

Pain Management and Opioids: Balancing Risks and Benefits

PRESENTED BY




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FACULTY INFORMATION



Rebecca Loveless, MHS, PA-C, DFAAPA graduated from the Quinnipiac University PA Program in 2000. She has practiced in orthopedics, emergency medicine, CT Surgery, ICU and hospitalist medicine. She is currently working for Vituity as a hospitalist and Washington University School of Medicine in a local St. Louis, MO ED.


Ms. Loveless has spent numerous hours lecturing to health care workers and law enforcement officials about responsible controlled substance prescribing, as well as the drug abuse epidemic that has taken over our country. She currently serves on the board of the Missouri Academy of PAs and is their Chief HOD Delegate.

In her free time, she spends time being a mom to her boys, Zeke and Keagan, and puppies, Skye and Maya.



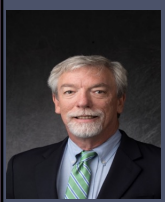
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DISCLOSURE:
No relevant relationships with ineligible companies to disclose within the past 24 months



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FACULTY INFORMATION



Dennis Rivenburgh, MS, ATC, PA-C, DFAAPA has been practicing as a PA since 1997 when he graduated from the George Washington University PA Program. He is currently working as a PA in Sports Medicine at Johns Hopkins University Department of Orthopaedics.


Prior to that he served as the Program Director of the Anne Arundel Community College/University of Maryland Baltimore Collaborative PA Program. In addition, he has worked as a PA in Sports Concussion, Primary Care/Sports Medicine, Emergency Medicine and Orthopaedic Sports Medicine.

Dennis has been a preceptor and clinical instructor throughout his career. He is also a certified athletic trainer. Dennis was the former chair of the AAPA Governance Commission. He currently is a member and served as former Chair of the AAPA Judicial Affairs Commission.



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ACKNOWLEDGMENTS

Presented by **AAPA**, a member of the CO*RE Collaborative, nine interdisciplinary organizations working together to improve pain management and prevent adverse outcomes.

This activity is supported by an independent educational grant from the Opioid Analgesics REMS Program Companies (RPC). Please see https://www.opioidanalgesicrems.com/Resources/Docs/List_of_RPC_Companies.pdf for a listing of REMS Program Companies. This activity is intended to be fully compliant with the Opioid Analgesic REMS education requirements issued by the U.S. Food and Drug Administration.

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THE CO*RE COLLABORATIVE











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BY THE END OF THIS SESSION YOU WILL BE ABLE TO:

- Describe the pathophysiology of pain as it relates to the concepts of pain management
- Accurately assess patients in pain
- Develop a safe and effective pain treatment plan
- Identify evidence-based non-opioid options for the treatment of pain
- Identify the risks and benefits of opioid therapy
- Manage ongoing opioid therapy
- Recognize behaviors that may be associated with opioid use disorder



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WHY ARE WE HERE?

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CO*RE STATEMENT

Historical over-prescribing, a massive and sustained exposure to opioids, and a gap in treatment availability have fueled the opioid overdose epidemic in the United States.

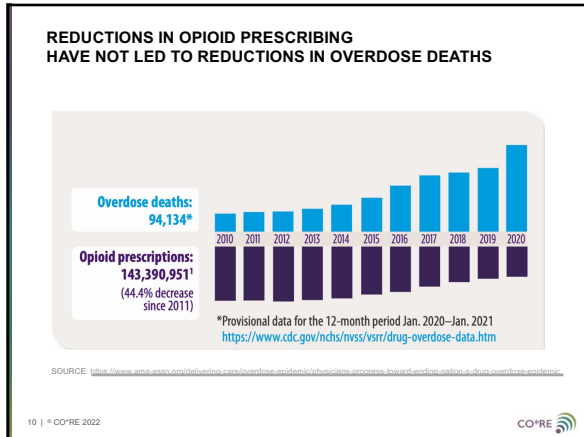
When prescribed well, and used as prescribed, opioids can be valuable tools for effective pain management.

Unintended consequences may occur from both under-prescribing (unmanaged pain) and over-prescribing (injudicious use of opioids).

This course does not advocate for or against the use of opioids. We intend to help health-care providers manage pain without putting vulnerable patients at risk for misuse or opioid use disorder. The goal is to keep our patients, our communities, and ourselves SAFE.

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TYPES OF OPIOIDS

NATURALLY OCCURRING OPIATES	SEMI-SYNTHETIC OPIOIDS	SYNTHETIC OPIOIDS
Codeine Morphine	Buprenorphine Hydrocodone Hydromorphone Oxycodone Oxymorphone	Alfentanil Fentanyl Methadone Remifentanil Tapentadol Tramadol
AGONISTS	PARTIAL AGONISTS	ANTAGONISTS
Codeine Methadone Morphine Oxycodone	Buprenorphine Nalbuphine	Naloxone Naltrexone

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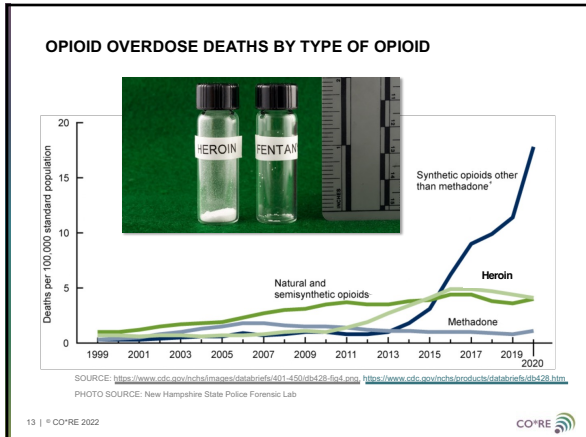
DEA SCHEDULED DRUGS

SCHEDULE	DESCRIPTION	EXAMPLES
I	High potential for abuse; no currently accepted medical use	Cannabis, ecstasy, heroin, LSD, peyote
II	High potential for abuse, which may lead to severe psychological or physical dependence	Codeine, fentanyl, hydrocodone combination products, hydromorphone, meperidine, methadone, morphine, opium, oxycodone,
III	Potential for abuse, which may lead to moderate or low physical dependence or high psychological dependence	Products containing ≤ 90 mg codeine per dose, buprenorphine, benzphetamine, phendimetrazine, ketamine, anabolic steroids
IV	"Low potential" for abuse	Alprazolam, carisoprodol, clonazepam, clorazepate, diazepam, lorazepam, midazolam, temazepam, tramadol
V	Low potential for abuse	Cough preparations containing ≤ 200 mg codeine/100 ml

Complete list of products covered under the Opioid Analgesic REMS available at: <https://www.opioidanalgesicrems.com/products.html>

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FENTANYL AND FENTANYL ANALOGUES

ON THE PLUS SIDE:

- Short-acting and easily metabolized
- Useful for controlling acute pain

ON THE MINUS SIDE:

- Cheap and easy to manufacture
- Easy to store, easy to smoke, easy to conceal
- Unpredictable dosing with non-prescribed fentanyl
- Two causes of fentanyl OD death: opioid-induced respiratory depression and rigid chest wall syndrome; higher or repeated doses of naloxone are required to reverse a fentanyl overdose.

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RISKS VERSUS BENEFITS OF PRESCRIBED OPIOIDS

POTENTIAL RISKS

- Life-threatening respiratory depression/overdose
- Development of SUD/ODU
- Diversion
- Inadvertent exposure to family and pets
- Interactions with other meds and substances
- Neonatal abstinence syndrome
- Physiologic dependence and withdrawal

POTENTIAL BENEFITS

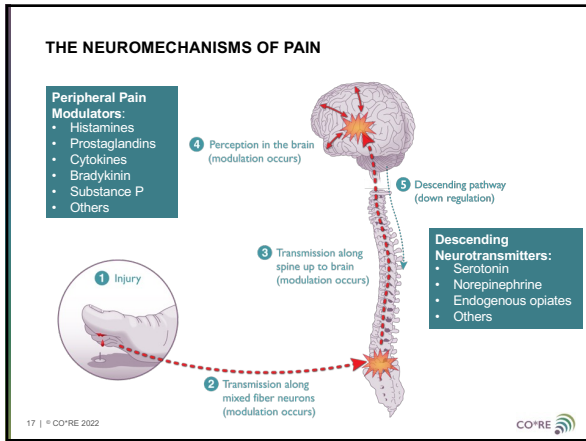
- Analgesia
- Option for patients with contraindications for non-opioid analgesics
- Relieves suffering
- May improve function and quality of life

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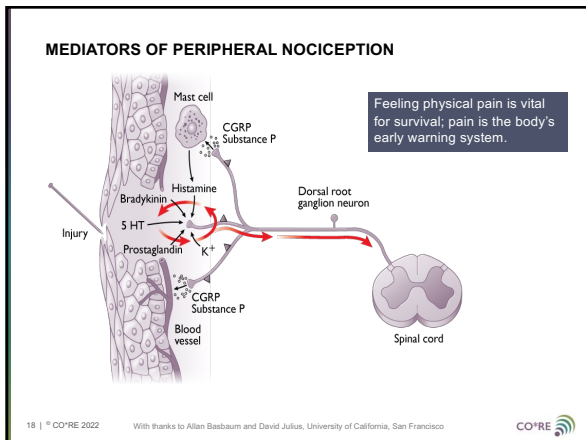
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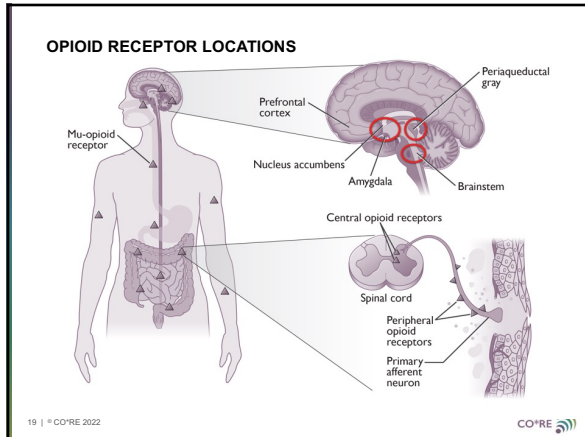
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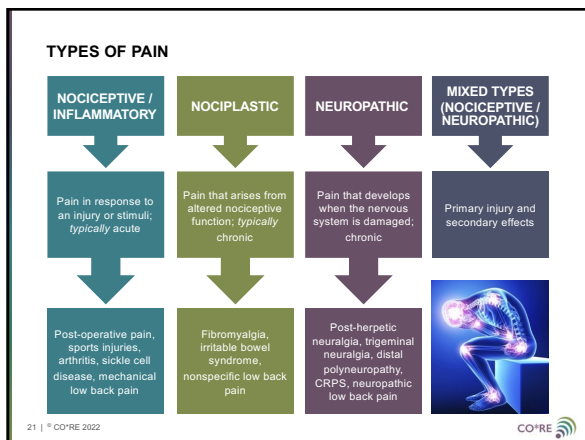
PAIN

"An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage."
—IASP (July 2020)

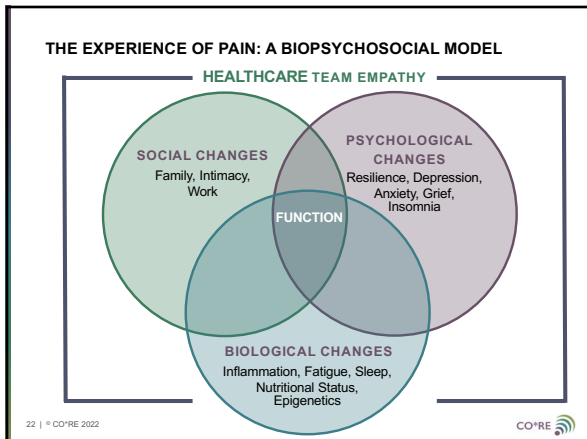
ACUTE	CHRONIC
<ul style="list-style-type: none"> Sudden onset, lasting weeks to months, self-limiting Ideally resolves with healing Triggered by tissue damage and inflammation Has protective value Inflammatory mediation 	<ul style="list-style-type: none"> Lasting three months or longer Generally steady-state or worsening Persists beyond normal healing period Serves no value Peripheral and central sensitization

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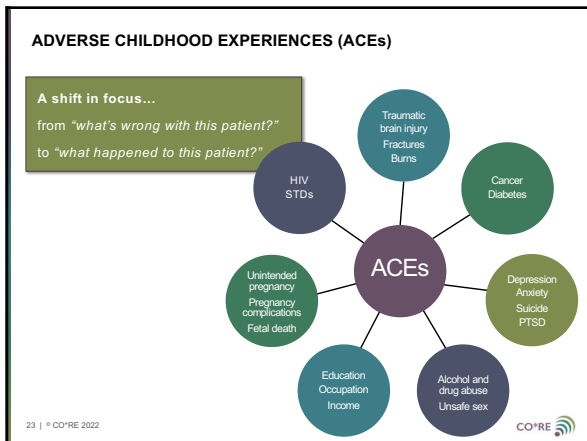
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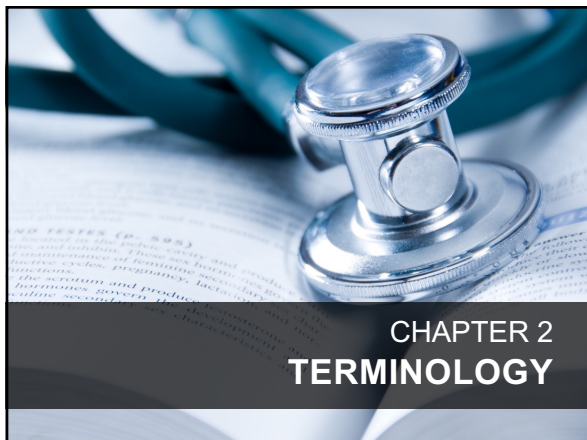
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WORDS MATTER: LANGUAGE CHOICE CAN REDUCE STIGMA

"If you want to care for something, you call it a flower; if you want to kill something, you call it a weed." —DON COYHIS

COMMONLY USED TERM	PREFERRED TERM
Addiction	Substance use disorder (SUD) or opioid use disorder (OUD) [from the <i>DSM-5-TR</i> ®]
Drug-seeking, aberrant/problematic behavior	Using medication not as prescribed
Addict/user	Person with a substance use disorder (SUD) or an opioid use disorder (OUD)
Dirty urine/failing a drug test	Testing positive on a urine drug screen
Abuse or habit	Misuse or "use other than prescribed"

SOURCE: <https://nida.nih.gov/research-topics/addiction-science/words-matter-preferred-language-talking-about-addiction>

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WORDS MATTER: DEFINITIONS

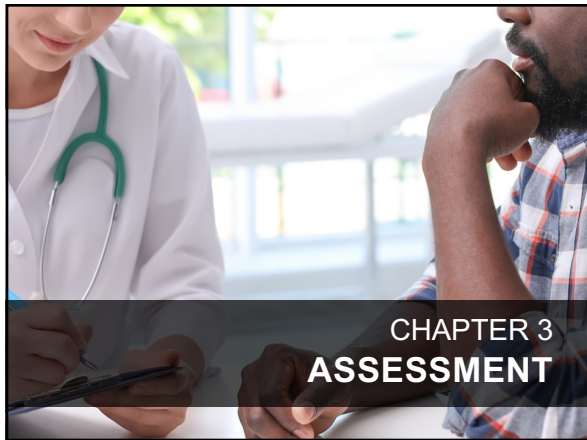
Misuse	Use of a medication in a way other than the way it is prescribed
Tolerance	Increased dosage needed to produce a specific effect
Dependence	State in which an organism only functions normally in the presence of a substance
Diversion	Transfer of a legally controlled substance, prescribed to one person, to another person for illicit (forbidden by law) use
Withdrawal	Occurrence of uncomfortable symptoms or physiological changes caused by an abrupt discontinuation or dosage decrease of a pharmacologic agent
MOUD	Medication for Opioid Use Disorder, an approach to treating Opioid Use Disorder that combines FDA-approved medication with counseling and behavioral therapies
MME	Morphine milligram equivalents; a standard opioid dose value based on morphine and its potency; allows for ease of comparison and risk evaluations
Chronic non-cancer pain (CNCP)	Any painful condition that persists for ≥ 3 months, or past the time of normal tissue healing, that is not associated with a cancer diagnosis

SOURCE: NIDA. <https://nida.nih.gov/research-topics/addiction-science/words-matter-preferred-language-talking-about-addiction>

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HOW IS PAIN MANAGED?

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PAIN ASSESSMENT

DESCRIPTION OF PAIN

Location Intensity Quality Onset/duration Variations/patterns/rhythms

WHAT RELIEVES THE PAIN?

WHAT CAUSES OR INCREASES THE PAIN?

EFFECTS OF PAIN ON PHYSICAL, EMOTIONAL AND PSYCHOSOCIAL FUNCTION

PATIENT'S CURRENT LEVEL OF PAIN AND FUNCTION

SOURCE: Hogans, B., Barneveld, A. (Eds.). Pain Care Essentials, New York, NY: Oxford University Press, 2020.

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MEDICAL AND TREATMENT HISTORY

RELEVANT ILLNESSES

PAST AND CURRENT OPIOID USE

- Query your state's Prescription Drug Monitoring Program (PDMP) to confirm patient report
- Contact past providers and obtain prior medical records
- For opioids currently prescribed, note the opioid, dose, regimen, and duration
- Determine whether the patient is opioid-tolerant

NONPHARMACOLOGIC STRATEGIES AND EFFECTIVENESS

PHARMACOLOGIC STRATEGIES AND EFFECTIVENESS

BARRIERS TO PREVIOUS TREATMENT STRATEGIES

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PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs)

PDMP DATABASES	BENEFITS
<ul style="list-style-type: none"> • Reports on opioid prescriptions filled by patient • Nearly all are available online 24/7 • 54 operational PDMPs in the U.S. • In some states, prescribers are required to access; know your state laws 	<ul style="list-style-type: none"> • Lower rates of prescription opioid-related hospitalization and ED visits • Reduction in "doctor shopping" • Reduction in prescribing high doses and over-prescribing • Identify drugs that increase overdose risk when taken together (such as benzodiazepines, gabapentinoids, opioids, and other sedatives)

Limitations: Often under-used, can be time consuming, may not have access to bordering state data, lack of intuitive format, privacy issues, no national PDMP connection

Multiple prescriptions from different providers is most predictive of opioid misuse.

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OBTAIN A COMPLETE SOCIAL AND PSYCHOLOGICAL HISTORY

SOCIAL HISTORY

Employment, cultural background, social network, relationship history, legal history, and other behavioral patterns

PSYCHOLOGICAL HISTORY

Screen for:

- Mental health diagnoses, depression, anxiety, PTSD, current treatments
- Alcohol, tobacco, and other drug use
- History of Adverse Childhood Experiences (ACES)
- Family history of substance use disorder and psychiatric disorders

Depression and anxiety can be predictors of chronic pain



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PHYSICAL EXAM AND ASSESSMENT

Seek objective data → Conduct physical exam and evaluate for pain → Order diagnostic or confirmatory tests

General: vital signs, appearance, and pain behaviors

Neurologic exam

Musculoskeletal exam

- Inspection
- Gait and posture
- Range of motion
- Palpation
- Percussion
- Auscultation
- Provocative maneuvers

Cutaneous or trophic findings


SOURCE: Hogans, B., Barneveldt, A. (Eds.). Pain Care Essentials, New York, NY: Oxford University Press, 2020.

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PAIN ASSESSMENT TOOLBOX

<http://core-rems.org/opioid-education/tools/>



Pain Assessment Tools
BPI or 5 A's

Functional Assessment
SF-36, PPS, Geriatric Assessment


Pain Intensity, Enjoyment of life, General activity
PEG

Adverse Childhood Experience Questionnaire
ACE

Assessment in Patients Unable to Self-Report
Hierarchy of Pain Assessment PAINAD Brief Pain Inventory (BPI)

Psychological Measurement Tools (PHQ-9, GAD-7, etc.)

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ASSESSMENT IS NOT A ONE-TIME OCCURRENCE

Assessment of a patient's response to pain treatment is a continual process:

- Routinely check the PDMP
- Check in with your patients
- Reassess to identify the underlying source of pain
- Investigate comorbid conditions that may arise
- Ask if patient is willing to engage with other modalities
- Modify plans as needed



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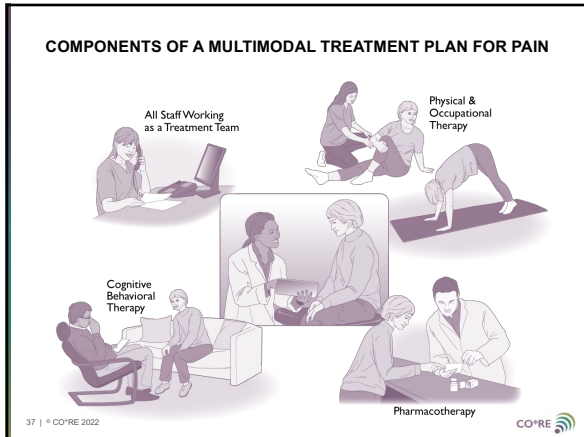


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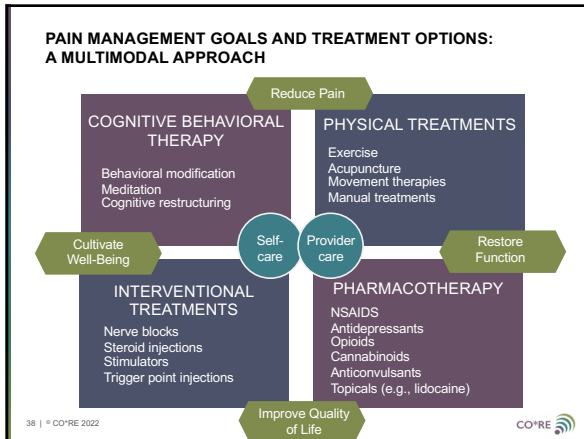


CHAPTER 4
CREATING THE PAIN TREATMENT PLAN

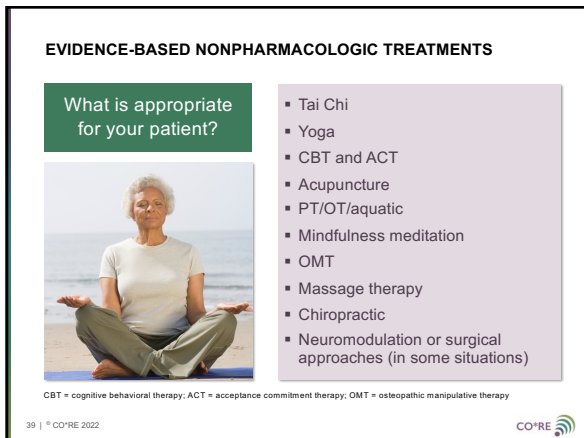
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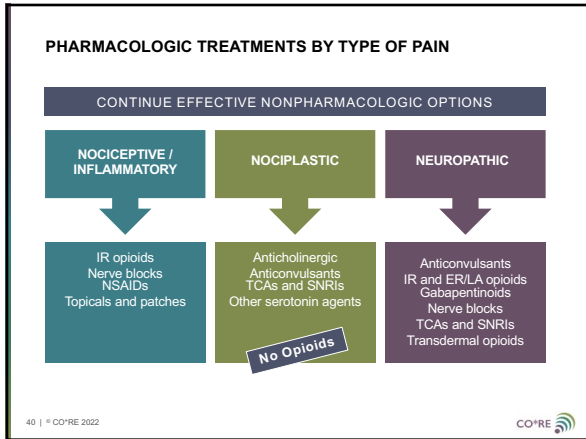
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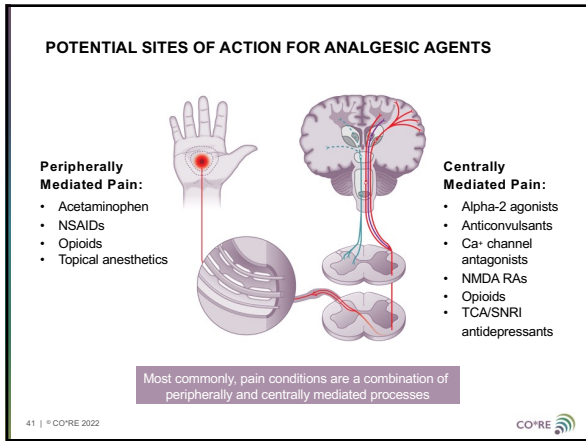
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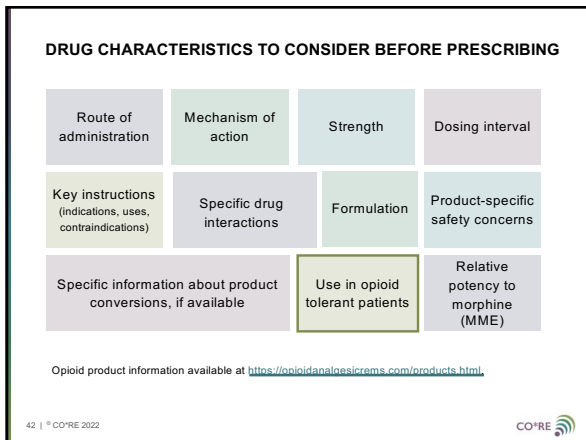
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CONSIDER AN OPIOID ONLY WHEN:

- Potential benefits are likely to outweigh risks
- Patient has failed to adequately respond to non-opioid and nonpharmacological interventions
- Patient has moderate to severe nociceptive or neuropathic pain

Begin as a therapeutic trial

SOURCES: Chou R, et al. J Pain. 2009;10:113-130. Department of Veterans Affairs, Department of Defense. VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain. 2017.

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OPIOID MISUSE RISK ASSESSMENT TOOLS
<http://core-rems.org/opioid-education/tools/>

TOOLS FOR PATIENTS CONSIDERED FOR OPIOID THERAPY

- ORT-OD Opioid Risk Tool
- SOAPP® Screener and Opioid Assessment for Patients with Pain
- DIRE Diagnosis, Intractability, Risk, and Efficacy score

TOOLS FOR SUBSTANCE USE DISORDER

- CAGE-AID Cut down, Annoyed, Guilty, Eye-Opener tool, Adapted to Include Drugs
- TAPS Tobacco, Alcohol, Prescription Medication and Other Substances Tool
- DAST Drug Abuse Screening Test
- CTQ Childhood Trauma Questionnaire
- ACEs Adverse Childhood Experiences

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A CLOSER LOOK AT THE ORT-OD

Opioid Risk Tool – OUD (ORT-OD)

This tool should be administered to patients upon an initial visit prior to beginning or continuing opioid therapy for pain management. A score of 2 or lower indicates low risk for future opioid use disorder; a score of >= 3 indicates high risk for opioid use disorder.

Mark each box that applies	YES	NO
Family history of substance abuse		
Alcohol	1	0
Illegal drugs	1	0
Rx drugs	1	0
Personal history of substance abuse		
Alcohol	1	0
Illegal drugs	1	0
Rx drugs	1	0
Age between 16-45 years	1	0
Psychological disease		
ADHD, OCD, bipolar, schizophrenia	1	0
Depression	1	0
Scoring totals		

Scoring:

- ≤ 2: low risk
- ≥ 3: high risk

SOURCE: Cheattle, M., et al. J Pain 2019; Jan 26.

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OPIOID SIDE EFFECTS AND ADVERSE EVENTS

SIDE EFFECTS	ADVERSE EVENTS
Respiratory depression	Death
Opioid-induced constipation (OIC)	Addiction
Myoclonus (twitching or jerking)	Overdose
Sedation, cognitive impairment	Hospitalization
Sweating, miosis, urinary retention	Disability or permanent damage
Allergic reactions	Falls or fractures
Hypogonadism	
Tolerance, physical dependence, hyperalgesia	

Prescribers should report serious AEs and medication errors to the FDA:
<https://www.fda.gov/media/76292/download> or 1-800-FDA-1088

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OPIOID-INDUCED RESPIRATORY DEPRESSION

MORE LIKELY TO OCCUR:	HOW TO REDUCE RISK:
<ul style="list-style-type: none"> In elderly, cachectic, or debilitated patients If given concomitantly with other drugs that depress respiration (such as benzodiazepines*) In patients who are opioid-naïve or have just had a dose increase In patients with conditions causing respiratory compromise 	<ul style="list-style-type: none"> Ensure proper dosing and titration Do not overestimate dose when converting dosage from another opioid product <ul style="list-style-type: none"> Can result in fatal overdose with first dose Avoid co-prescribing benzodiazepines* Instruct patients to swallow tablets/capsules whole <ul style="list-style-type: none"> Dose from cut, crushed, dissolved, or chewed tablets/capsules may be fatal, particularly in opioid-naïve individuals

*Greatest risk of respiratory depression

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DRUG INTERACTIONS COMMON TO OPIOIDS

Other CNS Depressants <ul style="list-style-type: none"> Increased risk of respiratory depression, hypotension, profound sedation, or coma Reduce initial dose 	Partial Agonists* or Mixed Agonist/Antagonists† <ul style="list-style-type: none"> Use caution with full opioid agonist May reduce analgesic effect and/or precipitate withdrawal
Skeletal Muscle Relaxants <ul style="list-style-type: none"> Concurrent use may enhance neuromuscular blocking action and increase respiratory depression 	Anticholinergic Medication <ul style="list-style-type: none"> Concurrent use increases risk of urinary retention and severe constipation May lead to paralytic ileus


*Buprenorphine; †Pentazocine, nalbuphine, butorphanol

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FOR SAFER USE: KNOW DRUG INTERACTIONS, PHARMACODYNAMICS, AND PHARMACOKINETICS

CNS depressants can potentiate sedation and respiratory depression (e.g., benzodiazepines, gabapentin)	Some ER/LA products rapidly release opioid (dose dump) when exposed to alcohol. Some drug levels may increase without dose dumping.
Opioid use with MAOIs may increase respiratory depression. Certain opioids with MAOIs can cause serotonin syndrome (e.g., tramadol)	Opioid use can reduce efficacy of diuretics. Inducing release of antidiuretic hormone.
Many opioids can prolong QTc interval, check the PI; methadone requires extra caution	Drugs that inhibit or induce CYP enzymes can increase or lower blood levels of some opioids.

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OPIOIDS AND CYP450 ENZYME INTERACTIONS


Metabolism of several commonly used opioids occurs through the cytochrome P450 system

Be aware of potential inhibitors (e.g., macrolides, azole antifungals) and inducers (e.g., carbamazepine)

Genetic and phenotypic variations in patient response to certain opioids


Refer to product-specific information in the drug package insert before prescribing

SOURCE: <https://dailymed.nlm.nih.gov/dailymed/index.cfm>

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TRANSDERMAL/TRANSMUCOSAL DOSAGE FORMS

 Do not cut, damage, chew, or swallow

Prepare skin: clip (not shave) hair and wash area with water	Rotate location of application	Do not apply buccal film products if film is cut, damaged, or changed in any way—use the entire film
Note that metal foil backings are not safe for use in MRIs	Monitor patients with fever for signs or symptoms of increased opioid exposure	

Note that exertion or exposure to external heat can lead to fatal overdose

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OLDER ADULTS

RISK FOR RESPIRATORY DEPRESSION



- Age-related changes in distribution, metabolism, excretion; absorption less affected

ACTIONS

- Monitor
 - Initiation and titration
 - Concomitant medications (polypharmacy)
 - Falls risk, cognitive change, psychosocial status
- Reduce starting dose to 1/3 to 1/2 the usual dosage in debilitated, non-opioid-tolerant patients
- Start low, go slow, but GO
- Routinely initiate a bowel regimen
- Patient and caregiver reliability/risk of diversion

SOURCES: American Geriatrics Society Panel on the Pharmacological Management of Persistent Pain in Older Persons. J Am Geriatr Soc. 2009;57:1331-46; Chou R, et al. J Pain. 2009;10:113-30.

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WOMEN OF CHILDBEARING POTENTIAL

Neonatal opioid withdrawal syndrome is a potential risk of opioid therapy



GIVEN THIS POTENTIAL RISK, CLINICIANS SHOULD:

- Discuss family planning, contraceptives, breastfeeding plans with patients
- Counsel women of childbearing potential about risks and benefits of opioid therapy during pregnancy and after delivery
- Encourage minimal/no opioid use during pregnancy, unless potential benefits outweigh risks to fetus
- Refer to a qualified provider who will ensure appropriate treatment for the baby

- Perform universal screening to avoid neonatal opioid withdrawal syndrome (NOWS)
- For women using opioids on a daily basis, ACOG recommends buprenorphine or methadone

ACOG = American College of Obstetricians and Gynecologists
SOURCES: Chou R, et al. J Pain. 2009;10:113-30; ACOG Committee on Obstetric Practice, August 2017

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CHILDREN AND ADOLESCENTS

HANDLE WITH CARE: JUDICIOUS AND LOW-DOSE USE OF IR FOR BRIEF THERAPY

THE SAFETY AND EFFECTIVENESS OF MOST OPIOIDS ARE UNESTABLISHED

- Pediatric analgesic trials pose challenges
- Transdermal fentanyl approved in children ≥ 2 years
- Oxycodone ER dosing changes for children ≥ 11 years



ER/LA OPIOID INDICATIONS ARE PRIMARILY LIFE-LIMITING CONDITIONS

WHEN PRESCRIBING ER/LA OPIOIDS TO CHILDREN:

- Consult pediatric palliative care team or pediatric pain specialist or refer to a specialized multidisciplinary pain clinic

SOURCES: Berde CB, et al. Pediatrics. 2012;129:354-364; Gregoire MC, et al. Pain Res Manag 2013;18:47-50; Mc Donnell C. Pain Res Manag. 2011;16:93-98; Slater ME, et al. Pain Med. 2010;11:207-14.

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OTHER POPULATIONS NEEDING SPECIAL TREATMENT CONSIDERATIONS

Persons with...

- Sleep disorders or sleep-disordered breathing (sleep apnea)
- Dementia/nonverbal patients
- Obesity
- Renal/hepatic impairment
- Psychiatric disorders
- Life-limiting illness
- Substance use disorder

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CHAPTER 5
MANAGING PATIENTS ON OPIOID ANALGESICS

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INFORMED CONSENT

When initiating a pain treatment plan, confirm patient understanding of informed consent to establish:

- ANALGESIC AND FUNCTIONAL GOALS OF TREATMENT
- EXPECTATIONS
- POTENTIAL RISKS
- ALTERNATIVES
- PATIENT'S UNDERSTANDING
- PATIENT'S DECISION


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PATIENT PROVIDER AGREEMENT (PPA)

Reinforce Expectations For Appropriate And Safe Opioid Use

- Clarify treatment plans and goals
- One prescriber
- Consider one pharmacy
- Safeguards
 - Do not store in medicine cabinet
 - Keep locked (medication safe)
 - Do not share or sell
- Instructions for disposal when no longer needed
- Prescriber notification for any event resulting in a pain medication prescription
- Follow-up plan
- Monitoring
 - Random urine drug test (UDT) and pill counts
- Refill procedure
- Identify behaviors indicating need for discontinuation
- Exit strategy
- Signed by both

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PATIENT PROVIDER AGREEMENT NONADHERENCE

Behavior outside the boundaries of agreed-on treatment plan

<ul style="list-style-type: none"> Unsanctioned dose escalations or other noncompliance with therapy on 1 or 2 occasions 	<ul style="list-style-type: none"> Multiple dose escalations or other noncompliance with therapy despite warnings
<ul style="list-style-type: none"> Unapproved use of the drug to treat another symptom 	<ul style="list-style-type: none"> Prescription forgery
<ul style="list-style-type: none"> Openly acquiring similar drugs from other medical sources 	<ul style="list-style-type: none"> Obtaining prescription drugs from nonmedical sources

Any of the above behaviors merits **Investigation**: proceed with caution


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INITIATING OPIOIDS

- Begin a therapeutic trial with an immediate release (IR) opioid
- Prescribe the lowest effective dosage
- Use caution at any dosage, but particularly when:
 - Increasing dosage to ≥ 50 morphine milligram equivalents (MME)/day
 - Carefully justify a decision to titrate dosage to ≥ 90 MME/day
- Always include dosing instructions, including daily maximum
- Be aware of interindividual variability of response
- Have PPA, baseline UDT, and informed consent in place
- Co-prescribe naloxone and bowel regimen
- Re-evaluate risks/benefits within 1–4 weeks (could be as soon as 3–5 days) of initiation or dose escalation
- Re-evaluate risks/benefits every 1–3 months; if benefits do not outweigh harms, optimize other therapies and work to taper and discontinue

There are differences in benefits, risks, and expected outcomes for patients with chronic pain and cancer pain, as well as for hospice and palliative care patients.

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ONGOING AND LONG-TERM MANAGEMENT OF PATIENTS ON OPIOID ANALGESICS

PERIODIC REVIEW OF PAIN

- Is the patient making progress toward functional goals?
- Reset goals if required or indicated; develop reasonable expectations
- Monitor for breakthrough pain
- Review adverse events/side effects at each visit
 - Evaluate bowel function
 - Screen for endocrine function as needed
 - Report adverse events to the FDA website
 - Implement opioid rotation, as indicated

Prescribers should report serious AEs and medication errors to the FDA: <https://www.fda.gov/media/76299/download> or 1-800-FDA-1088

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ONGOING AND LONG-TERM MANAGEMENT OF PATIENTS ON OPIOID ANALGESICS

MONITORING FOR SAFETY

- Check Prescription Drug Monitoring Program (PDMP)
- Use urine drug testing (UDT)
- Reassess risk of substance use disorder (SUD) and/or OUD
- Monitor adherence to the treatment plan
 - Medication reconciliation
 - Evaluate for nonadherence

DISCONTINUING AND TAPERING

- When is opioid therapy no longer necessary?

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MONITORING PAIN AND SUBSTANCE USE DISORDER

PAIN – 5 A's	SUD – 5 C's
<ul style="list-style-type: none"> • Analgesia • Activity/Function • Aberrant/Problematic behavior, not present • Adverse events • Affect 	<ul style="list-style-type: none"> • Control, loss of • Compulsive use • Craving drug • Continued use • Chronic problem

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WHEN TO MOVE FROM IR TO ER/LA OPIOIDS

PRIMARY REASONS	OTHER POTENTIAL REASONS
<ul style="list-style-type: none"> • Maintain stable blood levels (steady state plasma) • Longer duration of action • Multiple IR doses needed to achieve effective analgesia • Poor analgesic efficacy despite dose titration • Less sleep disruption 	<ul style="list-style-type: none"> • Patient desire or need to try a new formulation • Cost or insurance issues • Adherence issues • Change in clinical status requiring an opioid with different pharmacokinetics • Problematic drug-drug interactions 

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CONSIDERATIONS FOR CHANGE FROM IR TO ER/LA OPIOIDS

<p>DRUG AND DOSE SELECTION IS CRITICAL</p> <p>Some ER/LA opioids or dosage forms are only recommended for opioid tolerant patients</p> <ul style="list-style-type: none"> • ANY strength of transdermal fentanyl or hydromorphone ER • Certain strengths/doses of other ER/LA products (check drug prescribing information) 	<p>MONITOR PATIENTS CLOSELY FOR RESPIRATORY DEPRESSION</p> <ul style="list-style-type: none"> • Especially within 24–72 hours of initiating therapy and increasing dosage 	<p>INDIVIDUALIZE DOSAGE BY TITRATION BASED ON EFFICACY, TOLERABILITY, AND PRESENCE OF ADVERSE EVENTS</p> <ul style="list-style-type: none"> • Check ER/LA opioid product PI for minimum titration intervals • Supplement with IR analgesics (opioid and non-opioid) if pain is not controlled during titration
--	---	---

SOURCES: Chou R, et al. J Pain. 2009;10:113-130; FDA. Education Blueprint Healthcare Providers Involved in the Treatment and Monitoring of Patients with Pain 09/2018. https://www.accessdata.fda.gov/drugsatfda_docs/tepd/Chou09_18_FDA_Blueprint.pdf

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EMERGENCE OF OPIOID-INDUCED HYPERALGESIA

- An increased sensitivity to pain
- Usually occurs at high MME dosages and over long periods of time
- A physiological phenomenon that can happen to anyone
- Consider this explanation if:
 - Pain increases despite dose increases
 - Pain appears in new locations
 - Patient becomes more sensitive to painful stimuli
 - Patient is not improving in the absence of underlying cause or disease progression

SOURCE: Yi P, Przybykowski P. Opioid induced hyperalgesia. Pain Medicine 2015; 16: S32-S36

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OPIOID TOLERANCE

If opioid tolerant, still use caution at higher doses

Patients considered opioid tolerant are taking at least

- 60 mg oral morphine/day
- 25 mcg transdermal fentanyl/hour
- 30 mg oral oxycodone/day
- 8 mg oral hydromorphone/day
- 25 mg oral oxymorphone/day
- An equianalgesic dose of another opioid


IMPORTANT
FOR 1 WEEK OR LONGER

Also use caution when rotating a patient on an IR opioid to a different ER/LA opioid

Products restricted to opioid tolerant individuals include transdermal fentanyl (Duragesic) and hydromorphone (Exalgo).

SOURCE: The Opioid Analgesics Risk Evaluation & Mitigation Strategy product search, <https://opioidanalgesicsrems.com/products.html>

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OPIOID TOLERANCE VERSUS PHYSICAL DEPENDENCE

TOLERANCE

- Occurs when increased dose is needed to maintain the functional status no longer achieved by current dose
- Remember CNS and respiratory depression can develop with dose increase


↔

PHYSICAL DEPENDENCE

- Occurs when an individual only functions normally in the presence of the substance
- Abrupt discontinuation or dosage decrease causes uncomfortable symptoms of withdrawal

Both tolerance and physical dependence are physiological adaptations to chronic opioid exposure and **DO NOT** equal addiction or opioid use disorder

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OPIOID ROTATION

DEFINITION

A change from an existing opioid regimen to another opioid with the goal of improving therapeutic outcomes or to avoid AEs attributed to the existing drug




RATIONALE

Used when differences in pharmacologic or other effects make it likely that a switch will improve outcomes

- Effectiveness and AEs of different mu-opioids vary among patients
- Patient tolerant to first opioid might have improved analgesia from second opioid at a dose lower than calculated from an equianalgesic dosing table (EDT)

SOURCES: Fine PG, et al. J Pain Symptom Manage. 2009;38:418-425; Krokova M, et al. J Pain Symptom Manage. 2009;38:426-436; Pridemack GW. Neuropharmacol. 2004;47(suppl 1):312-323.

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EQUIANALGESIC DOSING TABLES (EDTs)

Many different versions:

Published Online calculators


Smartphone apps



Vary in terms of:


Equianalgesic values Whether ranges are used

Which opioids are included: May or may not include transdermal opioids, rapid-onset fentanyl, ER/LA opioids, or opioid agonist-antagonists


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START WITH AN EDT FOR ADULTS



DRUG	EQUIANALGESIC DOSE		USUAL STARTING DOSE	
	SC/IV	PO	PARENTERAL	PO
Morphine	10 mg	30 mg	2.5–5 mg SC/IV q3–4hr (1.25–2.5 mg)	5–15 mg q3–4hr (IR or oral solution) (2.5–7.5 mg)
Oxycodone	NA	20 mg	NA	5–10 mg q3–4hr (2.5 mg)
Hydrocodone	NA	30 mg	NA	5 mg q3–4hr (2.5 mg)
Hydromorphone	1.5 mg	7.5 mg	0.2–0.6 mg SC/IV q2–3hr (0.2 mg)	1–2 mg q3–4hr (0.5–1 mg)

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MU-OPIOID RECEPTORS AND INCOMPLETE CROSS TOLERANCE

MU-OPIOIDS BIND TO MU RECEPTORS

MANY MU RECEPTOR SUBTYPES

Mu-opioids produce **subtly different** pharmacologic responses based on distinct activation profiles of mu receptor subtypes

MAY HELP EXPLAIN:

- Interpatient variability in response to mu-opioids
- Incomplete cross tolerance among mu-opioids

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GUIDELINES FOR OPIOID ROTATION

Calculate equianalgesic dose of new opioid from EDT

REDUCE CALCULATED EQUIANALGESIC DOSE BY 25%–50%*

SELECT % REDUCTION BASED ON CLINICAL JUDGMENT

CLOSER TO 50% REDUCTION	CLOSER TO 25% REDUCTION
<p>IF PATIENT...</p> <ul style="list-style-type: none"> Is receiving a relatively high dose of current opioid regimen Is elderly or medically frail 	<p>IF PATIENT...</p> <ul style="list-style-type: none"> Does not have these characteristics Is changing route of administration

*75%–90% reduction for methadone

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GUIDELINES FOR OPIOID ROTATION (continued)

IF SWITCHING TO METHADONE:

- Standard equianalgesic dosing tables are less helpful in opioid rotation to methadone
- For opioid tolerant patients, methadone doses should **not** exceed 30–40 mg/day upon rotation
 - Consider inpatient monitoring, including serial EKG monitoring
- For opioid-naïve patients, do **not** give methadone as an initial drug

IF SWITCHING TO TRANSDERMAL:

- Fentanyl:** calculate dose conversion based on equianalgesic dose ratios included in the drug package insert

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GUIDELINES FOR OPIOID ROTATION: SUMMARY

VALUES FROM EDT*	PATIENT OPIOID VALUES	SOLVE FOR X	AUTOMATICALLY REDUCE DOSE
Value of current opioid	24-hr dose of current opioid	Equianalgesic 24-hr dose of new opioid	By 25%–50%†
Value of new opioid	X amount of new opioid		

➔

Frequently assess initial response

Titrate dose of new opioid to optimize outcomes

Calculate supplemental rescue dose used for titration at 5%–15% of total daily dose‡

* If switching to transmucosal fentanyl, use equianalgesic dose ratios provided in PI.
† If switching to methadone, reduce dose by 75%–90%.
‡ If oral transmucosal fentanyl used as rescue, begin at lowest dose irrespective of baseline opioid.

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BREAKTHROUGH PAIN (BTP)

PATIENTS ON STABLE ATC OPIOIDS MAY EXPERIENCE BTP

- Due to disease progression or a new or unrelated pain
 - Target cause or precipitating factors
- Dose for BTP: Using an **IR, 5%–15%** of total daily opioid dose, administered at an appropriate interval
- **Never use ER/LA for BTP**

CONSIDER ADDING

- PRN IR opioid trial based on analysis of benefit versus risk
 - There is a risk for problematic drug-related behaviors
 - High-risk: Add only in conjunction with frequent monitoring and follow-up
 - Low-risk: Add with routine follow-up and monitoring
- Consider non-opioid drug therapies and nonpharmacologic treatments


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ABUSE-DETERRENT FORMULATION (ADF) OPIOIDS

Drug formulations designed to discourage misuse


- An ER/LA opioid with properties to meaningfully deter misuse (less likely to be crushed, injected, or snorted)
- Consider as one part of an overall strategy
- Mixed evidence on the impact of ADF on misuse
- Overdose is still possible if taken orally in excessive amounts
- These products are expensive with no generic equivalents



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URINE DRUG TESTING (UDT)



- Urine testing is done **FOR** the patient, not **TO** the patient
- Helps to identify drug misuse/addiction
- Assists in assessing and documenting adherence


CLINICAL CONSIDERATIONS

- Recommend UDT before first prescription (baseline), then intermittently, depending on clinical judgment and state regulations
- Document time and date of last dose taken
- Be aware of possible false positives or negatives
- Clarify unexpected results with the lab before confronting patient to rule out poor specimen or error

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SCREENING VERSUS CONFIRMATORY UDTs



	SCREENING (Office-based)	CONFIRMATORY (Send to lab)
Analysis technique	Immunoassay	GC-MS or HPLC
Sensitivity (power to detect a class of drugs)	Low or none when testing for semi-synthetic or synthetic opioids	High
Specificity (power to detect an individual drug)	Varies (can result in false positives or false negatives)	High
Turnaround	Rapid	Slow
Cost/Other	Lower cost; intended for a drug-free population; may not be useful in pain medicine	Higher cost; legally defensible results

80 | © CO'RE 2022 GC-MS = gas chromatograph-mass spectrometry; HPLC = high-performance liquid chromatography CO'RE

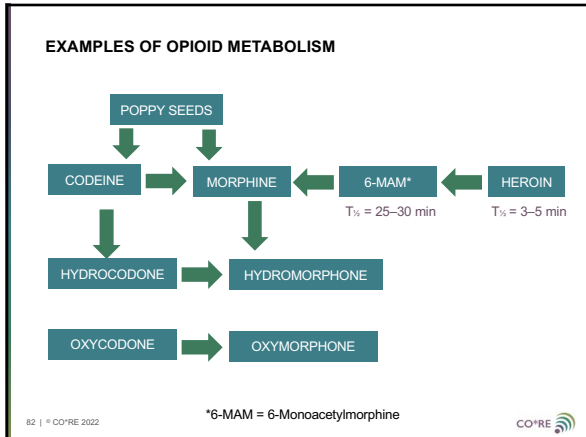
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WINDOWS OF SPECIFIC DRUG DETECTION

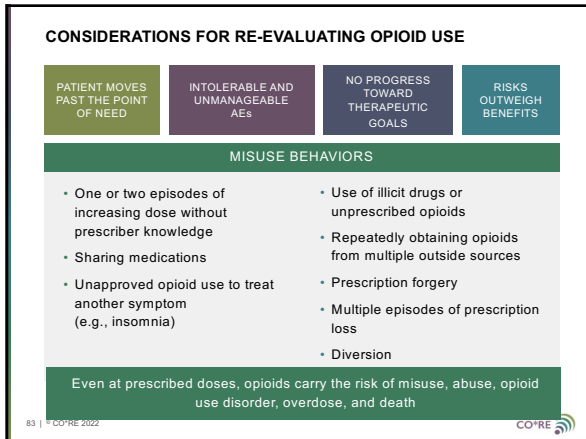
Drug	How soon after taking drug will there be a positive drug test?	How long after taking drug will there continue to be a positive drug test?
Cannabis/Tetrahydrocannabinol (THC)	1-3 hours	1-7 days (can be up to 1 month if long-term use)
Crack (cocaine)	2-6 hours	2-3 days
Heroin (opiates)	2-6 hours	1-3 days
Speed/upper (amphetamine, methamphetamine)	4-6 hours	2-3 days
Angel dust/PCP	4-6 hours	7-14 days
Ecstasy	2-7 hours	2-4 days
Benzodiazepine	2-7 hours	1-4 days
Barbiturates	2-4 hours	1-3 weeks
Methadone	3-8 hours	1-3 days (up to 2 weeks)
Tricyclic antidepressants	8-12 hours	2-7 days
Oxycodone	1-3 hours	1-2 days

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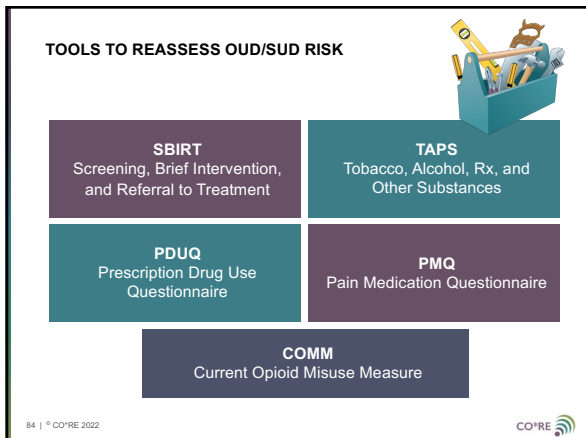
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APPROACHES TO SUPPORT THE DISCONTINUATION DECISION


- Discontinue through a taper schedule
- If OUD suspected:
 - Begin treatment: Medications for Opioid Use Disorder (MOUD)
 - Refer to an OUD specialist
- Consider rotation to partial agonist (e.g., buprenorphine)
- No single approach is appropriate for all patients
- May use a range of approaches, from a slow 10% dose reduction per week to a more rapid 25%–50% reduction every few days
- To minimize withdrawal symptoms in patients physically dependent on opioids, consider medications to assist with withdrawal (clonidine, NSAIDs, antiemetics, antidiarrheal agents)

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CONSULTING A PAIN SPECIALIST

- Appropriate when you feel you cannot provide the level of care needed
- First ensure you have a reliable specialist to refer to
- To find a pain specialist in your area:
 - Consult with state boards
 - Consult with colleagues
 - Use online resources
 - Consult payment source
- Prior to referral, contact the specialist and ask what is needed for referral





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OPTIMIZING PATIENT CARE THROUGH TELEHEALTH

- **New CO*RE CE/CME Module**
- Series of four short videos
- Help HCPs conduct successful telehealth patient visits
- Available online <https://learningioma.org>



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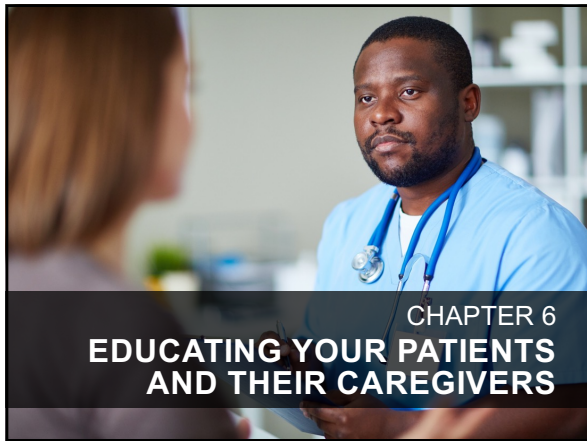
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Adequately **DOCUMENT**
all patient interactions,
assessments, test results,
treatment plans,
and expectations.

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CHAPTER 6
**EDUCATING YOUR PATIENTS
AND THEIR CAREGIVERS**

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COUNSEL PATIENTS ABOUT PROPER USE

- Take opioid as prescribed
- Use least amount of medication necessary for shortest time
- Use caution with long-term opioid use patients; avoid abrupt discontinuation or dose reduction; taper safely to avoid withdrawal symptoms
- Notify HCP if pain is uncontrolled
- Report side effects to HCP
- Inform HCP of ALL meds and supplements being taken
- Never share or sell opioids: can lead to others' deaths, against the law
- Use caution when operating heavy machinery and driving



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USE FDA PATIENT COUNSELING DOCUMENT

- What are opioids?
- What are the risks and benefits?
- How to take safely

What You Need to Know About Opioid Pain Medicines

This guide is for you! Keep this guide and the Medication Guide that comes with your medicine so you can better understand what you need to know about your opioid pain medicine. Go over this information with your healthcare provider. Then, ask your healthcare provider about anything that you do not understand.

What are opioids?

Opioids are strong prescription medicines that are used to manage severe pain.

What are the serious risks of using opioids?

- Opioids have a serious risk of addiction and overdose.
- Too much opioid medicine or too long use leaves your breathing too slow, which can lead to death. This risk is greater for people using other medicines that make you feel sleepy or people with sleep apnea.
- Addiction is when you crave and use the opioid pain medicine even when they make you feel pain. You know it is addiction because you keep using the drug even though you know it is not a good idea and bad things can happen to you. Addiction is a brain disease that may require ongoing treatment.

Risk Factors for Opioid Abuse:

- You have
 - a history of addiction
 - a family history of addiction

<https://tinyurl.com/5n6z2dja>

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PROVIDE ANTICIPATORY GUIDANCE ON OPIOID SIDE EFFECTS AND ADVERSE EVENTS

- Overdose and death: respiratory depression
- Opioid-induced constipation (OIC): most common
- Nausea, vomiting, GERD
- Sexual dysfunction and other endocrine abnormalities (hypogonadism)
- Tolerance, physical dependence
- Hyperalgesia
- Allergic reactions
- Sedation, cognitive impairment
- Falls and fractures
- Sweating, miosis, urinary retention
- Myoclonus (twitching or jerking)
- Opioid use disorder (OUD)

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COUNSEL PATIENTS AND CAREGIVERS

WARNINGS (Safe Administration)	WHAT TO LOOK FOR (Safety Concerns)
<ul style="list-style-type: none"> • Never break, chew, crush, or snort an opioid tablet/capsule • Never cut or tear patches or buccal films • If patient cannot swallow, determine if appropriate to sprinkle contents on applesauce or administer via feeding tube • Use of CNS depressants or alcohol with opioids can cause overdose 	<ul style="list-style-type: none"> • Cravings • Being unable to fulfill work/family obligations • Nodding off • Taking more than prescribed

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OPIOID-INDUCED RESPIRATORY DEPRESSION

If not immediately recognized and treated, may lead to respiratory arrest and death


More likely to occur in opioid-naïve patients during initiation or after dose increase

Instruct patients/family members to:

- Screen for shallow or slowed breathing
- Deliver NALOXONE
- **CALL 911**

Instructions may differ if patient is on hospice or near end of life

Greatest risk: when co-prescribed with a benzodiazepine

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SIGNS OF ACCIDENTAL OPIOID POISONING: CALL 911

- Person cannot be aroused or is unable to talk
- Any trouble with breathing, heavy snoring is warning sign
- Gurgling noises coming from mouth or throat
- Body is limp, seems lifeless; face is pale, clammy
- Fingernails or lips turn blue/purple
- Slow, unusual heartbeat or stopped heartbeat

Administer Naloxone




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NALOXONE

WHAT IT IS:

- An opioid antagonist administered intranasally (most common) or parenterally
- Reverses acute opioid-induced respiratory depression but will also reverse analgesia; may precipitate acute opioid withdrawal
- No misuse potential

WHAT TO DO:


- Discuss an overdose plan with patients; involve family/caregivers
- Ensure family/caregivers have access to naloxone; some states *require* co-prescribing
- Involve and train family, friends, partners, and/or caregivers in the proper administration of naloxone
- Know your local naloxone resources (e.g., the library, community centers)
- Check expiration dates and replace expired naloxone
- In the event of known or suspected overdose, **call 911** and administer naloxone

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NALOXONE OPTIONS


- Available as auto-injector, intramuscular injection, or nasal spray
- Cost and insurance coverage vary
- Make use of tutorial videos or live demonstration to educate patient/family/caregiver on proper administration
- Store at room temperature



Naloxone vials



Narcan nasal spray




Evzio (auto-injector)

Trade names are used for identification purposes only and do not imply endorsement.
SOURCE: FDA Information About Naloxone. <https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm472923.htm>

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SAFE OPIOID STORAGE AND DISPOSAL



STEP 1: MONITOR <ul style="list-style-type: none"> • Note how many pills are in each prescription • Keep track of dosage and refills • Make sure everyone in the home knows meds are tracked (if appropriate) 	STEP 2: SECURE <ul style="list-style-type: none"> • Keep meds in a safe place (locked cabinet or box) • Store away from children, family, visitors, and pets • Extra precautions needed with adolescents in the home 	STEP 3: DISPOSE <ul style="list-style-type: none"> • Discard expired or unused meds • Check your local disposal options (e.g., pharmacy, police)
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SOURCE: McDonald E, Kennedy-Hendrick A, McGinty E, Shields W, Barry C, Gielen A. Pediatrics. 2017;139(3):e20162161

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WHERE AND HOW TO DISPOSE OF UNUSED OPIOIDS



Authorized Collection Sites

- Use the DEA disposal locator website to find sites near you: <https://aops.dea/diversion.usdoj.gov/publicisearch>
- Search Google Maps for "drug disposal nearby"

Options

- Check with local pharmacy for disposal options
- Flush
 - Fold patch in half so sticky sides meet, then flush
- Trash (mix with noxious element like kitty litter or compost)



Mail-Back Packages

- Obtain from authorized collectors



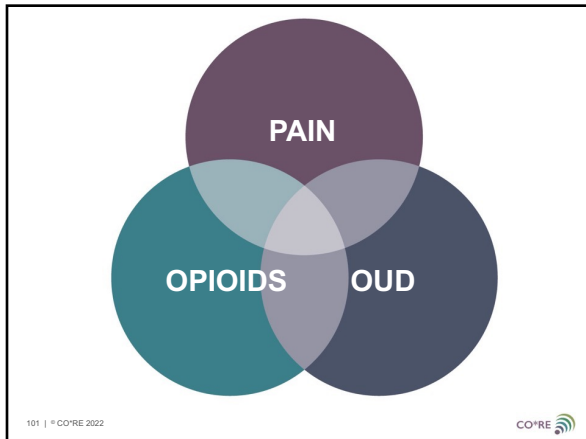
SOURCES: FDA, Where and How to Dispose of Unused Medicines. <https://www.fda.gov/consumers/consumer-updates/where-and-how-dispose-unused-medicines>
EPA, How to Dispose of Medicines Properly. <https://archive.epa.gov/region02/caspp/webp/dflppcpflfyer.pdf>

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WHAT IS ADDICTION?

PRACTICAL DEFINITION:

Addiction is the continued use of drugs or activities, despite knowledge of continued **harm** to one's self or others.

OFFICIAL ASAM DEFINITION:

Addiction is a treatable, chronic medical disease involving complex interactions among brain circuits, genetics, the environment, and an individual's life experiences. People with addiction use substances or engage in behaviors that become compulsive and often continue despite harmful consequences. Prevention efforts and treatment approaches for addiction are generally as successful as those for other chronic diseases.




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OPIOID USE DISORDER: DSM-5-TR CRITERIA

Be alert to these factors in your patients on long-term opioid therapy

1. Taking larger amounts and/or for longer periods than intended
2. Persistent desire or inability to cut down or control use
3. Increased time spent obtaining, using, or recovering
4. Craving/compulsion to use opioids
5. Role failure at work, home, school
6. Social or interpersonal problems
7. Reducing social, work, recreational activity
8. Physical hazards
9. Physical or psychological harm

❖ Tolerance
❖ Withdrawal




- 2-3 = mild
- 4-5 = moderate
- ≥6 = severe

❖ Not valid if opioid is taken as prescribed

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WORDS MATTER



Physical dependence or tolerance ↔ Doesn't necessarily equal ↔ OUD/addiction ↔ Doesn't necessarily equal ↔ Aberrant/problematic behavior

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HOW TO IDENTIFY RISK FOR MY PATIENTS

10%–26% of patients on chronic opioid therapy (COT) for chronic noncancer pain (CNCP) may develop an OUD

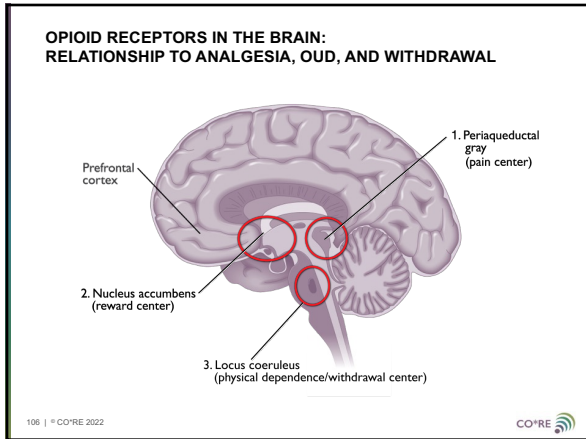
What to look for:

- High dosages
- Prolonged use
- Low hedonic tone
- Mental health disorders
- Past history of substance use disorder

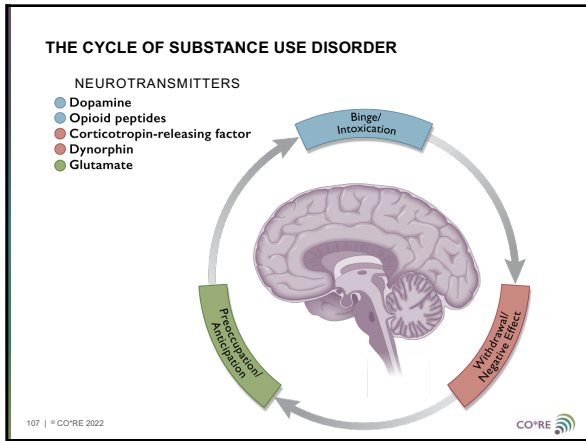
Clinical judgment is key.

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Medication for Opioid Use Disorder (MOUD)

- Important and evidence-based medication that saves lives
- You can start from your office, as an outpatient
- Patients with OUD have decreased mortality when treated

There are three medication options:

1. Buprenorphine (Schedule III)
2. Methadone (Schedule II)
3. Naltrexone (not a controlled substance)

Are we just replacing one drug with another?
Myth or fact?

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BUPRENORPHINE

- The most commonly prescribed pharmacotherapy for the treatment of OUD
- Partial mu-agonist with "plateau effect" for respiratory depression
- Good efficacy and safety profile
- If prescribing for pain, you **do not** need a buprenorphine waiver
- If using to treat OUD, you **do** need a waiver
- Obtaining the waiver to prescribe takes five minutes

FDA-approved bup products for pain:


- Butrans: 7-day transdermal patch
- Belbuca: buccal mucosal film; BID dosing

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AVOID OTHER SUBSTANCES THAT COULD CONTRIBUTE TO AN ACCIDENTAL OVERDOSE

- Benzodiazepines (BZDs), sedatives, muscle relaxants; they are CNS depressants
- More than 30% of opioid overdoses involve benzodiazepines (BZDs)
- Use a comprehensive SUD evaluation to support recovery efforts for all substances



SOURCE: NIDA, Takaki H, et al. Am Journal Addictions. 2019;1-8.


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USE A WHOLE-PERSON APPROACH WHEN TREATING A PATIENT WITH OUD FOR PAIN

- Must address *both* pain and opioid use disorder
- Remember that untreated pain is a trigger for return to use
- Avoid other potentially problematic medications
- Consider a multimodal pain program, including non-pharma options
- Avoid stigmatizing patients who are on long-term opioids for pain
- Consider buprenorphine for both pain and OUD
- Enlist patient's family/caregivers to secure and dispense opioids
- Recommend an active recovery program
- Remember to use PDMP
- Use screening methods (UDT, pill counts, PPA) to identify challenges and initiate discussion

SOURCE: Bailey J, et al. Pain Med 2010;11:1803-1818.

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REFERRALS AND TREATMENT CENTERS

ASAM, SAMHSA, and AAAP are all helpful referral resources.

ASAM resources:
https://asam.org/membersuite.com/directory/SearchDirectory_Criteria.aspx
 SAMHSA locator: <https://findtreatment.samhsa.gov/locator>
 AAAP locator: <https://www.aaap.org/patients/find-a-specialist/>

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IN SUMMARY

- 📍 There is a place for opioids, but use caution
- 📍 Use multimodal therapies as part of the pain management care plan
- 📍 Screen for OUD risk with a validated instrument
- 📍 Continually reassess patients using opioids
- 📍 Patient and family/caregiver education is essential
- 📍 If you suspect an OUD, begin treatment

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Our session stops here, but your review continues...

For detailed information, prescribers can refer to prescribing information available online via DailyMed at www.dailymed.nlm.nih.gov or <https://opioidalanalgesics.com/RocUI/products.u>

Please visit the CO'RE Tools Repository: <http://core-rems.org/opioid-education/tools/>

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