
SCOPE of Pain
Safer/Competent Opioid Prescribing Education
BU Chobanian & Avedisian School of Medicine
scopeofpain.org

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How the Program Works

- Web-based program, CME, CNE, and CPE credit available
- Two parts, with a post-test after each part (note: ★ in upper right-hand corner of slides indicate post-test content)
- Brief polling questions periodically in each part
- Certificate available upon completion of post-tests and evaluation
- Additional resources, tools, and supplemental educational activities available at www.scopeofpain.org

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Faculty

Faculty members have no relevant financial relationships to disclose.

This activity does include discussion of the off-label use of certain formulations of buprenorphine to treat pain. These formulations are approved to treat opioid use disorder but not to treat pain. This presentation does include discussion of the off-label use of clonidine and tizanidine to treat opioid withdrawal symptoms. Clonidine and tizanidine are not FDA approved for this use.

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Partners and Supporters

National Partner

- Federation of State Medical Boards

Opioid REMS

- Content dictated by FDA *"Blueprint for Prescriber Education"*
- FDA requires opioid analgesic manufacturers to fund CME-certified education by approved providers

Grant Support

This activity is supported by an independent educational grant from the Opioid Analgesic REMS Program Companies. See https://opioidanalgesicrems.com/Resources/Docs/List_of_RPC_Companies.pdf for listing of REMS Program Companies. This activity is intended to be fully compliant with the Opioid Analgesic REMS education requirements issued by the US FDA.

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About the Program

Through the case presented in this program, you will learn how to:

- Assess pain and function
- Educate patients about opioid risks and limitations of benefit
- Assess for prescription opioid misuse risk
- Develop patient-centered treatment goals
- Monitor patients prescribed opioids for benefits and harms
- Use a risk-benefit framework when initiating, maintaining, modifying, or tapering opioid analgesics
- Diagnose and manage patients with opioid use disorder with or without concurrent pain

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Purpose of the Training

- Covers strategies for safer use of opioids for managing pain by reviewing **best practices** and sharing **clinical pearls**
- Counts towards the **2023 DEA education requirement** of the **Medication Access and Training Expansion (MATE) Act**
- Aligns with the **2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain**
- Does NOT cover palliative care or end of life pain management

Alford DP, et al. *Pain Med*. 2016
Dowell D et al. *MMWR* 2022

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Introduction:
Setting the Stage

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Pain: *"An Unpleasant Sensory and Emotional Experience"*

Acute Pain *Life sustaining symptom*	Chronic Pain Pain persisting beyond expected healing (~3 months) *No evolutionary benefit, can be a disease in and of itself*
Adaptive eliciting motivation to minimize harm and allow healing	**Maladaptive** disorder influenced by genetics and epigenetics Categorization influences work-up, treatment and prognosis • **Nociceptive**: tissue (or potential) damage including **somatic** (e.g., bones, joints, muscle) and **visceral** (e.g., mucosal injury, obstruction/distention, ischemia) • **Neuropathic**: disease or injury affecting the somatosensory nervous system including **central** (e.g., traumatic, vascular, neurodegenerative) and **peripheral** (e.g., infection, compression, traumatic, ischemia) • **Nociplastic**: abnormal processing of pain signals without clear evidence of tissue damage or discrete pathology including **diffuse sensitization** (fibromyalgia), **function visceral pain** (irritable bowel syndrome), **regional somatic sensitization** (complex regional pain syndrome) • **Mixed Pain:** combination of the different types of pain, occurring simultaneously in the same area of the body

Raja SN, et al. *Pain*. 2020
Cohen SP, et al. *Lancet*. 2021
Fitzcharles MA et al. *Lancet*. 2021
Clauw DJ et al. *Postgrad Med*. 2019
Freynhagen R et al. *Curr Med Res Opin*. 2020

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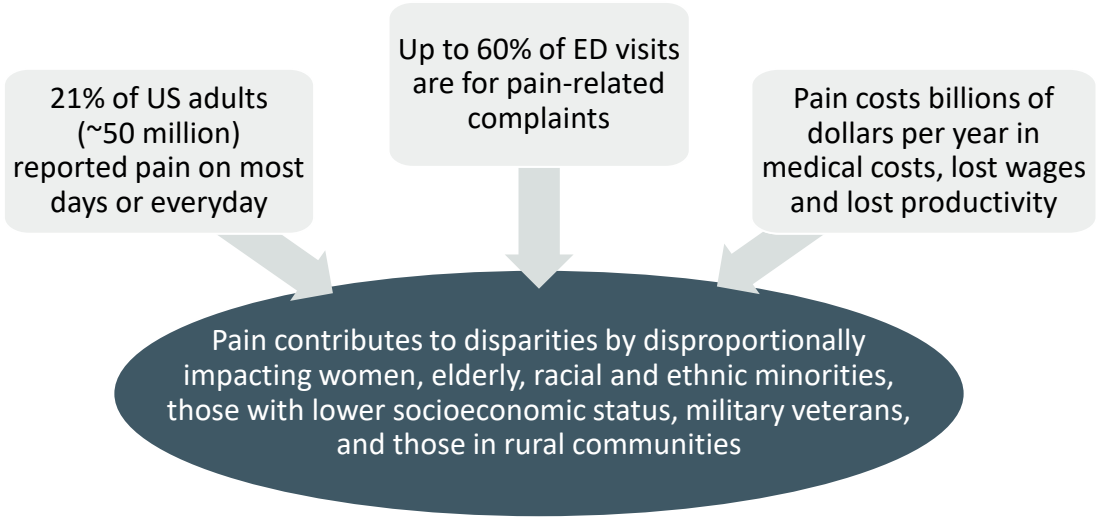
The State of Pain



Yong R et al. *Pain* 2022
Cordell WH, et al. *Am J Emerg Med*. 2002
Gaskin DJ, Richard P. *J Pain* 2012
Dahlammer J et al. *MMWR* 2018
Mills SEE et al. *Br J Anaesh.* 2019

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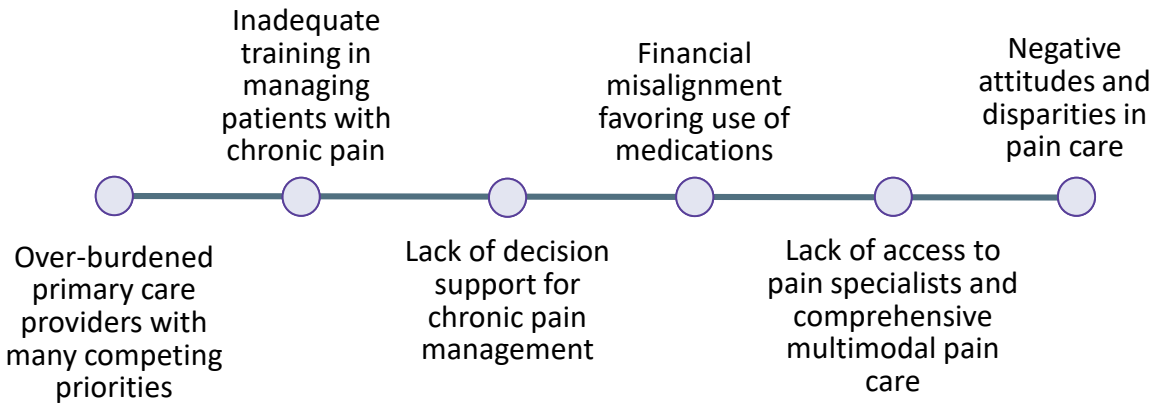
Barriers to Adequate Pain Care



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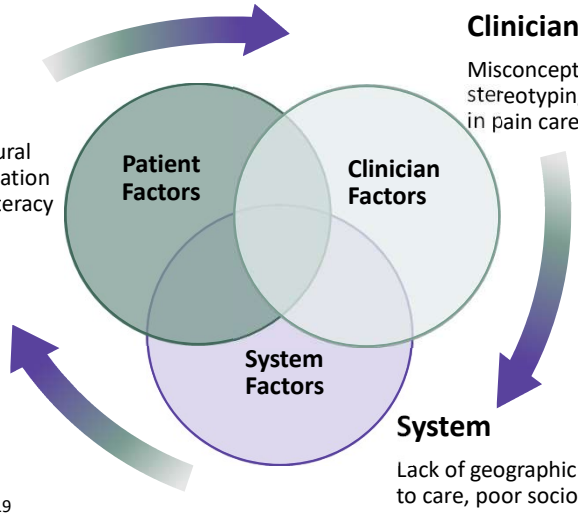
Disparities in Pain Care

*Racial minorities and vulnerable populations experience additional pain and suffering because of disparities in access and treatment**

Patient

Language barriers, cultural differences in communication and beliefs and health literacy can lead to poor pain treatment outcomes



Clinician

Misconceptions, negative attitudes, stereotyping, implicit bias result in disparities in pain care

System

Lack of geographic and/or financial access to care, poor socioeconomic status

Meints SM, et al. *Pain Manage.* 2019
*Nguyen LH, et al. *Anesthesiology Clinics.* 2023

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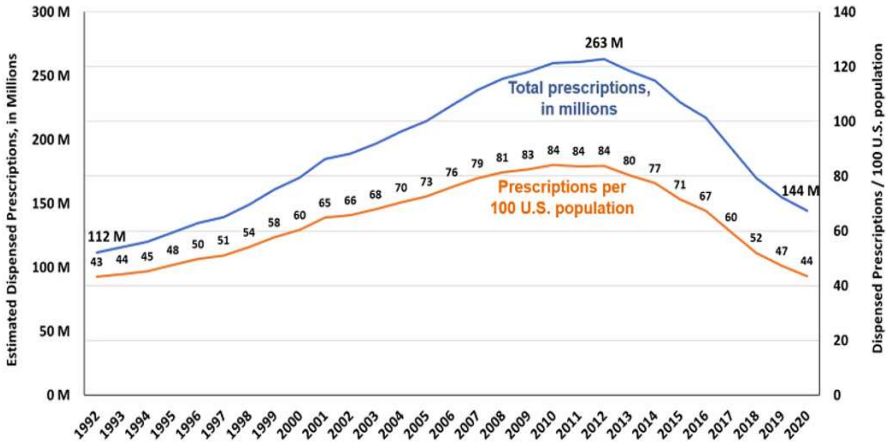
Trends in Opioid Prescribing for Pain



Racial Differences

Compared to White patients, Black and Hispanic patients are less likely to receive opioid analgesics for pain and when they do it is at a lower dose

www.fda.gov
Morden NE, et al. *NEJM* 2021

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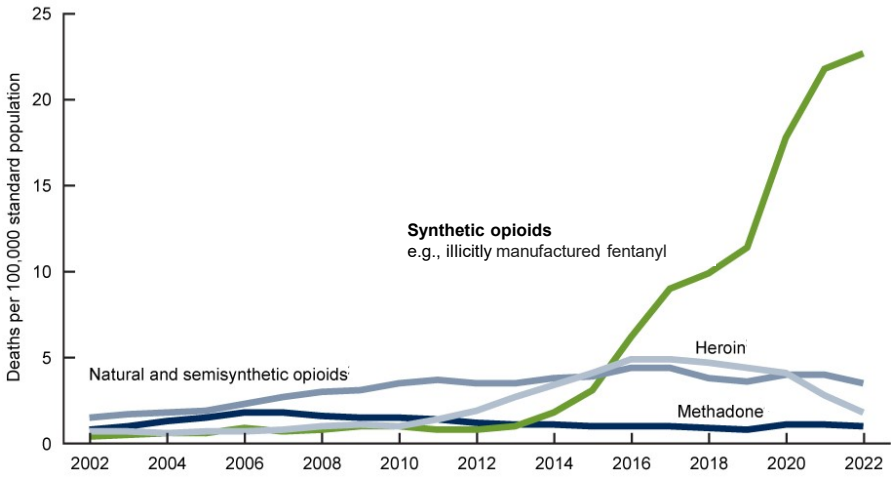
Trends in Opioid Overdose Deaths



Racial Differences

- Whites had early periods of acceleration 1999-2016 with decrease rate of change starting in 2016
- American Indian/ Alaska Native and non-Hispanic Black persons experienced the highest increases in drug overdose death rates starting in 2019

Furr-Holden D, et al. *Addiction.* 2020
Kariisa M, et al. *MMWR*. 2022
Spencer MR et al. *National Center for Health Statistics*. 2024

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Part 1: Understanding Pain and Opioids

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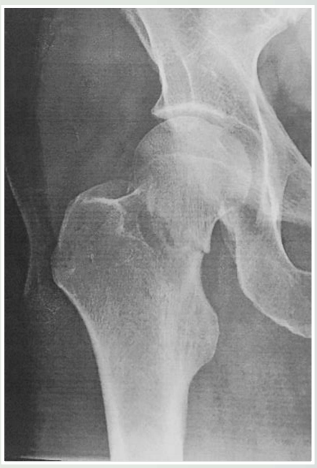
Case Study - Michelle Jones

Medical History

- 36-year-old female with no past medical history
- Displaced right femoral neck fracture after a motor vehicle crash
- Underwent internal fixation
- Perioperative pain managed with nerve blocks and parenteral hydromorphone



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Assessing Acute Pain

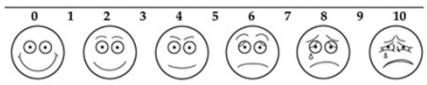
S	Site
O	Onset
C	Character
R	Radiation
A	Associations
T	Time course
E	Exacerbating/relieving factors
S	Severity

*"Many factors influence self-reported pain including **gender, social support, clinician characteristics, trust**."*

~ Barry S. Oken, MD, PhD

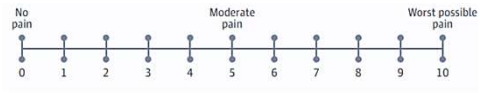
Pain intensity scales include:

- **Visual Analogue Scales (VAS)**



- **Emoji-based VAS**

- **Numerical Rating Scales (NRS) 10-point scale**



1-3 Mild | 4-6 Moderate | 7-10 Severe

He S, et al. *JAMA*. 2022
Oken BS. *Brain*. 2008
Breivik H, et al. *Br J Anaesth*. 2008
Mason ST, et al. *Handbook of Pain Assessment*. 2011

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Risk Factors: Developing Chronic Postsurgical Pain

Alterations in expression of neurotransmitters, receptors, and ion channels
Changes to neuron structure, connectivity, and survival

Patient-related
- Younger
- Female
- History of
  - Anxiety
  - Depression
  - Catastrophizing
  - Pre-existing pain syndrome
  - Preoperative opioid use

Persistent Pain

Intraoperative variables
- Surgical procedure
- Nerve ligation/injury
- Ischemia

Postoperative pain
- Uncontrolled high intensity pain
- Longer duration of postoperative pain

Voscopoulos C, Lema M. *Br J Anaesth*. 2010
Pozek JP, et al. *Med Clin North Am*. 2016

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Risk: Acute to Chronic Musculoskeletal Pain
STarT MSK Screening Tool

- Helps identify **modifiable risk factors** (biomedical, psychological, social) **for chronic musculoskeletal pain disability**
- Score stratifies risk:
  - Low (0-3)
  - Medium (4-7)
  - High (8-9)

	Last 2 weeks…(disagree [0] or agree [1])
Pain Characteristics	1. …**troublesome joint or muscle pain in more than one part** of your body?
	2. …**only been able to walk short distances** because of your pain?
	3. …**dress more slowly** than usual because of your pain?
	4. …**other important health problems**?
Catastrophizing	5. …**feel it is unsafe**…to be physically active?
	6. …**worrying thoughts** about your pain a lot of the time?
	7. …your pain condition **will last a long time**?
	8. … **stopped enjoying** all the things you usually enjoy?
	9. **How bothersome** has your pain been… *(not at all, slightly, moderately, very much, extremely)*

Campbell P, et al. *J Pain Res*. 2016

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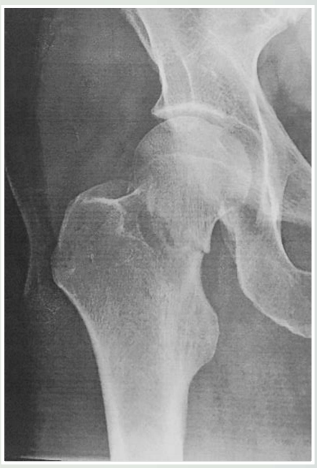
Case Study - Michelle Jones

?

What is the correct amount of opioid to discharge this patient on?

Discharged Home

- Visiting nurse and home physical therapy
- Orthopedic follow-up in 1 week
- Received prescriptions for
- Ibuprofen 600 mg every 8 hours prn pain
- Oxycodone (5 mg) 1-2 tablets every 4-6 hours prn pain (#40 tablets)



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Opioid Overprescribing for Acute Pain

Overprescribing	Overprescribing Risk
• Postoperatively over 70% of patients took half or less of their opioids	• Source of prescription opioids misused: 39% family & friends, 44% single prescriber
• After ED visit (e.g., renal colic, fracture/dislocation) 93% of patients had leftover pills, 52% of pills were unused	• 3-5% of opioid-naïve patients receiving an opioid became long-term (>3 months) opioid users *(risk factors: male, over 50, mental illness, substance use disorder)*

Since 2012 there has been a decrease in new opioid prescriptions for more than 7-day supply

Bartels et al. *Plos One*. 2016
Rodgers et al. *J Hand Surg*. 2012
SAMHSA. (2023). *2022 NSDUH*
Sun EC, et al. *JAMA Intern Med*. 2016
McCarthy DM, et al. *Pain Med*. 2021
Riva JJ, et al. *Ann Intern Med*. 2020
Deyo RA, et al. *J Gen Intern Med*. 2017
Zhu W et al. *N Engl J Med*. 2019

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Treating Acute Pain

Acute Dental Pain

Molar extractions:

NSAID + APAP more effective compared to oxycodone alone or in combination with APAP

Acute Musculoskeletal Pain

No significant difference in pain reduction with opioids versus NSAID + APAP or different opioid + APAP combinations

Acute Pain Guidelines

Multimodal, individualized approach

Some minor surgeries, appropriate to d/c patients w/ NSAIDs +/- APAP or limited opioids before transition to NSAIDs +/- APAP

CDC Recommendations 1 & 6

- Acute pain: maximize non-pharm and non-opioids
- Only consider opioids if benefits > risks
- Discuss realistic benefits and known risks
- Prescribe no greater quantity than needed for expected duration of severe pain

Dowell D, et al. MMWR. 2022

Moore RA, et al. *Cochrane Library* 2015
Chang AK, et al. *JAMA* 2017
Jones CMP, et al. *Lancet* 2023
Chou R, et al. *J Pain*. 2016
Qaseem A, et al. *Ann Intern Med* 2020
Fiore JF, et al. *Lancet* 2022

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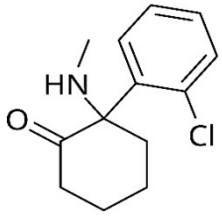
Ketamine for Acute Pain



- Developed in the 1960s as a dissociative anesthetic
  - Subanesthetic doses for treatment of perioperative, neuropathic and nociplastic pain, and depression and substance use disorders
  - Analgesic without respiratory depression
- Increased parenteral use (IV, IM) as analgesic in ED and perioperative settings
  - Low dose (0.3-0.5 mg/kg) safely reduces pain more rapidly but less sustained than morphine
  - Decreases opioid requirements ("opioid-sparing")
- Low oral bioavailability and limited evidence for outpatient treatment of chronic pain
  - Outpatient use (e.g., intranasal) is complex due to administration and monitoring requirements
- Dose-dependent adverse effects - hallucinations, agitation, anxiety, dysphoria, euphoria
- Misuse potential due to psychoactive effects

Bell RF, Kalso EA. *Pain Rep.* 2018
Schwenk ES et al. *Curr Pain Headache Rep*. 2021
Guo J, et al. *Am J Emerg Med*. 2024

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Case Study - Michelle Jones - 54 yo female

18 Years Later…

- Presents for primary care, at age 54, after her previous PCP retired
- Chief complaint: **"I need my pain med refilled today. My feet and hip are killing me!"**
- Past medical history:
  - Type 2 diabetes mellitus (A1C 7 %)
  - Painful diabetic neuropathy
  - Diabetic nephropathy (Cr 1.44, GFR 40)
  - Hypertension
  - Hyperlipidemia
  - Obesity (BMI 32)
  - Post-traumatic osteoarthritis of right hip

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Case Study - Michelle Jones - 54 yo female

Current Medications

Metformin, Empagliflozin, Lisinopril, Atorvastatin

Current Pain Medications

Oxycodone 10 mg 4x/day (60 MME*)
Gabapentin 300 mg 3x/day

Previous Pain Medications

NSAIDs (ibuprofen, naproxen)	*Diabetic nephropathy and GI upset*
Acetaminophen	*Inadequate pain relief*
Tricyclic antidepressants (TCA) (amitriptyline)	*Inadequate pain relief and dry mouth*
Serotonin-norepinephrine reuptake inhibitor (SNRI) (venlafaxine)	*Unable to tolerate due to nausea and dizziness*
Tramadol	*Inadequate pain relief*
Acetaminophen with codeine	*Inadequate pain relief and nausea*

**Morphine Milligram Equivalents*

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Case Study - Michelle Jones - 54 yo female

Social History

Paralegal law office 20 hours/week
Married, no children

Substance Use History

No tobacco use
Alcohol use: 1 glass of wine on special occasions
No illicit drug or cannabis use

Family History

Father being treated for lung cancer
Mother died from complications of alcohol-associated cirrhosis

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Case Study - Michelle Jones - 54 yo female

Pain Medications

- Spacing out oxycodone to avoid running out
- Took last oxycodone this morning
- Best pain relief with oxycodone 10 mg every 6 hours
- Current pain is more severe due to less frequent oxycodone
  - **"My pain pills don't last. I'm suffering. It's almost impossible to go to work."**
- Presents with some medical records from previous PCP

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Case Study - **Michelle Jones** - 54 yo female

Pain Assessment

- **Moderate right hip pain**
  - Constant deep, aching pain radiating to the right groin
  - Exacerbated with activity and relieved with rest
- **Severe bilateral foot pain**
  - Burning, numbness and tingling
  - Pain worse at night, trouble sleeping because of pain

On a scale of 0-10

Michelle states her pain is "20"

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Building Trust: Patient Issues

Patients may assume that you do not believe the severity of their pain complaints

Demonstrated by
exaggerating pain scores
and
exaggerating functional limitations

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Building Trust: Clinician Issues

After completing a thorough pain hx, focused exam, and appropriate diagnostic testing…

Show empathy for the patient's experience…empathy is associated with better outcomes among patients with chronic pain*

"I can't imagine how difficult this is for you."

"It must be really hard to live with pain like this."

Validate that you believe the patient's pain and suffering is real…

"Your pain is real."

"Please know that your pain matters and we'll work together to find you relief."

Believing the severity of a patient's pain complaint **does not mean opioids are indicated**

*Licciardone JC et al. *JAMA Network Open*. 2024

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Chronic Pain Assessment

Unidimensional Scales

☐ (e.g., Numeric rating) are of limited value for assessing chronic pain

Multidimensional Instruments

☐ McGill Pain Questionnaire

☐ Graded Chronic Pain Scale

☐ Brief Pain Inventory

} Impractical for use in most primary care settings

Brief Multidimensional Tool

Pain, Enjoyment, General Activity (PEG) Scale

1. What number best describes your pain on average in the past week:

0 1 2 3 4 5 6 7 8 9 10

No pain — Pain as bad as you can imagine

2. What number best describes how, during the past week, pain has interfered with your enjoyment of life?

0 1 2 3 4 5 6 7 8 9 10

Does not interfere — Completely interferes

3. What number best describes how, during the past week, pain has interfered with your general activity?

0 1 2 3 4 5 6 7 8 9 10

Does not interfere — Completely interferes

Breivik H, et al. *Br J Anaesth*. 2008

Salaffi F, et al. *Best Pract Res Clin Rheumatol*. 2015

Krebs EE, et al. *J Gen Intern Med*. 2009

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Case Study - Michelle Jones - 54 yo female

In the past week…

PEG Scale Assessment

Pain on average?

0 1 2 3 4 5 6 7 8 9 **10**

No pain — As bad as you can imagine

Pain interfered with **Enjoyment of life?**

0 1 2 3 4 5 6 7 8 **9** 10

Does not interfere — Completely interferes

Pain interfered with **General activity?**

0 1 2 3 4 5 6 7 8 **9** 10

Does not interfere — Completely interferes

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Case Study - Michelle Jones - 54 yo female

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How will you manage this patient's chronic pain?

Physical Examination

- No acute distress
- Normal vitals, weight 193 lbs (BMI 32)
- Musculoskeletal exam normal except right hip with decreased internal rotation
- Neurologic exam normal except absent Achilles tendon reflex bilaterally
- Diabetic foot exam:
  - No lesions, normal pulses
  - Loss of protective sensation by monofilament test

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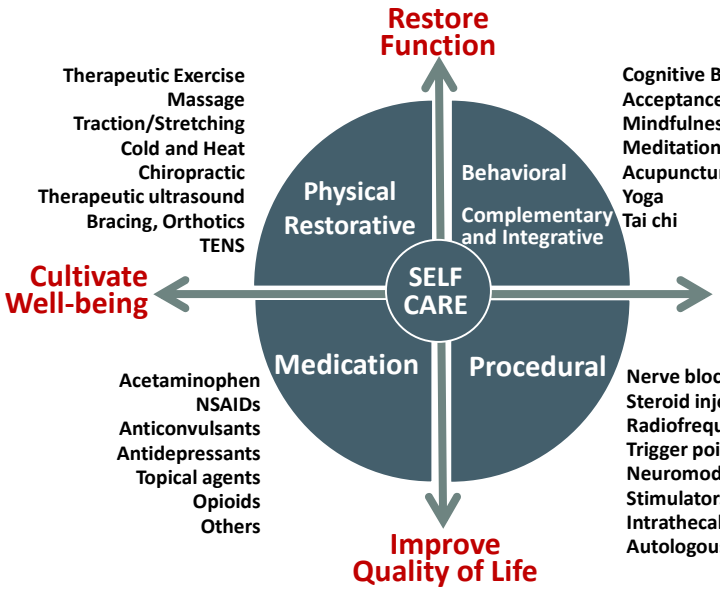
Multidimensional Approach for Chronic Pain



Study duration on **all treatments for chronic pain** are ≤ 12 months, vast majority are ≤ 12 weeks
Tayeb BO, et al. *Pain Med.* 2016

Multimodal approaches are more cost-effective than single modality options
Flor H, et al. *Pain* 1992
Roberts AH, et al. *Clin J Pain*. 1993
Patrick LE, et al. *Spine*. 2004
Kamper SJ, et al. *Cochrane Review*. 2014

Modified image courtesy of Seddon Savage, MD, MS
Cohen SP et al. *Lancet*. 2021

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Getting Help from a Pain Specialist

When to refer to a pain specialist:

- **Unsure of pain diagnosis**
- **Unsure of other treatment options**
- **Want second opinion on opioids for individual patient**

- **Know the services** your pain specialist offers
- **Set patient expectations** - let them know what to expect (e.g., full assessment) and NEVER send them with the expectation of a specific treatment (e.g., "I am here for my injection") as this sets up patients for disappointment and frustration
- **Know local or state requirements** requiring pain specialist consultation

Wang VC, Mullally WJ. *Am J Med.* 2020
Slitzky M et al. *J Pain Res.* 2024

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Non-Opioid Pharmacotherapies

Salicylates, Nonacetylated Salicylates

Non-steroidal Anti-inflammatory Drugs (NSAIDs)

- Nonselective and selective COX-2 inhibitor (celecoxib)
- Anti-inflammatory, analgesic, antipyretic

Acetaminophen (APAP)

- Analgesic, antipyretic
- Less effective than full dose NSAIDs in relieving chronic pain but fewer adverse effects

General Considerations

- Ceiling analgesic effects
- No known analgesic tolerance
- Additive role (NSAID+APAP)
- Some patients may respond better to one NSAID than another
- Side effects (GI, renal, CV) especially at high NSAID doses

Med Lett Drugs Ther. 2022
Finnerup NB. *N Eng J Med.* 2019

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Non-Opioid Pharmacotherapies

- Analgesics with primary indication other than pain
  - **Antidepressants** (TCAs, SNRIs)
  - **Anticonvulsants** (gabapentinoids, carbamazepine)

  } Mainstay of pharmacologic treatments for neuropathic and nociplastic pain syndromes
  - **Antispasmodics/muscle relaxants**
  - **Local anesthetics** (lidocaine)

⚠ **Caution**:

- Misuse and addiction potential with:
  - Gabapentinoids (gabapentin, pregabalin)
  - Muscle relaxants (carisoprodol metabolizes into meprobamate (barbiturate-like drug))
- Additive burden of anticholinergic side effects (e.g., TCAs, cyclobenzaprine)

Med Lett Drugs Ther. 2022
Finnerup NB. *N Eng J Med.* 2019
Evoy KE et al. *Drugs.* 2021
Hill J, Alford DP. *Semin Neurol.* 2018

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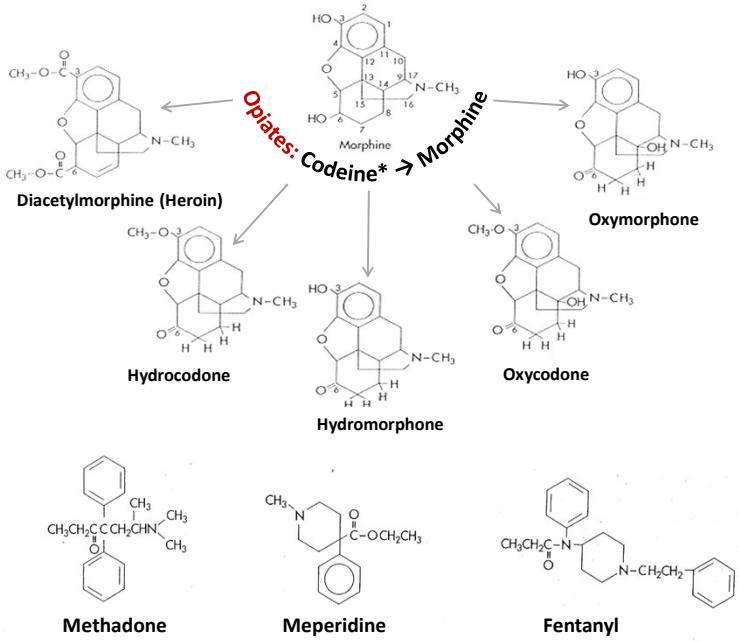
Opioids

Natural (Opiates)

Semisynthetic

Synthetic



** Codeine is a prodrug of morphine*

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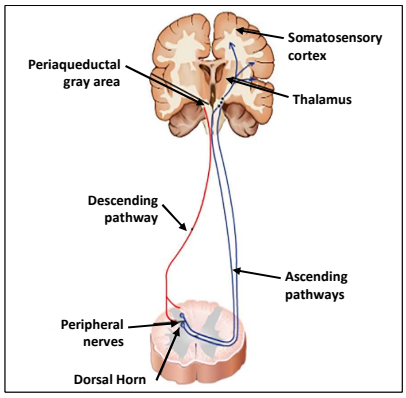
Opioid Analgesics

- Turn on descending inhibitory systems
- Prevent ascending transmission of pain signal
- Inhibit terminals of C-fibers in spinal cord
- Inhibit activation of peripheral nociceptors
- Responses are variable (not all patients respond to the same opioid in the same way)
  - >3,000 polymorphisms in human μ opioid receptor gene
  - Single nucleotide polymorphisms (SNPs) affect opioid metabolism, transport across the blood brain barrier, and activity at receptors and ion channels
- Activate the reward pathway



(ScienceMedia.com), *Acute versus Chronic pain and Pain Pathways*, Nov 2019.

McCleane G, Smith HS. *Med Clin N Am.* 2007. Smith HS. *Pain Physician*. 2008. Ren Z et al. *Pain Physician*. 2015

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Opioid Tolerance and Physical Dependence

Both tolerance and physical dependence are physiological adaptations to chronic opioid exposure

Tolerance:

- Increased dosage needed to produce specific effect
  - Develops readily for CNS and respiratory depression
  - Less so for constipation
  - **Unclear about analgesia**

Physical Dependence:

- Signs and symptoms of withdrawal by abrupt opioid cessation, rapid dose reduction or exposure to an opioid antagonist (naloxone)

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Opioid Efficacy and Safety

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Opioid Efficacy for Chronic Pain

Meta-analyses (3-6 m f/u)

- **Opioids vs placebo** *(high quality studies)* Opioids with statistically significant, but small, improvements in pain[1,2] and physical functioning[2]
- **Opioids vs nonopioids** *(low-mod quality studies)* Similar benefits[2]

RCT[3] found opioids **not superior** to nonopioids for improving musculoskeletal pain-related function over 12 months

Limitations to generalizability:[4]

- *Excluded patients already on long-term opioids*
- *89% of eligible patients declined to be enrolled*

Two longer term follow-up studies found **44.3%** on chronic opioids for chronic pain had **at least 50% pain relief** [5]

1. Meske DS, et al. *J Pain Res.* 2018
2. Busse JW, et al. *JAMA*. 2018
3. Krebs EE, et al. *JAMA*. 2018
4. Webster L. *Pain Med.* 2019
5. Noble M, et al. *Cochrane Syst Rev.* 2010

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Opioid Safety and Risks

Allergies: Rare

Immunosuppression

- Animal models, opioid induced immuno-suppression
- Humans increased risk invasive pneumococcal disease, and community acquired pneumonia

Organ Toxicities

Suppression of the hypothalamic-pituitary-gonadal and adrenal axes

- Menstrual irregularities, reduced fertility, erectile dysfunction
- Osteoporosis, fatigue
- Obesity, metabolic syndrome

Adverse Effects

- Nausea, sedation, urinary retention, sweating
- Constipation: (hypodynamic bowel, dry stool)
- Pruritus (histamine release)
- Respiratory depression → Death

Diasso PD, et al. Eur J Pain. 2019
Wiese AD, et al. *Ann Intern Med.* 2018
Edelman EJ, et al. *JAMA Intern Med.* 2019
Sharma P, et al. *J Soc. Health Diabetes*. 2016

Report AE to FDA 1-800-FDA-1088, www.fda.gov

42

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Managing Opioid Adverse Effects

Nausea and Vomiting	• Usually resolves in a few days • Antiemetics, switch opioids
Sedation Mostly during initiation or change in dose	• **Decrease dose**
Constipation Most common and should be anticipated	• Stool softeners, osmotic stimulants • Peripherally-acting opioid antagonists • Switch opioids, avoid bulking agents
Pruritus	• Switch opioids • Antihistamines
Urinary Retention	• Switch opioids

Paul AK, et al. *Pharmaceuticals.* 2021
Hanson B et al. *Gastroenterology.* 2019

43

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Opioids and Patient Considerations

- **Age**

  - Decline in therapeutic index
  - Predisposition to adverse drug effects
  - Fall risk, worsening cognitive function

- **Medical Co-morbidities**

  - **Liver disease**: decreased opioid clearance
    - When using morphine, oxycodone, hydromorphone: reduce doses and prolong dosing intervals

  - **Kidney disease**: decreased opioid excretion
    - Preferred are hydromorphone, fentanyl, buprenorphine, methadone
    - Oxycodone 2nd line, due to active metabolites
    - Morphine, codeine not recommended due to active metabolites

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Opioids: Drug-Drug Interactions (DDI)

- Mechanism includes inhibition or induction of **cytochrome P450** (CYP450)
  - **Opioids metabolized by CYP450:** numerous DDIs that can reduce or increase opioid effects (e.g., codeine, oxycodone, hydrocodone, fentanyl, tramadol, methadone)
  - **Opioids <u>not</u> metabolized by CYP450:** fewer DDIs (e.g., morphine, hydromorphone)
  - Helpful resource: http://dailymed.nlm.nih.gov/dailymed
- CNS depressants (benzodiazepines, alcohol, cannabis, other sedatives, hypnotics, TCAs, MAOI) may potentiate opioid effect on sedation and respiratory depression
- Alcohol may rapidly release opioid (dose dump) or increase drug levels w/out dose dumping
- Opioids can reduce efficacy of diuretics by inducing release of antidiuretic hormone

CDC

Recommendation 11

Use caution when concurrently prescribing opioids and benzodiazepines (and other CNS depressants)

Dowell D, et al. MMWR. 2022

45

Kotlinska-Lemieszek A, et al. *Drug Des Devel Ther.* 2015.

45

Problematic Opioid Use in Chronic Pain

Systematic review of 38 studies

(26% primary care, 58% pain clinics)

Misuse rates: **21% - 29%**

(95%CI: 13%-38%)

Misuse: Use contrary to the prescribed use, regardless of the presence or absence of harm or adverse effects

Addiction rates: **8% - 12%**

(95% CI: 3%-17%)

Addiction: Pattern of continued use with experience of, or potential for, harm

46

Vowles KE, et al. *Pain.* 2015

46

Collateral Opioid Risk

Risks

- Young children's ingestion and overdose*
- Adolescent experimentation leading to overdose and addiction
- Other household contacts (family, visitors)

Mitigating risk

- Safe storage (e.g., lock box)
- Child resistant packaging
- Safe disposal www.deadiversion.usdoj.gov/drug_disposal/
- Opioid overdose education and naloxone distribution**
  - More information: www.prescribetoprevent.org

Recommendation 8

Use strategies to mitigate risk including naloxone co-prescribing

Dowell D, et al. MMWR. 2022

* Gaither JR, et al. *JAMA Pediatr*. 2016
** Beletsky L, Rich JD, Walley AY. *JAMA* 2012
** SAMHSA *Opioid Overdose Prevention Toolkit* 2018

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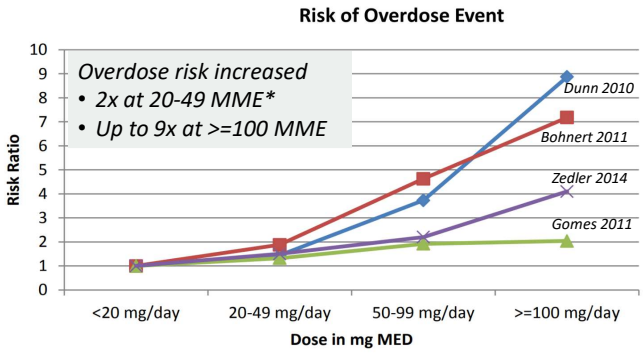
Higher Dose Opioids

A lack of high-quality evidence about the efficacy of high-dose opioids for chronic pain

Higher doses associated w/:

- Overdose risk
- Hyperalgesia
- Reduced function
- Immunosuppression



*MME: Morphine Mg Equivalent

Els C, et al. *Cochrane Reviews* 2023
Kobus AM, et al. *J Pain*. 2012
Huxtable CA, et al. *Anaesth Intensive Care*. 2011
Brush DE. *J Med Toxicol*. 2012
Lee M, et al. *Pain Physician*. 2011
Braden JB. *Arch Intern Med*. 2010
Paulozzi LJ. *Pain Med*. 2012
Edelman EJ, et al. *JAMA Int Med*. 2019
Dunn KM, et al. *Ann Intern Med*. 2010
Bohnert AS, et al. *JAMA*. 2011
Zedler B et al. *Pain Med*. 2014
Gomes T, et al. *Open Med*. 2011

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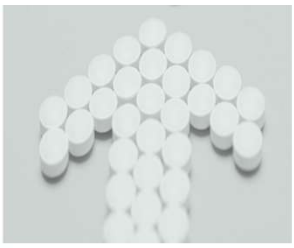
Higher Dose Opioids

Patient on high doses…

- Manage as higher risk
- Increase monitoring and support



CDC

Recommendation 4

- When starting opioids, prescribe lowest effective dosage
- Use caution at any dosage
- Carefully evaluate benefits and risks when considering increasing dosage
- Avoid increasing dosage above levels with diminishing benefit relative to risk

Dowell D, et al. MMWR. 2022

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Risk Factors

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Risk Factors for Opioid-Related Harm

(misuse, overdose, addiction)

Medication Factors
Higher opioid dose
Long-term opioid use (>3 months)
Extended release/long-acting (ER/LA) opioid
Initial 2 weeks after starting ER/LA opioid
Combination opioids and sedatives (e.g., benzodiazepines)

Patient Factors
Mental health disorder (e.g., depression, anxiety)
Substance use disorder (SUD) (e.g., alcohol, tobacco, illicit and prescription drug)
Family history of SUD
History of opioid overdose
Sleep-disordered breathing

Akbik H, et al. *J Pain Symptom Manage*. 2006
Ives J, et al. *BMC Health Serv Res*. 2006
Liebschutz JM, et al. *J Pain*. 2010
Michna E, et al. *J Pain Symptom Manage*. 2004
Reid MC, et al. *J Gen Intern Med*. 2002
Volkow ND, et al. *N Engl J Med*. 2016

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Screening for Sleep-Disordered Breathing

STOP-BANG Questionnaire

STOP
Do you **SNORE** loudly?
Do you often feel **TIRED**, fatigued, or sleepy during daytime?
Has anyone **OBSERVED** you stop breathing during your sleep?
Do you have or are you being treated for high blood **PRESSURE**?
BANG
BMI more than 35?
AGE over 50?
NECK circumference greater than 16 inches?
GENDER male?

Sleep Apnea Risk	Total Score
High Risk	5-8
Intermediate Risk	3-4
Low Risk	0-2

Chung F et al. *Anesthesiology* 2008; Chung F et al. *Br J Anaesth* 2012; Chung F et al. *J Clin Sleep Med* 2014.

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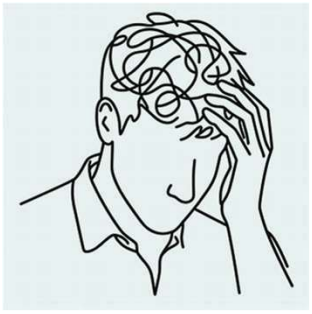
Psychiatric Co-Morbidities

- Almost every psychiatric diagnosis in the DSM-5 is also associated with increased rates of chronic pain

• Major depressive disorder	• Sleep disorder
• Generalized anxiety disorder	• PTSD
• Personality disorder	• Substance use disorder



- Bidirectional relationship
  - Psychiatric conditions make pain worse
  - Pain makes psychiatric conditions worse
- Should assess for psychiatric conditions and attempt to co-manage

Johnston KJA, Huckins LM. *Complex Psychiatry.* 2023

53

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Brief Screenings for Co-Morbidities

Depression	**PHQ-2** (Patient Health Questionnaire), *2-items*
Anxiety	**GAD-2** (Generalized Anxiety Disorder), *2-items*
PTSD	**PC-PTSD-5** (Primary Care PTSD Screen for DSM-5), *5-items*
Sleep Disorder	**ISI-3** Insomnia Severity Index, *3-items*
Suicidality	**ASQ** (Ask Suicide-Screening Questions), *4-items*

Kroenke K, et al. *Med Care.* 2003
Kroenke K, et al. Ann Intern Med. 2007
Prins A, et al. *J Gen Intern Med.* 2016
Thakral M, et al. *Sleep Med.* 2021
Horowitz LM, et al. *Psychosomtics.* 2020

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Screening for Substance Use

TAPS (Tobacco, Alcohol, Prescription Medication, and Other Substance Use) Tool

In the PAST 12 MONTHS, how often have you…
…used tobacco or any other nicotine (i.e., e-cigarette, vaping or chewing tobacco)?
…had **5 or more** drinks (men)/**4 or more** drinks (women) containing alcohol in one day?
…used any prescription medications just for the feeling, more than prescribed or that were not prescribed for you?
…used any drugs including marijuana, cocaine or crack, heroin, methamphetamine (crystal meth), hallucinogens, ecstasy/MDMA?

McNeely J, et al. *Ann Intern Med*. 2016

55

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Case Study - **Michelle Jones** - 54 yo female

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Will you prescribe opioids?

Screening Results

- Negative for sleep-disordered breathing
- Negative for insomnia, depression, and anxiety
- Negative for unhealthy substance use

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When Are Opioids Indicated?

- **Pain is severe**
- **Pain has significant impact on function and quality of life**
- **Pain type potentially opioid-responsive**
  nociceptive or neuropathic pain
  but less so for nociplastic pain and headache syndromes (e.g., migraines)
- **Inadequate benefit from non-opioid modalities**
- **If already on opioids, is there documented benefit** (pain, function, quality of life)**?**

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Opioids and Chronic Pain in Perspective

The efficacy of **long-term opioid therapy** for chronic pain has been **inadequately studied**

- Opioid prescribing should be more judicious
- Opioid misuse can be fatal (overdose, addiction)
- Opioids for chronic pain…
  - Are indicated after alternative safer options are inadequate
  - Are only one tool of a multimodal approach for managing severe chronic pain

CDC

Recommendation 2

- Maximize non-pharmacologic and non-opioid therapies
- Only consider opioids if expected benefits (pain/function) > risks
- Before starting opioids discuss realistic benefits and known risks
- Establish treatment goals and how opioids will be discontinued if benefits < risks

Dowell D, et al. MMWR. 2022

Chou R, et al. *Ann Intern Med.* 2015
Dowell D, et al. *JAMA.* 2016
Manchikanti L, et al. *Pain Physician.* 2011
Reuben DB, et al. *Ann Intern Med.* 2015
Volkow ND, McLellan T. *N Engl J Med.* 2016

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Patients on Opioid Therapy from Previous Clinician

"Legacy Patients" "Opioid Orphans"

- Review the patient history with the former clinician, if possible
- Review prescription history (e.g., Prescription Drug Monitoring Program)
- Assess the patient for opioid use disorder and treat or refer to specialty care, if indicated
- Consider a therapeutic bridge for the patient until a plan of care is determined given the risks associated with stopping opioid therapy abruptly
- Document rationale for treatment plan and next steps

Coffin PO, et al. *N Engl J Med*. 2022

CDC

Recommendation 5

For patients already on opioids, carefully weigh benefits and risks

- If benefits > risks, continue opioids and optimize other therapies
- If risks > benefits, optimize other therapies, gradually taper opioids to lower dosages
- Unless life-threatening issue (i.e., impending overdose), do not abruptly reduce opioids from higher dosages

Dowell D, et al. MMWR. 2022

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Assess for Opioid Misuse Risk Prior to Prescribing

Patient Medication-taking History	Urine Drug Testing (UDT)	Prescription Drug Monitoring Program (PDMP)	Speak to Previous Clinician and Co-Care Providers	Old Medical Records	Screening Tools *(no gold standard, lack of evidence* supporting use)*
History of loss of control, compulsive use, continued use despite harm	Check UDT to confirm substance use history	Check PDMP to confirm medication and prescriber history	History of concerning medication-taking behaviors (e.g., early refills, lost Rx)	History of unsafe medication use	**ORT:** Opioid Risk Tool **DIRE:** Diagnosis, Intractability, Risk, Efficacy **SOAPP:** Screener and Opioid Assessment for Patients with Pain **STAR:** Screening Tool for Addiction Risk **STORM:** VA Stratification Tool for Opioid Risk Mitigation **BRQ:** Brief Risk Questionnaire **PMQ:** Pain Medication Questionnaire **Others…**

Moore TM, et al. *Pain Med*. 2009
*Klimas J et al. *JAMA Network Open*. 2019

60

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Case Study - Michelle Jones - 54 yo female

PDMP showed oxycodone 10 mg #120 tablets per month with one prescriber and one pharmacy, last filled 7 weeks ago

At 1st visit

- Prescribed oxycodone 10 mg 4x/day x 2 weeks (#56)
- Continued gabapentin 300 mg 3x/day
- Added acetaminophen 500 mg 4x/day
- Sent urine drug test (UDT)
- Obtained release to contact previous PCP

Before 2nd visit

- Reviewed previous medical records
  - Problem and medication lists reconciled
  - Inadequate documentation about benefits (e.g., pain, function) or monitoring (e.g., UDT) BUT no evidence of worrisome behaviors (e.g., early refills)

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Questions for Next Visit

Clinician Concerns:

- Should I change the opioid dose?
- Should I change to an ER/LA opioid?
- What about any other adjuvant medications or therapies?
- What sort of treatment plan should I develop?

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Summary Part 1

Opioids…

- Should not be first line treatment option
- Are just one tool in a multimodal approach
- Side effects are common and can be managed
- Carry significant risk including addiction, overdose, death
- Misuse risk can be assessed using systematic approach which includes screening for co-morbidities

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SCOPE of Pain

Safer/Competent Opioid Prescribing Education

BU Chobanian & Avedisian School of Medicine

scopeofpain.org

1

Part 2:

Safer Opioid Prescribing

2

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Case Study - Michelle Jones - 54 yo female

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Should opioids be continued?

If so, should the opioid be changed?

In the interim…

- Unable to contact previous PCP who retired
- UDT positive for oxycodone only (as expected)

Office Visit 2

- PEG scores:
  - "6 out of 10" after oxycodone dose
  - "9 out of 10" right before next oxycodone dose
- Denied sedation
- Completed 2-week oxycodone prescription on schedule

3

3

Opioid Choices

Immediate Release/ Short-acting (IR/SA)	Extended Release/ Long-acting (ER/LA)
• Morphine	• Morphine
• Hydrocodone	• Hydrocodone
• Hydromorphone	• Hydromorphone
• Oxycodone	• Oxycodone
• Oxymorphone	• Oxymorphone
• Tramadol	• Tramadol
• Tapentadol	• Tapentadol
• Buprenorphine (buccal)	• Buprenorphine (transdermal)
• Fentanyl (transmucosal)	• Fentanyl (transdermal)
• Codeine	• Methadone

Product-specific information: http://dailymed.nlm.nih.gov/dailymed; pharmacy medication guide; www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass

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Choosing IR/SA vs ER/LA Opioids

IR/SA Opioids

- No opioid tolerance/opioid naïve
- Intermittent or occasional pain (PRN dosing)

Always **start low** and **go slow**

ER/LA Opioids

- Opioid tolerance exists
- Constant, severe, around-the-clock pain (scheduled dosing)
- To stabilize pain relief when patient using multiple doses of IR/SA opioids
- **MUST NOT be broken, chewed or crushed**

CDC

Recommendation 3

When starting opioids, use IR instead of ER/LA opioids

Dowell D, et al. MMWR. 2022

Note: No adequate studies of ER/LA opioids in pregnant women; use only if benefit significantly outweighs risk.

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IR/SA vs ER/LA Opioid Uncertainties

Insufficient Evidence

to determine whether ER/LA opioids are more effective or safer than IR/SA opioids

Individualize Treatment

Choose options that best meet patient's needs

Debate

whether bolus dosing (IR/SA) or continuous exposure (ER/LA) is more likely to result in analgesic tolerance, hyperalgesia or addiction

Chou R, et al. *J Pain Symptom Manage*. 2003
Argoff CE, Silvershein DI. *Mayo Clin Proc.* 2009

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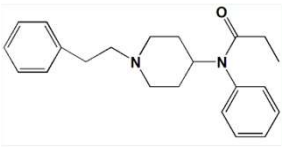
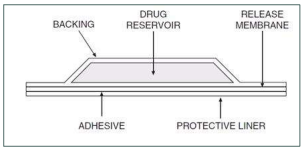
Transdermal Fentanyl





- Dosed in micrograms (mcg)
- Slow peak onset (>24-72h)
- Delayed offset (serum t½ life >17-26h)
- Sustained release requires predictable blood flow and adequate subcutaneous fat
- Absorption increased with fever or broken skin
- Absorption decreased with edema
- Some with metal foil backing not compatible with MRI

Fentanyl

- Every 72 hours
- Dosages (mcg/hr): 12, 25, 37.5, 50, 62.5, 75, 87.5, 100

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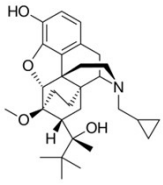
Buprenorphine



- Partial opioid agonist
- Formulations approved for treatment of pain or opioid use disorder (OUD)
- Precipitates opioid withdrawal if initiated while full opioid agonist highly bound

Pain (dosed in **mcg**)

- Taper prior opioid to <30 MME before starting buprenorphine

Buccal film 75-900 mcg q12-24

- Do not cut, chew or swallow

Transdermal patch 5-20 mcg/hr q 7 days

- (mcg/hr): 5, 7.5, 10, 15, 20 (max)
- Rotate sites wait min 3 wks before using same site

OUD (dosed in **mg**)

- Some formulations contain naloxone
- Induction procedure to avoid precipitating opioid withdrawal *(www.samhsa.gov/sites/default/files/quick-start-guide.pdf)*

Sublingual & buccal tablets & film (~12-24 mg/d)

SQ injection: **weekly** (24 mg or 32 mg) and **monthly** (100 mg or 300 mg)

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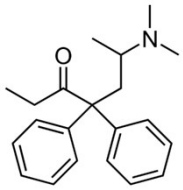
Methadone is Complex



- The problem…potentially the most dangerous opioid
- Long, variable, unpredictable half-life
  - Analgesia 6-8 hours while serum t½ 20-120 hours
- QTc prolongation, risk of torsades de pointes
- Only available in 5 mg & 10 mg tablets leading to large pill burden for patients on higher dosages

Some possible advantages:

- NMDA receptor antagonist
- Potentially less analgesic tolerance, better efficacy in neuropathic pain
- No active metabolites
- Inexpensive, small dosage units (5mg tablets)

Fredheim OM, et al. *Acta Anaesthesiol Scand.* 2008
Chou R, et al. *J Pain.* 2014

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Dual Mechanism Opioids

Norepinephrine and Serotonin reuptake inhibition

Tramadol

Weak μ-opioid receptor agonist
Minimal norepinephrine effect
Prominent serotonin effect

Tapentadol

Stronger μ-opioid receptor agonist
Prominent norepinephrine effect
Minimal serotonin effect

Seizure risk

Physical dependence

Serotonin syndrome

Controlled substances with addiction potential

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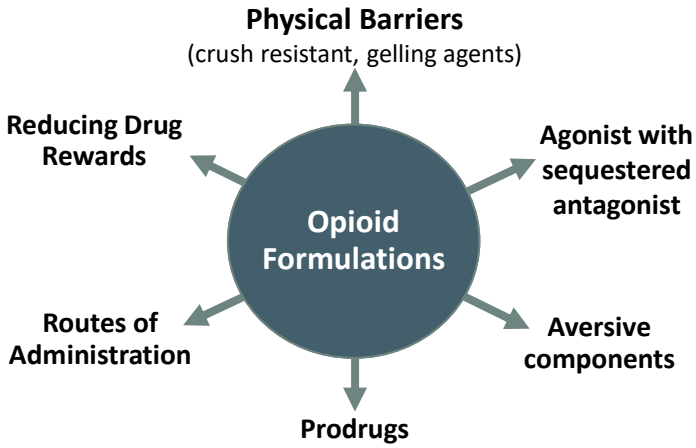
Abuse Deterrent/Resistant Formulations



- Decrease medication diversion and street price
- Does not prevent taking many intact tablets
- Are expensive and some insurers do not cover them

⚠ Currently, there are **no 100% proven misuse resistant opioids**

Passik SD. *Mayo Clin Proc.* 2009
Stanos SP, et al. *Mayo Clin Proc.* 2012
Michna E. et al. *Curr Med Res Opin.* 2014
Cassidy TA. et al. *Pain Med.* 2014
Medical Letter. June 5, 2017

Updated list of abuse-deterrent opioids: *www.fda.gov/drugs/drugsafety*

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Additional Considerations

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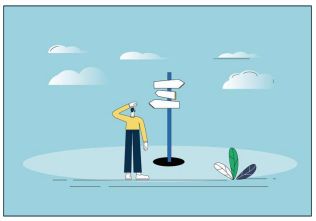
Opioid Choice Summary



- Duration and onset of action
  - Consider pattern of pain: intermittent vs. constant
- Patient's prior experience (effects & side effects)
  - Mu-opioid receptor polymorphisms and differences in opioid metabolism
- Patient's level of opioid tolerance (always assess before starting ER/LA opioid formulations)
- Age, other medications and diseases
- Route of administration
- Cost and insurance issues

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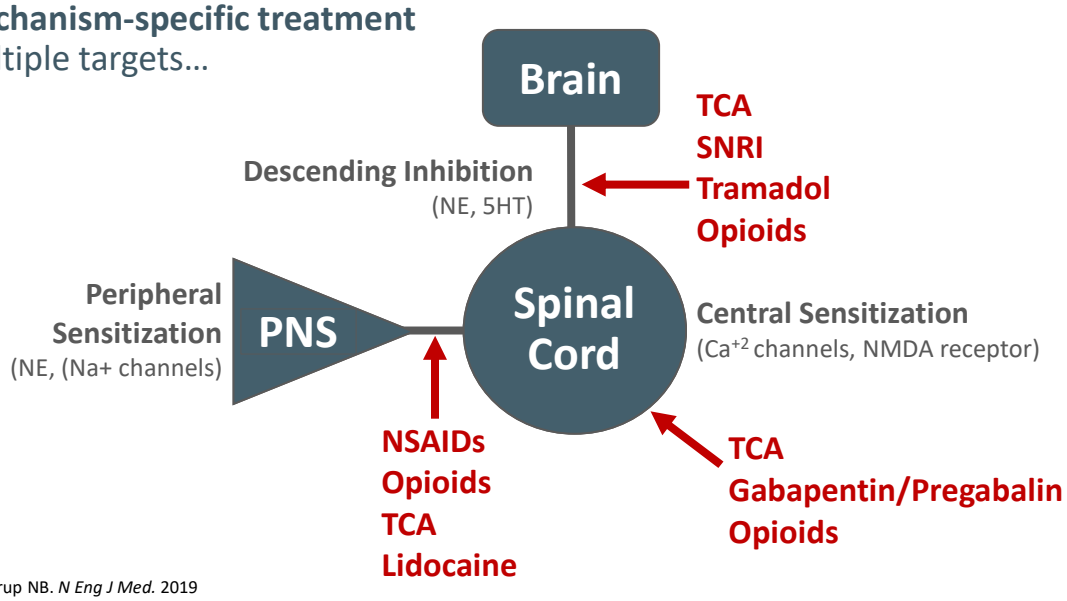
Rational Polypharmacy

Mechanism-specific treatment

Multiple targets…



Finnerup NB. *N Eng J Med.* 2019
Woolf CJ. *Ann Intern Med.* 2004

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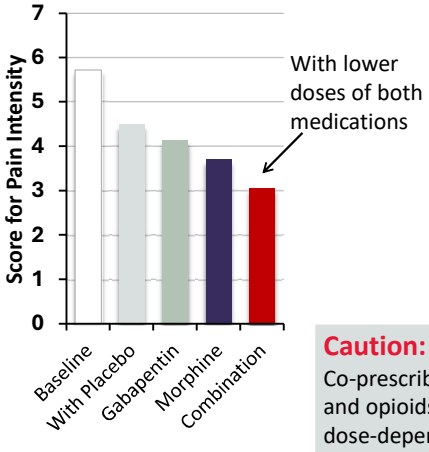
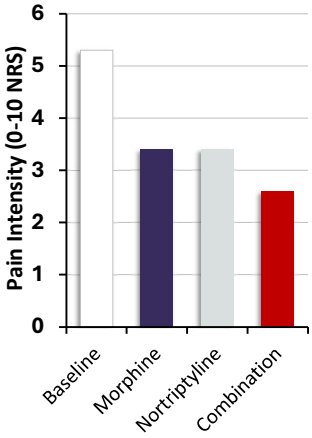
Exploit Synergism

e.g., Treating painful diabetic neuropathy



Caution:
Co-prescribing gabapentinoids and opioids is associated with dose-dependent increased risk for opioid-related deaths



Gilron I, et al. *N Engl J Med.* 2005

Gomes T, et al. *Ann Intern Med*. 2018
Goodman WC, Breatt AS. *N Engl J Med.* 2017

Gilron I, et al. *Pain.* 2015

15

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Case Study - **Michelle Jones** - 54 yo female

Over the ensuing months patient reported better pain control

Change Opioid Regimen

- Tolerates IR oxycodone 10 mg 4x/day (60 MME) but…
  - Periodicity of effects (on-off) may be causing inadequate pain control due to "withdrawal-mediated pain"
  - Analgesia may improve with more stable blood levels using ER/LA oxycodone requiring a lower daily dose (15 mg 2x/day) (45 MME)
  - Don't assume need for breakthrough medication
- Reviewed, signed Patient Provider Agreement (PPA)
- Referred to PT for chronic right hip pain
- Counseled on weight loss

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Universal Precautions when Prescribing Opioids

Predicting opioid risk and misuse is imprecise

Consistent application of precautions reduces stigma and standardizes care

Precautions include:

- Assess and document pain diagnosis(es) and opioid misuse risk
- **Prescribe opioids as a test or trial**; continued, modified or discontinued based on risks/benefits (e.g., every 1-3 months)
- State maximum number of tablets to be taken per day
- Use Patient Prescriber Agreements written at 5th grade level, without coercive language
- Monitor for adherence, misuse, and diversion

CDC

Recommendation 7

Evaluate benefits and risks 1-4 weeks of starting opioids or after dose escalation and then regularly

Dowell D, et al. MMWR. 2022

Gourlay DL, Heit H. *Pain Med.* 2005 Chou R, et al. J *Pain.* 2009 Franklin GM. *Neurology.* 2014 FSMB 2024 www.fsmb.org/opioids/

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Patient Provider Agreement (PPA)

Informed Consent

Realistic Goals

- Reduce *(not eliminate)* pain
- Improve function

(SMART goals):

Specific

Measurable

Action-oriented

Realistic

Time-sensitive

Potential Risks

- Adverse effects and DDI
- Over-sedation, impairment (esp. during dose adjustments)
- Misuse
- Overdose
- Death
- Risk of neonatal opioid withdrawal
- Hyperalgesia
- Victimization by others

Plan of Care

- Engage in other treatments as directed
- Safer opioid use: take as directed, don't double dose if dose missed, safe storage/disposal, no sharing
- No illicit drugs, avoid/minimize sedatives
- Report other meds, adverse effects
- Pregnancy plans
  - Discuss birth control
  - Monitor for pregnancy
  - Discuss risk of neonatal opioid withdrawal
  - Discuss all opioids transfer into human milk to some degree

Tobin DG, et al. *Cleve Clin J Med.* 2016
Nicolaidis C. *Pain Med.* 2011
Paterick TJ, et al. *Mayo Clin Proc.* 2008
Mailis-Gagnon A, et al. *Clin J Pain.* 2012
Cheatle MD, Savage SR. *J Pain Symp Manage.* 2012
Tolia VN, et al. *N Engl J Med.* 2015
Schumacher MB, et al. *Pschopharm.* 2017
Hale TW, Krutsch K. *Clin Pharmacol Ther.* 2021

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Monitoring: Urine Drug Testing

Objective data

- **Information on therapeutic adherence**
- **Information on use of illicit drugs**

- Document time of last medication use
- Discuss urine drug testing openly with patient → "If I send your urine now, what will I find in it?"
- Discuss unexpected findings with open-ended questions → "Your urine had "x" please tell me about it?"
- One medical data point to integrate with others
  - Cannot discriminate elective substance use from substance use disorder or diversion
  - Opioid concentrations cannot determine how much opioid is being taken
- Dedicated deceivers can beat the system

CDC **Recommendations 10**
Use strategies to mitigate risk including using toxicology testing
Dowell D, et al. MMWR. 2022

Argoff CE, Alford DP, Fudin J et al. *Pain Med*. 2018
Nagpal G et al. *JAMA.* 2017
Christo PJ, et al. *Pain Physician.* 2011

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Monitoring: Urine Drug Testing

Urine drug screens usually immunoassays	**Unexpected findings verified with definitive testing***

• Quick, inexpensive and can be done at point of care
• Know what is included in your testing panel
• Risk of **false negatives** due to cut offs and **false positives** due to cross reactions
	• Very specific (identifies specific molecules) but more expensive
	• Know opioid metabolism to interpret GC-MS or LC-MS results, for example:
	  • hydrocodone → hydromorphone
	  • oxycodone → oxymorphone

*Gas Chromatography (GC) or Liquid Chromatography (LC), and Mass Spectroscopy (MS)

Contact lab toxicologist for questions regarding unexpected results

Argoff CE, Alford DP, Fudin J et al. *Pain Med.* 2018
Reisfield GM, et al. *Bioanalysis.* 2009

20

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Monitoring: Medication Count and Prescription Drug Monitoring Program (PDMP)

Medication Count

Information on

- Medication adherence
- Possible diversion

28-day (rather than 30-day) prevents running out on weekends and medication hoarding

CDC **Recommendation 9**

Use strategies to mitigate risk including reviewing PDMP data

Dowell D, et al. MMWR. 2022

PDMP

Information on

- Harmful polypharmacy
- Multiple prescribers

Some states:

- *require utilization of PDMP*
- *allow delegating access to others*
- *have interstate data sharing*

Methadone dispensed at addiction treatment programs not included

Insufficient evidence that PDMPs increase or decrease opioid overdoses

Fink DS, et al. *Ann Intern Med.* 2018

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MINIMUM Level of Monitoring Based on Risk

TOPCARE (Transforming Opioid Prescribing in Primary Care) www.opioidresources.org

One example:

Risk Level • **ORT:** Opioid Risk Tool • **DIRE:** Diagnosis, Intractability, Risk, Efficacy • **SOAPP:** Screener & Opioid Assess for Pts w/ Pain	**Visits** (per year)	• **UDT** • **Pill Counts** • **PDMP** (per year)
Low	**4**	**2**
Moderate	**4**	**4**
High	**6**	**6**

- States laws may mandate level of monitoring
- Monitoring more intensive during first 6 months of opioid therapy

Liebschutz JM, et al. *JAMA Intern Med.* 2017

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Monitoring and Documentation: Office Visits

National study, found approximately **30% of charts had no pain diagnosis** at a visit when opioid was prescribed

Sherry TB, et al. *Ann Intern Med.* 2018

Six A's

- **A**nalgesia
- **A**ctivities
- **A**dverse effects
- **A**berrant behaviors
- **A**ffect
- **A**dherence

Passik SD, et al. *Clin Ther.* 2004

Include:

- **Subjective reports** from patient, co-care providers, caregivers and "reliable" family members (beware of those with secondary gain for giving inaccurate information)
- **Objective information** (observations, PEG scores, drug tests, pill counts, PDMP)
- **24-hour inventory** "Tell me how you are taking your medications." "Do you miss doses on some days?" "On average how many doses do you take per day?

Know federal and state guidelines and regulations: www.deadiversion.usdoj.gov/pubs/manuals/index.html
Templates in Resources at: www.scopeofpain.org and www.opioidresources.org

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What is the Clinician's Role?

Use a risk-benefit framework

Judge the opioid treatment, not the patient

NOT

Nicolaidis C. *Pain Medicine.* 2011

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Discussing Monitoring

Use a consistent approach
(Universal Precautions)
BUT *apply it individually* to match risk

Review the personal and public/community health risks of opioids

Discuss your responsibility to look for and manage early signs of harm

Discuss agreements, pill counts, and drug tests as ways that you are helping to protect patient from getting harmed by medications

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Safer opioid prescribing
is a lot of work!

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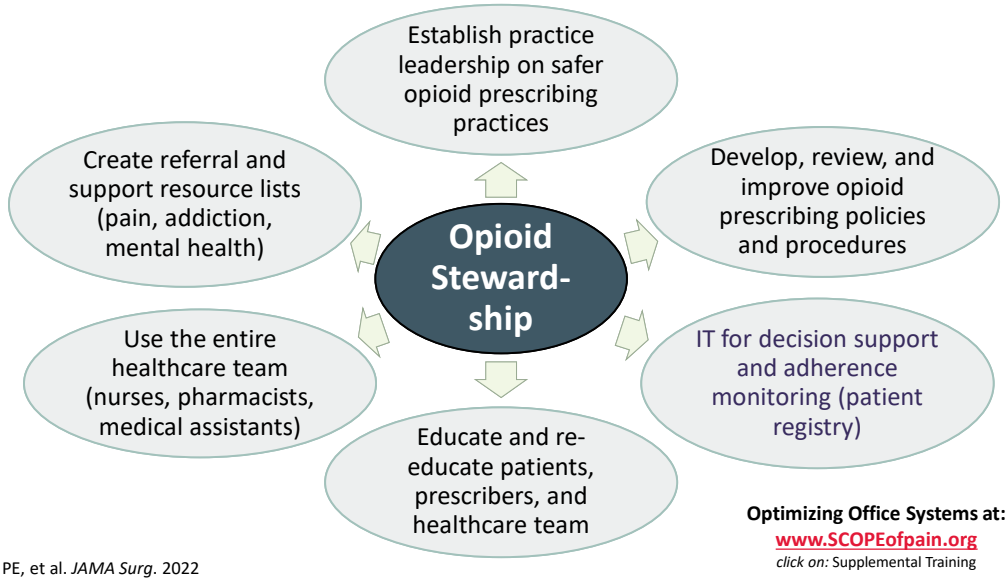
Implementing Opioid Stewardship

Prescribing opioids safely, correctly, and under the right circumstances



Optimizing Office Systems at:
www.SCOPEofpain.org
click on: Supplemental Training

MacIntyre PE, et al. *JAMA Surg*. 2022

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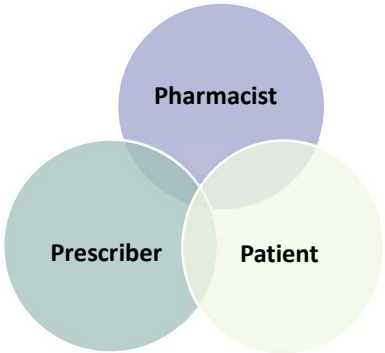
Community Pharmacist

- Must ensure that prescriptions are for "legitimate medical purpose"
- Help with medication choices, doses and substitutions
- Interact with patients
  - Educate on risks, proper use, storage and disposal, drug take-back programs, use of naloxone
  - Check PDMP, monitor for worrisome behaviors
  - Identify potential drug-drug interactions
  - Assist with formularies and prior authorizations
- Prescribers can help by including:
  - Diagnosis or indication on prescription
  - Parameters for when script should be filled
  - Maintain open lines of communication (direct phone lines)



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Case Study - Michelle Jones - 54 yo female

Did well on regimen of ER/LA oxycodone 15 mg bid with gabapentin 300 mg 3x/day for 11 months…

Scenario 1a
- Worrisome opioid taking
- Potential loss of benefit
- Switching opioids

Scenario 1b
- Continued lack of benefit after opioid switch
- Clinician initiated opioid discontinuation

Scenario 2
- Patient requested opioid discontinuation

Scenario 3
- Worrisome opioid taking
- Diagnosing and managing opioid use disorder

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Case Study - Michelle Jones - 54 yo female

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Case Study - Michelle Jones - 54 yo female

Scenario 1a

- She then went to the ED of her local hospital, **requesting early refill** of her oxycodone
- ED physician noted that she was in moderate opioid withdrawal and gave her enough ER/LA oxycodone to last until her next PCP appointment in one week
- ED physician left a message with the PCP office regarding patient visit and follow-up plan

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Case Study - Michelle Jones - 54 yo female

Post ED Follow-up

History since last visit

- Foot pain worse in past month "10 out of 10 most days"
- Extra oxycodone in the afternoon and ran out early
- Requests increase in her dose
- Concerned "body has become used to current dose"; doesn't seem to work all day anymore
- Husband says she has become "addicted"
- Difficult to go to work due to severe pain
- She is re-educated about risks including death of self-escalating her opioid dose

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Worrisome Medication-Taking Behaviors: Differential Diagnosis

Substance Seeking	Pain Relief and Substance Seeking	Pain Relief Seeking
• Opioid use disorder (OUD) • Self-treating other symptoms (e.g., anxiety, insomnia) • Diversion (sharing, selling)	Worsening pain, with OUD, while diverting some for income	• Disease progression • New painful condition • Poorly opioid responsive pain • Opioid analgesic tolerance • Withdrawal mediated pain • Opioid-induced hyperalgesia

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DSM-5 Opioid Use Disorders (OUD)

1. Tolerance*
2. Withdrawal*
3. Larger amounts and/or longer periods
4. Inability to cut down on or control use
5. Increased time spent obtaining, using or recovering

* This criterion is not counted if patient prescribed opioids under medical supervision

Loss of Control/Compulsive Use

6. Craving/ Compulsion
7. Role failure: work, home, school
8. Social, interpersonal problems
9. Reducing social, work, recreational activity
10. Physical hazards
11. Physical or psychological harm

Continued Use Despite Negative Consequences

Mild OUD: 2-3 Criteria
Moderate OUD: 4-5 Criteria
Severe OUD: ≥6 Criteria

Note: DSM-5 for OUD has been extensively validated for illicit opioids **but not for opioids prescribed for pain**

APA. (2013). *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.)

Hasin DS, et al. *Am J Psych.* 2022

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Discussing Possible Opioid Use Disorder (OUD)

- Give specific, timely feedback about behaviors that raise your concerns for possible OUD (e.g., loss of control, compulsive use, continued use despite harm)
- Remember patients may suffer from both chronic pain and OUD
- May need to "agree to disagree" with the patient
- Benefits no longer outweigh risks
- "I cannot responsibly continue prescribing opioids as I feel it would cause you more harm than good."
- Always offer referral to addiction treatment

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Opioid-Induced Hyperalgesia (OIH)

Paradoxical enhanced pain sensitivity in patients on chronic opioids (> 1 month)

Underlying pathophysiology and true incidence is unknown

No official criteria or guidelines for diagnosing OIH

Clinically pain is generalized, diffuse, ill-defined and not necessarily located at the source of original pain

Increased dose may improve analgesia but only temporarily

Uncertain on whether tapering or switching to a different opioid is more effective

Yi P, Pryzbylkowski P. *Pain Med*. 2015
Higgins C, et al. *Br J Anaesth*. 2019
Eisenberg E, et al. *J Pain Symptom Manage*.2014
Montgomery LS. *J Neurosci Res*. 2022

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Lack or Loss of Benefit

What are the next steps?

- Reassess factors affecting pain
- Re-attempt to treat underlying disease and co-morbidities
- Consider…
  - Add or increase non-opioid and non-pharmacologic treatment
  - Add breakthrough medications
  - Switch to a different opioid (“rotation”)
  - Avoid dose escalation to “high” dose opioids

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Consider Breakthrough Medication

1st Choice: Non-Opioid	• NSAIDs • Acetaminophen
IR/SA Opioid	• Same molecule • Different molecule
Dual Mechanism Opioid	• Tapentadol • Tramadol

Davies AN, et al. *Eur J Pain.* 2009

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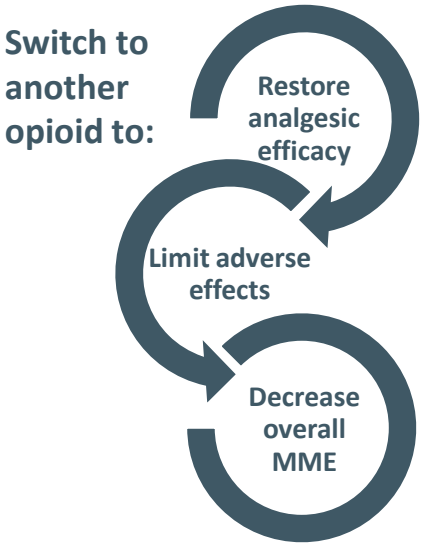
Consider Switching Opioids



- Based on large intra-individual variation in response to different opioids
- Different variants of mu-opioid receptors
- Limited evidence as most trials were retrospective and studied small numbers of patients

Fine PG , Portenoy RK. *J Pain Symptom Manage*. 2009
Smith HS, Peppin JF. *J Pain Res*. 2014
Treillet E, et al. *J Pain Res*. 2018

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Opioid Conversion Tables

- Derived from relative potency ratios using single-dose analgesic studies in opioid-naïve patients
- Based on limited doses or range of doses
- Does not reflect clinical realities of chronic opioid administration
- Are not reliable due to individual pharmacogenetic differences
- Most tables do NOT adjust for incomplete cross-tolerance

Opioid	Conversion Factor*
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	5
Methadone	4.7
Morphine	1
Oxycodone	1.5
Oxymorphone	3
Tapentadol+	0.4
Tramadol¥	0.2

www.cdc.gov

Treillet E, et al. *J Pain Res*. 2018
Webster LR, Fine PG. *Pain Med*. 2012
Pereira J, et al. *J Pain Symptom Manage*. 2001

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Case Study - Michelle Jones - 54 yo female

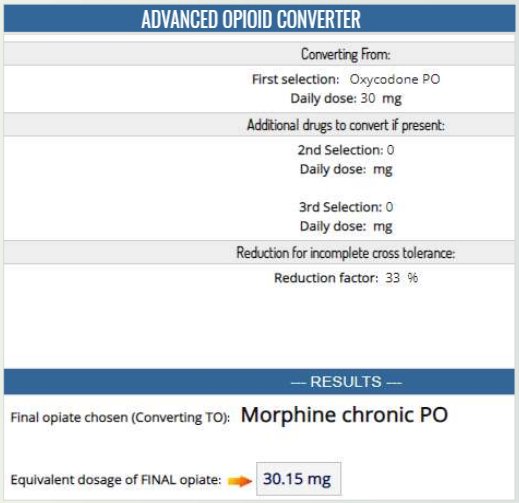
Scenario 1a

Switching Opioids

https://globalrph.com/medcalcs/opioid-pain-management-converter-advanced/

Rotated off
ER/LA oxycodone
15 mg bid
(45 MME)

Converted to
ER/LA morphine
15 mg bid
(30 MME)



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Case Study - Michelle Jones - 54 yo female

Over the next 18 months after switching to morphine

Scenario 1a

- Medication management
  - Continued ER/LA morphine 15mg 2x/day (30 MME)
  - Increased gabapentin to 400mg 3x/day
  - Continued acetaminophen
  - Added nortriptyline 25 mg at night
- Continued acupuncture therapy
- Joined monthly chronic pain support group
- PEG scores remained between 5-6/10
- Remained employed
- Remained adherent with treatment plan and monitoring
- Continued regularly scheduled follow-up visits

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Case Study - Michelle Jones - 54 yo female

Did well on regimen of ER/LA oxycodone 15 mg bid with gabapentin 300 mg 3x/day for 11 months…

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Scenario 1b
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- Clinician initiated opioid discontinuation

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Case Study - Michelle Jones - 54 yo female

After switching from oxycodone to morphine…

Scenario 1b

- Pain remained out-of-control (PEG scores 9-10/10)
- After one morphine dose increase, **she requested to be converted back to oxycodone**
- Continued to do poorly: on medical leave from work and spending most of the day in bed (according to her husband)
- On multiple occasions she was confrontational to the office staff when she was unable to be seen by her PCP without an appointment
- She started smoking marijuana to treat her pain

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Cannabis and Pain

Cannabis

- Contains >60 pharmacologically active cannabinoids including cannabidiol (CBD) and the psychoactive tetra-hydrocannabinol (THC)
- THC is a schedule I controlled substance (no currently accepted medical use)
- Endocannabinoid receptors are found in high concentration in the brain and spinal cord

- Moderate-quality evidence cannabinoids can be effective for short-term treatment (1-6 m) of chronic pain (neuropathic, nociplastic pain)
  - Treatment studies of nociceptive (musculoskeletal) pain are inconclusive
- **For 30% pain reduction** number needed to treat (NNT):
  - 24 for cannabinoids
  - 4-10 for TCAs, opioids, gabapentinoids, SNRIs
- Side effects are mild compared to opioids, but can cause dizziness, sedation, and impaired coordination
- Long-term use in younger individuals can result in cannabis use disorder and cognitive impairment

Stockings E et al. *Pain* 2018
Noori A et al. *BMJ Open* 2021
Busse JW et al. *BMJ* 2021
McDonagh MS, et al. *Ann Intern Med*. 2022
Ang SP, et al. *Pain Ther.* 2023

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Continued Lack of Benefit

Remember:

- ☐ Not all chronic pain is opioid responsive
- ☐ More opioid is not always better
- ☐ More opioid may increase risk of adverse effects
- ☐ Some chronic pain improves after opioid taper

Baron MJ, McDonald PW. *J Opioid Manage*. 2006

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Discussing Continued Lack of Benefit

- Stress how much you believe the patient's pain severity
- Show empathy for the patient's suffering
- Express frustration that the medication was not more effective
- Focus on patient's strengths and encourage therapies for "coping with" pain
- Show commitment to continue managing pain, even without opioids
- Schedule close follow-ups during and after taper and change in therapies

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Discontinuing Opioids

- You **do not** have to prove addiction or diversion, only assess and reassess the risk-benefit ratio
- If patient is unable to take opioids safely or is non-adherent with monitoring, then discontinuing opioids is appropriate, even in the setting of benefits
- Need to determine how urgent the discontinuation should be based on the severity of the risks and harms
- Determine if the opioid needs to be tapered due to physical dependence
- Document rationale for discontinuing opioids

You are <u>NOT</u> abandoning the patient, you are ABANDONING THE OPIOID

Tobin DG et al. *J Gen Intern Med.* 2021

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Opioid Discontinuation Risks

- Observational studies identified harms (suicide and overdose) associated with opioid tapering and discontinuation
- Comparative effectiveness study of ~200,000 individuals on stable* long-term opioid therapy, found opioid tapering was associated with a small absolute increase in opioid overdose or suicide compared with maintaining stable opioid dosages

"Tapering/discontinuation **should not** be considered a harm reduction strategy for patients receiving **stable** long-term opioid therapy **without evidence of misuse"**

*no evidence of opioid use disorder or opioid misuse

James JR, et al. *J Gen Intern Med*. 2019
Mark TL, Parish W. *J Subst Abuse Treat*. 2019
Oliva EM, Bowe T, Manhapra A, et al. *BMJ*. 2020
Hallvik SE, et al. *Pain*. 2022
Larochelle MR et al. *JAMA open*. 2022

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Risk-Benefit Framework

Benefits
Pain
Function
Quality of Life

Risks/Harm
Misuse
Addiction, Overdose
Adverse Effects

Useful to avoid pitfalls:
"But I really, really need opioids."
"Don't you trust me?"
"I thought we had a good relationship/I thought you cared about me."
"If you don't give them to me, I will drink/use drugs/hurt myself."
"Can you just give me enough to find a new doc?"

Response: "I cannot continue to prescribe a medication that is not helping you (or is hurting you, or both)."

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Case Study - Michelle Jones - 54 yo female

Scenario 1b

- Despite the PCP's best efforts to explain the rationale for opioid taper due to lack of benefit and possible harm (e.g., opioid induced hyperalgesia), she continued to demand higher doses of oxycodone
- She was offered alternative pain treatments including cognitive behavioral therapy
- She became increasingly angry and stood up and stated that she was going to find a new doctor
- She left the office…

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Case Study - Michelle Jones - 54 yo female

Did well on regimen of ER/LA oxycodone 15 mg bid with gabapentin 300 mg 3x/day for 11 months…

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Scenario 1b
- Continued lack of benefit after opioid switch
- Clinician initiated opioid discontinuation

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Case Study - Michelle Jones - 54 yo female

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How will you help her taper off oxycodone?

Scenario 2

- Calls the PCP office after she was unable to get her oxycodone refilled due to her insurance's new prior authorization requirement
  - "My insurance keeps refusing to pay for my pain pills which leaves me without them for days."
- Very upset when describing how badly she is treated by her family, the primary care staff, and at the pharmacy:
  - "I am tired of being treated like a drug addict or criminal."
  - "I tried to stop but got sick."
  - "I want to get off these pills!"

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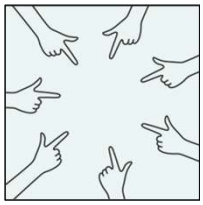
Stigma, Chronic Pain, and Opioids



- Stigma is being discredited, or undesirable, because of an attribute
- Stigma is common among people with chronic pain
- Individuals with pain with less clear pathophysiology report greater stigma
- Stigma can be internalized contributing to poorer pain-related outcomes
  - Positive correlation between stigma and pain intensity, disability, and depression
  - Patients might believe they deserve their pain, are being punished and do not deserve to be included in social activities
- Opioid-related stigma includes fears about anticipated negative attitudes and judgments from others

Hickling LM, et al. *Pain.* 2024
Bulls HW, et al. *Pain.* 2022

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Tapering Opioids

- No validated protocols in patients on opioids for chronic pain
- Very low-quality evidence suggests several types of opioid tapers may be effective and that pain, function, and quality of life may improve for some patients with decrease opioid dose
- Study found 62% of patients in a pain clinic completed a voluntary, patient-centered opioid taper over 4 months with >50% dose reduction
  - Neither pain intensity nor pain interference increased with opioid reduction
  - Success was not predicted by starting dose, baseline pain intensity, years prescribed opioids or any psychosocial variable
- Study of over 100,000 patients on long-term opioids found annual tapering has increased and more likely in women and those on higher opioid doses

Frank JW, et al. *Ann Intern Med.* 2017
Darnall BD, et al. *JAMA Intern Med.* 2018
Fenton JJ et al. *JAMA Network Open.* 2019

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55

Opioid Tapering: General Approach

A Patient Centered Approach to Opioid Tapering at:
www.SCOPEofpain.org
click on: Supplemental Training

Speed and Goal
(decrease dose or discontinuation)
depends on reason for taper

- Lack of benefit taper over weeks to months
- Apparent harm/risk taper over days to weeks
- Build up alternative pain treatments as short-term withdrawal can lead to transitory increased pain flares

1st STEP
Reduce medication dose
to the smallest dosage unit

CDC Recommendation

- Decrease 10%/month if on opioids for years
- Decrease 10%/week if on opioids for weeks to months

Dowell D, et al. MMWR. 2022

2nd STEP
Increase amount of time between doses

- IR opioid can be started when at lowest ER/LA opioid dose
- Can use α2-adrenergic agonist (e.g., lofexidine, clonidine*, tizanidine*) to treat withdrawal symptoms

**Off-label*

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Case Study - Michelle Jones - 54 yo female

Scenario 2

- Over 6 months she successfully tapered off oxycodone
- Her neuropathic pain was moderately well controlled on combination of nortriptyline 25 mg at night, gabapentin 600 mg 3 times per day and capsaicin cream 3-4 times per day
- Joined a monthly chronic pain support group
- PEG scores remained between 4-5/10 (patient stated she was surprised her pain improved off oxycodone)
- Remained employed
- Remained adherent with the treatment plan and monitoring
- Continued with regularly scheduled follow up visits

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Case Study - Michelle Jones - 54 yo female

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Case Study - **Michelle Jones** - 54 yo female

Scenario 3

- UDTs were consistently positive for oxycodone as expected except once her UDT was opiate positive (i.e., morphine and/or codeine) and oxycodone negative raising the concern for opioid misuse including diversion
  - She denied sharing or giving her oxycodone to others
  - Urine "quantity not sufficient" for confirmation testing
- Unexpected UDT resulted in increased monitoring frequency with no additional unexpected UDTs over the ensuing two months

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Discussing Possible Diversion

- Prescription drug diversion is one form of opioid misuse and is defined as the giving, selling, or trading prescription medications
  - Surveys* indicate that relatives and friends are a common source of diverted opioids
- Discuss why you are concerned about diversion
  - e.g., UDT negative for prescribed opioid, nonadherence with pill counts
- Discuss your inability to continue to prescribe opioids if the opioids are being diverted to others

SAMHSA. (2023). *2022 NSDUH*

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Case Study - Michelle Jones - 54 yo female

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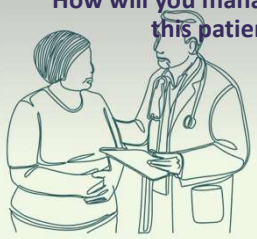
2 months later… brought to ED by ambulance after suffering an opioid overdose

How will you manage this patient?



Scenario 3

- Husband found her unresponsive, administered intranasal naloxone with brisk response and called 911
- In the ED, husband reported that his wife has been running out of her oxycodone, and taking her father's morphine
- Husband had been in denial of how bad his wife's problem had gotten. He reported that she's been fired from her job for missing too many deadlines, and that she once fell asleep with a stove burner on, and melted a teapot
- He heard a staff person in the ED refer to his wife as a "drug abuser"

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Words Matter

Stigmatizing Language	Non-Stigmatizing Language ✓
Addict, substance abuser, alcoholic	Person with a substance use disorder (SUD)
Substance abuse	Substance use
Clean urine	Expected test result
Patient is clean	Person with SUD in remission
Dirty urine	Unexpected test result
Patient is dirty	Active substance use

Botticelli MP, Koh HK. *JAMA*. 2016. Kelly JF, Wakeman SE, Saitz R. *Am J Med*. 2015

"Stigma surrounding SUD is perpetuated by the stigmatizing terminology used in healthcare settings, by the news and other media, and by society as a whole."

Zwick J, Appleseth H, Arndt S. *Subst Abus Treat Prev Policy.* 2020

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Treatment Gaps Following Opioid Overdose

Opioids were dispensed to 91% of patients after a nonfatal overdose

n=2,848

- **7%** had repeat opioid overdose
- At 2 years, cumulative incidence of repeated overdose was **17%** for patients on **high opioid dosages** after the index overdose

Less than a third of opioid overdose survivors receive medications for OUD (MOUD) in the subsequent 12 months

n= 17,568

- Receipt of MOUD was associated with decreased all-cause and opioid-related mortality

Larochelle MR, et al. *Ann Intern Med*. 2016
Larochelle MR , et al. *Ann Intern Med*. 2018

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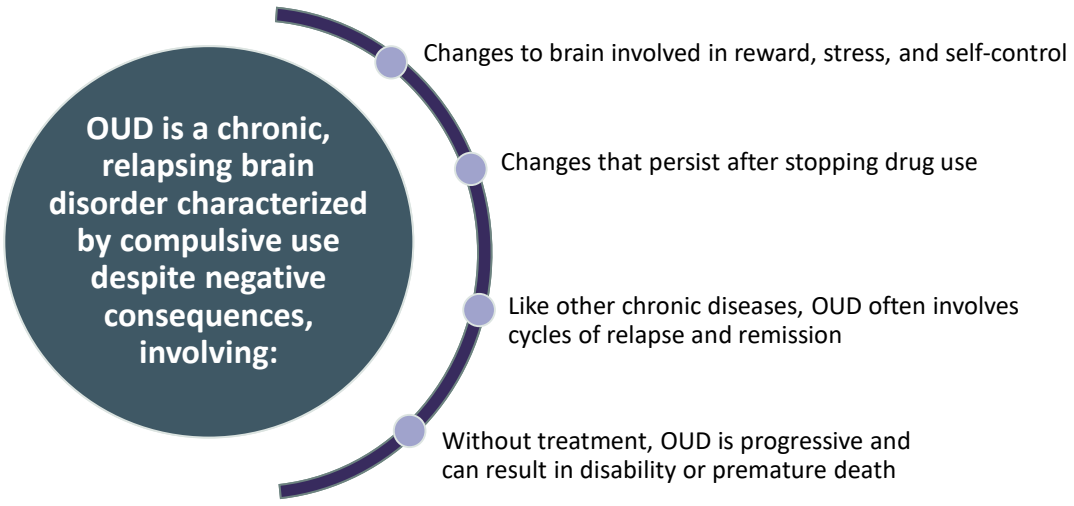
Opioid Use Disorder (OUD)



Volkow ND, Koob GF, McLellan AT. *N Eng J of Med.* 2016
Sordo L, et al. *BMJ.* 2017

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Medications for OUD (MOUD)

Normalize brain changes | Alleviate physical withdrawal | Provide opioid blockade | Alleviate drug craving

Methadone
(Dispensed in licensed program only)

Naltrexone
Oral, monthly IM injection

Buprenorphine
Submucosal, weekly & monthly SQ injection

Outcomes
- Increased treatment retention and employment
- Decreased relapse, HIV and hepatitis C incidence
- Decreased mortality (methadone, buprenorphine)

CDC **Recommendation 12**
- Offer or arrange evidence-based medications for treating OUD
- Detox only is not recommended due increased risks for relapse, overdose and death

Dowell D, et al. MMWR. 2022

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Case Study - Michelle Jones - 54 yo female

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Over the next 6 months…

How will you manage this patient perioperatively?

Scenario 3

- PCP continues buprenorphine for the treatment of OUD but doses it 3 times per day to treat both her pain and OUD
- Right hip pain from end-stage arthritis is affecting her quality of life despite trying nonoperative management
- She is schedule for a right hip arthroplasty

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Acute Pain in Patients on MOUD

Systematic Review

There is a growing consensus on perioperative management of patients on MOUD

- Patients with OUD history are often more sensitive to painful stimuli
- Continue methadone or buprenorphine throughout the perioperative period
- Treat pain with analgesics on top of the patient's daily MOUD
- Patients taking MOUD may need higher doses of opioid analgesics
- Ineffective pain management can result in disengage-ment in care

Veazie S et al. *J Gen Intern Med.* 2020
Kohan L, et al. *Reg Anesth Pain Med.* 2021

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Case Study - **Michelle Jones** - 54 yo female

Scenario 3

- Did well postop with improved pain control
- Painful diabetic neuropathy well controlled on combination of buprenorphine 4 mg sublingual 3x/day, duloxetine 30 mg 2x/day and nortriptyline 25 mg at night (Note: gabapentin discontinued due to misuse risk1 and overdose risk when combined with opioids)
- PEG scores remained between 5-6/10
- OUD in sustained remission with MOUD and counseling
- Remained employed
- Continued with regularly scheduled follow up visits

Hill J, Alford DP. *Semin Neuro*. 2018
Goodman CW, Brett AS. *N Engl J Med*. 2017

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Summary Part 2

- Employ universal precautions but individualize care based on risk
- Continue or modify opioids based on clinical indication and response
- Optimize office systems to involve the entire healthcare team including community pharmacists
- Document benefits, risks, harms and rationale for the plan of care
- Worrisome opioid-taking behavior can signify pain-relief or substance-seeking behaviors or a combination of both
- Decisions to continue, modify or discontinue opioids should be based on risks and benefits and should be well-documented
- Offer MOUD for patients with OUD and continue maintenance methadone or buprenorphine perioperatively

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Post-test and Evaluation

- Complete the post-test with a cumulative score of >70%
- Complete the evaluation
- Download your certificate, worth:
  - 2.5 *AMA PRA Category 1 Credits*™
  - 2.5 nursing contact hours, or
  - 2.5 ACPE credits

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