Controlled Substances: A Focus on Safe and Effective Prescribing

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Objectives

- At the conclusion of this lecture, the attendee will be able to:
  - Analyze CDC guidance for chronic pain management.
  - Discuss legislative considerations in opioid prescribing.
  - Evaluate opioid risk assessment tools

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Legislative Issues and National Guidance

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The Controlled Substances Act (CSA)

- Federal law that was enacted by Congress as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970
- Federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated

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CSA
(continued)

- Also served as the national implementing legislation for the Single Convention on Narcotic (opiate-derived) Drugs
- Even though the privilege to prescribe all controlled substances (opioid, stimulant, hallucinogen, etc.) is state mandated, the foundation legislation and classification are federal.

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CSA
(continued)

- Created five schedules (classifications) with varying qualifications for a substance to be included in each
  - Provides a mechanism for adding, deleting or changing drugs between schedules

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CSA
(continued)

- May be initiated by
  - Drug Enforcement Agency (DEA)
  - Department of Health and Human Services (DHHS)
  - Any interested party

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CSA
(continued)

- Classification decisions are required to be made on criteria including potential for abuse, currently accepted medical use in treatment in the United States, and international treaties.
- Amended numerous times since its initial presentation in 1970

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Scheduling Decisions

- Based upon several factors
  - Actual or relative potential for abuse
  - Scientific evidence of its pharmacological effect, if known
  - The state of current scientific knowledge regarding the drug or other substance
  - History and current pattern of abuse
  - Scope, duration and significance of abuse

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Scheduling Decisions (continued)

- Based upon several factors (cont.)
  - What, if any, risk to public health
  - Psychic or physiological dependence liability
  - Substance is an immediate precursor of a substance already controlled under this subchapter.

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Drug Enforcement Administration (DEA)

- A federal law enforcement agency created in 1973 under Dept. of Justice
- Responsibility for enforcing federal law drug policy domestically **and** only agency responsible for coordinating drug investigations out of the country

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DEA (continued)

- The narcotic registry system of the DEA allows healthcare, research and manufacturer professionals with state granted access to manufacture, research, dispense, prescribe and distribute a controlled substance.

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Scheduling

- Despite a few exceptions, every schedule requires a finding specifying the "potential for abuse" before a substance can be placed in that schedule.
- The CSA does not define abuse.

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Scheduling
(continued)

- The specific classification of any given drug or other substance is usually a source of controversy, as is the purpose and effectiveness of the entire regulatory scheme.
- The term "controlled substance" means a drug or other substance, or immediate precursor, included in Schedule I, II, III, IV or V.

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Scheduling
(continued)

- One of the big criticisms of the scheduling system is that alcohol and tobacco are not controlled substances even though they are the two most widely used drugs of abuse in the United States.
- A similar criticism exists of caffeine.

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Inconsistencies…

- In the classifications as is evident with a review of schedule criteria
  - Morphine and fentanyl are both Schedule II, while heroin is Schedule I.

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Schedule I Drugs

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Classification Requirements

- The drug or other substance has a high potential for abuse.
- The drug or other substance has no currently accepted medical use in treatment in the United States.
- There is a lack of accepted safety for use of the drug or other substance under medical supervision.
  - Source: https://www.dea.gov/drug-scheduling

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Schedule II

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Classification Requirements

- Substance has a high potential for abuse.
- Can cause severe psychological or physical dependence
- Currently accepted medical use

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Therapeutic Categories

- Opiates and opioids
- Stimulants
- Depressants
- Hallucinogens

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Schedule III Drugs

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Classification Requirements

- Substance has a potential for abuse less than Schedules I and II.
- The substance has a currently accepted medical use in treatment in the United States.
- Abuse can lead to low or moderate physical dependence or high psychological dependence.

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Schedule III Categories

- Stimulants
- Opioids and opiates
- Depressants
- Hallucinogens
- Corticosteroids

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Schedule IV

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Classification Requirements

- Substance has a low potential for abuse relative to the substances in Schedule III.
- The drug or other substance has a currently accepted medical use in treatment in the United States.
- Abuse may lead to limited physical or psychological dependence.

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Schedule IV Categories

- Depressants
- Opiates
- Stimulants
- Others

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Schedule IV Depressants

- Benzodiazepines
- Benzodiazepine receptor agonists
  - Zaleplon (Sonata®)
  - Zolpidem (Ambien®)
  - Eszopiclone (Lunesta®)

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Schedule IV Stimulants

- 12 in Schedule IV including mostly appetite suppressants
  - Phentermine
- Also includes armodafinil and modafinil

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Schedule V

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Classification Requirements

- Substance has a low potential for abuse relative to the drugs or other substances in Schedule IV.
- The drug or other substance has a currently accepted medical use in treatment in the United States.
- Abuse can lead to limited physical or psychological dependence.

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Schedule V Categories

- Opiates and opioids
  - 6 cough preparations not containing more than 200 mg codeine/100 mL
- Stimulant
  - Pyrovalerone used for chronic fatigue syndrome
- Others
  - Two antiepileptic drugs
    - Pregabalin
    - Lacosamide

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State Legislative Mandates

Know Your Nurse Practice Act

and

Any Other Relevant State Statutes

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State-by-state Guidance

- Each state has legislation specific to opiate prescribing in that state.
- Every prescriber should be familiar with the law in his or her practice state.
  - https://www.affirmhealth.com/blog/opioid-prescribing-guidelines-a-state-by-state-overview

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State-by-state Guidance (continued)

- Specifics will vary.
  - Some laws are…
    - Applicable to all prescribers
    - Specific to APRNs

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State-by-state Guidance (continued)

- Fifteen states limit prescribing to opiate-naïve patients in acute pain to 7 days.
- The majority of states have laws that restrict treatment of acute pain in some way.
- Restrictions placed in variety of ways

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State-by-state Guidance (continued)

- Examples of restricted prescribing
  - Duration
  - Condition
    - E.g., 4-day limit for post dental procedures, ophthalmic pain
  - Total daily dose
    - Calculated in terms of morphine milligram equivalents (MME)
  - Increased restrictions for minors

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Morphine Milligram Equivalents (MME)

- Total daily dosing is among the parameters monitored to reduce risk of overdose.
  - Several states limit MMEs by statute.
  - Other states direct specific agencies to limit MMEs.
  - Safest dosing <50 MME/day
  - Many states limit dosing to <90 MME/day.

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Morphine Milligram Equivalents (MME) (continued)

- Acute pain
  - Virtually no reason to exceed 90 MME daily
- Chronic pain
  - Doses in excess of 90 MME daily need careful justification.
  - Optimal use of adjuvants and nonpharmacologic agents

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Morphine Milligram Equivalents (MME) (continued)

Drug	Conversion factor	Dose	MME
Buprenorphine tab	10	16 mg	160
Codeine	0.15	60 mg	9
Fentanyl patch	2.4	25 mcg/hr	60
Hydrocodone	1	60 mg	60
Hydromorphone	4	1 mg	4
Methadone	10	50 mg	500
Oxycodone	1.5	60 mg	90
Oxymorphone	3	50 mg	150
Tapentadol	0.4	200 mg	80
Tramadol	0.1	400 mg	40

Source: http://www.agencymeddirectors.wa.gov/Calculator/DoseCalculator.htm

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Other State Requirements

- Many states mandate a prescription monitoring program query prior to prescribing.
- Other requirements can include
  - Informed consent
  - Records from all other prescribers
  - Varying levels of physical examination

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Chronic Pain Considerations

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CDC Guidelines for Prescribing Opioids for Chronic Pain

- In 2016 the Centers for Disease Control and Prevention (CDC) published guidelines for prescribing opioids for the management of chronic pain.
- 12 guidelines were developed based upon 5 key questions and an evidence review.

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CDC Guidelines for Prescribing Opioids for Chronic Pain (continued)

- These 12 guidelines are grouped according to 3 general domains.
  1. Determine when to initiate or continue opioids for chronic pain
  2. Opioid selection, dosage, duration, follow-up and discontinuation
  3. Assess risk and address harms of opioid use

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Determine When to Initiate or Continue Opioids for Chronic Pain

1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain.
   - Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient.
   - If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

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Determine When to Initiate or Continue Opioids for Chronic Pain (continued)

2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients.
   - Include realistic goals for pain and function
   - Consider how opioid therapy will be discontinued if benefits do not outweigh risks.
   - Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

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Determine When to Initiate or Continue Opioids for Chronic Pain (continued)

3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy, as well as patient and clinician responsibilities for managing therapy.

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Opioid Selection, Dosage, Duration, Follow-up and Discontinuation

4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.

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Opioid Selection, Dosage, Duration, Follow-up and Discontinuation (continued)

5. When opioids are started, clinicians should prescribe the lowest effective dosage.
   - Use caution when prescribing opioids.
   - Carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 MME per day.
   - Avoid increasing dosage to ≥90 MME per day or carefully justify the decision.

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Opioid Selection, Dosage, Duration, Follow-up and Discontinuation (continued)

6. Long-term opioid use often begins with treatment of acute pain.
   - When used for acute pain, prescribe the lowest effective dose of immediate-release opioids.
   - Prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids.
   - Three days or less will often be sufficient; more than 7 days will rarely be needed.

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Opioid Selection, Dosage, Duration, Follow-up and Discontinuation (continued)

7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation.
   - Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently.

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Opioid Selection, Dosage, Duration, Follow-up and Discontinuation (continued)

7. Clinicians should evaluate benefits… (cont.)
   - If benefits do not outweigh harms of continued opioid therapy
     - Optimize other therapies
     - Work with patients to taper opioids to lower dosages or to discontinue

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Assessing Risk and Addressing Harms of Opioid Use

8. Before starting and periodically during continuation of opioid therapy
   - Evaluate risk factors for opioid-related harms
   - Clinicians should incorporate into the management plan strategies to mitigate risk.
     - E.g., offering naloxone when risk factors for overdose are present

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Assessing Risk and Addressing Harms of Opioid Use (continued)

8. Before starting and periodically during continuation of opioid therapy (cont.)
   - Risk factors for opioid overdose include
     - History of overdose
     - History of substance use disorder
     - Higher opioid dosages (≥50 MME/d)
     - Concurrent benzodiazepine use

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Assessing Risk and Addressing Harms of Opioid Use (continued)

9. Review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data
   - Determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose.

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Assessing Risk and Addressing Harms of Opioid Use (continued)

9. Review the patient's history of controlled substance prescriptions…(cont.)
   - Clinicians should review PDMP data when starting opioid therapy for chronic pain.
     - Periodically during opioid therapy ranging from every prescription to every 3 months

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Assessing Risk and Addressing Harms of Opioid Use (continued)

10. When prescribing opioids for chronic pain, clinicians should…
    - Use urine drug testing before starting opioid therapy
      - Consider urine drug testing at least annually to assess for prescribed medications, as well as other controlled prescription drugs and illicit drugs

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Assessing Risk and Addressing Harms of Opioid Use (continued)

11. Clinicians should avoid prescribing opioid pain medication.
12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

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What to do with all of this information?

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Patient Selection and Risk Assessment

- Some patients need opioids!
  - Know your state legislative mandates; they trump evidence-based guidelines.
  - Incorporate multi-modal pain management strategies.
  - Risk assessment is a must when opioids are a necessary part of the plan of care.

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Identifying Opioid Abuse Risk

- Prevention is the best strategy.
- Risk factors for opioid abuse include
  - History of opioid abuse, misuse, addiction
  - Current or past substance abuse
  - Untreated psychiatric disorders
  - Social or family environments that encourage misuse

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Risk Assessment

- Opioid Risk Tool (ORT)
  - Brief self-report point scoring system
    - Family history
    - Personal history
    - Age
    - Preadolescent sexual abuse
    - Mental health disorders
  - Score of ≥8 indicates high risk

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Risk Assessment (continued)

- Screener and Opioid Assessment for Patients with Pain-Revised [SOAPP®-R])
- Clinician administered 24-item tool
  - Score of ≥18 indicates high risk of abuse
  - Topics similar to ORT although the family history is not well represented

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Risk Assessment (continued)

- The Brief Risk Questionnaire (BRQ)
  - 12-item self-administered screening tool
  - May be better correlated with risk that ORT and SOAPP®-R
  - Some concern about higher false positives
- Utility of screening tools is marginal at best.

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Risk Assessment (continued)

- Risk assessment tools are one of many mitigation strategies.
- No studies have evaluated the utility of risk assessment or mitigation strategies with respect to…
  - Overdose
  - Addiction
  - Abuse

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Assessment of Comorbidities

- Patients with mental health comorbidities are at risk for use disorders.
- Mental health comorbidities often produce pain that does not respond to pharmacotherapy.
- Dose escalations lead to chronic use and disorder syndromes.

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Psychiatric Comorbidities

- Underlying psychiatric conditions can…
  - Produce pain when no organic cause is apparent
    - Psychosomatic
    - Psychogenic
  - Exaggerate the pain experience when organic cause is present
    - Psychogenic modification

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Psychosomatic Pain

- Often a consequence of anxiety
- Anxiety results in structural change in muscle.
- A common finding in patients with generalized anxiety disorder
- Can occur acutely during times of high stress

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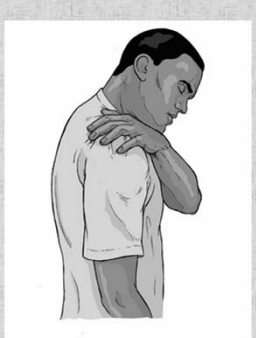

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Psychosomatic Pain
Patient Assessment

- Tense facial expression
- Fidgety and restless
  - Sit on edge of chair, wring hands
- Often feel need to stretch, massage
- Pain often accumulates with day's activities, especially if environment is tense.

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Psychosomatic Pain
Physical Examination

- Good range of motion
- Exam reveals trigger point.
- Patient can demonstrate crack.
- Localized area of significant pain with palpation
- No evidence of nerve root involvement
- No skin tenderness

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Psychogenic Pain

- The conversion of anxiety into pain without tissue change
- Characterized by underlying mental health disorder
- Usually, a history of emotional problems
- No organic cause will be found.

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Psychogenic Pain – Assessment

- Patient is convinced of illness.
  - Frequent demands for numerous consultations
- There are periods of symptom improvement.
- Upset body image can produce skin tenderness and dulled sensory appreciation.
- Physical findings are limited and inconsistent.

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Psychogenic Modification of Organic Pain

- Sincere emotional reaction to the organic event modifies the perception of organic pain.
- The organic problem alone would not cause disability; the psychogenic component often does.
- This patient is often the most difficult diagnostic and therapeutic challenge.

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Psychogenic Modification of Organic Pain – Assessment

- The physical findings will be consistent with mild disease.
- Life situation and personality of the patient are important assessment features.
- Psychogenic component interferes with treatment.

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Psychogenic Modification of Organic Pain (continued)

- Minor physical problems result in total disability.
- Treatment failures result in aggressive treatment.
  - Characteristic surgical failure

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Finally

Short- or Long-acting Agents?

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Short-acting Agents

- The half-life of common immediate-release (short-acting) opiates is 2.5 to 5 hours.
  - Results in dosing patterns of q4–6 h
    - Upside – Quick washout
    - Downside – Requires several doses daily

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Short-acting Agents (continued)

- Short-acting opioids are also often accompanied by postdose euphoria.
  - Differs from the pain relief action
  - Oxycodone among biggest offenders
  - Postdose euphoria contributes heavily to psychologic addiction.

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Long-acting Agents

- Less association with postdose euphoria
- Provides a more steady state pain control due to less frequent dosing
- Historically was encouraged for patients requiring chronic opioid therapy.

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Long-acting Opioids

Compound	Strengths	Typical Starting Dose and Dosing Interval	Name Branding
Morphine controlled-release tablet	15, 30, 60, 100, 200 mg	15–30 mg every 8–12 hours	MS Contin® Oramorph® SR
Morphine controlled-release capsule	20, 30, 50, 60, 100 mg	20 mg every 12 or 24 hours	Kadian®
Morphine extended-release capsule	30, 60, 90, 120 mg	30 mg every day	Avinza®
Oxycodone controlled-release	10, 20, 40, 80 mg	10 mg every 12 hours	OxyContin®
Oxymorphone extended-release	5, 10, 20, 30, 40 mg	5 mg every 12 hours	Opana® ER
Hydromorphone extended-release	8, 12, 16 mg	8 mg once daily	Exalgo® ER
Fentanyl transdermal	25, 50, 75, 100 mcg/hr patch	25 mcg applied every 3 days	Duragesic®
Buprenorphine transdermal	5, 10, 20 mcg/hr patch	5 mcg applied every 7 days	Butrans®

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What is the current approach? Short-acting or Long-acting?

- Short-acting always indicated for acute pain
  - The risk/benefit analysis universally favors benefit of short-acting agents.
  - Duration of therapy is anticipated to be quite short.

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Short- vs. Long-acting Opioids

- Remember 12 guiding principles for prescribing opioids for chronic pain.
  - #4…when starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.

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When are long-acting agents indicated?

- When it is clear that the patient will be on opioid therapy for an extended duration
  - Cancer care is the classic example.
  - In all clinical circumstances, optimize nonpharmacologic and non-opioid options.

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Case Study

52-year-old Male

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A 52-year-old Male with Back Pain

- Presents with lower back pain radiating to the left lower extremity
- Reports a remote history of similar pain 8 years ago
  - Treated successfully with physical therapy

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A 52-year-old Male with Back Pain (continued)

- Today he reports a 10-day history of recurrence.
- He was on vacation out-of-state when it started.
  - He presented to urgent care.
    - Was given ketorolac IM and a 5-day PO prescription
      - Reports some relief

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A 52-year-old Male with Back Pain (continued)

- After completing ketorolac he presents to his PCP.
  - He is given 7-day prescription for hydrocodone/APAP 7.5 mg/325 mg.
  - Referral to pain management is ordered.
- First available pain management appointment is 3 weeks later.

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A 52-year-old Male with Back Pain (continued)

- A detailed H and P is performed.
  - Patient admits taking over 90 OTC ibuprofen tablets in a 7-day period.
  - Patient also admits to taking some of his wife's hydrocodone.
  - A PMP report demonstrates only the opioid prescription that he has reported to the APRN.

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A 52-year-old Male with Back Pain (continued)

- He is scheduled for epidural corticosteroid injection therapy in 6 days.
- Today he reports 8–9 on 10 scale pain.
- How should he be managed pending his injection?

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Summary

- Pain is commonly encountered in clinical practice.
- Opioids are sometimes required; evidence-based guidance exists to promote healthy use.
- Opioids should always be used in combination with non-opioid therapies
- Risk assessment is critical to patient selection

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Summary (continued)

- Opioid use disorder is prevalent and dangerous.
  - Prescribers should always be vigilant to indicators and risk factors for opioid use disorder.
- Medication-assisted therapy (MAT) is among the most promising treatment options.

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Resources

- Centers for Disease Control and Prevention (CDC). (2019). "CDC Guidelines for prescribing opioids for chronic pain."
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