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Clinicians' Guide to Management of Opioid Therapy

FACULTY

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Clinicians' Guide to Management of Opioid Therapy

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1. OVERVIEW

IMPACT OF PAIN

PREVALENCE OF PAIN

- Pain is more frequently reported among adults in the United States than other common conditions **(Table 1)**[1]
- The findings from a National Center for Health Statistics survey show that 42% of adults ≥20 years and 57% of adults ≥65 years reported pain >1 year duration[2]

PAIN'S EFFECT ON PATIENTS

- Chronic pain has corollary effects, including sleep disturbances and depression **(Table 2)**[3]
- Pain, particularly chronic pain, also has an economic impact
  - 52.7% of workers reported having pain over the previous 2 weeks and 12.7% lost productive time during a 2-week period[1]
  - Among adults, 23% of ER visits result in prescription of an opioid analgesic, an indirect measure of the economic burden of pain[2]
  - Pain contributes to an estimated $61.2 billion of lost productive time/year[1]

Table 1

INCIDENCE OF PAIN COMPARED TO MAJOR CONDITIONS

Condition	Number (Millions)
Chronic pain	76.2
Diabetes	20.8
Coronary heart disease and stroke	18.7
Cancer	1.4

Source: American Academy of Pain Management.[1]

Table 2

IMPACT ON QUALITY OF LIFE

Patients with chronic pain reported the following due to their pain:	Percent (%)
Poor sleep	86
Feeling depressed	77
Lower energy level	74
Difficulty with concentration	70
Diminished overall enjoyment of life	59

Source: American Academy of Pain Management.[1]

ASSESSING AND DIAGNOSING PAIN

DIFFERENT TYPES OF PAIN

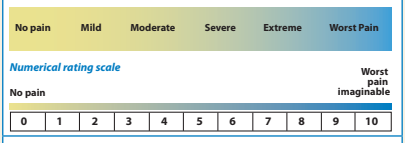
- Pain can be broadly categorized as acute or chronic, based on duration
  - Acute pain is a normal response to injury (ie, surgical incision) or warning of potential injury, which resolves when the stimulus is removed or injury heals[1]
  - Chronic pain persists and may last for months or years, either following an injury, as the result of ongoing illness (ie, arthritis, cancer), or in the absence of any direct stimulus[1]
- Pain types may also include *nociceptive*, *neuropathic*, or *mixed*
  - Nociceptive pain results from direct stimulation of pain receptors (nociceptors) due to tissue injury, trauma, or inflammation and is usually relieved by correction of the underlying condition[4]
  - Neuropathic pain results from abnormal structure or function of the nervous system. Symptoms may include increased sensitivity to painful stimuli (hyperalgesia), pain in response to stimuli not usually painful (allodynia), pain in an area of diminished sensation, and pain in the absence of painful stimuli[5]
  - Mixed pain has elements of both nociceptive and neuropathic pain[4,5]

COMMON PAIN ASSESSMENT TOOLS

- Pain is a subjective experience with individual variations and is best assessed verbally[5]
- Pain scales are a useful tool for assessing pain intensity[4] **(Figure 1)**
- Having a variety of scales on hand allows patients to use the one they are most comfortable with for quantifying their pain[4]
- Remember: The inability to communicate verbally does not eliminate the possibility that patients are experiencing pain and are in need of analgesia[5]
  - Behavioral scales may help guide analgesic use in this population

Figure 1

PAIN RATING SCALES*



*This is not an all-inclusive list of available pain scales.

Source: Williamson.[6]

PATIENT INTERVIEW AND EVALUATION

- All patients presenting with pain should be appropriately evaluated to determine the source of their pain. Evaluation should include the following:
  - Pertinent patient history and physical examination[4,7]
  - Potential causes of pain and/or exacerbating factors[4]
  - Comorbid physical and mental illness, including a personal or family history of substance abuse or recreational drug use[7]
  - Prescription, nonprescription, and herbal medication history, including current and previous response to analgesics[4]
  - Assessment and documentation of nonopioid therapy failure prior to initiating opioids[7]
- Consider potential barriers that may affect the patient's pain assessment or treatment adherence[4]

BARRIERS TO OPTIMAL PAIN MANAGEMENT

Providers	Patients	Healthcare System
• Concern over medication risks • Lack of assessment skills • Limited knowledge of treatment options • Cultural or social barriers	• Cognitive or communication issues • Fear of side effects, medication effects on clear thinking • Cultural or social barriers	• Limited specialist or treatment access • Formulary limitations • Inventory systems restrictions

Source: American Medical Directors Association.[4]

- A substance-abuse risk assessment should be completed when considering long-term opioid therapy, using tools such as the[7]
  - Opioid Risk Tool, *or*
  - Screener and Opioid Assessment for Patients with Pain (version 1 and revised)

REFERENCES: *See Reference Card*

2. TREATING PAIN

PAIN MANAGEMENT GOALS

The goal of pain management should be mutually developed with the patient to address the patient's "total" pain.[1] In addition to pain reduction, management goals should include:

- Addressing the fluctuating nature of pain: chronic pain is not usually steady but rather waxes and wanes[1]
- Improving the patient's physical, social, and psychological functional status[1]
- Improving the patient's quality of life[1]
- Educating the patient about their condition, treatment, and needed lifestyle modifications[2]

TREATMENT OPTIONS

NONPHARMACOLOGIC THERAPIES

Since pain is multifactorial in nature, patients may benefit from adjunct nonpharmacologic therapies.

NONPHARMACOLOGIC PAIN MANAGEMENT THERAPIES

Passive Therapies	Active Self-Management Interventions	Passive ± Active Therapies
• Acupuncture • Nerve blocks or trigger-point injections • Percutaneous electrical nerve stimulation • Massage • Therapeutic touch	• Exercise • Sleep hygiene • Relaxation response exercises • Cognitive restructuring	• TENS • Biofeedback • Physical or occupational therapy • Superficial heat or cold application

TENS = Transcutaneous electrical nerve stimulation.
Source: Wells-Federman.[3]

PHARMACOLOGIC THERAPIES

- Mild-to-moderate pain may be managed with nonopioid analgesics[4]
- Opioids are appropriate for moderate-to-severe pain or persistent mild-to-moderate pain[4,5]

FORMULATIONS OF OPIOID ANALGESICS*

Short-Acting Agents: Generic (Trade)

- Codeine/Acetaminophen (Tylenol® with Codeine)
- Hydrocodone/Acetaminophen (Lortab®, Vicodin®)
- Hydrocodone/Ibuprofen (Vicoprofen®)
- Oxycodone HCl/Aspirin (Percodan®)
- Oxycodone HCl/Acetaminophen (Percocet®)
- Tapentadol (Nucynta®)
- Morphine, immediate release (MSIR®)
- Oxycodone HCl, immediate release (OxyIR®)
- Hydromorphone (Dilaudid®)
- Oxymorphone, immediate release (Opana®)
- Fentanyl
  - Oral transmucosal (Actiq®)
  - Buccal soluble film (Onsolis®)

*This list is not an all-inclusive list. Registered trademarks are the property of their respective owners.
Source: Lacy.[6]

FORMULATIONS OF OPIOID ANALGESICS*

Long-Acting Agents: Generic (Trade)

- Fentanyl: transdermal (Duragesic®)
- Hydromorphone, extended-release (Exalgo™)
- Morphine sulfate, sustained release (Avinza®, KADIAN®, MS Contin®, Oramorph® SR)
- Morphine sulfate, sustained release/ naltrexone HCl (EMBEDA™)
- Oxymorphone, extended release (Opana® ER)
- Oxycodone, sustained release (OxyContin®)

*This list is not an all-inclusive list. Registered trademarks and trademarks are the property of their respective owners.

Source: Lacy.[6]

INITIATION, TITRATION, AND DISCONTINUATION OF OPIOID ANALGESICS

- In pain management, the analgesic chosen for initial therapy might need to be changed for chronic therapy[7]
- Four general principles can be used to guide initiation and titration of opioids[1]:
  - Establish the pain-relief goal (eg, 30% reduction on Numeric Pain Scale)
  - When initiating opioids, choose an appropriate dose of a short-acting opioid
  - Frequently monitor for improvement and adverse opioid effects
  - Select a titration schedule based on the drug's pharmacological properties
- Regularly reassess if opioid can be discontinued: if the pain has stabilized or resolved, consider slowly tapering the dose while monitoring for withdrawal symptoms[8]

SPECIAL CONSIDERATIONS

- In opioid-naive patients, carefully titrate low-dose, short-acting agents to individualize treatment; long-acting agents may be added if appropriate[8]
- Consider opioid rotation (or switching) if patients experience intolerable adverse events or inadequate analgesia despite increasing doses[8]
- Tapering a patient from opioids is recommended when intolerable side effects are present or opioid trial failed to relieve pain[8]
  - In cases of diversion, prescribing should be discontinued[8]
- For breakthrough pain (period of increased pain despite stable, around-the-clock opioid doses), consider using as-needed short-acting opioids (10% of daily opioid dose)[5,8]
- Long-acting opioids provide consistent analgesia and allow for less frequent dosing, which may help with adherence but may require more monitoring[7]
- Opioid-related adverse events should be anticipated, identified, and treated[8]
  - Hormonal deficiency may occur with chronic opioid therapy; evaluate if symptoms are present (eg, fatigue)[8]
- Adhere to the federal prescribing requirements for controlled substances, below[9]:
  - Date of issue
  - Patient's name and address
  - Practitioner's name, address, and DEA registration number
  - Drug name, strength
  - Dosage form
  - Quantity prescribed
  - Directions for use
  - Refills (if any) authorized
  - Prescriber signature

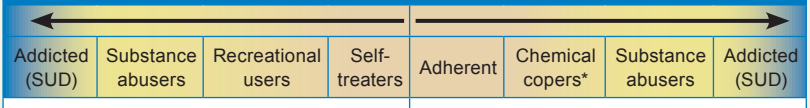
REFERENCES: *See Reference Card*

3. ABUSE AND DIVERSION

INTRODUCTION

- Patients managed on chronic opioid therapy may exhibit different types of behaviors, ranging from adherence to intentional abuse, regardless of legitimate medical reasons

SPECTRUM OF OPIOID USERS



*Patients who rely on the drug for psychological stability; similar to psychological dependence.
SUD = Substance use disorder.
Source: Passik.[1]

- Consequently, healthcare providers managing patients in pain, with opioids, must balance adequate pain relief with the need to avoid potential addiction
- The following list of common terms is useful in understanding patient behavior with regard to opioid use

TERMS DESCRIBING OPIOID USE

Aberrant drug-related behavior	• Behavior outside the boundaries of the agreed-upon treatment plan
Abuse	• Use of a drug with the intentional self-administration of a medication for nonmedical purpose, such as altering one's state of consciousness (eg, getting high)
Addiction (psychological dependence)	• Primary, chronic, neurobiologic disease influenced by genetic, psychosocial, and environmental factors • Characterized by one or more of the following behaviors: impaired control over drug use, compulsive use, continued use despite harm, and craving
Diversion	• Intentional transfer of medication from legitimate distribution and dispensing channels
Misuse	• Incorrect use of a medication (for a medical purpose) other than as directed or as indicated whether harm results or not; may be willful or unintentional
Pseudoaddiction	• Drug seeking and other behavior consistent with addiction driven by inadequate pharmacotherapy • Inappropriate behavior resolves when pain is adequately treated
Physical dependence	• Adaptive state manifested by a withdrawal syndrome caused by: – Abrupt cessation – Antagonist administration – Decreasing drug-blood levels of the drug – Rapid dose reduction
Pseudotolerance	• Need to increase pain medication (eg, opioids) when other factors are present (eg, new disease or progression, increased physical activity, noncompliance, medication change or interaction, addiction, and/or deviant behavior)
Tolerance	• Adaptive state where continued drug exposure results in decreased effect of the drug over time

Sources: Chou[2]; Heit[3]; Katz[4]; AAPM, APS, ASAM.[5]

IDENTIFY RISK FACTORS FOR DRUG ABUSE

■ Clinicians should be aware of risk factors for misuse, abuse, and addiction[1]

PATIENT RISK FACTORS FOR ADDICTION OR MISUSE
• Past or present patient history of substance abuse, misuse, or addiction
• Family history of substance abuse or addiction
• Young age
• Presence of psychiatric conditions
• Smoking history
Sources: Passik[1]; Chou.[2]

SCREENING AND MONITORING TOOLS

Screening tools based on patient characteristics may be helpful for risk stratification and to aid in patient assessment. Examples of tools providing good patient assessments and validity include:[2]

■ **Opioid Risk Tool (ORT)**
- – A 5-item yes/no questionnaire with gender-specific scoring
- – Scores ≥8 are considered high risk

■ **Current Opioid Misuse Measure (COMM)**
- – Quick and simple patient self-assessment to identify patients exhibiting aberrant behavior
- – Useful for monitoring patients currently on long-term opioid therapy

■ More examples are published in the APS/AAPM guidelines

MONITORING FOR PATIENT DRUG ABUSE AND DIVERSION

■ For patients on continued opioid therapy, regular monitoring (ie, every 3 months) can identify drug-related aberrant behaviors[1]

■ Look for yellow flags and red flags, which may indicate patient abuse or diversion

POTENTIAL SIGNS OF ABUSE	
Yellow flags: behavior less suggestive of addiction	**Red flags: behavior more suggestive of addiction**
• Complaints about need for more medication	• Illegal activities – selling, forging, buying from nonmedical sources
• Drug hoarding	• Injecting or snorting oral medication
• Requesting specific pain medications	• Multiple episodes of “lost” or “stolen” prescriptions
• Openly acquiring similar medications from other providers	• Resistance to change therapy despite adverse effects
• Occasional unsanctioned dose escalation	• Refusal to comply with random drug screens
• Nonadherence to other pain therapy recommendations	• Concurrent abuse of alcohol or illicit drugs
	• Use of multiple providers and pharmacies
Source: Alford.[6]	

REFERENCES: *See Reference Card*

4. DETERRING ABUSE

CURRENT METHODS OF MINIMIZING ABUSE

Numerous efforts are in place to deter abuse, many of which are described below.

WRITTEN OPIOID AGREEMENTS

- Effective tools for safe treatment of chronic pain[1]
- Establish a bond of trust between providers and patients[1]
- Include exclusivity clauses (ie, 1 provider, 1 medication at 1 dose, fillable only at 1 pharmacy)[1]

RECOMMENDED OPIOID AGREEMENT CRITERIA

- Goals of therapy
- Single prescriber (if possible)
- Informed consent on all opioid analgesic risks
- Definitions (addiction, tolerance, physical dependence)
- Patient disclosure of substance abuse history, psychiatric history (eg, history of sexual, physical, or verbal abuse), and current medications
- Need for complete, honest self-report of pain relief, side effects, and function at each healthcare visit
- Establish regular healthcare visits
- Require prescription renewal only during regular office hours
- Conditions of noncompliance (eg, evidence of drug hoarding or use of any illegal drug may terminate agreement)
- Use of the word *may* instead of *will* in the agreement (use clinical judgment on a per-patient basis)
- Based on patient risk assessment: consider random drug screenings (ie, urine drug tests) for certain patients
- Permission for the practice to contact appropriate sources to obtain or provide information about the patient's care or actions (based on patient-provided information)
- Recovery program for patients with a confirmed diagnosis of a substance abuse disorder (patients must agree to concurrent assessment and treatment of their substance-use disorder)

Source: Heit.[2]

PRESCRIPTION-WRITING CONTROL

- Require original prescriptions with each refill or use of limited prescription quantities[3,4]

EXPANDING THE TEAM

- For high-risk patients, guidelines recommend including addiction or mental health professionals as part of the treatment team[4]

VARIOUS OPIOID FORMULATIONS

Changes in product formulations decrease the product's attractiveness for abuse. Physical and pharmacological approaches to this challenge include:

- Tamper-resistant capsules and tablets[5,6]
  - Formulation uses physical barriers (eg, crush-proof capsules) to prevent abuse by unintended routes (ie, snorting)
  - It does not prevent abuse by those who ingest intact tablets or capsules

- Long-acting formulations[7]
  - Sustained-release, controlled-release, and extended-release mechanisms, for use in the management of chronic pain conditions, allow for less frequent dosing but still require routine monitoring
  - Long-acting opioids can be misused or abused by manipulating the dosage form (ie, crushing, snorting)
- Agonists-antagonists formulations[5]
  - Reduce opioid "reward" at the receptor level when drug is taken in unintended manner

PREVENTING OPIOID ABUSE

- Steps to minimize abuse risk begin with a comprehensive screening and appropriate patient selection[5]
- Counsel patients on appropriate opioid use and develop a medication-use agreement that specifies[4]
  - Patient and provider responsibilities
  - Expected follow-up intervals, *and*
  - Prescribed dosing
- Monitor patients at prespecified intervals (ie, 3 to 6 months; more frequently when initiating therapy and for high-risk patients) and review goals of therapy[4]
  - Assess progress toward therapeutic goals[8]
  - Assess and document pain severity and functional ability[8]
  - Determine presence of adverse effects[8]
  - Determine presence of aberrant drug-related behaviors[8]
- Clinical assessments for aberrant drug-related behaviors are appropriate for all patients on long-term opioid therapy and may include (but are not limited to)[4]:
  - Pill counts
  - Urine screenings, *and*
  - Family/partner interviews
- Modify monitoring schedules based on changes in patient behavior[5]
- Consider treating continuous pain with long-acting analgesics[9]
  - Reserve short-acting agents for acute pain or breakthrough pain, based on patient's condition
- Summary of risk management strategies is listed below

RISK MANAGEMENT FOR PATIENTS TREATED WITH OPIOIDS
• Complete screening and risk stratification prior to therapy initiation
• Compliance monitoring (eg, urine screening, pill counts)
• Education about drug storage and sharing
• Psychotherapy and highly structured approaches
• Documentation of all aspects of patient care
Source: Passik.[5]

REFERENCES: *See Reference Card*

5. FOR THE PATIENT

COMMON QUESTIONS ABOUT OPIOID ANALGESICS

WHAT ARE OPIOID ANALGESICS?

Opioids are strong pain medicines used to relieve pain. Vicodin®, Percocet®, Dilaudid®, and OxyContin® are examples.[1]

WHEN ARE OPIOID ANALGESICS USED?

Opioid analgesics are used to relieve moderate-to-severe pain for a short amount of time (eg, after surgery or injury) ***or*** long periods of time to help manage certain conditions (eg, cancer pain).[2,3]

Depending on the amount and intensity of pain, a nonopioid pain medication (eg, ibuprofen) may be used with or without an opioid.

WHAT ARE THE COMMON SIDE EFFECTS OF OPIOID ANALGESICS?

Common side effects, such as nausea, vomiting, itchiness (pruritus) and drowsiness, tend to resolve or decrease over time. Opioids may also slow breathing when starting therapy but it usually resolves. Constipation is a predictable and treatable side effect of opioid treatment.[4,5]

SHOULD I WORRY ABOUT ADDICTION WITH OPIOID ANALGESICS?

Some patients may be concerned about taking opioids because they are afraid of addiction. However, using opioids properly–meaning exactly as prescribed–and following up with the healthcare professional regularly can decrease the likelihood of addiction.[1]

CAN OVER-THE-COUNTER PAIN RELIEVERS (EG, ASPIRIN, TYLENOL®, ADVIL®) BE TAKEN WITH OPIOID ANALGESICS?

Some opioid products (eg, Percocet®, Vicodin®) already contain over-the-counter (OTC) medicines such as acetaminophen (Tylenol®); taking more than the recommended dose of OTC medicine can lead to accidental overdose or side effects. For example, taking more than 4000 mg of acetaminophen daily may cause liver damage or liver failure. **Always check with your healthcare professional before taking OTC pain relievers with an opioid.**[5]

TIPS FOR SAFE OPIOID USE

- Do not combine opioids with drugs, including alcohol, that can make you feel sleepy or tired[1]
- Consult with your healthcare professional before stopping or changing the dose of your opioid therapy. Abruptly stopping opioids may cause unpleasant withdrawal symptoms[1]
- Store your medication in a locked or secured cabinet in your home to prevent theft or wrongful use[4]
- Avoid driving or performing other complex tasks, especially when starting therapy or changing your dose, because opioid analgesics may cause drowsiness, impair concentration, or slow your reflexes[4]
- Never flush unused medication down the toilet or drain unless special instructions are provided. Never dispose of unused or intact medication in its original container. If a drug take-back program is not available, dispose of your medication with these steps[6]:
  - Remove any identifying personal and drug information

– Mix the drug with an undesirable substance (eg, used cat litter, coffee grounds) and dispose of it in a disposable sealed container (eg, Ziploc bag)

■ Never share your medication with others or take medication that has been prescribed for someone else

PATIENT RESOURCES FOR FURTHER INFORMATION

CHRONIC PAIN RESOURCES

painACTION

Patients can gain insight and get information about managing their pain as well as medication safety tips. Online tools to track pain are also available.
Web site: www.painaction.com

American Chronic Pain Association

Offers information about chronic pain, including coping with pain and helpful resources for patients in pain and their families. The Web site can be viewed in 12 languages.
Web site: www.theacpa.org

American Pain Foundation

Provides a library of resources to help educate patients and clinicians on pain-related health-system issues, get involved in pain advocacy groups, and more.
Web site: www.painfoundation.org

American Pain Society

Lists Web sites for many organizations and associations that focus on different types of pain, such as arthritis, headache, and cancer-related pain, among others.
Web site: www.ampainsoc.org/people

The Neuropathy Association

Established by people with neuropathy, this non-profit organization strives to promote public awareness, provide education, resources, and support for patients with neuropathic pain.
Web site: www.neuropathy.org

American Cancer Society

A useful resource for patients and family members to obtain resources and information about cancer-related pain.
Web site: www.cancer.org

PAIN MEDICATION ABUSE AND ADDICTION RESOURCES

Above the Influence

A Web site dedicated to telling adolescents the facts about drugs, their effects on the entire body, and addiction.
Web site: www.abovetheinfluence.com

Center for Substance Abuse Treatment

As part of the Substance Abuse and Mental Health Services Administration, this organization promotes community-based substance abuse treatment services for individuals and families who need them.
Phone: (800) 662-HELP (4357)
Web site: http://csat.samhsa.gov

National Alcohol Substance Abuse Information Center

An information center is available to help find local treatment or rehabilitation programs. Hotline is available 24 hours, 7 days a week to answer any drug addiction questions.
Phone: (800)-784-6776 (US)
Web site: www.addictioncareoptions.com

COMPLIMENTARY AND ALTERNATIVE MEDICINE FOR PAIN

National Center for Complimentary and Alternative Medicine [NCCAM]

Includes helpful resources to find practitioners of complimentary and alternative medicine, as well as information about complimentary and alternative medicine research.
Web site: www.nccam.nih.gov

REFERENCES: *See Reference Card*

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