CO*RE COLLABORATION FOR REMS EDUCATION PRESENTS

OPIOID PRESCRIBING: Safe Practice, Changing Lives

UPDATED IN 2017
CHAPTER 1

WELCOME
Gaylinn Breeze is an Adult Geriatric Nurse Practitioner who joined the TOSH team in August of 2016 coming to Intermountain Healthcare from the University of Utah’s neurosurgery department. Gaylinn has an extensive background as an RN in intensive care, hospice and palliative care. Gaylinn received her MSN and Adult Geriatric Nurse Practitioner from Maryville University and her BSN from Excelsior College. She is currently the APC clinical team lead at The Orthopedic Specialty Hospital (TOSH) where she works with patients managing surgical pain. Gaylinn enjoys camping, fishing, boating, but most of all, anything that involves her family.

Timothy Houden, MD has specialized in pain management since 1993 and has served as the Medical Director of Intermountain Healthcare Pain Management Services since 2005. Under his direction, the Functional Restoration/Chronic Pain Development Team has produced four Care Process Models related to chronic pain management, providing clinical guidelines and education for primary care physicians. He is currently serving as the President of the Utah Academy of Pain Medicine. He was an advisor for UMA Opioid task force. He is also a Diplomate of the American Board of Pain Medicine and Board Certified with the American Board of Anesthesia with a subspecialty in Pain Medicine. Dr. Houden is a Founder and Medical Director of Utah Spine Care, a multidisciplinary pain clinic, and a Master-level Instructor for the Spinal Interventional Society. Dr. Houden actively practices in pain management at Utah Spine Care and OB anesthesia at McKay-Dee Hospital in Ogden, UT.

Dr. Houden received his medical training at the Medical College of Wisconsin and completed his residency at the Univ. of Utah. Dr. Houden is married with 2 children and loves to powder ski.
Faculty Information

Robin R. Ockey, MD, is the Medical Director at the Utah Valley Pain Management in Orem, Utah. He received his Medical Degree from The George Washington University School of Medicine in Washington, DC and completed resident training in Physical Medicine and Rehabilitation at the University of Kansas Medical Center in Kansas City, Kansas. Dr. Ockey is board certified by the American Board of Physical Medicine and Rehabilitation with subspecialty certification in pain medicine. Dr. Ockey is also board certified by the American Board of Pain Medicine. Dr. Ockey is a fellow of the American Academy of Physical Medicine and Rehabilitation and the American Academy of Neuromuscular & Electrodiagnostic Medicine. He is also a member of the American Academy of Pain Medicine. He has authored numerous articles in peer-reviewed journals and presented posters and lectures of a range of topics in pain and pain management.

Jeremiah West is a board certified Physical Medicine and Rehabilitation physician (Physiatrist) who received his Bachelors of Science Degree from Brigham Young University in Exercise Science and Medical Degree from the University of Texas Medical Branch. He completed his residency training in Physical Medicine and Rehabilitation at the University of Texas, Southwestern where he was also chief resident. He is currently the Medical Director for the Intermountain Chronic Pain Clinic in Layton. Dr. West’s focus is on treating the patient as a whole, with a focus on wellness and exercise. He is passionate about helping patients meet their personal goals. Dr. West enjoys the outdoors, running, reading, sports, and spending time with his family.
NO CO*RE PARTNER HAS ANY CONFLICTS OF INTEREST TO REPORT (APPENDIX 2)
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NO CO*RE FACULTY HAS ANY CONFLICTS OF INTEREST TO REPORT (APPENDIX 2)
Presented in conjunction with the California Academy of Family Physicians, a member of the Collaborative for Risk Evaluation and Mitigation Strategy (REMS) Education (CO*RE), eleven interdisciplinary organizations working together to improve pain management and prevent adverse outcomes.

This educational activity is supported by an independent educational grant from the Extended-Release/Long-Acting (ER/LA) Opioid Analgesic REMS Program Companies. Please see this document for a listing of the member companies. This activity is intended to be fully compliant with the ER/LA Opioid Analgesic REMS education requirements issued by the US Food and Drug Administration.
PRODUCTS COVERED BY THIS REMS

BRAND NAME PRODUCTS

- Arymo ER morphine sulfate ER tablets
- Avinza® morphine sulfate ER capsules
- Belbuca® buprenorphine buccal film
- Butrans® buprenorphine transdermal system
- Dolophine® methadone hydrochloride tablets
- Duragesic® fentanyl transdermal system
- Embeda® morphine sulfate/naltrexone ER capsules
- Exalgo® hydromorphone hydrochloride ER tablets
- Hysingla® ER hydrocodone bitartrate ER tablets
- Kadian® morphine sulfate ER capsules
- MorphaBond® morphine sulfate ER tablets
- MS Contin® morphine sulfate CR tablets
- Nucynta® ER tapentadol ER tablets
- Opana® ER oxymorphone hydrochloride ER tablets
- OxyContin® oxycodone hydrochloride CR tablets
- Targiniq™ ER oxycodone hydrochloride/naloxone hydrochloride ER tablets
- Troxyca ER oxycodone hydrochloride/naltrexone capsules
- Vantrela ER hydrocodone bitartrate ER tablets
- Xtampza ER oxycodone ER capsules
- Zohydro® hydrocodone bitartrate ER capsules

GENERIC PRODUCTS

- Fentanyl ER transdermal systems
- Methadone hydrochloride tablets
- Methadone hydrochloride oral concentrate
- Methadone hydrochloride oral solution
- Morphine sulfate ER tablets
- Morphine sulfate ER capsules
- Oxycodone hydrochloride ER tablets
CHAPTER 2

WHY ARE WE HERE?

SOURCE: MMWR, January 1, 2016/64(50);1378-82
https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm
Utah Data

Overdose deaths: 646 (2015)
Rate of prescribing: 82-95 per 100 people (2012)

http://www.cdc.gov/drugoverdose/data/statedeaths.html

SOURCE: IMS, National Prescription Audit (NPA™), 2012.
OPIOID PRESCRIBING - THE PENDULUM SWINGS

PRESCRIBING BEHAVIORS

Under-Prescribing
Over-Prescribing
Appropriate Prescribing

RESULTING OUTCOMES

Unresolved Pain
Adverse Outcomes
Adequate Analgesia
**BENEFITS VS. RISKS**

**BENEFITS**
- Analgesia
  - Adequate pain control
  - Continuous, predictable (with ER/LAs)
- Improved function
- Quality of life

**RISKS**
- Overdose, especially as ER/LA formulations contain more opioids than Immediate Release
- Life-threatening respiratory depression
- Abuse by patient or household contacts
- Misuse, diversion, and addiction
- Physical dependence and tolerance
- Interactions with other meds and substances
- Risk of neonatal opioid withdrawal syndrome
- Inadvertent exposure/ingestion by household contacts especially children

Source where pain relievers were obtained for most recent misuse among 12.5 million people aged 12 or older who misused prescription pain relievers in the past year: percentages, 2015

- 54% - Given by, bought from, or taken from a friend or relative
- 36% - Through a prescription or stolen from healthcare provider
- 5% - Bought from a dealer or stranger
- 5% - Some other way

Source: Prescription Drug Use and Misuse in the United States: Results from the 2015 National Survey on Drug Use and Health, Sept 2016
FIRST SPECIFIC DRUG ASSOCIATED WITH INITIATION OF ILLICIT DRUG USE 2013

2.8 million initiates of illicit drugs

- 70.3% - Marijuana
- 12.5% - Pain Relievers
- 6.3% - Inhalants
- 5.2% - Tranquilizers
- 2.7% - Stimulants
- 2.6% - Hallucinogens
- 0.3% - Sedatives and Cocaine

SOURCE: SAMHSA Annual National Survey on Drug Use and Health, June 2015
https://www.drugabuse.gov/publications/drugfacts/nationwide-trends
THE FEDERAL PLAYERS

Many agencies involved

WE ARE HERE BECAUSE OF ...
REMS: RISK EVALUATION AND MITIGATION STRATEGY

• On July 9, 2012, the Food and Drug Administration (FDA) approved a Risk Evaluation and Mitigation Strategy (REMS) for extended-release (ER) and long-acting (LA) opioid medications

• First time FDA has ever used accredited CE/CME as part of a REMS
CO*RE STATEMENT

Misuse, abuse, diversion, addiction, and overdose of opioids has created a serious public health epidemic in the U.S.

When prescribed well and used as prescribed, opioids can be valuable tools to effectively treat pain.

This course does not advocate for or against the use of Immediate Release (IR) or Extended-Release/Long-Acting (ER/LA) opioids. Our purpose is to provide proper education about safe prescribing practices along with effective patient education.
LEARNING OBJECTIVES

- Accurately assess patients with pain for consideration of an opioid trial
- Establish realistic goals for pain management and restoration of function
- Initiate opioid treatment (IR and ER/LA) safely and judiciously, maximizing efficacy while minimizing risks
- Monitor and re-evaluate treatment continuously; discontinue safely when appropriate
- Counsel patients and caregivers about use, misuse, abuse, diversion, and overdose
- Educate patients about safe storage and disposal of opioids
- Demonstrate working knowledge and ability to access general and specific information about opioids, especially those used in your practice
You and Your Team *can* have an immediate and positive impact on this crisis while also caring for your patients appropriately.
CHAPTER 3

PAIN
UNDERSTANDING PAIN

Physiologic Stimulus

Nociceptive ↔ Neuropathic

Biopsychosocial

Spiritual

Context

Physical

Psychological

Social

Spiritual

Experience of Pain

Tissue injury
Mechanical abnormalities
Inflammation
Tissue invasion
Tissue injury

Peripheral neuropathy (neuritis)
Post herpetic neuralgia
Sympathetic dystrophy
Thalamic injury
Central hypersensitization

Sleep/fatigue
Sympathetic arousal
Inflammatory status
Barometric pressure
Nutritional status
Work status
Relationships
Avocations
Secondary gain
Intimacy
Conditioning

Anxiety
Resilience
ACEs
Grief
Depression

Past disease experience
Catastrophizing

Religious faith
Existential issues

Meaning of illness
Suffering

Experience of Pain

Experience of Pain

Experience of Pain
THE IMPACT OF PAIN

- SLEEP DISTURBANCE
- SECONDARY PHYSICAL PROBLEMS
- ANXIETY DEPRESSION
- SUBSTANCE MISUSE
- FUNCTIONAL DISABILITIES
- INCREASED STRESSES
- CHRONIC PAIN

COGNITIVE DISTORTIONS

Sleep disturbance, secondary physical problems, anxiety depression, substance misuse, functional disabilities, and increased stresses are all interconnected to chronic pain, with cognitive distortions as a key factor.
PAIN MANAGEMENT GOALS AND TREATMENT OPTIONS: A MULTI-MODAL APPROACH

COGNITIVE BEHAVIORAL THERAPY
- Behavioral Modification
- Meditation
- Cognitive Restructuring

INTERVENTIONAL TREATMENTS
- Nerve Blocks
- Steroid Injections
- Stimulators
- Trigger Point Injections

PHYSICAL
- Exercise
- Acupuncture
- Movement Therapies
- Manual Treatments

PHARMACOTHERAPY
- NSAIDS
- Antidepressants
- Opioids
- Cannabinoids
- Anticonvulsants
- Topicals (e.g., lidocaine)

Reduce Pain
Cultivate Well Being
Self Care
Provider Care
Restore Function
Quality of Life
• Explain neurophysiology of pain processing to patients
• When patients understand, their concerns are validated
• Pain has biological, psychological, social, and spiritual components
CHALLENGE: THE EARLY REFILL

RED FLAG:
Is this misuse? Abuse?

Your patient requests an early refill for the second time in six months. Took extra medications for headache and again for toothache. Prescription is for lower back pain.

Action:
Evaluate potential misuse. Confirm patient’s understanding of each medication's dosage, time of day, and maximum daily dose. Ask him/her to repeat these instructions back to you. Avoid clinical terms such as “prn”. Review treatment goals and expectations. Select and document a therapy plan that is compatible with patients’ individual needs, is safe, effective and balanced. Screen for risk with Current Opioid Misuse Measure (COMM) and, if indicated, refer to addiction specialist for treatment.
CHAPTER 4

ASSESSMENT
PAIN ASSESSMENT

DESCRIPTION OF PAIN

Location
Intensity
Quality
Onset/Duration
Variations/Patterns/Rhythms

WHAT RELIEVES THE PAIN?

WHAT CAUSES OR INCREASES PAIN?

EFFECTS OF PAIN ON PHYSICAL, EMOTIONAL, AND PSYCHOSOCIAL FUNCTION

PATIENT’S CURRENT PAIN AND FUNCTION

TREATMENT HISTORY

NON-PHARMACOLOGIC STRATEGIES AND EFFECTIVENESS

PHARMACOLOGIC STRATEGIES AND EFFECTIVENESS

PAST USE

CURRENT USE

• Query state Prescription Drug Monitoring Program (PDMP) to confirm patient report
  Contact current provider and obtain prior medical records

DOSAGE

• For opioids currently prescribed: opioid, dose, regimen, and duration
  – Important to determine if patient is opioid tolerant

GENERAL EFFECTIVENESS
PAST MEDICAL HISTORY

ILLNESS RELEVANT TO (1) EFFECTS OR (2) METABOLISM OF OPIOIDS

1. Pulmonary disease, constipation, nausea, cognitive impairment
2. Hepatic, renal disease

ILLNESS POSSIBLY LINKED TO SUBSTANCE USE DISORDER (SUD):

• Hepatitis
• HIV
• Tuberculosis
• Cellulitis
• STIs
• Trauma/Burns
• Cardiac Disease
• Pulmonary Disease

**OBTAiN A COMPLETE HISTORY OF CURRENT AND PAST SUBSTANCE USE**

**RISK FACTORS FOR OPIOID ABUSE**

- Controlled medications: prescribed or non-prescribed
- Alcohol and tobacco
- History of sexual abuse
- Family history of substance abuse and psychiatric disorders
- Age (16-45 YO)

Substance abuse history does not prohibit treatment with ER/LA opioids but may require additional monitoring and expert consultation/referral

**SOCiAL HISTORY**

Employment, cultural background, social network, marital history, legal history, and other behavioral patterns
PHYSICAL EXAM AND ASSESSMENT

Seek objective confirmatory data

Components of patient evaluation for pain

Order diagnostic tests (appropriate to complaint)

General: vital signs, appearance, and pain behaviors

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

Neurologic exam

Cutaneous or trophic findings

## OPIOID RISK TOOL (ORT)

Mark each box that applies

<table>
<thead>
<tr>
<th></th>
<th>Female</th>
<th>Male</th>
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<tbody>
<tr>
<td>1</td>
<td>Family history of substance abuse</td>
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<td></td>
<td>Illegal drugs</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Prescription drugs</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>Personal Hx of substance abuse</td>
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</tr>
<tr>
<td></td>
<td>Alcohol</td>
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<td></td>
<td>Illegal drugs</td>
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<tr>
<td></td>
<td>Prescription drugs</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>Age between 16 and 45 yrs</td>
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<tr>
<td>4</td>
<td>Hx of preadolescent sexual abuse</td>
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<tr>
<td>5</td>
<td>Psychologic disease</td>
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<tr>
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<td>Depression</td>
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</table>

**Scoring Totals:**

- **0-3:** low
- **4-7:** moderate
- **≥8:** high

SCREENER AND OPIOID ASSESSMENT FOR PATIENTS WITH PAIN (SOAPP)®

Identifies patients as high, moderate, or low risk for misuse of opioids prescribed for chronic pain

HOW IS SOAPP® ADMINISTERED?

- Usually self-administered in waiting room, exam room, or prior to an office visit
- May be completed as part of an interview with a nurse, physician, or psychologist
- Prescribers should have a completed and scored SOAPP® while making opioid treatment decisions

SOAPP®: 4 FORMATS AVAILABLE TO ASSESS MISUSE RISK

<table>
<thead>
<tr>
<th>SOAPP® 1.0 24Q VERSION (ORIGINAL)</th>
<th>14Q VERSION</th>
<th>5Q (SHORT-FORM) VERSION</th>
<th>SOAPP-R 24Q VERSION (REVISED)</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 questions (14 used to score tool)</td>
<td>14 questions*</td>
<td>5 questions*</td>
<td>24 questions</td>
</tr>
<tr>
<td>Add ratings for 14 &quot;screening&quot; questions</td>
<td>Add ratings for each question</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Score ≥12: high risk</td>
<td>Score ≥12: high risk</td>
<td>Score ≥4: increased risk</td>
<td>Score ≥22: high risk</td>
</tr>
<tr>
<td>&lt;8: low risk</td>
<td>&lt;8: low risk</td>
<td>≤9: low risk</td>
<td>≤9: low risk</td>
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<tr>
<td>&lt;10 min. to complete</td>
<td>&lt;8 min. to complete</td>
<td>&lt;5 min. to complete</td>
<td>&lt;10 min. to complete</td>
</tr>
<tr>
<td>10 &quot;unscored&quot; questions provide background</td>
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</table>

*Questions from SOAPP V.1.0   Patients rate all questions on scale of 0-4
Opioids

Pain

Addiction
Opioids

WHAT IS THE RISK FOR MY PATIENT?

• Risk of opioid use disorder in patients on chronic opioid therapy (COT) for chronic non-cancer pain (CNCP) is up to 30%

• Always highest with past history of substance use disorder (SUD) or psychiatric comorbidity

• Recognize that patient needs and patterns shift with age

SOURCE: Boscarino, J. Journal of Addictive Diseases, 30:3,185-194
PAIN AND ADDICTION

PAIN – 5 A’S

Analgesia
Activities/Function
Aberrant Behavior
Adverse Effects
Affect

ADDITION – 5 C’S

Control, loss of
Compulsive use
Craving drug
Continued use
Chronic problem
RISK AND PAIN ASSESSMENT TOOL BOXES

PAIN ASSESSMENT TOOL BOX

- Pain Assessment Tools (BPI, etc.)
- Functional Assessment (SF 36, PPS, geriatric assessment, etc.)
- Pain intensity, Enjoyment of life, General activity (PEG)

MENTAL HEALTH TOOLS (PHQ9, GAD7, etc.)

RISK ASSESSMENT TOOL BOX

- PDMP
- UDT
- Risk Assessment Tools (ORT or SOAPP®)
CONSIDER A TRIAL OF AN OPIOID?

- **POTENTIAL BENEFITS ARE LIKELY TO OUTWEIGH RISKS**
- **FAILED TO ADEQUATELY RESPOND TO NON-OPIOID & NONDRUG INTERVENTIONS**
- **PAIN IS MODERATE TO SEVERE**
- **INITIATE TRIAL OF IR OPIOIDS**

WHEN TO CONSIDER A TRIAL OF AN OPIOID

60-YR-OLD WITH CHRONIC DISABLING OA PAIN

- Non-opioid therapies not effective
- No psychiatric/medical comorbidity or personal/family drug abuse history
  - High potential benefits relative to potential risks
  - Could prescribe opioids to this patient in most settings with routine monitoring

30-YR-OLD WITH FIBROMYALGIA AND RECENT ALCOHOL USE DISORDER

- High potential risks relative to benefits (opioid therapy not first line for fibromyalgia)
- Requires intensive structure, monitoring, and management by clinician with expertise in both addiction & pain

Not a good candidate for opioid therapy

INITIATING OPIOIDS: CDC GUIDELINE (2016)

• Begin with IR
• Prescribe the lowest effective dosage
• Use caution at any dosage, but particularly when
  • Increasing dosage to ≥50 morphine milligram equivalents (MME)/day and carefully justify a decision to titrate dosage to ≥90 MME/day
• For acute pain, prescribe lowest effective dose of IRs, no more than needed
• Re-evaluate risks/benefits within 1 - 4 weeks of initiation or dose escalation
• Re-evaluate risks/benefits every 3 months; if benefits do not outweigh harms optimize other therapies, work to taper and discontinue
• Link to the Guideline:
  https://www.cdc.gov/drugoverdose/prescribing/providers.html

Cancer pain, hospice, and palliative care patients are not covered by CDC Guideline
**INFORMED CONSENT**

When initiating a trial of opioid analgesic therapy, confirm patient understanding of informed consent to establish:

| ANALGESIC AND FUNCTIONAL GOALS OF TREATMENT |
| EXPECTATIONS |
| POTENTIAL RISKS |
| ALTERNATIVES TO OPIOIDS |

**HOW TO MANAGE**

- Common Adverse Effects (AEs) (e.g., constipation, nausea, sedation)
- Risks (e.g., abuse, addiction, respiratory depression, overdose)
- AEs with long-term therapy (e.g., hyperalgesia, low testosterone, irregular menses or sexual dysfunction)
PATIENT-PRESCRIBER AGREEMENT (PPA)

Document signed by both patient and prescriber at time an opioid is prescribed

- CLARIFY TREATMENT PLAN AND GOALS OF TREATMENT WITH PATIENT, PATIENT’S FAMILY, AND OTHER CLINICIANS INVOLVED IN PATIENT’S CARE
- ASSIST IN PATIENT EDUCATION
- DISCUSS MEDICATION SAFE HANDLING, STORAGE, AND DISPOSAL
- DOCUMENT PATIENT AND PRESCRIBER RESPONSIBILITIES
PATIENT PROVIDER AGREEMENT (PPA)

REINFORCE EXPECTATIONS FOR APPROPRIATE AND SAFE OPIOID USE

- One prescriber
- Consider one pharmacy
- Safeguard
  - Do not store in medicine cabinet
  - Keep locked (medication safe)
  - Do not share or sell
- Instructions for disposal when no longer needed
- Prescriber notification for any event resulting in a pain medication prescription
- Follow-up
- Monitoring
  - Random UDT and pill counts
- Refills
- Identify behaviors for discontinuation
- Exit strategy
MONITOR ADHERENCE AND ABERRANT BEHAVIOR

ROUTINELY MONITOR PATIENT ADHERENCE TO TREATMENT PLAN

• Recognize and document aberrant drug-related behavior
  – In addition to patient self-report also use:
    • State PDMPs
    • UDT
      – Positive for non-prescribed drugs
      – Positive for illicit substance
      – Negative for prescribed opioid
    • Family member or caregiver interviews
    • Monitoring tools such as the COMM, PADT, PMQ, or PDUQ
    • Medication reconciliation (e.g., pill counts)

PADT = Pain Assessment and Documentation Tool
ADDRESS ABERRANT DRUG-RELATED BEHAVIOR

Behavior outside the boundaries of agreed-on treatment plan:

- Unsanctioned dose escalations or other noncompliance with therapy on 1 or 2 occasions
- Unapproved use of the drug to treat another symptom
- Openly acquiring similar drugs from other medical sources
- Multiple dose escalations or other noncompliance with therapy despite warnings
- Prescription forgery
- Obtaining prescription drugs from nonmedical sources

Any of these behaviors merit investigation, proceed with caution
Adequately **DOCUMENT** all patient interactions, assessments, test results, and treatment plans.
• Conduct a comprehensive and pain-focused history and physical
• Assess for risk of abuse and for mental health issues
• Determine if a therapeutic trial is appropriate
• Establish realistic goals for pain management and function
• Document EVERYTHING
CHALLENGE: THE DELAYED SURGERY

RED FLAG:
Patient may be stalling to continue an opioid regimen

Ms. Jones says she needs opioids to manage her pain until she can have surgery. She reports continued delays in getting to surgery. You phone the surgeon and discover that no date has been set and that she has cancelled several appointments.

Action:
Set a time limit and expectation. Offer non-pharmacologic methods and non-opioid interventions for pain management. Communicate with the surgeon and advise patient to make appointment with surgeon for discussion of treatment plan.
CHAPTER 5

MANAGEMENT

MONITORING AND DISCONTINUING
PART 1
MONITORING
OPIOID SIDE EFFECTS

• Respiratory depression – most serious
• Opioid-Induced Constipation (OIC) – most common
• Sedation, cognitive impairment
• Falls and fractures
• Sweating, miosis, urinary retention
• Hypogonadism
• Tolerance, physical dependence, hyperalgesia
• Addiction in vulnerable patients

Prescribers should report serious AEs to the FDA:
www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf
or 1-800-FDA-1088
OPIOID-INDUCED RESPIRATORY DEPRESSION

Chief hazard of opioid agonists, including ER/LA opioids

- If not immediately recognized and treated, may lead to respiratory arrest and death
- Greatest risk: initiation of therapy or after dose increase

Manifested by reduced urge to breathe and decreased respiration rate

- Shallow breathing
- CO₂ retention can exacerbate opioid sedating effects

Instruct patients/family members to call 911

Managed with

- Close observation
- Supportive measures
- Opioid antagonists
- Depending on patient’s clinical status

FDA. Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics. 01/2017.
OPIOID-INDUCED RESPIRATORY DEPRESSION

MORE LIKELY TO OCCUR

• In elderly, cachectic, or debilitated patients
  – Contraindicated in patients with respiratory depression or conditions that increase risk
• If given concomitantly with other drugs that depress respiration
• Patients who are opioid-naïve or have just had a dose increase

REDUCE RISK

• Proper dosing and titration are essential
• Do not overestimate dose when converting dosage from another opioid product
  – Can result in fatal overdose with first dose
• Instruct patients to swallow tablets/capsules whole
  – Dose from cut, crushed, dissolved, or chewed tablets/capsules may be fatal, particularly in opioid-naïve individuals
## WHEN TO MOVE FROM IR TO ER/LA OPIOIDS

### PRIMARY REASONS

- Maintain stable blood levels (steady state plasma)
- Longer duration of action
- Multiple IR doses needed to achieve effective analgesia
- Poor analgesic efficacy despite dose titration
- Less sleep disruption

### OTHER POTENTIAL REASONS

- Patient desire or need to try a new formulation
- Cost or insurance issues
- Adherence issues
- Change in clinical status requires an opioid with different pharmacokinetics
- Problematic drug-drug interactions
CONSIDERATIONS FOR CHANGE FROM IR TO ER/LA OPIOIDS

DRUG AND DOSE SELECTION IS CRITICAL

Some ER/LA opioids or dosage forms are only recommended for opioid-tolerant patients

- ANY strength of transdermal fentanyl or hydromorphone ER
- Certain strengths/doses of other ER/LA products (check drug prescribing information)

MONITOR PATIENTS CLOSELY FOR RESPIRATORY DEPRESSION

Especially within 24-72 hours of initiating therapy and increasing dosage

INDIVIDUALIZE DOSAGE BY TITRATION BASED ON EFFICACY, TOLERABILITY, AND PRESENCE OF AEs

Check ER/LA opioid product PI for minimum titration intervals

Supplement with IR analgesics (opioids and non-opioid) if pain is not controlled during titration


Patients considered opioid tolerant are taking at least
- 60 mg oral morphine/day
- 25 mcg transdermal fentanyl/hour
- 30 mg oral oxycodone/day
- 8 mg oral hydromorphone/day
- 25 mg oral oxymorphone/day
- An equianalgesic dose of another opioid

Still requires caution when rotating a patient on an IR opioid to a different ER/LA opioid

OPIOID ROTATION

DEFINITION

Change from an existing opioid regimen to another opioid with the goal of improving therapeutic outcomes or to avoid AEs attributed to the existing drug (e.g., myoclonus)

RATIONALE

Differences in pharmacologic or other effects make it likely that a switch will improve outcomes

- Effectiveness and AEs of different mu opioids vary among patients
- Patients show incomplete cross-tolerance to new opioid
  - Patient tolerant to first opioid can have improved analgesia from second opioid at a dose lower than calculated from an Equianalgesic Dosing Table (EDT)

EQUIANALGESIC DOSE TABLES (EDT)

Many different versions:

- Published
- Online
- Online Interactive
- Smartphone Apps

Vary in terms of:

- Equianalgesic Values
- Whether ranges are used

Which opioids are included: May or may not include transdermal opioids, rapid-onset fentanyl, ER/LA opioids, or opioid agonist-antagonists
## EXAMPLE OF AN EDT FOR ADULTS

<table>
<thead>
<tr>
<th>DRUG</th>
<th>SC/IV</th>
<th>PO</th>
<th>PARENTERAL</th>
<th>PO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine</td>
<td>10 mg</td>
<td>30 mg</td>
<td>2.5-5 mg SC/IV q3-4hr (1.25-2.5 mg)</td>
<td>5-15 mg q3-4hr (IR or oral solution) (2.5-7.5 mg)</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>NA</td>
<td>20 mg</td>
<td>NA</td>
<td>5-10 mg q3-4 (2.5 mg)</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>NA</td>
<td>30 mg</td>
<td>NA</td>
<td>5 mg q3-4h (2.5 mg)</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>1.5 mg</td>
<td>7.5 mg</td>
<td>0.2-0.6 mg SC/IV q2-3hr (0.2 mg)</td>
<td>1-2 mg q3-4hr (0.5-1 mg)</td>
</tr>
</tbody>
</table>
MU OPIOID RECEPTORS AND INCOMPLETE CROSS-TOLERANCE

MU OPIOIDS BIND TO MU RECEPTORS

MANY MU RECEPTOR SUBTYPES:

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

MAY HELP EXPLAIN:

Inter-patient variability in response to mu opioids

Incomplete cross-tolerance among mu opioids

MU OPIOID RECEPTOR SUBTYPE

Potency

Drug 1

Drug 2
### GUIDELINES FOR OPIOID ROTATION

**REDUCE CALCULATED EQUIANALGESIC DOSE BY 25%-50%**

**SELECT % REDUCTION BASED ON CLINICAL JUDGMENT**

<table>
<thead>
<tr>
<th>CLOSER TO 50% REDUCTION IF PATIENT IS</th>
<th>CLOSER TO 25% REDUCTION IF PATIENT</th>
</tr>
</thead>
</table>
| • Receiving a relatively high dose of current opioid regimen  
• Elderly or medically frail | • Does not have these characteristics  
• Is changing route of administration |

*75%-90% reduction for methadone

---

Calculate equianalgesic dose of new opioid from EDT
IF SWITCHING TO METHADONE:

- Standard EDTs are less helpful in opioid rotation to methadone
- In opioid tolerant patients, methadone doses should **not** exceed 30-40 mg/day upon rotation
  - Consider inpatient monitoring, including serial EKG monitoring
- In opioid-naïve patients, methadone should **not** be given as an initial drug

IF SWITCHING TO TRANSDERMAL:

- **Fentanyl**, calculate dose conversion based on equianalgesic dose ratios included in the PI
- **Buprenorphine**, follow instructions in the PI
### GUIDELINE FOR OPIOID ROTATION: SUMMARY

<table>
<thead>
<tr>
<th>VALUES FROM EDT*</th>
<th>PATIENT OPIOID VALUES</th>
<th>&quot;SOLVE&quot; FOR X</th>
<th>AUTOMATICALLY REDUCE DOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value of Current Opioid</td>
<td>24 Hr Dose of Current Opioid</td>
<td>Equianalgesic 24 Hr Dose of New Opioid</td>
<td>By 25%-50%†</td>
</tr>
<tr>
<td>Value of New Opioid</td>
<td>X Amount of New Opioid</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Frequently assess initial response
- Titrate dose of new opioid to optimize outcomes
- Calculate supplemental rescue dose used for titration at 5%-15% of total daily dose‡

* If switching to transdermal fentanyl, use equianalgesic dose ratios provided in PI
† If switching to methadone, reduce dose by 75%-90%
‡ If oral transmucosal fentanyl used as rescue, begin at lowest dose irrespective of baseline opioid
BREAKTHROUGH PAIN (BTP)

PATIENTS ON STABLE ATC OPIOIDS MAY EXPERIENCE BTP

- Disease progression or a new or unrelated pain
  - Target cause or precipitating factors
- Dose for BTP: using an IR is 5%-15% of total daily opioid dose, administered at an appropriate interval
- Never use ER/LA for BTP

CONSIDER ADDING

- PRN IR opioid trial based on analysis of benefit versus risk
  - Risk for aberrant drug-related behaviors
  - High-risk: only in conjunction w/ frequent monitoring & follow-up
  - Low-risk: w/ routine follow-up & monitoring
- Non-opioid drug therapies
- Non-pharmacologic treatments

ATC = Around the Clock
BE READY TO REFER

SUBSTANCE USE DISORDER

SAMHSA substance abuse treatment facility locator
https://findtreatment.samhsa.gov/locator/home

SAMHSA mental health treatment facility locator
https://findtreatment.samhsa.gov/locator/home

HIGH-RISK/COMPLEX PATIENTS

Refer to pain management, check state regulations for requirements

SAMHSA = Substance Abuse and Mental Health Service Administration
RATIONALE FOR URINE DRUG TESTING (UDT)

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

UDT FREQUENCY IS BASED ON CLINICAL JUDGMENT AND STATE REGULATIONS
TYPES OF UDT METHODS

Be aware of what you are testing and not testing

IMMUNOASSAY (IA) DRUG PANELS

- Either lab-based or point of care
- Identify substance as present or absent according to cutoff
- Many do not identify individual drugs within a class
- Subject to cross-reactivity and variability

GC/MS OR LC/MS

- Identify the presence and quantity of substance(s)
- Identify drugs not included in IA tests
- When results are contested

GC/MS= gas chromatography/mass spectrometry  -  LC/MS= liquid chromatography/mass spectrometry

SPECIFIC WINDOWS OF DRUG DETECTION

How long a person excretes drug and/or metabolite(s) at a concentration above a cutoff

DETECTION TIME OF DRUGS IN URINE

Governed by various factors; e.g., dose, route of administration, metabolism, fat solubility, urine volume and pH

For most drugs it is 1-3 days

Chronic use of lipid-soluble drugs increases detection time; e.g., marijuana, diazepam, ketamine
# Urine Specimen Integrity

## Specimen Color Related to Concentration
Concentrated samples more reliable than dilute samples

## Temp within 4 Minutes of Voiding is 90-100°F

## pH Fluctuates within Range of 4.5-8.0

## Creatinine Varies with Hydration

<table>
<thead>
<tr>
<th>Normal urine:</th>
<th>Dilute: creatinine &lt;20 mg/dL and specific gravity &lt;1.003</th>
<th>Creatinine &lt;2 mg/dL not consistent with human urine</th>
</tr>
</thead>
</table>
INTERPRETATION OF UDT RESULTS

POSITIVE RESULT

Demonstrates recent use
- Most drugs in urine have detection times of 1-3 days
- Chronic use of lipid-soluble drugs: test positive for ≥1 week

Does not diagnose
- Drug addiction, physical dependence, or impairment

Does not provide enough information to determine
- Exposure time, dose, or frequency of use

NEGATIVE RESULT

Does not diagnose diversion
- More complex than presence or absence of a drug in urine

May be due to maladaptive drug-taking behavior
- Binging, running out early
- Other factors: e.g., cessation of insurance, financial difficulties
EXAMPLES OF METABOLISM OF OPIOIDS

- **CODEINE** → **MORPHINE** → **6-MAM*** → **HEROIN**
  - $T_{1/2} = 25-30$ MIN
  - $T_{1/2} = 3-5$ MIN

- **HYDROCODONE** → **HYDROMORPHONE**
- **OXYCODONE** → **OXYMORPHONE**

*6-MAM = 6-MONOACETYLMORPHINE*
CHALLENGE: THE OFFENDED PATIENT

RED FLAG:
You decide not to request routine risk assessment for fear of creating conflict

Mrs. Lane and her family have been your patients for years. She has chronic headache and back pain treatment. When you ask her to take a UDT, she becomes upset and accuses you of not trusting her. You decide against further risk assessments because you are concerned about damaging the relationship.

Action:
Require all patients receiving opioids to follow a treatment plan and adhere to defined expectations. Create office policy for performing UDT for patients receiving opioids beyond two weeks. Practice universal precautions. Explain to patient that you must meet the standards of care that include evaluation of risk in all patients, use of PPAs, and other tools.
PART 2

DISCONTINUING
Relevant Definitions

• **Diversion:** Redirection of a prescription drug from its lawful purpose to illicit use

• **Misuse:** The intentional or unintentional use of a prescribed medication in a manner that is contrary to directions, regardless of whether a harmful outcome occurs

• **Abuse:** Self-administration of medications to alter one’s state of consciousness ("get high")

• **Addiction:** A primary, chronic, neurobiological disease, with genetic, psychologic, and environmental factors influencing its development and manifestations. Addiction is characterized by the 4 C’s—behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.
## Reasons for Discontinuing Opioids

### Pain Level Decreases in Stable Patients

### Intolerable and Unmanageable AEs

### No Progress Toward Therapeutic Goals

### Misuse

- 1 or 2 episodes of increasing dose without prescriber knowledge
- Sharing medications
- Unapproved opioid use to treat another symptom (e.g., insomnia)

### Aberrant Behaviors

- Use of illicit drugs or unprescribed opioids
- Repeatedly obtaining opioids from multiple outside sources
- Prescription forgery
- Multiple episodes of prescription loss
- Diversion
TAPER DOSE WHEN DISCONTINUING

- Minimize withdrawal symptoms in opioid-dependent patient, consider medications to assist with withdrawal

- May use a range of approaches from slow 10% dose reduction per week to more rapid 25%-50% reduction every few days

- If opioid use disorder or a failed taper, refer to addiction specialist or consider opioid agonist therapy

- Counseling and relaxation strategies needed
CHAPTER 5 – PEARLS FOR PRACTICE

• Establish informed consent and PPA at the beginning

• Educate the whole team: *patients, families, caregivers*

• Refer if necessary

• Anticipate opioid-induced respiratory depression and constipation

• Follow patients closely during times of dose adjustments

• Periodically evaluate functional outcomes

• Discontinue opioids slowly and safely
CHALLENGE: IS THIS A LAB ERROR?

RED FLAG:
The questionable Urine Drug Test

Donald has been prescribed oxycodone for six months to treat back pain. His UDT at six months comes back negative in all areas. He tells you that he is taking his meds.

Action:
Do not discharge the patient as the first action. Contact the lab and discuss the test and any metabolite or specimen integrity issues. Ask: Is this the right lab test? Repeat the UDT and document everything. Discuss with the patient.
OLDER ADULTS

RISK FOR RESPIRATORY DEPRESSION

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

MONITOR

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

ROUTinely INITIATE A BOWEL REGIMEN

WOMEN WITH CHILDBEARING POTENTIAL

KNOW THE REPRODUCTIVE PLANS AND PREGNANCY STATUS OF YOUR PATIENTS

- 40% of women with childbearing potential are prescribed opioids
- Opioid exposure during pregnancy causes increased risk for fetus
- Most women do not know they are pregnant in first few weeks
- Therefore all women of childbearing age are at risk
- No adequate nor well-controlled studies of opioids for pain in pregnancy

THE PREGNANT PATIENT

Potential risk of opioid therapy to the newborn is neonatal opioid withdrawal syndrome

GIVEN THESE POTENTIAL RISKS, CLINICIANS SHOULD:

• Counsel women of childbearing potential about risks and benefits of opioid therapy during pregnancy and after delivery
• Encourage minimal/no opioid use during pregnancy, unless potential benefits outweigh risks to fetus
• Refer to a high risk OB/Gyn who will ensure appropriate treatment for the baby

• If chronic opioid therapy is used during pregnancy, anticipate and manage risks to the patient and newborn
• If using opioids on a daily basis, consider methadone or buprenorphine

CHILDREN AND ADOLESCENTS: HANDLE WITH CARE

JUDICIOUS USE OF IR FOR BRIEF THERAPY

SAFETY AND EFFECTIVENESS OF MOST ER/LA OPIOIDS UNESTABLISHED

• Pediatric analgesic trials pose challenges
• Transdermal fentanyl approved in children aged ≥2 yrs
• Oxycodone ER dosing changes for children ≥11 yrs

ER/LA OPIOID INDICATIONS ARE PRIMARILY LIFE-LIMITING CONDITIONS

WHEN PRESCRIBING ER/LA OPIOIDS TO CHILDREN:

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

**RED FLAG:**

**Questionable family diversion**

78-year-old Thelma comes into clinic, accompanied by grandson, who is in the exam room with you and Thelma. Thelma says her oxycodone 10 mg tablets q 4 hours is no longer working for her back pain. She asks for more medicine. You ask grandson to leave the exam room so you can examine her privately.

**Action:** Based on exam findings and her request for more medication:

- UDT and PDMP check
- Discuss whether or not it is possible her grandson, or another family member, might be using her medications.
- Patient education: Do not give opioids to another person. Store in secure place – locked. Let you know if medications are not secure or if she feels any pressure about sharing medications.
CHAPTER 7

KNOW YOUR FEDERAL
AND STATE LAWS
Comply with federal and state laws and regulations that govern the use of opioid therapy for pain

**FEDERAL**

- Code of Federal Regulations, Title 21 Section 1306: rules governing the issuance and filling of prescriptions pursuant to section 309 of the Act (21 USC 829)
  

- United States Code (USC) - Controlled Substances Act, Title 21, Section 829: prescriptions
  

**STATE**

- Database of state statutes, regulations, and policies for pain management
  

  [www.painpolicy.wisc.edu/database-statutes-regulations-other-policies-pain-management](http://www.painpolicy.wisc.edu/database-statutes-regulations-other-policies-pain-management)
State Legislative Activity Overview

- Utah is seventh in the U.S. for opioid-related deaths
- Legislators have passed several bills in hopes of preventing substance abuse and improving access to treatment
- 4 bills will have a direct impact on prescribing practices
Legislation Impacting Prescribers

H.B. 50 – Opioid Prescribing Regulations

• Limits prescriptions for Schedule II and III opioids for acute conditions to 7-day quantity
  o Exceptions: Chronic conditions, 30-day supply post-surgical prescriptions

• Prescribers must check the Controlled Substance Database (PDMP) when prescribing Schedule II and III opioids for the first time and periodic review for repeated prescribing
  o Exceptions: < 3-day quantity, post-surgical prescriptions, known patient history
  o Designees may be selected to access the database – background check required
**PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs)**

**INDIVIDUAL STATE LAWS DETERMINE**

- Who has access to PDMP information
- Which drug schedules are monitored
- Which agency administers the PDMP
- Whether prescribers are required to register with the PDMP
- Whether prescribers are required to access PDMP information in certain circumstances
- Whether unsolicited PDMP reports are sent to prescribers
- Bordering states may be available
- Designated surrogates may have access

**NOT ALL FEDERALLY LICENSED FACILITIES REPORT TO PDMPs**

[Link to state PDMP sites](#)
# PDMP: Prescription Drug Monitoring Program

## General
- **Utah Controlled Substance Database Program (CSD)**
- Administered by the **Division of Occupational and Professional Licensing**
- **Schedule II-V** are monitored
- **Dispensers are required** to register and input data
- Before prescribing, there is **an obligation** to review under certain circumstances

## Access
- Prescribers, dispensers, patient or parent of minor, health care agent or signed consent form, Department of Health, law enforcement and judicial/prosecutorial, licensing/regulatory boards, Medicaid, substance abuse or mental health professionals, worker’s compensation, coroner, 3rd party designee
- Prescribers **can authorize** a registered delegate

## Reporting
- Must be entered into PDMP **24 hours** after dispensing
- Unsolicited reports/alerts **are sent** to prescriber, dispensers, and law enforcement
- Utah **does share** data with other states’ PDMP
- Out-of-state pharmacies **are required** to report to the patient’s home state
- Patient **will be notified** if their record has been accessed

---

UTAH Controlled substance Dashboard: 4 Metrics

<table>
<thead>
<tr>
<th>Total Dispensing Records</th>
<th>Total Active Daily Morphine Milligram Equivalents (MME)</th>
<th># Prescribers in 6 Months</th>
<th># Pharmacies in 6 Months</th>
<th>Active Benzodiazepines and Opioids</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>No</td>
</tr>
</tbody>
</table>
### PDMP BENEFITS

Provides full accounting of prescriptions filled by patient

<table>
<thead>
<tr>
<th>RECORD OF A PATIENT’S CONTROLLED SUBSTANCE PRESCRIPTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Some are available online 24/7</td>
</tr>
<tr>
<td>• Opportunity to discuss with patient</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PROVIDE WARNINGS OF POTENTIAL MISUSE/ABUSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Existing prescriptions not reported by patient</td>
</tr>
<tr>
<td>• Multiple prescribers/pharmacies</td>
</tr>
<tr>
<td>• Drugs that increase overdose risk when taken together</td>
</tr>
<tr>
<td>• Patient pays with cash (vs insurance) for controlled meds</td>
</tr>
</tbody>
</table>

- Provides full accounting of prescriptions filled by patient
- Record of a patient’s controlled substance prescriptions
- Opportunity to discuss
- Existing prescriptions not reported by patient
- Multiple prescribers/pharmacies
- Drugs that increase overdose risk when taken together
- Patient pays with cash (vs insurance) for controlled meds
Legislation Impacting Prescribers

H.B. 175 – Opioid Abuse Prevention and Treatment

- As a condition of licensing renewal, controlled substance prescribers must receive 3.5 continuing education hours in a nationally recognized opioid abuse screening method
  - Beginning with the January 1, 2024 licensing period
  - Prescribers are permitted to fulfill continuing education requirements through this training
  - Allows the use of a DATA 2000 waiver to fulfill certain continuing education requirements for two consecutive licensing periods
Effective 5/9/2017 - A controlled substance prescriber* shall complete at least 3.5 hours of continuing education in one or more controlled substance prescribing classes approved by the DOPL. This course has been approved by DOPL as meeting this requirement.

*Controlled substance prescriber means an individual, other than a veterinarian, who: (i) is licensed to prescribe a controlled substance under Title 58, Chapter 37, Utah Controlled Substances Act; and (ii) possesses the authority, in accordance with the individual's scope of practice, to prescribe schedule II controlled substances and schedule III controlled substances that are applicable to opioid narcotics, hypnotic depressants, or psychostimulants.
**Prescriber Status & Education Requirements**

<table>
<thead>
<tr>
<th>Prescriber Status</th>
<th>Physician</th>
<th>Physician Assistant</th>
<th>Advanced Practice Nurse</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Licensed</strong></td>
<td>Licensed</td>
<td>Schedule II-V</td>
<td>Schedule II-V</td>
</tr>
<tr>
<td><strong>4 hrs/ 2 yrs</strong></td>
<td>4 hrs/ 2 yrs</td>
<td>4 hrs/ 2 yrs</td>
<td>4 hrs/ 2 yrs</td>
</tr>
</tbody>
</table>

Source: Beswick-Escanlar, V. (March 10, 2016) SAMHSA Liaison Quarterly meeting sub-group compilation

Legislation Impacting Prescribers

H.B. 146 – Partial Filling of a Schedule II Controlled Substance Prescription

- Authorizes the partial filling of Schedule II controlled substances at the request of the prescriber or the patient
Legislation Impacting Prescribers

H.B. 90 – Insurance Opioid Regulation

• Authorizes insurers to enact policies to minimize risk of opioid misuse:
  o Chronic co-prescribing opioids with benzodiazepines and other sedating substance
  o Prescribing very high opioid doses by primary care providers ("very high doses" is not defined in the legislation)
  o Inadvertent transition of short-term opioids for an acute injury into long-term dependence

• Authorizes insurers to enact policies that facilitate:
  o Non-narcotic treatment alternative for patients with chronic pain
  o Medication-assisted treatment for patients with opioid use disorder

• Policies may include evidence-based opioid prescribing guidelines, including the adoption of CDC guidelines
Utah Clinical Guidelines On Prescribing Opioids For Treatment Of Pain

GUIDELINES:
Download the FULL version
Download the SUMMARY version
Download individual TOOLS included in the Guidelines

OTHER RESOURCES:
Printable Copies of Guideline Tools
Guideline Development Information

Public Comment Information
To request a copy of the full or summary version of the guidelines click here or email: useonlyasdirected@utah.gov
Opioid Treatment for Acute Pain

1) Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice and after determining that other non-opioid pain medications or therapies will not provide adequate pain relief.

2) When opioid medications are prescribed for treatment of acute pain, the number dispensed should be no more than the number of doses needed based on the usual duration of pain severe enough to require opioids for that condition.

3) When opioid medications are prescribed for treatment of acute pain, the patient should be counseled to store the medications securely, to not share with others, and to dispose of medications properly when the pain has resolved in order to prevent non-medical use of the medications.

4) Long duration-of-action opioids should not be used for treatment of acute pain, including post-operative pain, except in situations where monitoring and assessment for adverse effects can be conducted. Methadone is rarely if ever indicated for treatment of acute pain.

5) The use of opioids should be reevaluated carefully, including assessing the potential for abuse, if persistence of pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition.

Opioid Treatment for Chronic Pain

1) A comprehensive evaluation should be performed before initiating opioid treatment for chronic pain.

2) Alternatives to opioid treatment should be tried (or adequate trial of such treatment by a previous provider documented), before initiating opioid treatment.

3) The provider should screen for risk of abuse or addiction before initiating opioid treatment.

4) When opioids are to be used for treatment of chronic pain, a written treatment plan should be established that includes measurable goals for reduction of pain and improvement of function.3

5) The patient should be informed of the risks and benefits and any conditions for continuation of opioid treatment, ideally using a written and signed treatment agreement.

6) Opioid treatment for chronic pain should be initiated as a treatment trial, usually using short-acting opioid medications.

7) Regular visits with evaluation of progress against goals should be scheduled during the period when the dose of opioids is being adjusted (titration period).

8) Once a stable dose has been established (maintenance period), regular monitoring should be conducted at face-to-face visits during which treatment goals, analgesia, activity, adverse effects, and aberrant behaviors are monitored.

9) Continuing opioid treatment after the treatment trial should be a deliberate decision that considers the risks and benefits of chronic opioid treatment for that patient. A second opinion or consult may be useful in making that decision.

10) An opioid treatment trial should be discontinued if the goals are not met and opioid treatment should be discontinued at any point if adverse effects outweigh benefits or if dangerous or illegal behaviors are demonstrated.

11) Clinicians treating patients with opioids for chronic pain should maintain records documenting the evaluation of the patient, treatment plan, discussion of risks and benefits, informed consent, treatments prescribed, results of treatment, and any aberrant behavior observed.

12) Clinicians should consider consultation for patients with complex pain conditions, patients with serious co-morbidities including mental illness, patients who have a history or evidence of current drug addiction or abuse, or when the provider is not confident of his or her abilities to manage the treatment.

13) Methadone should only be prescribed by clinicians who are familiar with its risks and appropriate use, and who are prepared to conduct the necessary careful monitoring.
Summary of Recommendations for Prescribing Opioids
Opioid Treatment for Acute Pain

- Use alternative treatments whenever possible
- Check the Controlled Substance Database
- Consider patient risks
- Prescribe immediate-release/short-acting opioids (IR/SA)
- Prescribe the lowest effective dose
- Avoid combining opioids with CNS depressants
- Counsel patients on safe storage, disposal, and diversion
# Opioid Treatment for Chronic Pain

## Before prescribing opioids
- Use alternative treatments whenever possible
- Identify if benefits outweigh the risks
- Complete a comprehensive patient evaluation
- Check disease-specific guidelines
- Screen for risk of opioid use disorder
- Obtain a urine drug screen
- Check the Controlled Substance Database

## Establishing treatment goals and a written treatment plan
- Establish a written plan with the patient
- Identify measurable treatment goals
- Document information about patient treatment and history
- Plan for potential discontinuation in the treatment plan
- Obtain an informed consent form
- Educate patient and family/caregivers

## Initiating opioid treatment
- Combine opioids with other therapies
- Initiate a short-term treatment trial
- Begin with immediate-release/short-acting (IR/SA)
- Do not prescribe methadone
-Prescribe the lowest effective dose
- Prevent prescription fraud
- Implement dose titration and re-evaluation
- Avoid parenteral opioids

## Mitigating risks
- Avoid combining opioids with CNS depressants
- Evaluate risks associated with sleep apnea
- Obtain urine drug screens on randomly selected visits
- Check the Controlled Substance Database at least quarterly
- Co-prescribe naloxone
- Provide overdose education/counseling
- Counsel patients on safe storage, disposal and diversion

## Maintaining/discontinuing treatment
- Monitor treatment at face-to-face visits
- Evaluate patient progress with treatment goals
- Adjust/prescribe medication during clinic visits
- Obtain second opinion/consultation for patients with complex pain conditions
- Refer high-risk/abusing patients to a substance use disorder specialist
- Offer medication-assisted treatment for opioid use disorder
- Refer patients with psychiatric disorders to mental health services
- Discontinue treatment when pain is resolved, treatment goals not met, disadvantages outweigh benefits, or dangerous/illegal behaviors demonstrated
- Safely taper or refer treatment for patients who discontinue opioid treatment
CDC RECOMMENDATIONS

1) Opioids are not the first line therapy
2) Establish Goals for Pain and Function
3) Discuss Risks and Benefits
4) Use immediate-release opioids when starting
5) Use the lowest effective Dose
5) Lowest Effective Dose

>50 MME/day (reassess evidence of individual Risk/Benefits)

>90 MME/day (Document Justification of this dose)
CDC RECOMMENDATIONS

6) Prescribe for only short durations (Acute Pain)
7) Evaluate Risk/Benefit ratio Frequently
8) Use Strategies to Mitigate Risk (Ex/Naloxone)
9) Review PDMP
10) Use Urine Drug testing
CDC RECOMMENDATIONS

11) Avoid concurrent opioid and benzodiazepine
12) Offer Treatment for Opioid Use Disorder
CHAPTER 8
COUNSELING PATIENTS AND CAREGIVERS
USE PATIENT COUNSELING DOCUMENT

DOWNLOAD:

ORDER HARD COPIES:
www.minneapolis.cenveo.com/pcd/SubmitOrders.aspx

COUNSEL PATIENTS ABOUT PROPER USE

**EXPLAIN**

• Product-specific information about the IR or ER/LA opioid (especially when converting)
• Take opioid as prescribed
• Adhere to dose regimen
• How to handle missed doses
• Notify prescriber if pain not controlled
• Call prescriber for options on side effect management

**INSTRUCT PATIENTS/CAREGIVERS TO**

• Read the ER/LA opioid Medication Guide received from pharmacy every time an ER/LA opioid is dispensed
COUNSEL PATIENTS ABOUT PROPER USE (continued)

EXPLAIN

- Inform prescriber of ALL meds being taken
- Warn patients not to abruptly discontinue or reduce dose
- Risk of falls
- Caution with operating heavy machinery and when driving
- Sharing or selling opioids can lead to others’ deaths and is against the law

OPIOIDS CAN CAUSE DEATH EVEN WHEN TAKEN PROPERLY

- Signs/symptoms are respiratory depression, gastrointestinal obstruction, allergic reactions
COUNSEL PATIENTS ABOUT PROPER USE (continued)

<table>
<thead>
<tr>
<th>EXPLAIN</th>
<th>OPIOIDS SHOULD BE STORED IN A SAFE AND SECURE PLACE</th>
</tr>
</thead>
</table>
| • Tell patients and caregivers, medications must be kept in a locked container  
  • Will periodically assess for benefits, side effects, and continued need for IR/ER/LA opioids  
  • Need for re-evaluation of underlying medical condition if the clinical presentation changes over time | • Away from children, family members, visitors, and pets  
  • Safe from theft |

Opioids are scheduled under Controlled Substances Act and can be misused and abused
WARN PATIENTS

Never break, chew, crush, or snort an oral ER/LA tablet/capsule, or cut or tear patches prior to use

- May lead to rapid release of ER/LA opioid causing overdose and death
- If unable to swallow a capsule whole, refer to PI to determine if appropriate to sprinkle contents on applesauce or administer via feeding tube

Use of CNS depressants or alcohol with ER/LA opioids can cause overdose & death

- Use with alcohol may result in rapid release and absorption of a potentially fatal opioid dose – “dose dumping”
- Other depressants include sedative-hypnotics and anxiolytics, illegal drugs
OVERDOSE POISONING, CALL 911

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

**Naloxone:**
- An opioid antagonist administered by injection or intranasally, or IV
- Reverses acute opioid-induced respiratory depression but will also reverse analgesia

**Available as:**
- Naloxone kit (with syringes, needles)
- Injectable
- Nasal spray

**What to do:**
- Discuss an ‘overdose plan’
- Involve and train family, friends, partners, and/or caregivers
- Check with pharmacy if they are prescribing
- Check expiration dates and keep a viable dose on hand
- In the event of known or suspected overdose, administer naloxone and call 911

**Consider offering a naloxone prescription to all patients prescribed IR and ER/LA opioids**

ABUSE-DETERRENT FORMULATION/TAMPER RESISTANT (ADF/TR) OPIOIDS

- Response to growing non-medical use problem
- An ER/LA opioid with physical barrier to deter extraction
  - Less likely to be crushed, injected, or snorted
- Consider as one part of an overall strategy
- Mixed evidence on the impact of ADF/TR on misuse
- Remember overdose is still possible if taken orally in excessive amounts
• Consider the behavior you are modeling
• 45% of parents have taken pain medications without a prescription at some point
• 14% have given their children pain medications without a prescription
• Teens report that their parents do not talk with them about prescription drug risks
  • Evidence suggests that pre-college parental conversation helps reduce high-risk substance abuse among college students

SUBSTANCES PARENTS HAVE DISCUSSED WITH TEENS*

*As reported by teens

- Beer/alcohol: 81%
- Marijuana: 77%
- Cocaine/crack: 30%
- Rx pain reliever w/o doctor’s Rx: 23%
- Any Rx drug used w/o doctor’s Rx: 22%
- Heroin: 21%
- Ecstasy: 21%
- Methamphetamine: 21%
- Non-Rx cold/cough medicine to get high: 15%
- Steroids w/o doctor’s Rx: 15%
- Inhalants: 14%

% of teens whose parents have discussed
RX OPIOID DISPOSAL

New “Disposal Act” expands ways for patients to dispose of unwanted/expired opioids

Collection receptacles
Call DEA Registration Call Center at 1-800-882-9539 to find a local collection receptacle

Mail-back packages
Obtained from authorized collectors

Look for local take-back events
• Conducted by Federal, State, tribal, or local law enforcement
• Partnering with community groups

DECREASES AMOUNT OF OPIOIDS INTRODUCED INTO THE ENVIRONMENT, PARTICULARLY INTO WATER

Voluntarily maintained by:
• Law enforcement
• Authorized collectors, including:
  ▪ Manufacturer
  ▪ Distributor
  ▪ Reverse distributor
  ▪ Retail or hospital/clinic pharmacy
    • Including long-term care facilities
OTHER METHODS OF OPIOID DISPOSAL

IF COLLECTION RECEPTACLE, MAIL-BACK PROGRAM, OR TAKE-BACK EVENT UNAVAILABLE, THROW OUT IN HOUSEHOLD TRASH

- Take drugs out of original containers
- Mix with undesirable substance
- Place in sealable bag, can, or other container
- Remove identifying info on label
FDA: PRESCRIPTION DRUG DISPOSAL

As soon as they are no longer needed

Includes transdermal adhesive skin patches
  - Used patch (3 days) still contains enough opioid to harm/kill a child
  - Dispose of used patches immediately after removing from skin

Fold patch in half so sticky sides meet, then flush down toilet

Do NOT place used or unneeded patches in household trash
  - Butrans (buprenorphine transdermal system)
    exception: can seal in Patch-Disposal Unit provided and dispose of in the trash
• Use formal tools (PPAs, counseling document) to educate patients and caregivers
• Emphasize safe storage and disposal to patients and caregivers
• Consider co-prescribing naloxone
RED FLAG: **Patients do not safeguard their opioid medications correctly**

Your patient’s daughter stole her father’s opioids from his bedside drawer to take to a “fishbowl party.” Her best friend consumed a mix of opioids and alcohol and died of an overdose.

**Action:**

Always counsel patients about safe drug storage; warn patients about the serious consequences of theft, misuse, and overdose. Tell patients that taking another person’s medication, even once, is against the law.
CHAPTER 9

DRUG CLASS CONSIDERATIONS
CNS depressants can potentiate sedation and respiratory depression

Use with MAOIs may increase respiratory depression
Certain opioids with MAOIs can cause serotonin syndrome

Methadone and buprenorphine can prolong QTc interval

Some ER/LA products rapidly release opioid (dose dump) when exposed to alcohol
Some drug levels may increase without dose dumping

Can reduce efficacy of diuretics
Inducing release of antidiuretic hormone

Drugs that inhibit or induce CYP enzymes can increase or lower blood levels of some opioids
TRANSDERMAL/TRANSMUCOSAL DOSAGE FORMS

Do not cut, damage, chew, or swallow

- Exertion or exposure to external heat can lead to fatal overdose
- Rotate location of application
- Prepare skin: clip (not shave) hair & wash area with water
- Monitor patients with fever for signs or symptoms of increased opioid exposure
- Metal foil backings are not safe for use in MRIs
- For buccal film products the film should not be applied if it is cut, damaged, or changed in anyway -- use entire film
<table>
<thead>
<tr>
<th>DRUG INTERACTIONS COMMON TO OPIOIDS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>• Concurrent use with other CNS depressants can increase risk of respiratory depression, hypotension, profound sedation, or coma</strong></td>
</tr>
<tr>
<td><strong>• Reduce initial dose of one or both agents</strong></td>
</tr>
<tr>
<td><strong>• May enhance neuromuscular blocking action of skeletal muscle relaxants and increase respiratory depression</strong></td>
</tr>
<tr>
<td><em><em>• Avoid concurrent use of partial agonists</em> or mixed agonist/antagonists† with full opioid agonist</em>*</td>
</tr>
<tr>
<td><strong>• May reduce analgesic effect and/or precipitate withdrawal</strong></td>
</tr>
<tr>
<td><strong>• Concurrent use with anticholinergic medication increases risk of urinary retention and severe constipation</strong></td>
</tr>
<tr>
<td><strong>• May lead to paralytic ileus</strong></td>
</tr>
</tbody>
</table>

*Buprenorphine; **Pentazocine, nalbuphine, butorphanol*
DRUG INFORMATION COMMON TO OPIOIDS

USE IN OPIOID-TOLERANT PATIENTS

• See individual PI for products which:
  – Have strengths or total daily doses only for use in opioid-tolerant patients
  – Are only for use in opioid-tolerant patients at all strengths

CONTRAINDICATIONS

• Significant respiratory depression
• Acute or severe asthma in an unmonitored setting or in absence of resuscitative equipment
• Known or suspected paralytic ileus
• Hypersensitivity (e.g., anaphylaxis)
• See individual PI for additional contraindications
## SPECIFIC CHARACTERISTICS

Know for opioid products you prescribe:

<table>
<thead>
<tr>
<th>Drug substance</th>
<th>Formulation</th>
<th>Strength</th>
<th>Dosing interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key instructions</td>
<td>Use in opioid-tolerant patients</td>
<td>Product-specific safety concerns</td>
<td>Relative potency to morphine</td>
</tr>
</tbody>
</table>

- Specific information about product conversions, if available
- Specific drug interactions

For detailed information, refer to online PI:
Prescription opioid abuse and overdose is a national epidemic. Clinicians must play a role in prevention.

- Assess patients for treatment with IR and ER/LA opioids
- Counsel patients and caregivers about the safe use of opioids, including proper storage and disposal
- Initiate therapy, modify dose, and discontinue use of opioids
- Be familiar with general and product-specific drug information concerning opioids
- Monitor ongoing therapy with IR and ER/LA opioids
Thank you for completing the post-activity assessment for this CO*RE session.

Your participation in this assessment allows CO*RE to report de-identified numbers to the FDA.

A strong show of engagement will demonstrate that clinicians have voluntarily taken this important education and are committed to patient safety and improved outcomes.

THANK YOU!
THANK YOU!
WWW.CORE-REMS.ORG
Opioid REMS Knowledge Test
Question #1

Among the risk factors contained in screening tools for predicting aberrant drug-related behavior in patients receiving opioids for chronic pain are family and personal history of substance abuse, legal problems, history of preadolescent sexual abuse, psychological problems and:

- A. Age (12-15 years)
- B. Age (16-45 years)
- C. Age (46-75 years)
- D. Age (≥ 76 years)
- E. Risk is even across age
Question #1

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- B. Age (16-45 years)
- C. Age (46-75 years)
- D. Age (≥ 76 years)
- E. Risk is even across age
Question #1: Question

- Correct answer: B

- Rationale: Epidemiologic studies of prescription overdoses reveal risk factors include male sex, middle age, non-Hispanic white race, low income, and mental health problems. Rates of fatal overdose are lower at the extremes of age. The Opioid Risk Tool (ORT) lists age 16-45 as a risk factor. Fatal overdose rates are highest among people 45-54 years old for both unintentional and suicidal overdoses and those of undetermined intent.
Question #2

Which of the following is most important to consider when determining a starting dosage of an extended-release/long-acting opioid?

- A. Results of urine drug test
- B. Patient preference
- C. Cost of the medications
- D. Assessment of individual needs
- E. Starting dosage listed in the package insert
Question #2

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- B. Patient preference
- C. Cost of the medications
- D. Assessment of individual needs
- E. Starting dosage listed in the package insert
Question #2 Answer

- Correct answer: D

- Rationale: Opioid selection, initial dosing, and titration should be individualized according to the patient’s health status, previous exposure to opioids, attainment of therapeutic goals and predicted or observed harms. Genetic differences are increasingly understood to help explain individual differences in analgesic response and tolerance to various opioids.
Question #3

A 55-year-old man who is being treated for chronic low back pain after undergoing laminectomy comes for follow-up evaluation. A trial of oxycodone ER therapy is planned. Completion of which of the following is the most appropriate step before initiation of therapy?

- A. Oswestry Disability Index
- B. Roland Morris Disability Questionnaire
- C. Patient-Prescriber Agreement
- D. MRI of the lumbar spine
- E. Routine blood tests
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- C. Patient-Prescriber Agreement
- D. MRI of the lumbar spine
- E. Routine blood tests
Question #3 Answer

- Correct answer: C

- Rationale: Informed consent and patient-prescriber agreements are important strategies to ensure that patients understand treatment goals and potential opioid risks.
Question #4

A 63-year-old woman with a history of spinal stenosis and peripheral neuropathy secondary to breast cancer treatment comes for evaluation because of increasingly severe back pain. She reports that the pain started two weeks ago after doing yard work. She underwent chemotherapy 12 years ago. Medications include an opioid. Which of the following is the most appropriate next step?

- A. Assure the patient that the heightened sensitivity to pain is to be expected
- B. Reevaluate the underlying medical condition
- C. Refer the patient to physical therapy and administer a short-acting opioid as necessary
- D. Increase extended-release/long-acting opioid therapy dosage for up to one month
- E. Consider adding an adjuvant analgesic for neuropathic pain
A 63-year-old woman with a history of spinal stenosis and peripheral neuropathy secondary to breast cancer treatment comes for evaluation because of increasingly severe back pain. She reports that the pain started two weeks ago after doing yard work. She underwent chemotherapy 12 years ago. Medications include an opioid. Which of the following is the most appropriate next step?

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- D. Increase extended-release/long-acting opioid therapy dosage for up to one month
- E. Consider adding an adjuvant analgesic for neuropathic pain
Question #4 Answer

- Correct answer: B

- Rationale: A change in pain or new pain may indicate significant progression in a disease or a new underlying medical disorder that warrants further medical evaluation. New or worsening pain, especially if worse at night or with recumbency in the cancer survivor is concerning for return of malignancy.
Use of ER/LA opioids in pediatric patients <18 years of age deserves special consideration because:

- A. Safety & effectiveness of most ER/LA opioids has not been established in this population
- B. Many children experience chronic pain conditions with indications for ER/LA opioids
- C. Starting doses of opioids are reduced by one-third to one-half that in adults
- D. Opioid risk screening tools have not been validated in this population
- E. Many state laws require consultation with a pediatric pain specialist or pain clinic
Question #5

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- C. Starting doses of opioids are reduced by one-third to one-half that in adults
- D. Opioid risk screening tools have not been validated in this population
- E. Many state laws require consultation with a pediatric pain specialist or pain clinic
Question #5 Answer

- Correct answer: A
- Rationale: Opioid use in children deserves special consideration in part because the safety and effectiveness of most ER/LA opioids in pediatric patients under 18 years has not been established with the exception of transdermal fentanyl that has been approved in children age greater or equal to 2 years of age. Few children with chronic pain due to non-life-limiting conditions warrant opioid treatment and referral to a pediatric pain specialist is warranted (but not required) when prescribing opioid to children.
A 59 year-old with long-standing hypertension and Stage 3 chronic kidney disease continues treatment with disease-modifying anti-rheumatoid drugs (DMARDs) for rheumatoid arthritis (RA). Recently she has exhibited increasing pain and further functional decline likely due to progression of RA and osteoarthritis of the hips, knees and feet as well. She is determined to remain as functional as possible and participates in Aquatherapy and yoga classes. Which of the following pharmaceutical options is the best next step for addressing this patient’s pain?

- A. Acetaminophen 650 mg two tabs q 4 hours prn
- B. Duloxetine 20 mg daily
- C. Oxycodone IR 5 mg q 4 hours prn
- D. Morphine sulfate ER 15 mg q 8 hours
- E. Ibuprofen 600 mg q 4 hours prn
Question #6

A 59 year-old with long-standing hypertension and Stage 3 chronic kidney disease continues treatment with disease-modifying anti-rheumatoid drugs (DMARDs) for rheumatoid arthritis (RA). Recently she has exhibited increasing pain and further functional decline likely due to progression of RA and osteoarthritis of the hips, knees and feet as well. She is determined to remain as functional as possible and participates in Aquatherapy and yoga classes. Which of the following pharmaceutical options is the best next step for addressing this patient’s pain?

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- D. Morphine sulfate ER 15 mg q 8 hours
- E. Ibuprofen 600 mg q 4 hours prn
Question #6 Answer

- Correct answer: C

- Rationale: Adding an immediate release opioid is the next best step for this patient experiencing moderate to severe pain. Adding acetaminophen would likely not offer sufficient pain relief. Adding duloxetine may impact her mood and perception of pain, but her pain would be best addressed by an analgesic. Use of an extended release preparation (Morphine Sulfate ER) is not indicated prior to the use of an immediate release preparation. Ibuprofen would not be indicated in this patient with compromised renal function.
Question #7

An inappropriate method to dispose of unused opioid medication is:

- A. Return the medication to a pharmacy
- B. At a law-enforcement sponsored drug take-back event
- C. Mix into an undesirable substance before putting in the regular trash
- D. Dispose of medication in the regular trash
- E. Flush down the toilet
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- B. At a law-enforcement sponsored drug take-back event
- C. Mix into an undesirable substance before putting in the regular trash
- **D. Dispose of medication in the regular trash**
- E. Flush down the toilet
Correct answer: D

Rationale: Recommendations from FDA, package inserts, and the literature for best methods of disposal vary, but all agree that simply throwing away medications is inappropriate.
The most important reason a patient should be counseled to never break, cut, chew, or crush a ER/LA opioid tablet or cut or tear patches is because:

- A. The medicine will expire
- B. It is against the law
- C. The dose will be less than prescribed
- D. The patient may die
Question #8

The most important reason a patient should be counseled to never break, cut, chew, or crush an ER/LA opioid tablet or cut or tear patches is because:

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- B. It is against the law
- C. The dose will be less than prescribed
- D. The patient may die
Question #8 Answer

- **Correct answer:** D

- **Rationale:** Tablets should not be chewed, crushed or dissolved. Crushing or dissolving the tablet results in the immediate release of the dosage leading to overdose which can result in respiratory depression and death.
Question #9

To avoid inadvertent overdose and death a patient should be counseled to avoid co-administration of an extended-release/long-acting opioid with which of the following?

- A. Alcohol
- B. Diphenhydramine
- C. St John’s wort
- D. Aspirin
- E. Methamphetamine
Question #9

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- A. Alcohol
- B. Diphenhydramine
- C. St John’s wort
- D. Aspirin
- E. Methamphetamine
Question #9 Answer

- Correct answer: A
- Rationale: Use of other CNS depressants such as sedative-hypnotics and anxiolytics, alcohol, or illegal drugs with ER/LA opioid analgesics can cause overdose leading to death.
Question #10

Which of the following extended-release/long-acting opioids is most likely to induce a peak respiratory depression that occurs later and persists longer than the analgesic effect?

- A. Fentanyl transdermal patch
- B. Hydromorphone ER
- C. Methadone
- D. Oxycodone CR
- E. Tapentadol ER
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- B. Hydromorphone ER
- C. Methadone
- D. Oxycodone CR
- E. Tapentadol ER
Question #10 Answer

- Correct answer: C

- Rationale: Methadone has a long, biphasic elimination half-life. It may take up to 10 days to reach steady-state serum levels. Peak respiratory depression occurs later and persist longer than the analgesic effect of methadone. Methadone is a highly lipophilic drug. Tissue binding predominates over binding to plasma proteins, and accumulation of the drug occurs in these tissues with repeated dosing. Methadone reabsorption from the tissue may continue for weeks after administration has ceased.
When using an equianalgesic table to rotate opioids other than methadone, an important step to account for incomplete cross-tolerance among mu opioids includes:

- A. Initiate the new opioid at the calculated equianalgesic dose
- B. Increase the calculated equianalgesic dose by 10%-30%
- C. **Reduce calculated equianalgesic dose by 25%-50%**
- D. Convert and total all opioids to oral morphine equivalents
- E. Refer to the package insert for appropriate supplemental rescue dose
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- D. Convert and total all opioids to oral morphine equivalents
- E. Refer to the package insert for appropriate supplemental rescue dose
Question #11 Answer

- Correct answer: C

- Rationale: Equianalgesic doses are approximate and most are based on single dose studies. The doses are to be used only as a guide for calculating an initial conversion dose. Patients can become tolerant to the analgesic and side effects of a given opioid but not exhibit the same tolerance to another opioid. This is called incomplete cross-tolerance; meaning caution must be used when an equianalgesic dose of a different opioid is administered. When switching to a different opioid, it is recommended that a dose reduction of 25-75% should be administered initially depending on the clinical situation.
Question #12

A 72 year-old grandfather with severe persistent abdominal pain from colon cancer has been taking an immediate release opioid every four hours around the clock. He and his wife care for their two young grandchildren, and he states that he can no longer help with their care due to his pain level. He wants to increase the dose of his medication and asks what else he might do to control the pain. Which of the following supports the addition of an ER/LA opioid as treatment for this patient?

- A. More consistent plasma concentrations
- B. Fewer adverse events
- C. Less risk for respiratory depression with the addition of the ER/LA opioid
- D. Less need for ongoing monitoring
A 72-year-old grandfather with severe persistent abdominal pain from colon cancer has been taking an immediate release opioid every four hours around the clock. He and his wife care for their two young grandchildren, and he states that he can no longer help with their care due to his pain level. He wants to increase the dose of his medication and asks what else he might do to control the pain. Which of the following supports the addition of an ER/LA opioid as treatment for this patient?

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- C. Less risk for respiratory depression with the addition of the ER/LA opioid
- D. Less need for ongoing monitoring
Question #12 Answer

- Correct Answer: A

- Rationale: An ER/LA opioid offers more consistent plasma concentration. It would not offer fewer adverse events. Respiratory depression is a risk for all opioids. Opioid treatment IR or ER requires ongoing monitoring.
Question #13

A 67 year-old female with severe knee osteoarthritis has recently been converted from an immediate release opioid to an extended release opioid for pain control. She has chronic obstructive pulmonary disease that has made her a poor surgical candidate. In addition to extended release opioid, which second prescription would be the most appropriate to dispense to her?

- A. naloxone
- B. nortriptyline
- C. duloxetine
- D. acetaminophen
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- A. naloxone
- B. nortriptyline
- C. duloxetine
- D. acetaminophen
Question #13 Answer

- Correct Answer: A

- Rationale: Naloxone is appropriate for co-prescribing with all opioid prescriptions. The addition of the other medications may be appropriate in the future, but medications changes are best done one at a time. Naloxone prescribing is strictly for safety and reversal of adverse side effects, particularly respiratory depression particularly in this patient with underlying pulmonary disease.
Question #14

A positive result of hydromorphone of a urine drug toxicology test for a patient on prescribed morphine can be interpreted as

- A. Use of heroin in past month
- B. Proof of supplemental hydromorphone
- C. Presence of the oxycodone metabolite
- D. Presence of the morphine metabolite
- E. Presence of semisynthetic opioids
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- C. Presence of the oxycodone metabolite
- **D. Presence of the morphine metabolite**
- E. Presence of semisynthetic opioids
Correct answer: D

Rationale: In certain cases, small amounts of opioid metabolites may appear in the urine (hydrocodone from codeine, hydromorphone from hydrocodone or morphine, oxymorphone from oxycodone) and should not be interpreted as evidence of the use of nonprescribed agents. Though heroin metabolizes to morphine and could ultimately produce hydromorphone metabolites it would be out of the system if taken more than a few days ago.