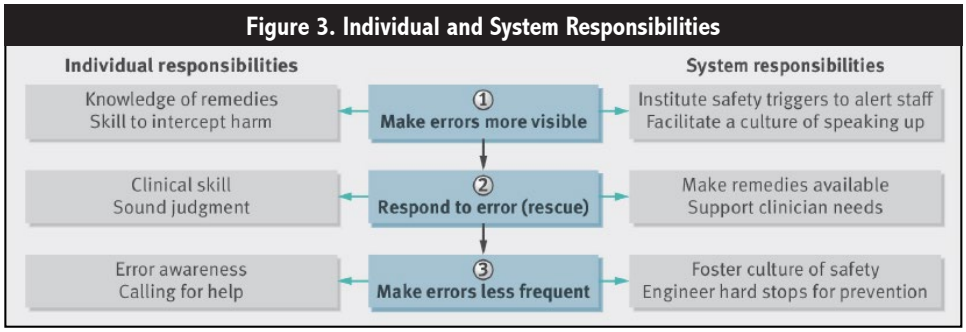


Figure 3. Individual and System Responsibilities



Wrong-Site Surgery

Three primary strategies have been identified to reduce the likelihood of wrong-site surgery.[31]

Preoperative Verification and Reconciliation. The verification and reconciliation process is typically initiated by the admitting nurse in the preoperative area, but ultimately includes all staff members. The process includes the verification of the procedure to be performed with the patient or patient representative and allows for review of all relevant documents. Any discrepancies are immediately resolved with the attending surgeon.

Site Marking. The marking of the surgical site is a preoperative procedure that allows the surgeon to mark the surgical site after a verbal confirmation with the patient or patient representative, and the attending nurse. The site mark acts as a visual confirmation to not only the surgeon, but the entire surgical team.

Timeout and Intraoperative Verification. The timeout is the final pause prior to initiating a surgical procedure and should include all staff participating in the procedure. Intraoperatively, a verification process should be utilized to ensure accuracy (site and side) for the consented procedure.

Partnership for Patients Core Safety Measures

Studies show the potential risk of some errors is far greater than others, with some likely to happen repeatedly. A Partnership for Patients study described the most common medical errors in the United States. Nine core patient safety areas of focus were identified:[32] Adverse Drug Events (Medication Errors); Catheter Associated Urinary Tract Infections (CAUTIs); Central Line-Associated Bloodstream Infections; Injuries from Falls and Immobility; Obstetrical Adverse Effects; Pressure Ulcers; Surgical Site Infections; Venous Thromboembolism; Ventilator-Associated Events.

The following are strategies might be used to enhance safety and decrease the occurrence of some of these core safety issues.

Adverse Drug Events/Medication Errors: A medication error is an error, of commission or omission, at any step along the pathway that begins when a clinician prescribes a medication and ends when the patient actually receives the medication. An adverse drug event is defined as harm experienced by a patient as a result of exposure to a medication. The occurrence of an adverse drug event does not necessarily indicate an error or poor-quality care. It is estimated that approximately 50% of adverse drug events are preventable.[33] In some cases, an adverse drug event is an unseen consequence of a medication reaction with therapeutic intent.

The incidence of medication errors is an issue of contention. Because definitions of medication errors can differ, many medication errors must be self-reported to be recorded, and data suggest a significant percentage of medication errors are not reported.[19] In addition, there is no central agency or institution responsible for collecting reports of medication errors, so no one knows how many medication errors actually occur.

A medication error is defined as "any preventable event that my cause or lead to inappropriate medication use or patient harm while the mediation is in the control of the healthcare professional, patient, or consumer."[19] Medication errors are the most common type of medical error. About 1.3 million people are injured annually in the United States following such errors.[34]

The incidence of medication errors varies according to patient population and clinical setting. Children and the elderly are more likely to be harmed by medication errors than other segments of the population; children are more susceptible to harm from dosing errors due to their small size, while older individuals tend to take more medications, increasing their potential for medical error and adverse drug interactions. Polypharmacy is not uncommon is patients older than 62 years.[35] Medication errors are more likely to occur in fast-paced, stressful environments such as intensive care units, where errors are more likely to be more severe and cause harm.[36]

Data from the FDA show that the most common error involving medications was related to the administration of an improper dose of medicine, accounting for 41% of fatal medication errors. Administering the wrong drug and using the wrong route of administration each accounted for 16% of the errors.[34]

Some drugs that are frequent causes of medication errors are commonly used (e.g., insulin and antibiotics). Others are sufficiently potent and there is little room for therapeutic error and substantial potential for harm from seemingly small mistakes (e.g., the cardiovascular drug nitroprusside, heparin, warfarin, insulin, or colchicine).

Another set of drugs are common causes of medication errors because they can be easily confused (e.g., Percocet® [acetaminophen and oxycodone] confused with Vicodin® [acetaminophen and hydrocodone]).

The Institute of for Safe Medication Practices (ISMP) identified some specific medications classified as high-risk, meaning that they are associated with a heightened risk of causing significant patient harm when used inappropriately:[37]

- Ephinephrine subcutaneous.
- Epoprostenol (Flolan) IV.
- Insulin U-500 (All forms of insulin are considered high-risk. Insulin U-500 has been singled out for special emphasis to bring attention to the need for distinct strategies to prevent the types of errors that occur with this concentrated form of insulin).
- Magnesium sulfate injection.
- Methotrexate, oral, nononcologic use.
- Opium tincture.
- Oxytocin, IV.
- Nitroprusside sodium for injection.
- Potassium chloride for injection concentrate.
- Potassium phosphates injection.
- Promethazine, IV.
- Vasopressin, IV or intraosseous.

In an effort to identify root causes, a great deal of attention focused on why medication errors occur. Among a variety of reasons or these mistakes are poor staffing, unskilled/new nurses, stress, personal error, and distraction. These data suggest the most common medication errors are related to an improper dose of medication, administering the wrong dose of medication or the wrong drug, or administering medication via the wrong route.[34]

The FDA has also commented on common causes of medication errors as follows: poor communication; ambiguities in product names, directions for use, medical abbreviations, or writing; poor procedures or techniques; patient misuse because of poor understanding of the directions for use of the product; job stress; lack of knowledge or training; similar labeling or packaging.[38]

The following list describes the most common causes of medication errors according to specific definitions:[37]

- An *action-based* medication error is defined as the performance of an unintended. Examples of action-based medication errors would include selecting the wrong medication or administering an incorrect dose.
- A *rule-based* medication error occurs because the provider did not follow proper rules or procedures for medication administration.
- A *memory-based* medication error occurs when a provider forgets to perform a task or forgets important information about the patient. The provider may forget to give a dose of a medication, that the medication has been discontinued, or that the patient is allergic to the medication.
- *Knowledge-based* medication errors are errors that could be avoided with a reasonable and appropriate level of professional knowledge. If the provider is familiar with the drug and the patient, knowledge-based medication errors are avoidable. Knowledge-based medication errors can be *general, specific,* or *expert*:[37]
    - A *general knowledge-based error* occurs when someone makes an error because of lack of or disregard for information that is considered general knowledge (e.g., warfarin can cause bleeding).
    - A *specific knowledge-based error* occurs when someone makes an error because of lack of or disregard of information that would be considered specific knowledge (e.g., a patient is given warfarin even though the INR is high).
    - An *expert knowledge-based error* occurs when someone makes an error because of lack of, or disregard, for information that would be considered expert knowledge (e.g., the failure to use genetic testing to check for variations in patient response prior to initiating therapy with warfarin).

Strategies to decrease the risk of medication error include[28, 34, 39]:

- Adhere to the eight rights of medication administration: right patient, right medication, right time, right dose, right route, right position, right documentation, and right to refuse.
- Ensure that handoffs involve the transfer of essential information when the responsibility for care shifts from one provider to another.
- Use barcode technologies and electronic health records with computerized prescriber order entry.
- Involve pharmacists throughout a patient's hospitalization.
- Require providers who are administering medicine to wear a colored sash or vest to prevent interruptions.
- Have two providers independently verify doses prior to administering medication.

Central-Line Associated Bloodstream Infections: In 2020, 3,687 general acute care hospitals in the US reported 21,399 central-line associated blood stream infections, which represent a significant increase in infections between 2019 and 2020.[40] Strategies to reduce the incidence of central-line associated bloodstream infections are outlined below.

Hand Hygiene: Proper hand hygiene is the most important infection control measure and the most effective way to prevent the transmission of healthcare-associated infections.[41]

Maximum Sterile Barrier Precautions: Maximum sterile barrier precautions must be taken when inserting the venous catheter. These precautions include, not only the person inserting the catheter, but anyone assisting with the procedure and the patient as well.[42]

Skin Antisepsis; An alcoholic chlorhexidine antiseptic should be used for skin preparation that contains more than 0.5% CHG in patients over 2 months of age.[42] Povidone- iodine or alcohol may be used in patients 2 months or younger. Skin antisepsis should be performed at the time of insertion and with every dressing change [43] Busby et al., 2015).

Selection of Catheter Site: The site of insertion is important to optimal outcomes. The use of the subclavian site is preferred to the jugular or femoral sites in adults to minimize infection risk.[43]

Dressing Change: Dressings for insertion sites must be impermeable to water vapor. They can be either sterile gauze or sterile transparent, which is semipermeable dressing that covers the catheter insertion site. Topical antibiotic ointments or creams should not be applied to the insertion site because of the possibility of promoting fungal infections or pathogen resistance. Dressings are changed when they become wet, loose, or soiled.[42 43]

Assessment and Removal: The catheter should be removed as soon as it is no longer needed. The risk for infection increases with the length of time the device is left in place and decreases when the catheter is removed.[42, 43]

Injuries from Falls and Immobility: Patient falls that cause serious injury are among the top 10 sentinel events reported to The Joint Commission Sentinel Even Database.[44] Falls are among the leading causes of injury and death among Americans older than 65 years . Almost one-third of adults in this age group report a fall every year, and the annual cost of falls to Medicare is approximately $31 billion.[45] A study found that rates of falls were even higher in patients with chronic kidney disease, which is common in older adults with comorbidities.[46]

The Joint Commission reports that from January 2009 through October 2014, the most common contributing factors contributing to reported falls included.[44]

- Communication failures.
- Deficiencies in the physical environment.
- Failure to adhere to protocols and safety practices.
- Inadequate assessment.
- Inadequate staff orientation, supervision, staffing levels, or skill mix.
- Lack of leadership.

Pressure Ulcers: Although most hospital-acquired pressure ulcers area reasonably preventable, approximately 2.5 million Americans develop a pressure ulcer in US acute care facilities every year.[47] These injuries can result in extensive harm, including chronic wounds, and as many as 60,000 deaths annually.[47]

Hospital-acquired pressure ulcers are responsible for a huge financial burden. According to a recent estimate, based on 2016 dollars, the national burden of hospital-acquired pressure ulcers could exceed $26.8 billion. The cost of treatment was estimated to be approximately $10,708 per person.[47] Approximately 59% of the costs associated with these ulcers are attributable to a small number of patients with stage 3 and 4 full-thickness wounds.[47]

There are a number of factors that increase risk for pressure ulcers[48, 49]:

- Advanced age: An elderly person's skin has less subcutaneous fat, which leads to decreased protection from pressure.
- Friction/Shear: Decreases the epidermal layer, reducing protection of the skin.
- Hypotension: Increases the response of local tissues, making skin more vulnerable to breakdown.
- Immobility: Lack of mobility can lead to sustained pressure on bony prominences.
- Length of stay in critical care units: Longer stays are indicative of more critical conditions. Such conditions are generally associated with decreased mobility and position change and increased shear force, all of which increase the risk for skin breakdown.
- Length of time on mechanical ventilation: Indicates inadequate oxygenation and the need to provide ventilation mechanically. Decreased oxygen levels mean decreased oxygen to body tissues, including the skin.
- Moisture: Moisture (e.g., incontinence, sweat, failure to dry skin after bathing) contributes to skin breakdown.
- Nutrition: Inadequate nutrition alters the proper state of the skin, contributing to skin breakdown.
- Pressure: The longer pressure is sustained, the more likely is local tissue ischemia, edema, and tissue death.
- Pressure scale risk scores: The higher the score on a pressure scale score, the greater the risk of pressure ulcer development.
- Vasoactive medications: Vasoactive medications given to improve blood pressure increase vasoconstriction. This may decrease perfusion of skin tissue.

Venous Thromboembolism (VTE): VTE includes both deep vein thrombosis (DVT) and pulmonary embolism (PE). According to the CDC, VTE is a leading preventable cause of hospital death.[50] VTE may affect as many as 900,000 people each year in the US, and be responsible for between 60,000 and 100,000 deaths.[50] Approximately 5% to 8% of the US population has one of several genetic risk factors, known as inherited thrombophilias in which a genetic defect can be identified that increases the risk for thrombosis.[50]

Risk factors for VTE include[51]

- Birth control pills or hormone therapy.
- Blood-clotting disorders.
- Some malignancies.
- Increasing age.
- Overweight or obese.
- Personal or family history of DVT or PE.
- Pregnancy and the postpartum period.
- Smoking.
- Vein disease(s).

Strategies for the prevention of DVT include[51, 52]

- Administrating anticoagulant therapy as indicated.
- Promoting early movement and physical therapy.
- Facilitating position change in patients who have difficulty moving themselves.
- Applying compression stockings or pneumatic compression devices as ordered and indicated.
- Teaching patients and families about the importance of early movement and position change.

MEDICAL ERROR REDUCTION

The following Congressional actions and ACA policies were developed with the objective of reducing medical error:

- In 2011, the Centers for Medicare and Medicare Services (CMS) launched the Hospital Patient Safety initiative, which piloted new surveyor tools for assessing compliance with federal regulations.[53]
- Under the Hospital Inpatient Quality Reporting (HIQR) program, CMS reimburses hospitals that successfully report designated quality measures a higher annual update, while failure to report the measures results in a payment reduction. CMS publicly reports the data on its "Hospital Compare" website.

- The Deficit Reduction Act of 2005 required CMS to select at least two hospital-acquired conditions for which hospitals would not be paid higher Medicare reimbursement. Since 2008, CMS has maintained a list of hospital-acquired conditions that includes catheter-associated UTIs, falls and trauma, late-stage pressure ulcers, surgical site infections, and DVT.[54] Under the Patient Protection and Affordable Care Act of 2009, starting in 2011, CMS applied this payment policy to the Medicaid program to encourage hospitals to actively prevent these conditions.
- The Patient Safety and Quality Improvement Act of 2005 established Patient Safety Organizations under supervision of the AHRQ. Patient Safety Organizations receives reports of patient safety events from healthcare providers and provides analyses of these events.[53] They operate under federal privacy protections to encourage providers to report medical errors and to work with healthcare systems to resolve systemic issues.
- The Patient Safety and Quality Improvement Act of 2005 authorized AHRQ to promulgate "Common Formats" so that hospitals can report adverse events in a uniform, unambiguous manner.[54] The goal of Common Formats is to allow for the "apples to apples" comparison of medical errors across multiple hospital systems.
- The Patient Protection and Affordable Care Act also authorized three pay-for-performance programs that adjust Medicare payments to hospitals based on the quality of care delivered. The Hospital Readmission Reduction Program began in October 2012 and penalizes hospitals with higher-than-expected readmissions for beneficiaries initially admitted for selected conditions. The Value Based Purchasing Program began in October 2012 and provides penalties, as well as incentive payments, based on hospitals' performance on quality measures, including reducing surgical site infections.[53]
- The Hospital-Acquired Condition Reduction Program reduces payments to hospitals that are in the top quartile for hospital-acquired conditions; the program started on October 1, 2014.[53] CMS has adopted AHRQ safety indicators encompassing pressure ulcer rate and DVT rate, among others, as well as measures from the CDC, such as central line-associated bloodstream infection and CAUTIs.
- The Office of the National Coordinator is developing a system for reporting medical errors, similar to the method of Common Formats established by AHRQ, allowing hospitals to more easily and accurately collect data on errors, including critical information about where and when they occur.

FUTURE EFFORTS TO ENSURE PATIENT SAFETY

Since the launch of *To Err is Human* in 1999, a campaign to improve patient safety and reduce adverse events, improvements have been made in specific areas of care. However, much work needs to be done to continue to ensure patient safety in all healthcare settings. In 2015, the National Patient Safety Foundation described eight recommendations to continue improvements for patient safety. These recommendations are as follows:[55]

- **Ensure that leaders establish and sustain a safety culture.** Safety should be engrained in the culture of healthcare facilities and promoted by leadership.
- **Create centralized and coordinated oversight of patient safety.** Patient safety should be coordinated and monitored by safety and national organizations.
- **Create a common set of safety metrics that reflect meaningful outcomes.** Standardized metrics that identify and measure risks should be used.
- **Increase funding for research in patient safety and implementation science.** Research should be utilized to understand risks and how to best mitigate those risks.
- **Address safety across the entire care continuum.** Safety should be ensured in all healthcare settings,
- **Support the healthcare workforce.** Provide support to all healthcare staff.
- **Partner with patients and families for the safest care.** Communicate information and actively involve patient and families in their care.
- **Ensure that technology is safe and optimized to improve patient safety.** It is crucial to utilize benefits and minimize unintended hazards of health IT.

The Role of Information Technology

Although the appropriate use of information technology can help to reduce errors, challenges exist. Electronic medical records, electronic prescribing, bar coding of medications, and decision support systems have been shown to be effective. However, many hospitals/organizations have been slow to invest in these technologies.[1]

In addition, it has been reported that at least 50% of patient EHRs contain an error, many of which are related to medications.[8] Overburdened providers may import inaccurate medication lists, propagate other erroneous information electronically by copying and pasting older parts of the record, or enter erroneous examination findings. EHRs may also lack critical information (errors of omission) because of limited interoperability among healthcare sites. Among primary care physicians sharing notes with patients, 26% anticipated that patients would find nontrivial errors that could therefore lead to medication errors, wasteful duplication, unnecessary or incorrect treatment, and delayed diagnoses. Despite these problems, systems for checking the accuracy of notes are almost nonexistent.[8]

BEFORE MOVING ONTO THE NEXT SECTION, PLEASE COMPLETE CASE STUDIES 1 & 2 ON THE NEXT PAGE.

CONCLUSION

As summarized in this activity, medical errors remain a significant challenge for all aspects of the healthcare system and error rates are significantly higher in the United States compared with other developed countries. Root cause analysis reports are a useful tool to determine the primary systems-based factors of common medical errors. In the future, information technology, including electronic medical records, electronic prescribing, bar coding of medications, and decision support systems needs to be better, and more broadly, utilized in an effort to improve patient safety.

Case Study 1

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

John L Smith is admitted to a midsize urban hospital for ambulatory left knee replacement on the same day that John R Smith is admitted for ambulatory left hip replacement. Both surgeries were scheduled to be performed by the same orthopedic surgeon and surgical team. The same admitting nurse performs the verification and reconciliation process in the preoperative area and the patients wait to be called for surgery.

The surgeon's first surgery ran late so his entire surgical schedule was delayed for the day. Once his first surgery was completed, he left the ambulatory surgery area to perform emergency surgery on an accident victim. The admitting nurse informs James R Smith that his surgery needs to be rescheduled.

When the orthopedic surgeon arrives back to the ambulatory surgery area, John L Smith has been prepped for left hip surgery by the surgical team and the surgery proceeds.

It is only after the surgery that the team realized that the surgical site was never marked, the wrong chart traveled with the patient to the operating room, and in the rush to perform the surgery, no verification process was undertaken in the operating room.

Review the 24 analysis questions from the Joint Commission Framework for Root Cause Analysis and Corrective Actions to identity potential root causes of errors highlighted in this case.

1. **Were there any steps in the process that did not occur as intended?**_____

2. **What human factors were relevant to the outcome?**_____

3. **What are the other areas in the healthcare organization where this could happen?**_____

Case Study 2

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

A ten-year-old boy was brought to a clinic by his parents. The child had a running nose for the past ten days. The nurse was out sick at the time of the visit, and the receptionist was assisting the physician. On examination, the physician diagnosed simple allergic rhinitis and advised the parents to use over-the-counter antihistamine cetirizine. The parents were provided with a post visit summary and instructions. After two days, the mother returned to the clinic and reported that the boy was lethargic. The clinic's front desk said that they would convey the information to the physician, who was very busy that day. The physician later said that it is typical for children taking cetirizine to be slightly sleepy. He had the front deck tell the parents to keep the child home from school for the next few days.

The mother decided to take the child to a specialist because she was concerned about the level of sedation. On the second opinion, a review of current medications was performed. It was noted that the child was taking a cetirizine tablet 10 mg two times a day, which is higher than typically recommended. A review of the error was performed at the clinic. It was noted that there was a typographical error in the instructions given to the parents, saying 10 mg twice a day, instead of 5 mg twice a day, which was the dose the physician intended.

Review the 24 analysis questions from the Joint Commission Framework for Root Cause Analysis and Corrective Actions to identity potential root causes of errors highlighted in this case.

1. **Were there any steps in the process that did not occur as intended?**_____

2. **Was staff properly qualified and currently competent for their responsibilities?**_____

3. **How did actual staffing compare with ideal level?**_____

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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. According to a 2021 review article, which 3 missed conditions were responsible for 75% of serious harms from diagnostic errors?
- A. Vascular events, infections, cancers.
- B. Infections, cancers, heart attack in women.
- C. Cancers, multiple sclerosis, and infections.
- D. Vascular events, infections, pressure ulcers.

12. How many reports of suspected medication errors does the FDA receive each year?
- A. ≈50,000.
- B. ≈100,000.
- C. ≈150,000.
- D. ≈250,000.

13. According to the Joint Commission framework, which of the following is not a situational factor that contributes to a sentinel event?
- A. Equipment malfunctions.
- B. Organizational factors.
- C. Staffing factors.
- D. Nondisclosure of error.

14. In the study by Gill et al. of adverse events in the Veterans Health Administration EDs, what was the most common root cause category that led to an adverse event?
- A. Knowledge/educational deficits.
- B. Policies/procedures needing improvement.
- C. Lack of standardized policies/procedures.
- D. Poor environmental design.

15. What was the average number of wrong-site surgeries reported each week in Pennsylvania during the period of 2015-2019?
- A. 1.42.
- B. 2.42.
- C. 3.42.
- D. 4.42.

16. According to the CDC, what is the leading cause of preventable hospital deaths?
- A. Stage 4 pressure ulcers.
- B. Medication errors.
- C. Wrong-site surgery.
- D. Venous thromboembolism.

17. Which of the following is the best definition of a memory-based medication error?
- A. Provider did not follow proper procedures.
- B. Provider forgot important information about the patient.
- C. Provider makes an error because of disregard for information considered common knowledge.
- D. Provider lacks reasonable and appropriate level of professional knowledge.

18. What percent of patient EHRs are estimated to contain an error?
- A. 20%.
- B. 40%.
- C. 50%.
- D. 60%.

19. What was the most frequently reported sentinel event to the Joint Commission in 2020?
- A. Wrong-side surgery.
- B. Medication management.
- C. Self-harm.
- D. Fall.

20. What percent of errors in the ED are preventable?
- A. 50%.
- B. 60%.
- C. 70%.
- D. 80%.

INTIMATE PARTNER VIOLENCE: COMPASSIONATE CARE, EFFECTIVE ASSESSMENT

COURSE DATES:	MAXIMUM CREDITS:	FORMAT:
Release Date: 5/2023 Exp. Date: 4/2026	*2 AMA PRA Category 1 Credits*™	Enduring Material (Self Study)

TARGET AUDIENCE

This course is designed for all physicians, physician assistants, nurse practitioners and other health care professionals who see patients abused in a current relationship, distressed by abuse in a prior relationship, or who suffer adult health effects that stem from witnessing IPV.

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 improve physician understanding of and competence in addressing intimate partner violence in their patient populations. It will provide information on evidence-based screening tools, and instructions for responding in compassionate and effective manners to their affected patients. Instructions for assisting patients in creating safety plans will be reviewed, and suggestions to identify resources helpful to victims of intimate partner violence.

LEARNING OBJECTIVES

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

1. Describe the barriers experienced by patients and physicians that can prevent effective, compassionate care of potential survivors of IPV.
2. Describe two screening tools for identifying potential victims of IPV.
3. Identify three patient interviewing techniques of potential value in situations involving suspected IPV.
4. Describe the key elements of a safety plan for survivors of IPV.

ACCREDITATION STATEMENT

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COURSE SATISFIES

SPECIAL DESIGNATION

This course satisfies the mandatory requirement for two (2) hours on domestic violence.

CE Broker Provider # 50-25874

The Florida Boards of Medicine and Osteopathic Medicine require physicians (MD/DO) to complete a minimum of two (2) hours on domestic violence once every third biennium.

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DISCLAIMER

Introduction

Intimate partner violence (IPV) is a serious public health issue in the United States, affecting approximately 36% of American women and 33% of American men in their lifetime.[1] IPV is defined as deliberate coercive and harmful control by someone who is currently, or was previously, in an intimate relationship with another person, regardless of the duration or significance of the relationship. The term "intimate partner violence" is preferred to "domestic violence" because IPV is more inclusive—it doesn't imply a shared residence between the two people.[2] IPV covers a spectrum of assaultive and coercive behaviors that can occur in any combination, in sporadic episodes or chronically, over a period of days, months, or even decades. They may include, but are not limited to:

- Actual or threatened physical assault
- Sexual violence, including forced sexual intercourse and other forms of sexual coercion or exploitation
- Psychological/emotional abuse such as insults, belittling, constant humiliation, intimidation, threats of harm, or threats to take away children
- Controlling behaviors, including isolating a person from family and friends, monitoring movements, or restricting access to financial resources, employment, education or medical care
- Destruction of property or personal possessions
- Sustained social isolation
- Spiritual abuse (i.e., coercion or manipulation justified by religious or spiritual beliefs)
- Maltreatment of dependents including children, other family members, or animals/pets

Although most intimate partner violence is against women in heterosexual relationships, violence can be directed at any individual in any kind of relationship. Both survivors and perpetrators of abuse may self-identify as male, female, transgender, gender non-conforming, or as a member of another gender or sexual minority.[2] Because the bulk of violence occurs against women in heterosexual relationships, however, this guide focuses primarily on cis-heteronormative IPV.

Clinicians may take an overly narrow view of IPV, seeing it only in terms of physical or sexual abuse in a relationship. IPV is not a situation where a couple is arguing or having a disagreement. It is a chronic and potentially life-threatening interpersonal situation. A broader view of IPV as a dysfunctional situation involving misuse of power and control is preferable.[3] How this dysfunction plays out – physically, emotionally, financially, or through isolation or other forms of mistreatment, varies widely and may not conform to stereotypical ideas of "violence." For example, perpetrators of IPV may harass a partner hundreds of times a day with phone calls, demand online access to passwords, or relentlessly stalk a partner or former partner in threatening or intimidating ways.

Nearly all practicing healthcare professionals see patients who are either abused in a current relationship, are distressed by abuse in a prior relationship, or who suffer adult health effects that stem from witnessing IPV.[3] Yet, fewer than 9% of women are asked about IPV in the primary care setting.[4] In view of the prevalence and scope of intimate partner violence, it is prudent for clinicians to inquire routinely about a history of trauma and/or abuse across the lifespan, across genders, and across variations in sexual orientations.

Extensive literature describes the "dose effect" of early childhood trauma on later adverse health outcomes.[5] A history of trauma is a risk factor for current trauma. By addressing trauma and IPV, healthcare providers can address and, perhaps, prevent potentially severe physical and mental health consequences. A clinician intervention may simultaneously help a patient in an acute situation and uncover the root causes of health consequences due to IPV in that patient.

As noted below, unaddressed or treatment non-responsive health conditions (e.g., delayed dental, neurological, gynecological, gastroenterological, or mental health conditions) may be due to underlying IPV[6,7]. The prevention and treatment of IPV should thus be an integral component of routine medical practice.

Prevalence of IPV

According to the most recent data from the National Intimate Partner and Sexual Violence Survey, conducted by the Centers for Disease Control and Prevention (CDC), 41% of women and 26% of men have experienced contact sexual violence, physical violence, and/or stalking by an intimate partner at some point during their lifetimes.[6] Over 53 million American men and 61 million women have experienced psychological aggression by an intimate partner in their lifetime[6].

Other measures of the problem in the United States include:

- Over half of female homicides in the United States were committed by a current or former male intimate partner.[6]
- Women between the ages of 18 – 24 experience the highest rates of IPV.[8]
- IPV is involved in 1 of every 4 women who attempt suicide.[9]
- The average healthcare cost of each incident of IPV for women was $4273.[10]
- Overall costs related to IPV are estimated to exceed $9.3 billion each year, which includes medical and mental health care and lost productivity.[10]

Although IPV affects both women and men, and cuts across all age, racial, ethnic, religious, educational, and socioeconomic strata, research indicates a higher prevalence in certain groups:[11]

- Women who are single, separated, or divorced.
- Individuals who have recently sought a restraining/vacate order.
- Individuals who abuse alcohol or other drugs, or whose partners do.
- Those with a partner:
  - who are excessively jealous or possessive
  - experiencing unemployment or job instability
- Women who are pregnant and have been previously abused.
- Low-income individuals, especially those in financial distress.
- Adolescents and young adults.
- Ethnic minorities.
- Non-U.S.-born (immigrant) women.
- Being gender non-conforming or a gender sexual minority.
- Vulnerable groups such as those who are sex workers or disabled.

Consequences of IPV

The physical and psychological consequences of intimate partner violence can be profound.[12,13] Injuries from physical and sexual assault affect approximately 75% of female survivors and 48% of male survivors[6]. Female survivors have higher risks of sexually transmitted infections, including HIV, pelvic inflammatory disease, unintended pregnancy, and psychological distress.[7] Long-term conditions associated with IPV include chronic pain, neurologic disorders, gastrointestinal disorders, migraine headaches, and other physical disabilities, as well as post-traumatic stress disorder, depression, and anxiety.[7]

Theoretical Models

Several models describe the dynamics of abusive relationships, two of which – The Duluth Power and Control Wheel, and Johnson's Typology of Domestic Violence, are summarized here.

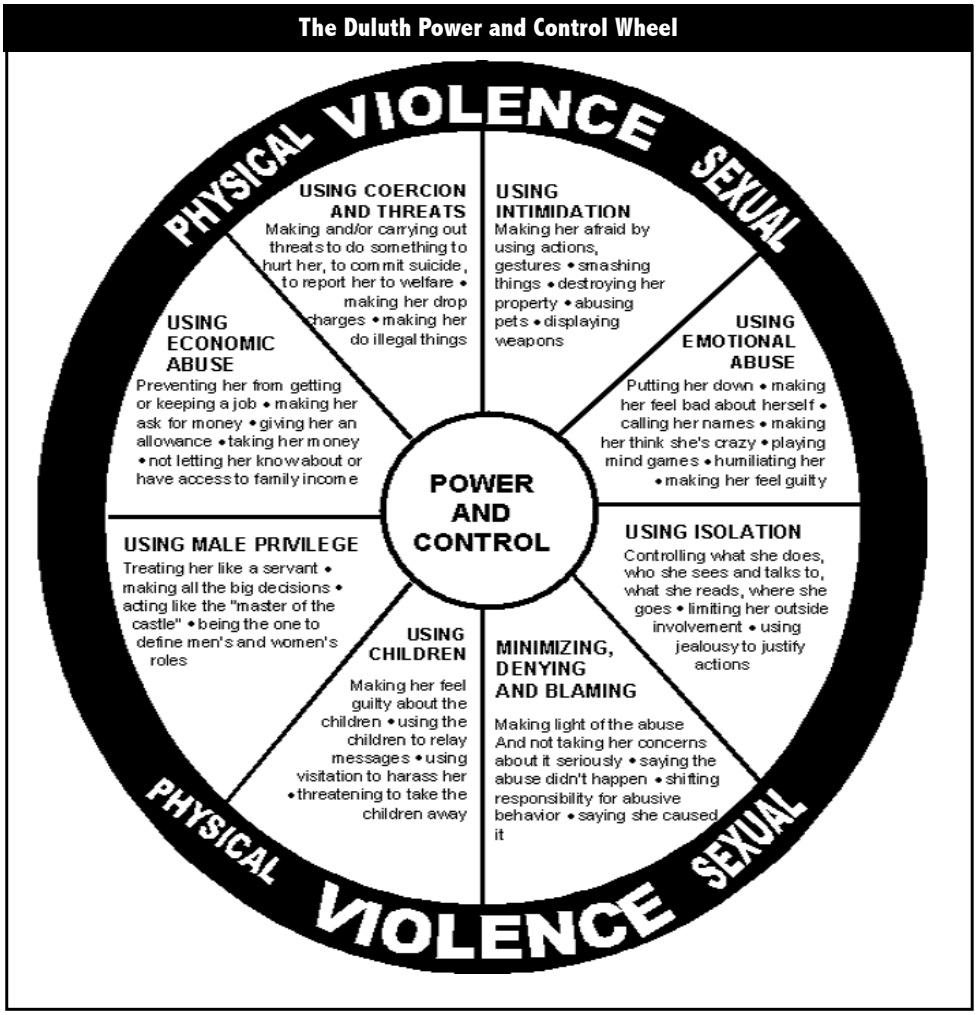
The Duluth Power and Control Wheel

In 1984, the Duluth Domestic Abuse Intervention Project developed a framework to describe the behavior of men who physically and emotionally abuse their female partners.[14] Derived from the experiences of women living with men who batter, the Power and Control Wheel was developed to graphically represent the idea that acts of physical or sexual violence are part of a more general pattern of controlling behaviors, rather than isolated incidents of abuse, or as cyclical expressions of pent-up anger, frustration, or painful feelings.

Johnson's Typology of Domestic Violence :

Although the perpetrators of IPV are most often men, research that defines "violence" more broadly than just physical violence, finds that men and women use "violent" tactics equally often in relationships.[15] Michael Johnson's research divided couples into those who use what he terms "intimate terrorism," in which an abuser (usually male) uses violence and power and control tactics that usually escalate. Their targets are the women most often seen in hospital emergency departments with severe injury, those likely to be abused during pregnancy, those most often forced into sex, and those with severe psychological trauma.

The Duluth Power and Control Wheel



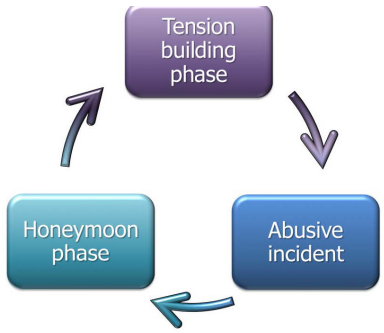
In contrast, "situational couple violence," is a more frequent type of IPV and this term describes relationships in which both partners (heterosexual as well as same-sex) use aggressive tactics characterized by less severe and less controlling tactics. Generally, these arise as a result of an argument in which one or both parties physically lash out. Situational couple violence is also less likely to involve sexual violence.[15]

The Cycle of Violence

Many times abuse occurs in a predictable pattern or cycle. When the perpetrator shows affection to the survivor between abusive episodes, it can make it difficult for the survivor to leave the relationship. The cycle can involve the following phases:

- Abuse – the perpetrator abuses their partner, asserting their power and control.
- Guilt – the perpetrator feels guilty and fears that the abuse may lead to getting caught and facing consequences.
- Excuses – the perpetrator rationalizes their abusive actions by blaming the partner and avoiding responsibility.
- "Normal" behavior or "Honeymoon Phase" – the perpetrator attempts to regain control and keep the partner in the relationship, either by showing affection or acting as if the abuse never happened.
- Fantasy and planning – the perpetrator starts to fantasize about abusing their partner again and plan the next episode of abuse.
- Set-up – the perpetrator creates a situation where they can justify or blame their partner for the next abusive episode.

The IPV Cycle[16]



Myths vs. Realities of IPV

Frustration is common among professionals who work with IPV survivors, and this frustration can be rooted in fundamental misunderstandings about the way survivors of IPV behave. For example, contrary to a common perception that many women don't leave abusive relationships, the majority do indeed leave or manage to make the violence end.[17] But leaving an abusive relationship is a process that may involve leaving and returning several times. Behavior change takes time and cycles of "relapse" and "remission" commonly seen in people trying to stop addictive behaviors such as smoking or drinking alcohol are also seen in people trying to escape abusive relationships. Patients need to move from a familiar unhealthy environment to a healthy unfamiliar one.

Several studies have shown that formerly abused women are no more likely to go on to an abusive relationship than are other women in unhappy relationships.[17] Other studies have shown that survivors of IPV are best able to stay out of future abusive relationships and improve their health if economic and/or employment and/or housing opportunities are available to enable financial independence.[18]

It is important to remember that there is no "classic" type of victimized individual. Any person can be abused. Survivors come from all backgrounds, sexual orientations, genders, capabilities, education levels, and economic backgrounds. Universally, survivors desire lives free from abuse and are most likely to take steps toward this goal if provided with validation, support, opportunity, and health and economic security. The following statements reflect faulty beliefs or dysfunctional attitudes toward IPV, which are explained in the associated text.

"She doesn't look battered."

Often there are no obvious physical signs of abuse and/or the abuse may be psychological or emotional, rather than physical. Many elements that increase risk for lethality in IPV (i.e., threats of violence, jealousy) leave no signs.

"He beats her but she keeps going back!"

As noted above, the victim and perpetrator may live in the cycle of violence where, after the abusive event, the perpetrator feels guilty, apologies, brings flowers, and promises to never repeat the abuse. The victim hopes the perpetrator will embody their better sides moving forward. Other factors to consider are that the victim may be emotionally or financially dependent on the relationship, making it difficult to leave. Often victims have a family history of violence and so IPV relationships may be seen as normal. Lastly, women may internalize blame and responsibility. The message that IPV is the victim's fault gets reinforced by repeated messages from the abuser and/or generalized societal, cultural, and media-transmitted messages that support social norms of submissiveness, inadequacy, or disempowerment. Women are often socialized to avoid conflict and promote harmony within the family at all costs. If they feel, for example, that the abuse prevents abuse of their children, then it may be perceived as not too high a price to pay for a peaceful household.

"Yes, he hit me but it's my fault. I made him angry."

Viewing an instance of abuse as a result of one's own actions is more empowering than if the person has no control. So justifying the abuser's actions is one way to legitimize his actions. Additionally, with the cyclic nature of the IPV relationship, the terrorism and intimidation often build up prior to the event and usually become so intolerable that the abused does something to end the terrorism and initiate the abuse.

"She presents with arm pain and odd injuries, but always denies IPV."

Reluctance on the part of a patient to disclose information about current or past abuse, even when specifically asked, may be due to embarrassment, shame, hope that the relationship can improve, or fear of retaliation by the perpetrator. External factors can also play a role: for example, the social pressure to avoid "losing" a partner or economic dependency.

"We just fight. I hit him and he hits me."

Abuse occurs most often in a one-way direction. However, survivors may strike back in self-defense, which can then be used to excuse the behavior of the abuser.

"He seems to be such a caring guy – there with her every visit and won't leave the room."

Caring and controlling can manifest as similar, or even identical, behaviors that can be difficult or impossible to distinguish without long-term observation.

"He's losing his job and now, for the first time in 20 years, he hit me."

Abuse may evolve from non-violent to violent in tandem with stressors experienced by the perpetrator. Pregnancy, which can refocus a woman's exclusive attention away from her partner, can also serve as a trigger.

Obstacles to Leaving an Abusive Relationship

Survivors of IPV may face many barriers to leaving an abuser or to taking steps to prevent further abuse. The abuser may threaten to hurt or kill the victim, for example, or take away or hurt the children if the victim attempts to leave. Other potential obstacles include:

Economic and Logistical Constraints

Abusers often control the financial resources of the household as well as access to telephones, computers, passwords, car keys, and even medication and food, making it difficult for survivors to leave because they cannot (or believe they are unable to) independently support themselves and their children. They may track their partner electronically or call and text hundreds of times a day. Survivors may not know where to seek shelter or may be afraid to ask.

Social Isolation

The abuser often prevents the victim from communicating with friends and family. Isolation leaves abused individuals psychologically dependent on the abuser as the sole source of social support and the only person who explains or interprets what is happening in the relationship.

Feelings of Failure

Many survivors have been made to feel, by the abuser as well as by others, that they are failures and are responsible for having brought on the mistreatment. Survivors may also believe that their children need or deserve a two-parent family, even at the expense of their own safety. Social pressures, e.g. "not keeping your man" can also play a role.

Promises of Change

A victim may believe the abuser's expressions of remorse and subsequent promises that it will never happen again. He or she may feel that the abuser can change. Some survivors also feel it is somehow their responsibility to change or redeem their abusers. While some survivors may want the relationship to continue, most also clearly want the violence to stop.

Religion

Some victims may expect to endure sacrifices in life, and that suffering in this life will be rewarded in the next life, or that their current situation is due to acts committed in a past life. Others believe deeply in forgiveness and the power and grace it brings them to forgive the transgression of others. Some people view the breaking of marriage vows as sinful, or interpret religious texts as reinforcing control and domination. Religiously based support may not embrace personal safety and resources for abused women. Influences by religious leaders may reinforce a subordinate role for wives.

Culture

Some patients may come from cultures where leaving a marriage is shameful or virtually unheard of, regardless of how unsatisfying or even dangerous the relationship may be. If a survivor leaves, they would become even more socially isolated as a result.

Prior Lack of Intervention

All too often, survivors of abuse are either blamed for the violence or not taken seriously by family, healthcare professionals, social service providers, and law enforcement authorities, leaving survivors feeling even more helpless and vulnerable.

IPV Screening and Assessment

The Clinician's Role

The healthcare encounter can be invaluable for those in abusive relationships. Although survivors of IPV access medical services more frequently than non-abused individuals, most do not volunteer a history of abuse even to their primary care clinicians. Sensitive inquiry about IPV during an annual physical examination, scheduled visit, or non-acute appointment, may reveal previously undisclosed abuse or can shed light on the underlying cause of an established chronic medical problem. In addition, research has shown that most patients both welcome and appreciate inquiry about violence and abuse in the course of the medical visit when questions are asked in a manner that is sensitive, respectful, and confidential.[19]

Abused individuals are more likely to disclose a history of abuse to their healthcare provider if the provider is perceived to be knowledgeable, nonjudgmental, respectful, and supportive. Patients prefer that their clinicians take the initiative to inquire, as a matter of standard practice, about violence and abuse during the course of clinical encounters.

The gender of the physician is not an important factor in the willingness of most patients to disclose or discuss abuse. The physician may need to ask on multiple occasions and over time, as a patient may need to feel they have a safe relationship to disclose their status. The physician can then help the patient develop a safety plan to prime the patient's next leave attempt.

It's important to reiterate that a patient who remains in a dangerous or potentially dangerous relationship should not be labeled as a treatment failure or non-compliant. As noted earlier, choosing not to leave usually reflects the limited resources available to the survivor, or the patient's reasonable assessment of available options and safety needs.

Clinician barriers to effective, compassionate care

Some healthcare providers find it challenging to address IPV, as well as other forms of violence and abuse. Survivors present frequently for medical care, and/or may come across as difficult patients. Many survivors believe that healthcare providers do not know about or understand the dynamics of violence and abuse, may not take the situation seriously, may not believe them, or may even blame the survivor for the abuse. As a result, survivors may exhibit a variety of problematic responses to the stress of ongoing or prior abuse (e.g., hypervigilance from PTSD, substance abuse), many of which make them "less than ideal" patients in a busy medical practice.

When interviewed about their beliefs about partner abuse, and about their personal experiences of victimization, many primary care providers expressed fear of "opening Pandora's Box" by broaching the topic of IPV with patients.[20] Associated with this metaphor were five strong themes identified as distinct challenges. The first was "too close for comfort," relating to the finding that 14% of male physician respondents and 31% of female physician respondents in the study disclosed a previous personal experience of abuse. Other themes were fear of offending, powerlessness, loss of control, and "tyranny of the time schedule."

Patient Barriers to Disclosure

Patients may hesitate to disclose current or past abuse to a healthcare provider for a variety of reasons:[21]

1. Fear of:
   - the healthcare provider confronting the perpetrator.
   - retribution if the perpetrator learns of the disclosure.
   - a breech in confidentiality if medical records are accessed by the perpetrator, child protective services, employers, police, or immigration authorities.
2. Shame and humiliation that abuse is taking place, or took place in the past, or not wanting to be perceived as a "victim".
3. Belief that they deserved the abuse.
4. Protective feelings for the partner.
5. Inability to fully comprehend the situation.
6. Assumptions that:
   - the doctor and staff are not knowledgeable or do not care about IPV because IPV may not be viewed as a medical issue.
   - the doctor is too busy to spend time talking about IPV.
   - the doctor can't help with this problem or that it is inappropriate to discuss it.
   - same-sex abuse is not recognized, screened for, or treated.
7. Language, culture, and religion:
   - language barriers when communicating with providers, and fear of losing confidentiality with the use of an interpreter.
   - religious customs pushing survivors to stay silent about abuse.
   - reluctance to "air dirty laundry" and cast a bad light on their community.
8. Immigration status being contingent on their current relationship, especially if they're trafficked foreign nationals.
9. Sexual orientation and gender identity leading to fear of being "outed" or shamed.

Additionally, perpetrators can control a patient's ability to access healthcare. They may accompany the patient to healthcare visits and even dominate the encounter and speak for the patient. Perpetrators can also affect a patient's ability to adhere to medical instructions. They may confiscate or discard medications or medical devices as a way to control the patient.

The RADAR Model

The United States Preventive Services Task Force (USPSTF) and the Affordable Care Act, along with many other organizations, support routine screening for IPV and IPV counseling as part of preventive services. Research clearly shows that identifying survivors can promote their safety and improve health outcomes.[22-24]

The "RADAR" acronym developed by The Massachusetts Medical Society summarizes steps that healthcare providers can take to identify IPV and support victims:

- **R**outinely screen: ask about IPV in the course of routine care.
- **A**sk direct questions about violence such as, "At any time, has a partner or ex-partner hurt you, frightened you, isolated you, or made you feel unsafe?" Interview your patient in private whenever possible.
- **D**ocument in the patient's chart any findings related to suspected IPV.
- **A**ssess for safety. Is the patient safe at home? Are firearms or other weapons kept in the house? Are children in danger? Is abuse or violence escalating?
- **R**eview options with your patient, and make appropriate community-based referrals (e.g., support groups, counseling, emergency shelter, legal advocacy).

A single question, asked routinely and non-judgmentally in the course of the social history, can significantly increase the detection rate of IPV in office practice and can allow your patient to feel safe in disclosing a history of abuse. These sample questions can be adapted as needed to individual practices; all have been shown to be accurate assessment questions for IPV:[25]

- "At any time, has a partner hit, kicked, choked, threatened or otherwise hurt or frightened you?"
- "Have you ever been in a relationship in which you felt unsafe or felt you had to 'walk on eggshells' to keep the peace?"
- "Do you feel safe in your relationship?"

Screening Tools

Several instruments can be used to screen women for IPV. Those with the highest levels of sensitivity and specificity for identifying IPV, according to research by the USPSTF, are:[1]

1. Hurt, Insult, Threaten, Scream (HITS); self- or clinician-administered 4-item questionnaire assessing the frequency of IPV.
2. Extended Hurt, Insult, Threaten, Scream (E-HITS): includes an additional question on the frequency of sexual violence.
3. Humiliation, Afraid, Rape, Kick (HARK): self-administered 4-item questionnaire assessing physical and emotional IPV in the past year.
4. Partner Violence Screen (PVS): 3 item questionnaire assessing physical abuse and safety.
5. Woman Abuse Screen Tool (WAST): 8 item questionnaire assessing emotional and physical IPV.

The USPSTF found no valid, reliable screening tools to specifically identify abuse of men or elderly or vulnerable adults in the primary care setting.[1]

If your patient discloses that she or he has been abused, or if you suspect abuse without a disclosure, asking the following specific questions in a safe and confidential setting can help to determine the extent of abuse and the possible risk to your patient:

- How were you hurt?
- Has this happened before?
- When did it first happen?
- How badly have you been hurt in the past?
- Have you needed to go to an emergency room for treatment?
- Have you ever been threatened with a weapon, or has a weapon ever been used on you?
- Have you ever tried to get a restraining order against a partner?
- Have the children ever seen or heard you being threatened or hurt?
- Have the children ever been threatened or hurt?
- Do you know how you can get help for yourself if you were hurt or afraid?

For adolescent patients, the following questions might be appropriate:

- Have you begun to date?
- Has your boyfriend/girlfriend ever threatened to hurt you?
- Are you ever afraid of your boyfriend/ girlfriend?
- Have you ever had a pushing or shoving fight with a boyfriend/girlfriend?
- Have you ever gotten hurt from a fight with a boyfriend/ girlfriend?
- Have you begun to have sex?
- Has anyone ever forced you to have sex when you didn't want to?
- Have you been able to talk to anyone you trust about what is going on?

Safety Assessment

If a patient has disclosed being in a threatening or violent relationship, the clinician can help the patient assess the level of risk, initiate a discussion of the need for a safety plan, and make referrals to appropriate services.

The most important determinants in assessing risk are the patient's level of fear and their own appraisal of both immediate and future safety needs. Since patients may minimize the danger of their situations, however, the following questions have been found to provide a more objective assessment of IPV risk and whether it has been escalating and therefore likelihood for lethality:[26]

- Has the physical violence increased in frequency or severity over the past 6 months?
- Has you ever been threatened with a weapon or actually had a weapon used against you?
- Do you believe your abuser is capable of killing you?
- Have you ever been beaten while you were pregnant?
- Is the person abusing you violently and constantly jealous of you?

If any three of the above risk indicators are present, the patient should be referred immediately to a domestic violence community agency and, if necessary, to appropriate law enforcement authorities. Since lethality is augmented by the presence of a weapon, screening for the presence of a firearm, either one owned by the patient or the abuser, is extremely important.

PLEASE COMPLETE CASE STUDY 1 ON THE NEXT PAGE.

Case Study 1

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

Marcy is a 22-year-old immigrant from the Philippines who is presenting with an older man for an annual primary care exam. The man introduces himself to the provider as Marcy's husband and insists on sitting close to the patient with his arm around her shoulders or hips. Marcy's husband has a purse over his shoulder, and they both wear religious jewelry. Her husband states that Marcy moved from the Philippines with him when they got married last March, and that she does not have family in town. During routine interviewing, Marcy's husband consistently answers for her, although Marcy's English appears adequate for expressing herself.

A physical exam reveals bruises on the woman's breasts and abdomen; her husband states these injuries occurred because of a stumble down the stairs. Marcy averts her eyes during his explanation of the injuries and appears uncomfortable.

1. **What potential obstacles exist that would prevent the clinician from providing effective, compassionate care to Marcy?**

2. **If it is possible to safely separate the husband and wife, what screening options can be considered to determine if Marcy has a history of IPV?**

Discussion: Providing care to a patient in Marcy's situation can be complex. Since Marcy presents with her husband, who appears to be controlling the situation, it may be difficult to have a discussion with Marcy without potentially confronting the perpetrator of violence. In addition, it is unclear if there are any language barriers to communicating with Marcy, and religious or cultural customs may also be barriers to disclosure of violence. It is possible that Marcy's immigration status may also be contingent on her relationship with her husband, presenting another potential barrier.

If Marcy can be safely questioned alone, a single question can help the provider determine if abuse is occurring. A question as simple as 'do you feel safe in your relationship?' can show the patient that the provider is compassionate, show the patient that the provider is alert to the situation in front of them, and open the line of communication between the patient and provider. If time allows and communication barriers are absent, screening tools such as HITS, HARK, or WAST can be utilized.

Clinical Presentations

An abusive act is rarely an isolated event. Violent behavior usually recurs and often increases in frequency and severity over time. Although abused individuals may sustain life-threatening physical injuries, they often can suffer less obvious effects that are just as debilitating. In addition to physical trauma, survivors may present with a variety of other medical problems.[27] While some patients exhibit such "red flag" indicators of current or prior abuse, many others show no obvious signs or symptoms of medical or psychiatric distress, underscoring the importance of routine inquiry by clinicians or others on a healthcare team.

In both ambulatory and emergency settings, survivors may present with a wide range of signs and symptoms that may include:[2]

- Physical trauma, particularly lacerations, contusions, dislocations, fractures, head injury, or findings consistent with attempted strangulation (e.g., facial petechiae, laryngeal edema). Note that visible signs of strangulation may be more difficult to detect in darker-skinned patients than in those with fairer skin coloration.
- Gynecological problems (genital lacerations and contusions, sexually transmitted infections, including HIV/AIDS, rapid repeat pregnancies).
- Medical signs and symptoms such as headache, chest pain, abdominal pain, pelvic pain, fatigue, eating disorders, or functional gastrointestinal disorders.
- Localized or generalized neurological findings such as altered mental status, seizures, motor or sensory deficits, and memory problems.
- Behavioral/psychiatric signs such as anxiety, depression, panic, suicidal ideation or attempt, substance abuse.
- Social "red flags" such as frequent missed appointments, or non-adherence to prescriptions or medical instructions.
- Partner "red flags" such as excessively attentive or jealous behavior on the part of a companion, a partner who insists on accompanying a patient during examinations, or a partner who speaks for the patient or displays dominant behaviors.
- Delay between onset of injury and presentation for care.
- New diagnoses of sexually transmitted infections may also result from sexual assault in an IPV relationship.

If any of these signs and symptoms are suspected to be the result of IPV, additional and more thorough questioning is warranted.[5]

Behavioral Signs of IPV

Even in the absence of disclosure, patients may appear frightened, ashamed, embarrassed, defiant, or even overtly angry. Basic questions on the medical history may be answered in a manner that appears ambiguous or evasive. Other behavioral clues may include:

- Partner accompanies the patient to clinical visit, insists on staying close, and speaks for the patient, answering questions or monitoring/controlling the patient's responses.
- The patient appears reluctant to speak independently or to disagree with partner.
- Intense irrational jealousy or possessiveness expressed by partner or reported by patient.
- Patient and/or partner deny, minimize, or divert questions about medical problems or injuries.
- Patient displays an exaggerated sense of personal responsibility for the relationship, including self blame for partner's violence or for staying in the relationship.
- Explanations that are inconsistent with observed illness or injury pattern.

Documenting IPV

Documentation in the medical record can provide valuable information if your patient seeks legal redress for abuse, as well as being the basis for optimal medical care.

Even if the patient does not intend to take action now, the records may be needed later, for instance, in child custody proceedings. As vigorous criminal prosecution of intimate partner assault increases, accurate and legible medical records can often substitute for a physician's personal testimony in court.

Some electronic medical record systems (EMRs) have templates to facilitate IPV screening and/or sexual assault documentation. Robust EMRs include prompts to remind providers to screen, and include links for inquiry and documentation formatting, lethality assessment questions, safety plan tips, and local resources. Additionally, for reasons of safety and confidentially, these systems have documentation and listing of IPV specifically excluded from clinical visit summaries, billing statements, and electronic health portals. One example is the Kaiser Permanente Systems Model approach.[28,29]

Many EMRs are currently used nationwide, resulting in wide variances in the use of prompted IPV screening. Whether using an EMR or not, clinicians should document findings carefully and non-judgmentally. Drawings or labeled photographs may supplement a written description. It is important to describe the patient's symptoms and signs accurately and to indicate "intimate partner violence" as a diagnosis or problem if appropriate.

Documentation details

Records should be kept in a precise, professional manner, and should include the following:

For patients with acute physical injuries:

a. Date and time of visit (if scheduled appointment) or arrival (if in the emergency department).
b. Contact information for anyone accompanying the survivor.
c. Chief complaint and description of the event, using the patient's own words in quotation marks whenever possible rather than the physician's assessment. For example, "My husband hit me with his fist on _____ date at _____time" is preferable to "Patient has been abused," "Patient hit with a fist," or "Patient alleges/claims she was hit."
d. Include the partner's name in the record if possible.
e. Complete medical history.
f. Relevant social history.
g. A detailed description of injuries and other relevant physical findings. Where applicable, the location and nature of injuries should be recorded on a body chart, drawing, or digital photograph.
h. An opinion on whether the injuries were adequately explained or not.
i. Documentation if the explanation of injuries given is inappropriate or inconsistent with the injury pattern.
j. Documentation that the physician asked the patient about IPV, together with the patient's response.
k. Results of pertinent laboratory and other diagnostic procedures.
l. If the police were called, the name, badge number, and phone number of the investigating officer and any actions taken.
m. Name of treating health care provider(s).

The EMR can facilitate interviews and a template can be created to ensure all of the above pertinent information is obtained. Make sure the patient knows how to access their records, and also that the patient knows the document is confidential, thus requiring their permission or a subpoena for the partner or anyone else to view it.

Documenting Abuse With Photographs

In addition to complete written records, photographs can be of particular value as evidence. Additional imaging studies may be useful, depending on the clinical situation. The physician should obtain written consent for photographic documentation from the patient prior to taking photographs. Digital images should be dated and signed by the physician (freehand or electronic signature), and accompanied by a statement that indicates that the images are authentic and unaltered.

Techniques for optimal photographic documentation include:

- Whenever possible, take photographs before medical treatment is provided.
- Photograph from different angles, full body, and closeup.
- Hold up a coin, ruler, or another easily identifiable object to illustrate the size of an injury.
- Include a date marker on the photograph. If not available from within the camera, that day's newspaper or other dated material may be used.
- Include the patient's face in at least one picture and some identifiable part of the patient in all photographs.
- Take at least two pictures of every major trauma area.
- Mark photographs precisely as soon as possible with the patient's name, location of injury, names of the photographer and others present, and the date and time of the photograph.
- To maintain chain of custody and confidentiality, be consistent as to where photographs are filed and who has responsibility for and access to photographs.
- Arrange for the patient to return in two or three days for additional photographs to document the progression (and healing) of visible injuries.

Sexual assault forensic documentation and evidence collection

Documentary evidence of an attempted or completed rape can be collected up to five days after the crime occurs. Physical evidence that can be used for medical assessment and possible criminal prosecution should be obtained using a Sexual Assault Forensic Evidence (SAFE) kit, which can be found in most hospital emergency departments.Unless the patient is unwilling or unable to present to the emergency department, the examination and evidence collection should be conducted in the emergency setting. An increasing number of hospital emergency departments use the services of Sexual Assault Nurse Examiners (SANE nurses) who have specific training in forensic nursing, evidence collection, and crisis counseling. If a patient calls your office before presenting to the emergency department, he or she should be told to refrain from showering, bathing, or douching before arriving at the hospital. Victims of sexual assault should be instructed to put all clothes worn during the assault in a paper bag to bring to the hospital as additional evidence.

Strategies for Improving Care for IPV Victims

Effective Communication Strategies

As important as it is to ask the right questions, it is equally important to refrain from asking questions in a manner that might frighten or intimidate your patient, increase the sense of humiliation and shame about the violence, or be interpreted as blaming the survivor for the situation. Here are some pitfalls to avoid:[30]

- Do not inquire about abuse in the presence of the partner, friends, or family members. Children older than three should not be present while discussing IPV.
- Discussing IPV can be very difficult and can leave patients feeling vulnerable. Do not inquire about abuse until the patient is fully clothed.
- Do not break patient confidentiality by disclosing any information or discussing your concerns with the patient's partner.
- Most survivors do not identify themselves as abused because of the perception of shame and worthlessness associated with that term. Therefore, avoid using the words "victim," "abused," or "battered" when speaking with the survivor. Instead, use words like "hurt," "frightened," or "treated badly."
- Assure the survivor that everyone deserves to feel safe and no one deserves to be abused. Never ask your patient what they did to bring on the violence.
- Do not ask your patient why they have not left their partner.
- A survivor may leave a partner only to later return. If this is the case with your patient, avoid asking why they have returned.

The Trauma-Informed Care Model

As potentially valuable as they may be, medical encounters can also be stressful for abused patients. Because of this, healthcare providers should care for all patients in a trauma-informed manner. The nine principles of trauma-informed care are:[31]

1. ***Respect***

Because abuse undermines a person's personal boundaries and autonomy, they may be sensitive to any hint of disrespect. Many survivors say that being accepted and heard by a clinician helped them feel respected.

2. ***Taking time***

The time pressures in clinician/patient interactions may compound survivors' feelings of being depersonalized and devalued.

3. ***Rapport***

Rapport is essential in every therapeutic relationship, but it is particularly necessary when supporting survivors of IPV. Good rapport not only increases patients' sense of safety, it promotes clear communication and engenders cooperation.

4. ***Sharing information***

Some IPV survivors say they don't know what clinicians do and, therefore, don't know what to expect in terms of questions, procedures, or decisions. Having these things explained clearly and simply on an ongoing basis can help allay fear and anxiety. Clinicians should also seek ongoing feedback from patients about their understanding as well as any reactions they might have to questions or procedures.

5. ***Sharing control***

A core aspect of sexual or physical abuse is the loss of control over one's body, hence it's vital for patients to have a sense of control with clinicians who unavoidably occupy a position of power. Sharing control of what happens in the clinician/patient interaction enables individuals to be active participants in their own care, rather than passive recipients of treatment.

6. ***Respecting boundaries***

Beginning a procedure without first asking for the consent of the patient, or asking very personal questions before establishing rapport can feel like a violation of personal boundaries (both physical and emotional).

7. ***Fostering mutual learning***

The best teachers about the health effects of IPV and about how to work effectively with survivors are often survivors themselves. Clinicians who demonstrate genuine compassion and an interest in learning from their patients will be better positioned to respond effectively to future survivors of IPV.

8. ***Understanding non-linear healing***

The degree to which a survivor is able to tolerate or participate in treatment may vary from one healthcare encounter to the next due to the natural variability in the dynamics at work in IPV. Clinicians need to recognize and accept this variability and check in with patients at each encounter and adjust behavior as needed.

9. ***Demonstrating awareness and knowledge of IPV***

Many survivors of IPV look for signs of a clinician's awareness of issues of interpersonal violence, such as in posters or pamphlets from local IPV-related organizations or the Family Violence Prevention Fund (www.endabuse.org). It's also important that visible signs of a clinician's awareness be inclusive, for example mentioning, or illustrating, that abuse can occur in same-sex couples. Office staff should receive periodic in-service training about IPV, referral resources, protocols, and office safety procedures.

Time Management

Clinicians may not screen for IPV because they think they don't have enough time in their daily practice to inquire, assess, and respond appropriately. Judicious time management and an outlined protocol or established clinical process, however, will allow for universal inquiry, appropriate guidance, and targeted follow-up.

Routinely asking about IPV (usually as part of the social history) should take no more than 10 seconds, and yet may have a dual beneficial effect: if the answer is negative, the clinician will be reassured that the patient is not at risk for abuse (or that the patient, if affected, is not ready or able to disclose at that time); and the patient will be made aware that the clinician is concerned, knowledgeable, and able to respond should IPV become an issue at any time in the future.

Most patients with a history of being abused, although perhaps dealing with difficult medical and emotional sequelae, are not in acute danger at the time of the visit. If the patient discloses victimization, the physician should conduct a brief safety assessment (see above), offer information and hotline numbers, convey concern and support for the patient, and arrange a follow-up to discuss the abuse and possible options in greater detail. Only rarely will the clinician be confronted with a patient in extreme danger or who has acute needs. In this situation, as in the case of any medical emergency, urgent action is needed.

While there are various guidelines outlining what patients may need from the health care system after experiencing IPV, there is little guidance on how to actually integrate and implement these practices within clinics. Treating IPV in a chronic care model and creating a team within clinical settings helps improve screening rates and provides interventions in a timely manner. The following six-point model summarizes how to create a sustainable system-level program:[32]

- Step 1- Identify an IPV Champion (someone with on-site IPV expertise).
- Step 2- Train all staff and define roles when responding to IPV (i.e., saturation training).
- Step 3- Create clinic-based policies and procedures. These will outline staff training efforts, use of EMR documentation, identification of "at risk" patients longitudinally, create follow-up plans, and streamline referral to internal and local community programs.
- Step 4- Use the IPV Champion to build bridges and collaboration with local advocacy agencies and IPV experts. This ultimately allows for effective communication and "warm" referrals.
- Step 5- Evaluate all clinical efforts regarding screening and periodically re-evaluate for dissemination to the clinical team.
- Step 6- Provide general information to patients outlining healthy relationships as well as healthy conflict resolution strategies (e.g., pamphlets, posters, signage).

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

Using Community Resources/Referrals

Clinicians who may encounter survivors of IPV should explore all local support resources and keep an updated patient hand-out with their contact information. Establishing personal relationships with key personnel in community support organizations can not only improve a clinician's understanding of the many social and legal dimensions of IPV, but it can facilitate referrals.

Many community IPV programs include a confidential emergency shelter or safe house program. Some can provide temporary transitional housing or safe-at-home services. Although emergency shelter is usually a last resort for those who are in acute danger, the shelter offers a safe haven from violence and can also provide the survivor with information about rights and options as well as vital emotional and logistical support. In many programs, specialized services are available for children who have been traumatized by witnessing abuse. In shelter programs, women have a chance to meet other women who have sought shelter, which can help women break out of the profound social isolation that is so often a component of abuse.

In addition, many IPV agencies offer counseling programs for survivors living in the community. These individuals may not need emergency shelter but nevertheless want to deal with the trauma of current or past abuse, and may be ready to take advantage of available support as they move forward with their lives.Many of these programs offer structured groups for parents of children exposed to IPV that deal with issues such as understanding the dynamics of violence, dealing with anger, understanding legal rights, understanding the effects of IPV on children, making and maintaining safety plans, and offering one another emotional support during important life decisions. These groups are often held in community settings so women not in shelter can also attend.

Case Study 2

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

Jennifer is a 32-year-old married woman who presents for an annual exam with her 6 year old daughter. She works full-time as an ophthalmologist and appears clean, professional, and poised. Jennifer and her husband have been your patients for 5 years, and her overall health is good, with only minor health concerns in her past medical history.

Jennifer's appointment is in the afternoon, and you are running late after a series of delays with previous patients. You review her vitals and start to perform a physical exam. You glance at the clock and see you are already out of time for this appointment. To save time, while you are performing a breast exam, you ask Jennifer "Do you feel safe in your relationship?" To your surprise, she suddenly tears up and averts her eyes. She does not immediately respond to the question.

1. **What are some examples of communication strategies you should avoid when collecting more information?**

2. **What IPV-specific documentation should you include in your progress note for this encounter?**

Discussion: In the interview with Jennifer, it is important to refrain from asking questions in a manner that might frighten or intimidate your patient, increase the sense of humiliation and shame about the violence, or be interpreted as blaming the survivor for the situation. Since discussing IPV can be very difficult and can leave patients feeling vulnerable, Jennifer may feel more comfortable having a discussion while fully clothed. Discussions about IPV should be avoided in the presence of children who can comprehend the situation, so it may be best to have Jennifer's daughter leave the room or have Jennifer call the clinic later to discuss when she is alone. In addition, Jennifer should be assured that patient confidentiality will not be broken by disclosing any information or discussing concerns with her husband.

When documenting the encounter in a progress note, it is important to use Jennifer's words in quotations whenever possible to detail her description of her relationship safety. If any injuries are found during the physical exam, they should be described in detail, as well as an opinion on whether the injuries were adequately explained. Photographs or additional imaging studies may be included if appropriate.

Many IPV programs staff a daytime or 24-hour hotline, or link with regional or state-wide hotlines. A 24-hour national hotline is available at 1-800-799-SAFE (7233). It is not unusual for survivors in the community to use hotline services anonymously and also to call multiple times before actually visiting an agency for in-person help. Crisis hotlines are available not only to survivors but also to concerned friends and family, as well as professionals who are seeking more accurate information about community-based services.

Some IPV programs offer legal advocacy, and in some cases, actual legal representation. Legal advocates can educate survivors about their legal rights and options, including applying for orders of protection, or representation in divorce and custody hearings.

Translation Services

Professional interpreters or translators who are trained in maintaining patient confidentiality should be used whenever possible if a language barrier is evident in a clinical encounter involving IPV. Otherwise, there is a risk of compromising the quality of the information being translated and can put the survivor in danger or lead to a missed opportunity for intervention. Providers should never use accompanying persons (i.e., friends, relatives, children) as interpreters. The person chosen could actually be the perpetrator or they could inadvertently breach confidentiality by speaking about the conversation with others.

Additionally, if the translator is a member of the survivor's community, shame or stigma may prevent the survivor from disclosing the abuse. Remote telephone interpretation services are an appropriate alternative when an in-person interpreter is from the survivor's small community or is not available. Regardless of language, providers need to avoid assuming literacy. Just because a patient can speak a language does not mean they can read or write it, and vice versa.

Intervention Strategies

The USPSTF, in a systematic review of the literature, found "adequate" evidence that effective IPV interventions that provide or refer patients to ongoing support services can reduce violence, abuse, and physical or mental harms for women of reproductive age.[1] Evidence from randomized trials support various interventions including counseling, home visits, information cards, referrals to community services, and mentoring support. Depending on the type of intervention, these services may be provided by clinicians, nurses, social workers, non-clinician mentors, or community workers. Counseling generally includes information on safety behaviors and community resources. In addition to counseling, home visits may include emotional support, education on problem-solving strategies, and parenting support.[1]

Health care providers should bear in mind four guiding principles of intervention when addressing IPV with their patients:[33]

Patient Safety

Patient assessment, documentation, safety planning, communication, intervention, and follow-up must be conducted with utmost concern for the immediate and long-term safety of the survivor and their dependent children. The clinician should ask, "Is what I am asking/doing/recommending going to help my patient become safer, or at least not place the patient at risk for further harm?"

Survivor Empowerment

Abused individuals have often been denied their freedom to make informed, independent choices about their (and their children's) lives. Facilitating the patient's ability to make their own choices is key to restoring a sense of purpose and well-being for survivors of IPV, and can facilitate a patient's readiness to take proactive steps to end the violence.

Perpetrator Accountability

It is important to frame violence as occurring because of the perpetrator's behavior and actions, not the survivor's. It thus follows that the problem of violence in the relationship, and thus the need to take definitive steps to end the violence, is the perpetrator's responsibility. This guiding principle assumes the importance of survivor safety, but rejects victim-blaming and other excuses offered by the offender as "explanations" for the violence.

Advocacy for Social Change

Clinicians acting alone cannot meet all the needs of survivors of IPV. As healthcare professionals and systems grapple with the complex issues involved in understanding and responding to IPV, the need to collaborate with others in healthcare, as well as those in law enforcement, the faith community, and society at large, becomes apparent. Establishing linkages with dedicated violence prevention community agencies and sexual victims crime units in advance can provide a more seamless inclusion of these resources into clinical care when needed. Clinicians can be important catalysts for change so that IPV can be more effectively identified, and ultimately prevented.

Specific Interventions

Clinicians need to establish realistic and achievable goals with their abused patients. One goal may be to aid the patient in leaving the relationship. That may not be what the patient wants or thinks is appropriate at that time. There are many goals from self-disclosure, education, and empowerment to departure that often need to occur first. The survivor knows their situation better than anyone else and needs to incorporate information about risks and danger into decisions regarding leaving and safety. Leaving an abuser is usually a process that takes time—often years. Clinicians can help their patients make progress toward leaving by giving them information about options, and by letting them know that they are there to provide help, safety planning, and support as they take the steps necessary to break free from abuse.

Specific steps the physician can take include:

- Offer messages of validation and support:
  - Thank the patient for sharing what must be a difficult and painful situation.
  - Validate the patient's courage, integrity, and worth as an individual.
  - Communicate concern for patient's safety
  - Reinforce that the patient is believed, and that the patient does not deserve to be abused.
  - Reframe abusive behavior as unacceptable and possibly criminal.
  - Place responsibility for the abuse unequivocally on the perpetrator.
  - Assess for safety.
  - Initiate safety planning.
- Evaluate mandated reporter requirements for patients who are:
  - Children
  - Elderly
  - Disabled
- Oversee clinical evaluation and care:
  - Carefully and without judgment, document findings in the medical record (see details of documentation above).
  - Diagnose and treat (or refer for treatment) specific injuries and other medical problems related to ongoing or past victimization, or any psychological and behavioral problems in survivors and dependent children.
  - Discuss safer sex practices and protection against sexually transmitted diseases and pregnancy, especially for patients who have been raped or who have experienced coercive sexual activity. The pregnancy prevention approaches with the least risk of external intervention should be recommended (e.g. implantable contraception over condoms or pills).
  - Consider the risks of prescribing potentially sedating medications that could impair the survivor's ability to respond appropriately if rapid action or escape become necessary.
- Arrange appropriate referrals to community-based advocates and other experts who provide direct service to survivors of IPV (see resources at the end of this document) .
- Assure follow-up both for the presenting complaint and for comprehensive primary care.

Offering validation, support, and basic information about IPV to survivors are legitimate therapeutic interventions.

Developing a Safety Plan

To develop a safety plan, the patient's level of danger and the resources needed to allow the patient to escape a situation quickly must be addressed. The plan should include a place to go (friends, family, or shelter) and other resources for daily living such as money, personal papers (health insurance cards, house deed, social security/ green card, pay stubs, driver's license or photo identification), car and house keys, and a change of clothing for the patient and their children. If an order of protection (restraining order) has been issued, your patient should carry a copy of it at all times and, if possible, have a digital image of the document saved on their phone. Inform your patient that local domestic violence programs provide free and confidential services, and that trained advocates from these programs can provide information about:

Legal rights

- Police and court procedures for protective orders.
- Shelter availability.
- Support groups and other support resources.

Encourage your patient to call a local or national hotline for further information. Provide a private, safe space for your patient to make those calls if at all possible. Such a call in no way commits the patient to a course of action, but can better inform and empower them. Give your patient brochures or written resources only if they feel it is safe for them to have. Numbers and contact information can be programmed into personal phones under "Code Names" to avoid identification. Some perpetrators go through their partner's belongings, including technological devices, and finding information on IPV could be perceived as the partner attempting to leave and put them at increased risk of violence.

Specific IPV Issues or Patient Populations

Pregnancy

IPV may be associated with:

- Restricted access to contraception.
- Unintended or coerced pregnancy, as well as rapid repeat pregnancy.
- Delayed or unreliable access to prenatal care.
- Spontaneous, elective, or coerced abortions.
- Antepartum hemorrhage.
- Premature labor.
- Increased risk of maternal injury, substance abuse, and poor nutrition.

Violence during pregnancy is a serious medical and public health problem, with the majority of published studies in the US reporting prevalence rates between 4% - 8%.[34,35] IPV against pregnant women is more prevalent than preeclampsia, gestational diabetes, and placenta previa, all of which are routinely screened for in prenatal care. In addition, homicide is the most common cause of pregnancy-associated maternal death.[36]

Prenatal visits provide access to and continuity of care for pregnant women and thus represent an excellent opportunity for clinicians to assess for and intervene in IPV.

Patients should be routinely screened for new or ongoing abuse during each prenatal visit. Women are more often physically abused in the year before pregnancy and even if the abuse stops or decreases during pregnancy, it usually starts again postpartum.[34] Thus, it is important to ask about abuse before, during, and after pregnancy.

Adolescent Dating Violence

Adolescents may suffer from an array of abusive behaviors, ranging from verbal and emotional abuse, to physical abuse, rape, and even homicide. Some teens are battered by people with whom they are dating, while others may be abused by parents or other caregivers. Teens in dating relationships often confuse jealousy with love. They may willingly give up passcodes and private electronic information under the pressure of an abusive partner. Lack of experience and perspective regarding healthy relationships can also affect the power dynamics in the relationship, especially if the teen's partner is significantly older. All of these factors make teens more vulnerable to being controlled. Striving for independence, battered teens may be especially reluctant to seek help from authority figures such as health care providers.

Clinicians should reassure teens about the confidential and supportive nature of the doctor-patient relationship. Doctors should screen adolescents for abuse as described below, remembering that the abuser may be a parent, another family member, boyfriend, or girlfriend. The teen's knowledge and behavior around violence, coercion, alcohol, drugs, and sexual activity needs to be assessed. An abused teen particularly needs to be told that the abuse is not their fault and that help is available (see the list of resources at the end of this document).

Violence in Lesbian, Gay, Bisexual, Transgender, and other Gender and Sexual Minority (GSM) Relationships

IPV in GSM relationships appears to be as common, or possibly more common, than in heterosexual relationships.[37-39] Many GSM individuals do not feel comfortable disclosing their sexual orientation to healthcare providers, and are likely to be even more reluctant to disclose abuse. GSM individuals who do disclose their sexual orientation are still rarely asked about IPV. Barriers to inquiry include gender-related myths, for example, that men cannot be victims of abuse, or that same-sex relationships are inherently "equal" because parties are of the same gender.[37,40]

Additional obstacles specific to GSM survivors include homophobia and transphobia and resulting discrimination in society and among healthcare providers as well as social consequences of revealing one's sexual orientation, such as loss of children and other family relationships, employment, or community standing. Shelter space and support services may not be available specifically for battered gay men, transgender, and gender nonconforming individuals.

Lesbian and bisexual women have the option of going to more traditional domestic violence programs that accept women, but many of these programs may not be suitable for or sensitive to members of the GSM community. Transgender and gender-nonconforming individuals face particular barriers in getting help because providers, and the public in general, often understand even less about gender identity and expression than they do about sexual orientation. Healthcare providers should therefore approach screening, diagnosis, and treatment with special sensitivity to the difficult issues that abused GSM patients may face.

Violence in Diverse Cultures and Immigrant Populations

IPV is prevalent in every culture and segment of society. Immigrants and members of minority cultures, however, face extra hurdles as they attempt to access available services to protect themselves, their children, and other dependents. Patients of different cultures may hold belief systems and traditions that make it harder for them to perceive their own danger, understand their right to live in safety, know their legal rights and options, or even speak to anyone about their situation. Survivors whose native language is not English may find it difficult to communicate with healthcare providers, advocacy services, and law enforcement personnel. They may also harbor legitimate fears of becoming homeless, losing their children, or deportation, if their abuse is revealed. These patients may not trust the health care system, and thus suffer in silence and be at risk. Healthcare providers who are sensitive to the potential barriers and problems that immigrants and members of diverse cultures face can better establish trusting relationships with their patients, which is critical for uncovering and dealing with IPV.

Substance Abuse

Substance abuse is often associated with violence. Perpetrators are more likely to use or abuse alcohol and other substances, and, in addition, patients who abuse alcohol and other drugs are more likely to become victims. Further, survivors of partner violence are more likely to abuse alcohol and to receive multiple prescriptions for tranquilizers, sedatives, and opioid analgesics to treat the pain or distress of present or past abuse.[9] With rising rates of opioid abuse, physicians should consider increasing screening of violence in their patient population.

Although most abused individuals are neither dependent on alcohol nor involved with other drugs, those who are addicted are often doubly stigmatized. They may be labeled as sexually promiscuous, unfit as parents, unworthy as partners, have low self-control or willpower, or being just plain "crazy." They are more likely to be blamed for the violence in their lives, further impeding efforts to resolve issues and regain health.

Intervention goals for chemically dependent abused patients include sobriety as well as safety. For some, addiction treatment may be a necessary first step, but intervention for the violence should not be neglected. For others, achieving safety may be necessary before participating in an addiction recovery program. Becoming sober may threaten an abuser's sense of control, and place the survivor at risk for increased violence. Ideally, both issues are treated together. Addiction or intoxication, although maladaptive, may serve as coping strategies for the victimized individual. Sobriety in the absence of safety and resiliency-oriented support may unmask previously undiagnosed mental health issues for marginally functioning abused patients.

The success of safety planning can be compromised by ongoing drug use, and the success of addiction recovery can be impeded by continued violence. Therefore, healthcare providers should always carefully assess for IPV where there is evidence of substance abuse, and screen for substance abuse where there is evidence for IPV. In addition, providers should weigh carefully the risks and benefits of prescribing controlled substances for symptom relief in patients with chemical dependence, particularly opioid pain medications.[41]

Sexual Assault and IPV

According to the National Intimate Partner and Sexual Violence Survey (NISVS), the lifetime incidence of rape is 19.3% for women and 1.7% for men.[42]

Patient responses to sexual assault can vary from visible distress to calm composure. Some survivors of recent rape have difficulty trusting hospital personnel and the evidence collection process. Thus, sensitivity and patience are critical when examining or referring a patient to the emergency department. Clinicians trained in empathetic evidence collection such as Sexual Assault Nurse Examiners can be invaluable collaborators. In addition to collecting physical evidence in cases of recent sexual assault, healthcare providers can offer validation, support, and appropriate referrals for sexual assault counseling.

Clinicians should be mindful of asking questions that might sound victim-blaming or judgmental, such as "why were you wearing that?" or "why didn't you report this to the police?" Instead encourage contact with a local rape crisis center and appropriate therapeutic and community services, even if an assault took place months or years ago. Supportive approaches such as these can be fundamental to the recovery and reintegration process for survivors of sexual assault.

Strategies providers can use to assess patients for sexual violence are discussed further at the end of this monograph.

Human Trafficking

Human trafficking is associated with significant physical and psychological harm including the risk for IPV.[43] The abuses suffered by people who are trafficked include many forms of physical violence or abuse (e.g., beating, burning, rape, confinement) as well as many psychologically damaging tactics such as threats to themselves or their family members, blackmail, extortion, lies about the person's rights, and confiscation of vital identity documents.[43]

Healthcare professionals are uniquely positioned to identify and intervene on behalf of trafficking victims. Outside of law enforcement, healthcare settings are among the few places where the lives of human trafficking victims may intersect with the rest of society, if only for brief periods.[44] In a study of 98 sex trafficking survivors, 88% had at least one encounter with a healthcare provider while they were being trafficked, with 63 percent of these encounters happening in an emergency department.[45]

Some patients meet criteria for human trafficking, even if they don't identify themselves as trafficking victims. Trafficked people, like IPV patients, often do not accurately perceive their status. They may view their situation, for example captivity, as a requirement for being brought into the country or an expectation they must obey. Adolescents are groomed by traffickers who may call themselves "boyfriends," "daddies," or romantic partners. Key tactics of manipulation and entrapment include seduction, gifts, and actions made to look like emotional support. Once the trafficker creates a romantic connection, the victim is coerced into engaging in commercial sex acts. Federal anti-trafficking laws exist and clinicians should be familiar with their general principles.[46]

Child-related Issues

Observing or hearing violence can be traumatic and damaging for children of all ages. Prolonged, severe, and repeated stress adversely affects brain development in young children. Witnessing violence affects children's abilities to focus and learn in school, form healthy peer relationships, and develop normally. Witnessing violence may exacerbate health problems such as asthma, eating disorders, or behavior problems such as bedwetting.

Many children exposed to IPV have a distorted view of the world, one that is not hopeful, welcoming, or safe. They have a foreshortened view of their lives, in which they cannot picture themselves as adults, or see a future for themselves. Adolescents who grew up in violent homes are more likely to be involved with substance abuse and dating violence.

Children who witness family violence are also at greater risk of being physically harmed themselves, especially if they attempt to defend or protect the abused individual during an assault.[48] An estimated 15.5 million children are exposed to IPV annually, and approximately 1 in 4 children are exposed to IPV before age 18.[49]

Children, like adults, may find it difficult to talk about the violence in their lives, and thus become "silent victims."[48] Clinicians need to attend to children's needs for safety and security as well as provide support and interventions for physical and mental health problems. Appropriate assessment and intervention can help children learn that violence perpetrated by anyone, especially by a family member or loved one, is wrong and unacceptable. Efforts such as these can serve as a crucial link to help children cope with, and recover from, the devastating effects of exposure to IPV.

Violence is, in part, a learned behavior. Although most abused and neglected children do not become victims or perpetrators as adults, research has shown that up to 75% of men in batterer intervention programs report witnessing the abuse of their mothers, or being physically abused themselves as children.[50] Girls who have been abused or neglected, or who have witnessed the abuse of their mothers, may be more likely to become victimized in their own adolescent or adult relationships. Abused and neglected children also are at greater risk for exhibiting delinquent, violent, and criminal behavior as well as long-term health problems.[51,52]

Disclosure of IPV may herald a particularly dangerous period for both survivors and children. Therefore, once disclosure is made, particular attention must be paid to the safety and well-being of the children and of others living in a home in which IPV is occurring. If a health care provider suspects physical, sexual, or emotional abuse or neglect of children, contact the Department of Children and Families' (DCF) Child Abuse and Neglect Careline (1-800-842-2288). Child Protective Services can then consult with specialists in IPV to take action to protect both the adult survivor and the child or children.

In addition, the clinician should communicate the decision to contact DCF, and the reasons for doing so, to the survivor. Such a conversation, although difficult to initiate, can help to establish trust and promote safety for both survivors and children.

Elder Abuse

Healthcare providers can be pivotal in the detection, management, and prevention of elder abuse. Understanding the dynamics of elder abuse is crucial to breaking the intergenerational cycle of this form of abuse. Approximately 1 in 10 Americans over the age of 60 have experienced some form of elder abuse. Elder abuse can include physical and sexual abuse, emotional abuse, confinement, passive neglect, willful deprivation, and financial exploitation.[1,53]

Abused or mistreated elders may only come to the attention of clinicians after having been abused for years or even decades. Some elderly individuals exhibit signs and symptoms of current or past domestic violence. Patients no longer in acute danger may nonetheless suffer long-term morbidity from past abuse. For independently living elders, fear of being placed in a nursing home and losing autonomy may limit disclosure of abuse.

Clinicians who care for elders often have established and trusting relationships with their patients. Clinicians and extended care providers who provide home care can observe behaviors and conditions that can lead to earlier intervention in at-risk patients. All healthcare professionals should remain mindful of their mandated reporter responsibilities as they evaluate elderly at-risk patients.

BEFORE MOVING ONTO THE NEXT SECTION, PLEASE COMPLETE CASE STUDY 3.

Case Study 3

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

Shanice is an 18-year-old female presenting for an annual exam. Her BMI is 35, and she is diabetic. She reports that she has not been taking the metformin prescribed last year because she lost it and couldn't afford to buy more. She has a history of alcohol and opioid abuse; she reports that her last opioid use was at a party the previous weekend.

Her exam today reveals that she is approximately 5 months pregnant. Shanice is devastated to hear this information; she already has a 2-year-old and doesn't want to be pregnant again. She has bruises on her upper left arm as well as discoloration and mild swelling on one side of her face. Upon inquiry, you discover she dropped out of school when her first child was born, recently lost her job, and lives with "a friend." When asked how she is supporting herself, she is evasive. When asked if she feels safe in her relationship, she says her baby's father caused her injuries, and she wants to move away from him to get away from the abuse, but she doesn't have any money.

1. **What should be included in a safety plan for Shanice?**_____

2. **What community resources could you refer Shanice to?**_____

Discussion: Shanice's safety plan should include a planned place to go, such as to stay with friends, family, or a shelter, as well as resources needed for daily living, including money, a photo identification card, car keys, a change of clothing for herself and her child, and items to care for her child such as diapers.

Shanice can be encouraged to call a local or national hotline, such as the National Domestic Violence Hotline at 1-800-799-SAFE. If possible, provide a private, safe space for her to call from the office. Information on local resources, such as shelter locations and local advocacy groups, can also be provided, though caution is advised when providing written materials. It would also be prudent to refer her to an obstetrician and a substance abuse specialist for further care.

The Legal Dimensions of IPV

A number of legal remedies are available to survivors of IPV. Clinicians should familiarize themselves with these options so that they can inform at-risk patients. Because state laws change over time, and vary from state to state, the following information is a general guide only. Legal statutes by state are available at Womenslaw.org (https://www.womenslaw.org/laws/statutes). Providers should obtain more detailed information from community domestic violence programs, their state medical board, or their state attorney's general regarding laws and policies in their jurisdictions. Health facilities' IPV referral lists should include resources for free legal services for economically disadvantaged patients, bar association referral services, legal advocacy services in intimate partner violence agencies and shelters, criminal justice advocacy programs, and immigration assistance organizations. The US Department of Health and Human Services offers detailed information and resources on the legal aspects of IPV (https://www.childwelfare.gov/topics/systewmwide/domviolence/overview/legislation-policies/).

Criminal Justice Relief

Many, but not all, abused patients are considered to be crime victims. Such crimes may include assault, battery, rape, stalking, threats, false imprisonment, destruction of property, weapon crimes, and specific "intimate partner violence" crimes. Legislation such as the National Violence Against Women Act has been passed to improve the criminal justice response to violence against women. Clinicians should inform at-risk patients that what occurred may be a crime and that they may consider calling the police. Whether calling the police will result in arrest, prosecution, and/or jail time will depend on prevailing laws and policies, as well as the attitudes and practices of the individuals handling the case. Some communities have created dedicated IPV units within police departments.

Clinicians should find out who the best police representative is to call in IPV situations in their community so that information can be made readily available for patients. The more informed the survivor is regarding legal rights when navigating the criminal justice system, the better off they will be.

Civil Protection Orders

The types of protection orders that are available to survivors vary from state to state and may include: restraining the abuser from further violence, requiring the abuser to vacate the household, ordering no contact with the victim, confiscation of firearms, withdrawal of child custody, requiring attendance in a batterer intervention program, and awarding the survivor compensation for medical bills and other expenses incurred as a result of the violence. Violation of a protection order is a felony in some states and may result in incarceration. Though police, prosecutors, and judges may not always respond adequately to protection order violations, such orders may reduce subsequent violence. Clinicians should inform their patients of the option and the process of obtaining a protection order, but respect their judgment about whether or not such an order will enhance safety. State-by-state information about civil protection orders (CPOs) is available at: *https://www.americanbar.org/content/dam/aba/administrative/domestic_violence1/Resources/charts/cpo2020.pdf*

Additional Legal Options

Additional legal options for IPV survivors include divorce, legal separation, annulment, and child and spousal support orders. Division of property or awards of financial support can be critical to enable the survivor and dependent children to live independently from the batterer. Abused immigrant women often face particular obstacles, as they may be relying on coercive partners to assist them in obtaining legal status. Abused immigrants who are married can apply for permanent status independent of an abusive partner, and documentation of the abuse from a physician can be extremely important in that process. Immigrant patients who are abused by partners should be referred to an IPV, domestic violence, or immigration advocacy program for assistance with such proceedings.

Legal and Regulatory Issues for Clinicians Related to IPV

Healthcare providers must comply with relevant requirements regarding the implementation of IPV protocols and educational programs. The Joint Commission on Accreditation of Healthcare Organizations' standards call for identification and assessment of abuse victims, appropriate documentation, intervention and referral, and staff education.[54] Some states have enacted laws mandating IPV protocol development or training for providers in practice (e.g. required continuing medical education credits) and in professional schools.

Mandatory Reporting

Most states require healthcare providers to file a report to a state criminal justice or public health agency when a patient has an injury that appears to be caused by a weapon. States may also mandate reporting of injuries due to criminal acts, acts of violence, or non-accidental acts. Since IPV injuries are sometimes caused by weapons and involve crimes, these laws may apply.

Some states have laws that specifically address reporting of suspected IPV. Laws vary from state to state regarding such factors as who must report, the degree of suspicion that triggers a report, to whom reports are made, penalties for failure to report, and immunity from liability for clinicians who make reports in good faith. A state may also have case law governing liability for failure to report abuse or for reporting when not required by law.

Unlike pediatric child abuse reporting, IPV-related reporting needs to occur in a collaborative fashion with the patient. Not doing so has potentially harmful consequences. Reporting without the patient's knowledge or consent—even when required by law—may put abused individuals at risk of retaliation from the batterer, and thus may deter survivors from seeking health care or being candid with their clinicians about the cause of their injuries.

Reporting without patient consent also infringes on patient autonomy and may further victimize an abused person. The abrogation of physician-patient confidentiality that may result from unrequested reporting may undermine the patient's trust in the physician and in the healthcare system as a whole.

While required to comply with all legal requirements, clinicians should strive to minimize the potential harms of laws that may place patients in danger. Most importantly, clinicians and their staff should provide ongoing, supportive care, address patient safety, and educate the patient about available options and community-based resources.

Treatment Options for Abusers

Although the focus of this learning activity, and of much of the medical, cultural, and sociological efforts over the past several decades, has been on the survivors of IPV, professional attention may also be necessary for the perpetrators of violence, their own problematic emotional conditions, and the need for interventions with abusers that may reduce future violence.[50]

Edward Gondolf summarized and published an evaluation of programs for perpetrators of domestic violence, as well as data from his own large national study.[50] The vast majority of offenders will not seek help voluntarily; most come into an intervention program only as the result of a court order. The second most frequent way that offenders enter a program is when their partner has "mandated" intervention, often by leaving with a condition that the partner enrolls in an intervention program before returning to the relationship. It is also important to realize that even once ordered, many offenders choose not to participate or will drop out before program completion. Monitoring by a probation office/agent or another official within the court system is needed to ensure that if the offender does not complete treatment, there will be additional legal sanctions.

Studies have shown that among men who complete treatment, a significant percentage are not reported to engage in violence during the following year. The percentage remaining nonviolent varies from 53% to 85%, with lower rates reported in studies based on survivor reports of violence.[50] Men who drop out of treatment are significantly more likely to continue to be violent than men who complete the treatment. Substance abusers are also more likely to continue to be violent, and substance abuse treatment may be needed in addition to offender intervention programs. In fact, research has shown that both treatment modalities are needed; substance abuse treatment alone will not end the violence, and abuser intervention alone will not address substance abuse problems.

In some clinical trials, the mean difference in violent acts has not been significantly different between those attending programs and those not, showing that although some offenders do indeed improve, others do not.

Additionally, some of the more dangerous abusers may not be appropriate candidates for offender intervention programs. It is also important to realize that research suggests that simply going to court and being monitored may account for a significant proportion of the deterrent effect.

Treatment is best offered in a community-based setting backed by the courts, in a program that is both certified and also long enough to be potentially successful. Many certified abuser intervention programs have treatment programs lasting up to 48 weeks. Other counseling programs may also be helpful for abusers who have PTSD from child abuse or from warfare, however, the therapist needs to know that there is violence in the relationship and be knowledgeable about IPV dynamics as well as PTSD treatment.

Recent evidence-based data reveals that perpetrator intervention best occurs within system change through a local coordinated community response– not exclusively on an individual level.[50] Couple counseling is generally contraindicated. There are a few programs specifically designed for low-level violence between couples that have been shown to be effective, but few communities have these models in place, and regular marital counseling can be dangerous for the survivor. Generally, the focus must be on ending the violence first, with any couples-focused work waiting until the survivor is no longer afraid of being attacked if they speak candidly about issues within the relationship. At each point, it is important that the offender and the survivor are assessed separately and treated separately, and that no couple's counseling occurs until the survivor requests it and there is no longer a danger of physical violence.

The delay between the offense and the start of treatment should be as minimal as possible to make sure that there are sanctions for noncompliance. Knowledge that an offender will either go to jail or go back to court and suffer a stiffer penalty can be an important motivator for change.

Steps should be taken to provide for the survivor's safety while the offender is going through court-ordered intervention. It is important that the survivor has realistic expectations and not assume false hopes. The abused individual needs to have a protection plan in place while the offender is going through treatment. Perpetrator intervention offers offenders a chance at rehabilitation, but it cannot work with those who do not attend or complete the program.

ASSESSING PATIENTS FOR SEXUAL VIOLENCE*

Sexual violence is a common experience in the lives of women and men[55]. People who have been sexually victimized are more likely to suffer from chronic physical and mental health problems than those who have not been victimized, and believe that their health is fair or poor[56]. Female survivors of sexual violence visit the doctor more often than women who have not been victimized[57].

Given the high rates of sexual violence and potential health impacts, it is therefore likely that most healthcare providers will come into contact with victims of sexual violence.

A variety of tools and guidelines have been created to address the need for screening patients for histories of sexual violence. This guide aims to build on those tools and encourage healthcare providers to conduct full assessments with patients to encourage interventions that provide adequate treatments and recommendations for survivors of sexual violence.

Assessing patients

While studies have shown that most female patients want to be asked about their experiences with sexual violence by their healthcare providers[58], few medical professionals screen any patients, female or male, for such trauma.[59] This may be due to a lack of training, time, or comfort on the part of the healthcare provider.[60] However, doctors' offices can be safe, confidential places to address sexual violence in which survivors can feel comfortable disclosing and confident in receiving the care and services they need.

Many prominent health organizations recommend that providers screen their patients for violence, including the American Medical Association, the World Health Organization, the American College of Obstetricians and Gynecologists, the American Academy of Pediatricians, and the American Nurses Association.[61]

Although most of the current research and recommendations regarding screening patients for sexual violence focuses on women, some programs have begun screening both male and female patients with promising results. The Veterans Health Administration recently implemented a universal screening program for male and female veterans, providing free care for patients experiencing conditions resulting from military sexual trauma.[62]

Screening patients is only one step in the process. A full assessment requires that healthcare providers also develop plans and protocols for what to do when a patient discloses incidents of sexual victimization.

Developing assessment protocols

Healthcare providers should develop protocols that ensure consistent, effective practices for providing care to patients that experience sexual violence. One promising tool that can aid providers in these efforts is the SAVE method, which was developed by the Florida Council Against Sexual Violence (2003).

- Screen all of your patients for sexual violence
- Ask direct questions in a non-judgmental way
- Validate your patient's response
- Evaluate, educate, and make referrals

How to discuss sexual violence

Normalize the Topic

I need to ask you some personal questions. Asking these questions can help me care for you better.

Since I am your doctor, we need to have a good partnership. I can better understand your health if you would answer some questions about your sexual history."

I ask all of my patients this question because it is important for me to know what has gone on in their lives.

Provide context to your questions

We know that sexual violence is common in the lives of many women, men, girls, and boys.

Connect sexual violence to the patient's physical health and well being

Sexual violence can affect a person's health.

Ask about sexual experiences that were unwanted or made the person feel uncomfortable

Have you ever been touched sexually against your will or without your consent?

Have you ever been forced or pressured to have sex?

Do you and your partner ever disagree about sexual things? Like what? How do you resolve these conflicts?

Do you feel that you have control over your sexual relationships and will be listened to if you say "no" to having sex?

(Pennsylvania Coalition Against Rape [PCAR], 2005)

Healthcare providers should avoid

- Asking patients about their victimization when other people are present
- Only asking patients who "seem" like victims about their experiences
- Using the term "rape," as some survivors may not label their experience as rape[64]
- Using formal, technical, or medical jargon[61]
- Only asking about specific types of violence or recent violence[63]
- Expressing value judgments

If a patient discloses sexual violence

Clearly describe to patients what your reporting requirements are and what information might be included in their medical records so that they can make informed decisions about what they disclose. Demonstrate through body language that you are listening to your patient's response. Respond with validating messages that allow the patient to feel heard and believed.

Some examples:

- "I'm really sorry that happened to you."
- "That sounds like it was a terrifying experience."
- "I'm really glad you had the courage to tell me."
- "I want you to know it wasn't your fault."

When documenting responses in a medical chart, use the patient's own words.

Evaluate the patient's needs

- Is the patient in current danger?
- If the assault happened recently, does the patient want a forensic exam to be performed?
- If the assault happened within the past 120 hours, and the patient is female, does the patient want emergency contraception?
- Does the patient need or want prophylaxes for HIV or other sexually transmitted infections?
- Does the patient have acute injuries that need medical attention?
- Do special accommodations need to be made to make the patient feel safe?
- Does the patient need to schedule a follow-up appointment?
- Does the patient wish to speak with a sexual assault advocate?

Provide education (verbally and in writing) about violence and health issues.

Make referrals

- The Rape, Abuse, and Incest National Network (RAINN) offers a hotline (1-800-656-HOPE) that refers victims to local rape crisis centers.
    - The NSVRC's Directory of Sexual Assault Centers in the United States contains contact information for sexual assault crisis centers and state, territory, and tribal coalitions in the United States and its territories. www.nsvrc.org or 877-739-3895.
    - Crime victim compensation programs are often able to provide financial support to victims of violence for medical expenses and other costs that arise as a result of the crime. A directory of these programs is available online at https://ovc.ojp.gov/directory-crime-victim-services.[65]

If the patient does not disclose sexual violence

Offer education and prevention information and provide follow-up at the next visit.

Collaborating with community partners

Collaborating with local sexual violence experts is key to successful assessment and support for victims. Each program in such collaborations can provide the others with referrals, professional in-services, training, public education/outreach, and specialized services. For example, state sexual violence coalitions and community-based sexual violence prevention and services centers can often provide publications to help healthcare providers educate patients about sexual violence. Collaborations can ensure that sexual violence assessments are effective while strengthening the community effort to identify and respond to victims of sexual violence.

Selected assessment instruments

The CDC has compiled a list of instruments that can be used to screen for sexual violence entitled Intimate Partner Violence and Sexual Violence Victimization Assessment Instruments for Use in Health care Settings.[66] Instruments outlined in this document include:

- Abuse Assessment Screen (AAS) - Five items that assess physical, sexual, and emotional abuse.
- Screening Tools-Sexual Assault - Five items that assess sexual assault and knowledge of risk reduction strategies.
- Sexual and Physical Abuse History Questionnaire - Six of the items in this scale assess sexual abuse.
- Two-Question Screening Tool - One of two items assesses sexual violence.
- Universal Violence Prevention Screening Protocol - Five items that assess recent physical, sexual, and emotional abuse.
- Victimization Assessment Tool - Five items that assess a variety of kinds of violence, including sexual violence.

*This material was reprinted, with permission, from the National Sexual Violence Resource Center's publication entitled Assessing patients for sexual violence: A guide for health care providers. This guide is available by visiting www.nsvrc.org

Conclusions

IPV is a relatively recent priority as a public health issue, and is driven by the insistence that IPV is wrong, unacceptable, and usually illegal. Clinicians can help communicate this message in the course of medical practice. When clinicians and their staff model competence and concern about IPV, patients can more effectively face these difficult issues, and lives can be saved.

Resources

Academy on Violence and Abuse
www.avahealth.org

CDC National Center for Injury Prevention and Control, Division of Violence Prevention
www.cdc.gov/ncipc/dvp/dvp.htm

Faith Trust Institute
www.faithtrustinstitute.org

Futures Without Violence
www.futureswithoutviolence.org

Health Professional Education, Advocacy and Linkage (HEAL) Trafficking
www.healtrafficking.org

National Center on Elder Abuse
https://ncea.acl.gov/
National Domestic Violence Hotline
https://www.thehotline.org/
800-799-SAFE (7233)
TTY 800-787-3224

National Coalition Against Domestic Violence
www.ncadv.org

National Health Collaborative on Violence and Abuse
www.nhcva.org

National Human Trafficking Hotline
https://humantraffickinghotline.org/
888-373-7888

National Network to End Domestic Violence
www.nnedv.org

National Resource Center on Domestic Violence
www.nrcdv.org

National Teen Domestic Violence Hotline
866-331-9474
TTY 866-331-8453
Text: loveis to 22522
www.loveisrespect.org

Nursing Network on Violence Against Women International
www.nnvawi.org

Partnership Against Domestic Violence
www.padv.org

Rape, Abuse and Incest National Network
www.rainn.org

U.S. Department of Justice, Office of Violence Against Women
www.justice.gov/ovw

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INTIMATE PARTNER VIOLENCE: COMPASSIONATE CARE, EFFECTIVE 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.

21. The term Intimate Partner Violence (IPV) is preferred to the term Domestic Violence, because:

A. IPV is recognized by the law and courts, whereas "Domestic Violence" is not.
B. IPV includes a wider spectrum of possible victims (e.g., gay, lesbian, transgender).
C. IPV covers more types of abuse than the term Domestic Violence.
D. IPV is more inclusive, since it does not imply co-habitation by the individuals involved.

22. When a partner rationalizes their abusive actions by blaming the partner and avoiding responsibility, which phase of the cycle of violence is occurring?

A. Abuse.
B. Guilt.
C. Excuses.
D. Honeymoon phase.

23. Which of the following DOES NOT represent a typical obstacle to leaving an abusive relationship?

A. The abuser controlling access to money, telephones, and car keys.
B. The survivor has a large, socially supportive community of local friends and family.
C. The survivor wants to believe the abuser's expressions of remorse and promises that it will end.
D. The survivor is from a culture where leaving a marriage is shameful.

24. Which of the following is an example of a single question shown to provide an accurate screening for IPV?

A. "Do you feel safe in your relationship?".
B. "Do you or your partner keep a firearm in the house?".
C. "Have you been a victim of intimate partner violence in the past?".
D. "Has your partner ever been arrested for a violent crime?".

25. "Hurt, Insult, Threaten, Scream" (HITS) is an example of _____.

A. Common types of IPV.
B. A screening tool for suspected IPV.
C. A support program for victims of IPV.
D. A mnemonic to help clinicians remember which questions to ask potential victims of IPV.

26. Which of the following clinical presentations may be more difficult to detect in a patient with darker skin?

A. Rapid, repeat pregnancies.
B. Visible signs of strangulation.
C. Anxiety.
D. Sexually transmitted infections.

27. When documenting potential IPV, all of the following should be included EXCEPT:

A. A detailed description of injuries detected.
B. The provider's opinion on whether injuries were adequately explained.
C. The provider's interpretation of the patient's description of an abusive event.
D. The date and time of the patient's appointment.

28. Which of the following words or phrases would be most appropriate when speaking with a survivor of IPV:

A. "Victim".
B. "Abused".
C. "Battered".
D. "Frightened".

29. Which of the following is NOT a principle of the trauma-informed care model?

A. Respect.
B. Taking control.
C. Rapport.
D. Fostering mutual learning.

30. Routinely asking about IPV can have which of the following benefits?

A. The patient will feel reluctant to discuss IPV with the provider.
B. The patient will be made aware that the clinician is concerned, knowledgeable, and able to respond should IPV become an issue at any time in the future.
C. The provider will utilize a significant amount of appointment time discussing IPV.
D. The patient will feel ashamed and embarrassed about IPV.

31. All of the following are guiding principles of intervention when addressing IPV with patients EXCEPT:

A. Survivor accountability.
B. Patient safety.
C. Survivor empowerment.
D. Advocacy for social change.

32. Which of the following would NOT typically be part of a safety plan for a patient who has experienced IPV?

A. Food stockpile.
B. Shelter.
C. Source of money.
D. Personal papers or documents.

33. IPV can be associated with all of the following EXCEPT:

A. Premature labor.
B. Decreased risk of maternal injury.
C. Antepartum hemorrhage.
D. Restricted access to contraception.

34. Most states require healthcare providers to file a report to a state criminal justice or public health agency when:

A. A patient has an injury that appears to be caused by a weapon.
B. A provider suspects IPV.
C. A patient refuses to be treated for an injury.
D. A patient discloses that they feel unsafe in their home.

35. When a patient discloses sexual violence, which of the following is a validating message that can allow a patient to feel heard and believed?

A. "Do you think this could be your fault?"
B. "That sounds like it was a terrifying experience."
C. "Rape can be difficult for victims to recover from"
D. "Do you feel that your vulvovaginal candidiasis could have been caused by the rape?"

LEARNER RECORDS: SAMPLE

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JOHN	F	DOE

Mailing Address: 123 CHERRY STREET

Suite / Floor / Apt. Number	City (do not abbreviate)	State
456	TALLAHASSEE	FL

Zip Code	Telephone Number	Florida Medical License#
32399	919-456-7890	ME123456

E-mail address (Include to receive processing confirmation and instant certificate access): JOHNDOE@EMAIL.COM

Required Information for MOC Reporting (if desired)

Specialty Board	ID Number	License Type	Date of Birth (mm/dd/yyyy)
ABIM	123456	MD	12/21/1980
(ABA, ABIM, ABO, ABOHNS, ABPath, ABP)		(MD, DO, PA, etc.)	

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Medical Doctors (MD):
"ME" followed by 4-6 numbers
(Ex: ME25228)

Osteopathic Physician (DO):
"OS" followed by 4-5 numbers
(Ex: OS12345)

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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Learner Records: Answer Sheet and Payment Information

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E-mail address (Include to receive processing confirmation and instant certificate access)

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Specialty Board (ABA, ABIM, ABO, ABOHNS, ABPath, ABP) | ID Number | License Type (MD, DO, PA, etc.) | Date of Birth (mm/dd/yyyy)

Payment Method

☐ Check / M.O. Enclosed ☐ Credit Card

☐ Entire Program $50.00 ☐ Courses 1 & 2 $40.00

Visa / Mastercard / AMEX / Discover Number | Credit Card Expiration Date | Security Code

Cardholder Signature: _____

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	○	○	○	○

Medical Errors and the United States Healthcare System

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

Intimate Partner Violence: Compassionate Care, Effective Assessment

	A	B	C	D
21	○	○	○	○
22	○	○	○	○
23	○	○	○	○
24	○	○	○	○
25	○	○	○	○
26	○	○	○	○
27	○	○	○	○
28	○	○	○	○
29	○	○	○	○
30	○	○	○	○

	A	B	C	D
31	○	○	○	○
32	○	○	○	○
33	○	○	○	○
34	○	○	○	○
35	○	○	○	○

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FL24CME

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Book expires: 9/30/2024 Program: FL24CME Courses 1 & 2: FL24CME-40 Course 1: FL24CME-201 Course 2: FL24CME-202 Course 3: FL24CME-203

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 - MEDICAL ERRORS AND THE UNITED STATES HEALTHCARE SYSTEM:

		A	B	C	D
5.	Conduct appropriate root cause analysis of medical errors	○	○	○	○
6.	Utilize strategies for the prevention and reduction of medical errors.	○	○	○	○

7. Please identify a specific change, if any, you will make in your practice related to reducing medical errors._____

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

COURSE 3 - INTIMATE PARTNER VIOLENCE: COMPASSIONATE CARE, EFFECTIVE ASSESSMENT:

		A	B	C	D
9.	Identify the barriers that prevent effective and compassionate care of potential survivors of IPV between patient and physicians.	○	○	○	○
10.	Utilize patient interviewing techniques in situations where IPV is suspected	○	○	○	○

11. Please identify a specific change, if any, you will make in your practice related to intimate partner violence._____

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

OVERALL PROGRAM:

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

15. How can this program be improved? _____

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

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

○ Course 1 ○ Course 2 ○ Course 3 ○ None

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- **BOOK CODES:** You may notice a book code on the back cover of the latest InforMed program you've received in the mail. When entered on our new site, this code will take you directly to the corresponding self-assessment. See more information below.

Need to complete the DEA's new requirement under the Medication Access and Training Expansion (MATE) Act?

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Get the training you need in a self-paced, convenient format with a course specifically designed for physicians to meet the Drug Enforcement Administration (DEA)'s new requirement under the Medication Access and Training Expansion (MATE) Act.

How to complete

Please read these instructions before proceeding.

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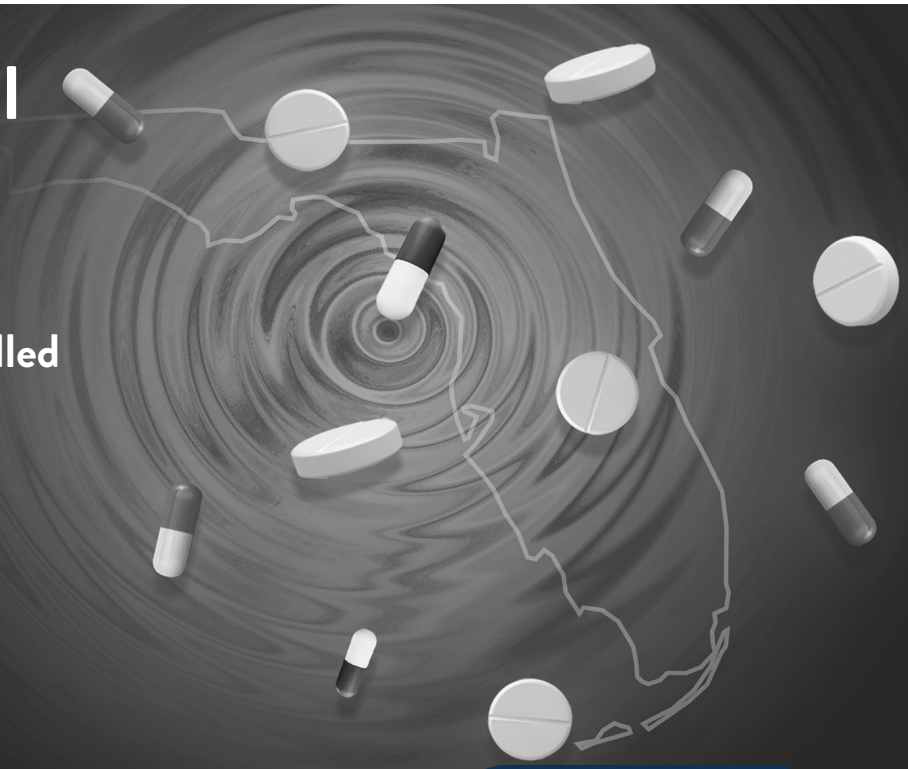

- **2 HOURS**
  BOARD-APPROVED Controlled Substances/Opioids*
- **2 HOURS**
  Medical Errors*
- **2 HOURS**
  Intimate Partner Violence*

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***Mandatory CME Requirements:**

2 Hours on Board-Approved Controlled Substances/Opioids, Medical Errors, and Intimate Partner Violence

Need to complete the ***DEA's new one-time MATE requirement?*** See page i for more details.

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