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CME Information

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of NORCAL Insurance Company and ProAssurance Indemnity Company, Inc. The NORCAL Insurance Company is accredited by the ACCME to provide continuing medical education for physicians.

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Disclaimer

The information provided in this presentation offers risk management strategies and resources, and the slide content is intended to be used only with the accompanying oral presentation.

Guidance and recommendations contained in this presentation are not intended to determine the standard of care but are provided as risk management advice only. The ultimate judgment regarding the propriety of any method of care must be made by the healthcare professional.

The information does not constitute a legal opinion, nor is it a substitute for legal advice. Legal inquiries about this topic should be directed to an attorney.

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Objectives

This enduring educational activity will support your ability to:

- Identify and mitigate the primary risks associated with prescribing opioid medications.
- Evaluate current processes and incorporate best practice guidelines.
- Apply risk reduction strategies to reduce potential patient harm and professional liability claims.

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Pathophysiology of Pain

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Cortical Processing of Pain

- Sensory aspects of pain seem to be processed in the Somatosensory Cortex.
- Emotional distress associated with pain seems to be processed in the Anterior Cingulate Cortex (ACC).
- Subjects with lesions in ACC could still accurately judge the intensity of pain, but they were not in the least bothered by it.
- On the other hand, subjects' empathy for the pain of others only elicits activity in ACC, not Somatosensory Cortex.

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Risk Factors

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Risk Factors for Chronic Pain: Role of Psychosocial Factors

- Lower educated (< H.S. education; no GED)
- Lower socioeconomic status
- Cognitively compromised
- Psychologically compromised
- Marginally employed/vocationally dissatisfied
- History of abuse or interpersonal violence
- Poor health status

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Alternative Ways to Assess Pain

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Risk Reduction Strategies

- **Alternatives to Assessing Outcomes**
  - Consider alternative tools to simple pain scales as a measure of patient treatment outcomes.
  - Document use of these tools and reassess treatment regimen depending on results. Examples of such tools include:
    - Patient Global Impression of Change
    - Global Percentage Improvement
    - 5-As
    - Pain, Enjoyment of Life and General Activity Scale
- **Opioid Reduction Strategies**
  - Ensure careful risk assessment and supportive interventions are in place when considering opioid discontinuation to decrease overdose and suicide outcomes.

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Treatment Principles

- Shared decision-making
- Share the burden and responsibility
- Lifestyle matters
- Keep it simple
- Make use of a "trial"
- "Breakthrough" pain
- Don't say yes if you can't say no
- "Placebo effect": What you say can make a difference

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Risk Reduction Strategies

- **Chronic Pain Risk Factors**
  - Understand those most at risk of developing chronic pain and the weight of psychological factors as you identify, diagnose, and treat chronic pain.
- **Chronic Pain Treatment**
  - Consider multiple therapies available to treat chronic pain and select those depending on the unique clinical picture of your patient. Examples include:
    - Lifestyle Management (smoking, exercise, and diet)
    - Behavioral and Psychological Therapies
    - Interventional Pain Management
    - Pharmacotherapeutics

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Opioid Therapy: Be Aware of Opioid-Induced…

Disorder	Incidence	MOA
Neurotoxicity	15% Ca Pain Study	Neuroexcitatory metabolites, e.g. morphine-6-glucuronide, oxymorphone-3-glucuronide; NMDA activity
Endocrinopathies	21 – 86%	Hypothalamic-pituitary-gonadal system
Hyperalgesia	Rare – 27%	Central glutaminergic system, spinal dynorphins, descending facilitation, genetic mechanisms, and decreased re-uptake, and enhanced nociceptive response
Immunosuppression	Unknown	Impaired immune system function by affecting the H-P-A system, and suppressing natural killer (NK) cells

Marudhai S, et al. Long-term opioids linked to hypogonadism and the role of testosterone supplementation therapy. Cureus. 2020 Oct 5;12(10):e10813. doi: 10.7759/cureus.10813. PMID: 33173622; PMCID: PMC7645309.
Matzo M, Dawson KA. Opioid-induced neurotoxicity. Am J Nurs. 2013 Oct;113(10):51-6. doi: 10.1097/01.NAJ.0000435351.53534.83. PMID: 24067833. Godwin B, et al. Identification and management of opioid-induced neurotoxicity in older adults. Can Fam Physician. 2022; ;68(4): 269-270..

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Risk Reduction Strategies

- **Opioid Therapy Risks and Management**
  - Be aware and monitor for opioid-induced conditions like neurotoxicity, endocrinopathies, and hyperalgesia.
  - Be equally aware of underlying conditions which inhibit successful treatment with opioids.
  - Adjust treatment accordingly and treat underlying condition to increase efficacy of treatment and improve patient safety.

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Hyperalgesia: Contributing Factors

- Opioids
- Sleep disturbance
- Hypogonadism
- Activity avoidance
- Pain catastrophizing
- DOC and SAC
- End-of-dose (mimics opioid withdrawal)

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Buprenorphine Prescribing

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Pivotal Milestones in Treatment

Year	Milestone
1970	Methadone is approved by the FDA for detoxification
1973	Methadone is approved by the FDA for maintenance
1974	Opioid Treatment Programs (OTPs) able to dispense Methadone for maintenance treatment
1984	Oral Naltrexone is approved by the FDA
2000	Drug Addition Treatment Act of 2000 (DATA 2000) allowed qualified physicians to offer Office Based Opioid Treatment (OBOT)
2002	Buprenorphine is approved by the FDA
2010	Extended-release injectable naltrexone is approved by the FDA
2016	Comprehensive Addiction and Recovery Act (CARA) Allows Nurse Practitioners and Physician Assistants to become eligible to prescribe buprenorphine for treatment of opioid use disorder

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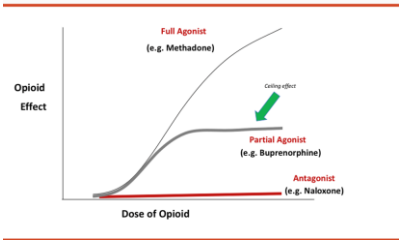
Combinations of controlled substances override the ceiling effect of a partial agonist to behave more like the linear effect of a full agonist.



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Examples of Initiation

- Important questions
  - When you wake up, how long is it before you drink your first caffeine, smoke your first cigarette, and take your pain medicine?
  - Do you admit having a dependence to caffeine, nicotine, morphine?
- Patient on hydrocodone
  - Over the past years from 5 mg bid ->7.5 bid->7.5 tid ->10 tid -> 10 qid
  - Now asking for just one more tablet daily.
- First
  - Discuss the dosing for pain with buprenorphine.

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Examples of Initiation

- For Belbuca FDA maximum dose of 900 mcg bid=1800 mcg= 1.8 mg.
- The general film strip (in bioavailability of Suboxone) is 8mg/2mg and is over 4 times as strong as the highest dose for pain.
- This is a great time to explain that one 8mg/2mg strip will keep the withdrawal symptoms of a patient suffering from fentanyl dependence mitigated for 2-44 DAYS.
- The way I have ended up doing the initiation is as follows:
  - Explain to the patient to stop the pain medicine.
  - EXPLAIN the discomfort from transition.

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Risk Reduction Strategies

- Understanding Buprenorphine's Role
  - Recognize buprenorphine's effectiveness in opioid use disorder treatment, including its pharmacological properties and appropriate use.
- Diversion
  - Be aware of the risks associated with the diversion of buprenorphine and implement strategies to minimize this risk.
- Patient Education to Improve Safety
  - Understand heightened risk of opioid overdose death after prolonged buprenorphine treatment due to mu-opioid receptor changes, and continue counseling patients on these risks to improve safety.

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Risks of Buprenorphine Therapy


Relapse


Diversion


Drug holidays


Combination controlled substances

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Examples of Initiation

- When there are the beginnings of withdrawal queasiness, loose stool, and discomfort—only then take 1/4 of an 8mg/2mg strip.
- Wait two hours, and if the patient is feeling better take another 1/4 of 8mg/2mg.
- Wait another 2 hours.
  - If the patient is feeling worse don't take any more buprenorphine until the following day.
- The following day, take the agreed daily dose.
  - Take that dose for a few days, and then visit again to discuss the dose between patient and prescriber.

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Examples of Initiation

- New Patient—Roxicodone 30 mg po qid and fentanyl 25 patch.
- Here I would half the Roxicodone because the oxycodone has a longer half-life than fentanyl.
  - Stay on the reduced dose for 5-7 days.
- Then stop and start the previous protocol.
- The ultimate decided dose may be higher to begin with.

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Non-Narcotic Pain Management

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Pain

Acute Pain	Chronic Pain
• Most common reason for and emergency room department visit • Post Surgery	• Chronic back pain is the leading cause of years lived with disability • Long term opioid therapy has minimal effects on chronic pain and can cause tolerance, drowsiness, dependence, and impaired memory, concentration and judgement

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Assessment of Pain

- 0-10 Pain Scale
- Overemphasis on pain intensity
  - Pain intensity is not a measure of suffering
  - Purposeful pain vs. threatening pain

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Nonopioid Treatments

- Patient Education
- Psychological Treatment
- Nonopioid Analgesic Agents
- Interventional Pain Management
- Complementary Therapies

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Acetaminophen, Aspirin, and NSAIDs

Acetaminophen – Unknown mechanism of action, small risk of skin reaction and liver damage, leading cause of acute liver failure in the U.S. since 1998 yet still considered the safest analgesic; max dose 4 gm a day from all sources.

Aspirin and NSAIDs – Anti-inflammatory, inhibit platelet aggregation, risk of GI bleeding and hypersensitivity reaction; non-ASA NSAIDs have a low risk of heart attack and stroke.

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Antidepressant Agents

- Tricyclic antidepressants and Serotonin Norepinephrine Reuptake Inhibitors
  - Reduce pain in patients who don't have depression
  - Even more effective if the patient has both pain and depression
  - MOA: Unsure, but may be related to presynaptic inhibition of serotonin and no reuptake in pain inhibitory pathways as well as peripheral mechanisms involving Beta-adrenergic receptors and the opioid system
  - First line treatments for neuropathic pain, prophylactic treatment of migraine and tension-type headache, fibromyalgia
  - SE and Risks: Somnolence, tremor, dizziness, ortho hypotension (TCA), hypertension (SNRI), weight gain; avoid abrupt cessation, TCA contraindicated with dysrhythmia or recent MI, don't stack SNRIs and SSRIs

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Antiepileptic Medications

- MOA: lower neurotransmitter release or neuronal firing
- Gabapentin and Pregabalin
  - Neuropathic pain, fibromyalgia
  - Perioperative use has an opioid sparing effect on acute postoperative pain but an increased risk of serious adverse events, and is therefore not recommended
  - SE: sedation, dizziness, risk of misuse and abuse
- Oxcarbazepine, Carbamazepine, lamotrigine and Lacosamide
  - Trigeminal neuralgia

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Interventional Pain Management

- Local injections
- Surgery
- Devices – weak evidence for benefit of spinal cord stimulator and transmagnetic cranial stimulation
- Epidurals
- Microvascular decompression
- Percutaneous radiofrequency rhizotomy

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Risk Reduction Strategies

- **Comprehensive Pain Assessment**
  - Appreciate the importance of thorough assessment to distinguish between different types of pain and identify any underlying issues.
- **Nonopioid Treatment Approaches**
  - Consider the use of nonopioid analgesics and complementary therapies in pain management to reduce the reliance on opioids.
- **Psychological Impact of Pain**
  - Recognize the role of psychological factors in pain management and the importance of psychological therapies like cognitive behavioral therapy.

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Risk Reduction Strategies

- **Establish Realistic Expectations**
  - Educate patients regarding pain management expectations and the realistic goals of treatment.
- **Referral to Pain Specialists**
  - Establish criteria for referring patients to pain management specialists, especially in complex cases.

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When to Refer to Pain Management

- Uncomfortable with medications
- History of addiction
- History of overdose – intentional or unintentional
- Combinations
  - More than one pain medication needed, holy trinity, quartet
- High MMEs

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Risk Reduction Strategies

- **Pain Pathophysiology and Overlapping Categorial Sources of Pain**
  - Ensure an understanding of the complex pathophysiology of pain and overlapping categorial sources of pain to better establish treatment regimens.
  - Document your decision-making process supporting the treatment regimen selected.
- **Evolving Nature of Chronic Pain**
  - Understand chronic pain is not a static condition.
  - As the disease process itself and evidence-based understanding evolves, modify both pharmacologic and non-pharmacologic treatment options accordingly.

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THANK YOU