Pharmacology for Advanced Practice Clinicians

Pain Management including Opioid Prescribing: Safe Practice, Changing Lives

Acknowledgement

Presented by the Nurse Practitioner Healthcare Foundation, a member of the Collaborative on REMS Education (CO*RE), 11 interdisciplinary organizations working together to improve pain management and prevent adverse outcomes.

This educational activity is supported by an independent educational grant from the 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 & Drug Administration.

Organizations

Presented by

Product Covered by This REMS

Brand Name Products

- Aromia ER morphine sulfate ER tablets
- 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
- Metohydron® morphine sulfate ER tablets
- MS Contin® morphine sulfate CR tablets
- Oxycet® oxycodone ER tablets
- Oxycodone hydrochloride ER tablets
- Targiniq™ oxycodone hydrochloride/naloxone hydrochloride ER tablets
- Troxyca ER oxycodone HCl-naltrexone capsules
- Zohydro® ER hydrocodone bitartrate ER capsules
- Zohydro® ER hydrocodone bitartrate ER tablets
- Zohydro ER hydrocodone bitartrate ER capsules

Generic Products

- Fentanyl ER transdermal systems
- Hysingla ER (hydrocodone bitartrate) ER tablets
- Methadone ER tablets
- Methadone hydrochloride ER tablets
- Methadone hydrochloride oral concentrate
- Methadone hydrochloride oral solution
- Morphine sulfate ER tablets
- Morphine sulfate ER capsules
- Oorpine hydrochloride ER tablets

Presented by

Alan P. Agins, Ph.D.
Jody Agins, MSN, RNP, FNP/GNP-BC  2018
WHY ARE WE HERE?


Drugs Involved in U.S. Overdose Deaths 2000-2016
Opioid Prescribing Rates & Overdose Deaths

Prescribing Rates (per 100 people)

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2014</th>
<th>2016</th>
</tr>
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<tbody>
<tr>
<td>OH</td>
<td>98</td>
<td>90</td>
<td>75</td>
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Opioid Overdose Deaths

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>US 2017</th>
<th>47,872</th>
</tr>
</thead>
<tbody>
<tr>
<td>OH</td>
<td>3613</td>
<td></td>
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</table>

Fentanyl and Fentanyl Analogues

OD deaths from fentanyl and fentanyl analogues, such as carfentanil, have increased 540% in three years.

Street fentanyl is illegally manufactured – generally NOT diverted pharmaceutical product.

Two causes of fentanyl OD death: Opioid-induced respiratory depression and rigid chest wall syndrome; higher or repeated doses of naloxone required to reverse fentanyl overdose.

Fentanyl has either contaminated or replaced all heroin across the U.S., also found in cocaine and methamphetamine.

OPIOID PRESCRIBING – Finding the "sweet spot"

Under-prescribing
Patient seeks more for self-medication

Appropriate Prescribing

Over-prescribing
More than enough for patient to abuse or divert.
BENEFITS VS. RISKS WITH OPIOIDS

**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 IRs
- 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 maternal opioid withdrawal syndrome
- Inadvertent exposure/ingestion by household contacts especially children

THE FEDERAL PLAYERS

Many agencies involved

WE ARE HERE BECAUSE OF …

REMS: RISK EVALUATION 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
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.
THE NEUROPSYCHOBIOLOGY OF PAIN

1. Perception in the brain (neurotransmission occurs)
2. Transmission along spinothalamic tract
3. Transmission along spinocerebellar tract (neurotransmission occurs)
4. Injury

OPIOID SITES OF ACTION IN THE BRAIN

Properdural gray area
Nucleus accumbens
Amygdala

UNDERSTANDING PAIN

Physiologic Stimulus
- Nociceptive → Neuropathic
- Peripheral neuropathy (neuropathy)
- Postherpetic neuralgia
- Complex regional pain syndrome
- Traumatic injury
- Central hypersensitization

Biopsychosocial Spiritual Context
- Inflammatory/immune system
- Emotional/behavioral
- Somatoform
- Personality
- Cognitive
- Family/relationships
- Financial issues
- Spirituality
- Meaning of illness
- Suffering

Experience of Pain
- Pain
- Stress
- Anxiety
- Depression
- Grief
- Loss
- Resilience
- Secondary gain
- Secondary gain
- Significance
- Hope
- Religious faith
- Existential issues
THE IMPACT OF PAIN

- SLEEP DISTURBANCE
- SUBSTANCE MISUSE
- SECONDARY PHYSICAL PROBLEMS
- FUNCTIONAL DISABILITIES
- ANXIETY DEPRESSION
- COGNITIVE DISTORTIONS
- INCREASED STRESSES

PAIN MANAGEMENT GOALS AND TREATMENT OPTIONS: A MULTI-MODAL APPROACH

- Cognitive Behavioral Therapy
  - Behavioral Modification
  - Meditation
  - Cognitive Restructuring
- Physical Therapy
  - Exercises
  - Acupuncture
  - Movement Therapies
- Interventions
  - Nerve Blocks
  - Steroid Injections
  - Stimulants
  - Trigger Point Injections
- Pharmacotherapy
  - NSAIDs
  - Antidepressants
  - Opioids
- Self Care
- Provider Care
- Restored Function

CHAPTER 3 - PEARLS FOR PRACTICE

- Explain neurophysiology of pain processing to patients
- When patients understand, their concerns are validated
- Pain has biological, psychological, social, and spiritual components
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?

EFFECT OF PAIN ON PHYSICAL, EMOTIONAL & PSYCHOSOCIAL FUNCTION

PATIENT'S CURRENT PAIN & FUNCTION

TREATMENT HISTORY

NONPHARMACOLOGIC STRATEGIES & EFFECTIVENESS

PHARMACOLOGIC STRATEGIES & EFFECTIVENESS

PAST USE

- Query state PDMP to confirm patient report
- Contact past providers & obtain prior medical records

CURRENT USE

- For opioids currently prescribed: opioid, dose, regimen & duration
- Important to determine if patient is opioid tolerant

DOSAGE

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 & PAST SUBSTANCE USE

RISK FACTORS FOR OPIOID ABUSE

- Prescription drugs, controlled medications (Benzodiazepine)
- Alcohol & tobacco
  - Substance abuse Hx does not prohibit treatment w/ ER/LA opioids but may require additional monitoring & expert consultation/referral
- History of sexual abuse
- Family Hx of substance abuse & psychiatric disorders
- Age (16-45 YO)

SOCIAL HISTORY

Employment, cultural background, social network, marital history, legal history & other behavioral patterns


PHYSICAL EXAM & ASSESSMENT

Seek objective confirmatory data

Order diagnostic tests (appropriate to complaint)

Components of patient evaluation for pain

Musculoskeletal Exam
- Inspection
- Gait & posture
- Range of motion
- Palpation
- Percussion
- Auscultation
- Provocative maneuvers

Cutaneous or trophic findings

General: vital signs, appearance, & pain behaviors

Neurologic exam

Components of patient evaluation for pain

Cough

**RISK ASSESSMENT TOOLS**

<table>
<thead>
<tr>
<th>TOOL</th>
<th>PATIENTS CONSIDERED FOR LONG-TERM OPIOID THERAPY</th>
<th>ADMINISTERED BY</th>
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</thead>
<tbody>
<tr>
<td>Opioid Risk Tool</td>
<td>5</td>
<td>Patient</td>
</tr>
<tr>
<td>SOAPP® Screener &amp; Opioid Assessment for Patients w/Pain</td>
<td>24, 14, &amp; 5</td>
<td>Patient</td>
</tr>
<tr>
<td>DARE Diagnosis, Irresistability, Risk, &amp; Efficacy Score</td>
<td>3</td>
<td>Clinician</td>
</tr>
</tbody>
</table>

**CHARACTERIZE MISUSE ONCE OPIOID TREATMENTS BEGINS**

- PMQ: Pain Medication Questionnaire
- COMM Current Opioid Misuse Measure
- PDUIQ Prescription Drug Use Questionnaire
- NOT SPECIFIC TO PAIN POPULATIONS:
  - CAGE-AID: Cut Down, Annoyed, Guilty, Eye-Opener Tool, Adjusted to Include Drugs
  - RAFFT: Relax, Alone, Friends, Family, Trouble
  - DAST: Drug Abuse Screening Test
  - SBIRT: Screening, Brief Intervention, & Referral to Treatment

**OPIOID RISK TOOL (ORT)**

Mark each box that applies:

1. Family History of substance abuse
   - Alcohol
   - Illegal drugs
   - Prescription drugs
2. Personal History of substance abuse
   - Alcohol
   - Illegal drugs
   - Prescription drugs
3. Age between 16 & 45 yrs
4. History of preadolescent sexual abuse
5. Psychologic disease
   - ADD, OCD, bipolar, schizophrenia
   - Depression

**ADMINISTER**

- On initial visit
- Prior to opioid therapy

**SCORING (RISK)**

0-3: low
4-7: moderate
≥8: high

**SCREENER & OPIOID ASSESSMENT FOR PATIENTS WITH PAIN (SOAPP)®**

Identifies patients at 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 w/a nurse, physician, or psychologist
- Prescribers should have a completed & scored SOAPP® while making opioid treatment decisions


WHAT IS THE RISK FOR MY PATIENT?

- Risk of opioid use disorder in patients on COT for Chronic Non-Cancer Pain (CNCP) is up to 30%
- Always highest with past history of SUD or psychiatric comorbidity
- Recognize that patient needs and patterns shift with age

RISK & PAIN ASSESSMENT TOOL BOXES

PAIN ASSESSMENT TOOL BOX

- Pain Assessment Tools (VSP, etc)
- Functional Assessment (SF-36, etc)
- Pain intensity, Enjoyment of life, General activity (PEG)

MENTAL HEALTH TOOLS (PHQ9, GAD7, etc)

RISK ASSESSMENT TOOL BOX

- PDMP
- IOT
- Risk Assessment Tools (ORT or SGRAPP)

CONSIDER A TRIAL OF AN OPIOID?

- Potential benefits are likely to outweigh risks
- Failed to adequately respond to nonopioid & nonpharmacological interventions
- Pain is moderate to severe
- Initiate trial of IR opioids
INITIATING OPIOIDS: CDC GUIDELINE

- 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
- Carefully justify a decision to titrate dosage to ≥100 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](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:

<table>
<thead>
<tr>
<th>ANALGESIC &amp; FUNCTIONAL GOALS OF TREATMENT</th>
<th>HOW TO MANAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>EXPECTATIONS</td>
<td>• Common AEs (e.g., constipation, nausea, sedation)</td>
</tr>
<tr>
<td>POTENTIAL RISKS</td>
<td>• Risks (e.g., abuse, addiction, respiratory depression, overdose)</td>
</tr>
<tr>
<td>ALTERNATIVES TO OPIOIDS</td>
<td>• AEs with long-term therapy (e.g., hyperalgesia, testosterone, irregular menses or sexual dysfunction)</td>
</tr>
</tbody>
</table>

PATIENT-PRESCRIBER AGREEMENT (PPA)

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

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

**REINFORCE EXPECTATIONS FOR APPROPRIATE & 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 Rx.

- Follow-up
- Monitoring
  - Random UDT & pill counts
  - Refills
  - Identify behaviors for discontinuation
  - Exit strategy

**MONITOR ADHERENCE AND ABERRANT BEHAVIOR**

**ROUTINELY MONITOR PATIENT ADHERENCE TO TREATMENT PLAN**

- Recognize & document aberrant drug-related behavior
  - In addition to patient self-report also use:
    - State PDMPs
    - UDT
      - Positive for nonprescribed 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)

**ADDRESS ABERRANT DRUG-RELATED BEHAVIOR**

Behavior outside the boundaries of agreed-on treatment plan:

- Unsanctioned dose escalations or other noncompliance w/ 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 w/ 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, & treatment plans.

CHAPTER 4 – PEARLS FOR PRACTICE

- Conduct a comprehensive and pain-focused H&P
- 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

CHAPTER 5

**MANAGEMENT MONITORING AND DISCONTINUING**
Part 1
Monitoring

Opioid Side Effects

- Respiratory depression – most serious
- QT-prolongation (methadone, buprenorphine)
- Opioid-Induced Constipation (OIC) – most common
- Sedation, cognitive impairment, sweating, miosis, urinary retention, flushing, hypothermia,
- Neuro-excitement - agitation, confusion, myoclonus
- Opioid-induced hyperalgesia (OIH), hypogonadism
- Tolerance, physical dependence
- “Reward”, abuse and 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 & treated, may lead to respiratory arrest & 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 w/ close observation, supportive measures, & opioid antagonists, depending on patient’s clinical status

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

REDUCE RISK
- Proper dosing & 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
- Longer duration of action
- Multiple IR doses needed to achieve effective analgesia
- Poor analgesic efficacy despite dose titration
- Less sleep disruption

CONSIDERATIONS FOR CHANGE FROM IR TO ER/LA OPIOIDS

Drug & Dose Selection Is Critical
Some ER/LA opioids or dosage forms are only recommended for opioid-tolerant patients
- > 25 mcg/hr Transdermal fentanyl or hydromorphone ER
- Certain strengths / doses of other ER/LA products (check drug PI)

Monitor Patients Closely For Respiratory Depression
Especially within 24-72 h of initiating therapy & increasing dosage

Individual Dosage By Titration Based On Efficacy, Tolerability & Presence Of AEs
Check ER/LA opioid product PI for minimum titration intervals
Supplement with IR analgesics (opioids & non-opioid) if pain is not controlled during titration
Patients considered opioid tolerant are taking at least:
- 60 mg oral morphine/day
- 30 mg oral oxycodone/day
- 8 mg oral hydromorphone/day
- 25 mg oral oxymorphone/day
- 25 mcg transdermal fentanyl/hr

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

OPIOID TOLERANCE

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 & 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 EDT

OTHER POTENTIAL REASONS FOR ROTATION

- Cost or insurance issues
- Adherence issues
- Change in clinical status requires an opioid with different PK (ie., hepatic / renal impairment)
- Problematic drug-drug interactions
- Patient desire or need to try a new formulation
EQUIANALGESIC DOSE TABLES (EDT)

Many different versions:

- PUBLISHED
- ONLINE
- ONLINE INTERACTIVE
- SMART-PHONE 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>Equianalgesic Dose</th>
<th>Usual Starting Doses</th>
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</thead>
<tbody>
<tr>
<td>Morphine</td>
<td>10 mg 30 mg</td>
<td>2.5-5 mg SC/IV (1.25 – 2.5mg) 5-15 mg q3-4hr (IR or oral solution) (2.5-7.5 mg)</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>NA 20 mg</td>
<td>5-10 mg q3-4 (2.5 mg)</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>NA 30 mg</td>
<td>5 mg q3-4h (2.5 mg)</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>1.5 mg 7.5 mg</td>
<td>0.2-0.8 mg SC/IV (0.2-0.8 mg) 1.2 mg q3-4hr (0.5-1 mg)</td>
</tr>
</tbody>
</table>

MU OPIOID RECEPTORS & 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
GUIDELINES FOR OPIOID ROTATION

Reduction Calculated Equianalgesic Dose by 25% - 50%*

Select % Reduction Based on Clinical Judgment

Closer to 60% Reduction if Patient Is

- Receiving a relatively high dose of current opioid regimen
- Elderly or medically frail

Closer to 20% Reduction if Patient Is

- Does not have these characteristics
- Is changing route of administration

*75%-90% reduction for methadone

GUIDELINES FOR OPIOID ROTATION (continued)

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

Example - Rotate patient from 30 mg bid Oxycodone ER to Hydromorphone ER

Example - Rotate patient from 30 mg bid Oxycodone ER to Hydromorphone ER

Example - Rotate patient from 30 mg bid Oxycodone ER to Hydromorphone ER
GUIDELINE FOR OPIOID ROTATION: SUMMARY

Frequently assess initial response
- Check for pain, side effects, withdrawal symptoms

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

Tritate dose of new opioid, based on product PI titration interval, to optimize outcomes

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 Breakthrough Pain (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
- Nonopioid drug therapies
- Nonpharmacologic treatments

* Around the clock

BE READY TO REFER

SUBSTANCE USE DISORDER

SAMHSA substance abuse treatment facility locator
http://findtreatment.samhsa.gov/TreatmentLocator/

SAMHSA mental health treatment facility locator
http://findtreatment.samhsa.gov/MHTreatmentLocator/

HIGH-RISK / COMPLEX PATIENTS

Refer to pain management, check state regulations for requirements
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’re testing and not testing

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
  * IA = immunoassay
  * LC/MS = liquid chromatography/mass spectrometry


INTERPRETATION OF UDT RESULTS

NEGATIVE RESULT
- Demonstrates recent use
  - Most drugs in urine have detection times of 1-3 d
  - Chronic use of lipophilic drugs: test positive for ≥1 wk
- Does not diagnose
  - Drug addiction, physical dependence, or impairment
  - Does not provide enough information to determine
    - Exposure time, dose, or frequency of use

POSTIVE RESULT
- Does not diagnose diversion
  - More complex than presence or absence of a drug in urine
  - May be due to maladaptive drug-taking behavior
    - Bingeing, running out early
    - Other factors e.g., cessation of insurance, financial difficulties
EXAMPLES OF METABOLISM OF OPIOIDS

- **Codeine** → **Morphine** → **6-MAM** → **Heroin**
  - T½ = 25-30 min
- **Codeine** → **Hydrocodone** → **Hydromorphone**
- **Oxycodone** → **Oxymorphone**
  - T½ = 3-5 min

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PART 2
DISCONTINUING

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REASONS FOR DISCONTINUING OPIOIDS

- **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 unapproved opioids
  - Repeatedly obtaining opioids from multiple outside sources
  - Prescription forgery
  - Multiple episodes of prescription loss
  - Diversion

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- **Pain Level Decreases in Stable Patients**
- **Intolerable & Unmanageable**
- **No Progress Toward Therapeutic Goals**
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

Example of Discontinuation Schedule

<table>
<thead>
<tr>
<th>Current opioid dose is oxycodone 60 mg/d</th>
<th>Prescribe oxycodone ER 20 mg q12h (#60) + oxycodone IR 5 mg prn (#60) w/ instructions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day</td>
<td>Oxycodone ER 20 mg tablet</td>
</tr>
<tr>
<td>------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>1-7</td>
<td>20 mg q12h</td>
</tr>
<tr>
<td>8-14</td>
<td>20 mg q12h</td>
</tr>
<tr>
<td>15-28</td>
<td>20 mg q12h</td>
</tr>
</tbody>
</table>

Follow-up office visit
- Pain is well controlled
- Has not needed to use IR oxycodone
- No withdrawal symptoms

Example of Discontinuation Schedule (cont)

<table>
<thead>
<tr>
<th>Current dose is oxycodone 40 mg/d</th>
<th>Prescribe oxycodone ER 10 mg q12h (#60) + oxycodone IR 5 mg (#90) w/ instructions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day</td>
<td>Oxycodone ER 10 mg tablet</td>
</tr>
<tr>
<td>------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>1-7</td>
<td>10 mg q12h</td>
</tr>
<tr>
<td>8-14</td>
<td>10 mg q12h</td>
</tr>
<tr>
<td>15-21</td>
<td>–</td>
</tr>
<tr>
<td>22-30</td>
<td>–</td>
</tr>
</tbody>
</table>
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 & constipation
- Follow patients closely during times of dose adjustments
- Periodically evaluate functional outcomes
- Discontinue opioids slowly and safely

CHAPTER 6
SPECIAL POPULATIONS

OLDER ADULTS

RISK FOR RESPIRATORY DEPRESSION

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

MONITOR
- Initiation & 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 & 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 don’t know they’re 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 & benefits of opioid therapy during pregnancy & 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 insure appropriate treatment for the baby
- If chronic opioid therapy is used during pregnancy, anticipate & manage risks to the patient and newborn
- If they are using opioids on a daily basis, consider Methadone or Buprenorphine

CHILDREN & ADOLESCENTS: HANDLE WITH CARE

JUDICIOUS USE OF IR FOR BRIEF THERAPY

SAFETY & EFFECTIVENESS OF MOST ERLA OPIOIDS UNESTABLISHED

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

ERLÅ OPIOID INDICATIONS ARE PRIMARILY LIFE-LIMITING CONDITIONS

WHEN PRESCRIBING ERLÅ OPIOIDS TO CHILDREN:

- Consult pediatric palliative care team or pediatric pain specialist or refer to a specialized multidisciplinary pain clinic
Palliative & Hospice Considerations

• Palliative Care
  • No different than prescribing for other patients in your care
  • MME standards continue unchanged

• Hospice
  • Comfort dosing is not limited to MME
  • Check PDMP
  • Consider PPA for family or home caregiver
  • Diversion considerations
  • Destruction following death
  • Who owns the C-2?

FEDERAL & STATE REGULATIONS

Comply with federal & state laws & regulations that govern the use of opioid therapy for pain

FEDERAL
• Code of Federal Regulations, Title 21 Section 1306: rules governing the issuance & filling of prescriptions pursuant to section 309 of the Act (21 USC 829)
  www.deadiversion.usdoj.gov/21cfr/cfr/2106cfrt.htm
• United States Code (USC) - Controlled Substances Act, Title 21, Section 829: prescriptions
  www.deadiversion.usdoj.gov/21usc/829.htm

STATE
• Database of state statutes, regulations, & policies for pain management
  www.painpolicy.wisc.edu/database-statutes-regulations-other-policies-pain-management
  www.painpolicy.wisc.edu/database-statutes-regulations-other-policies-pain-management
Prescribing Limits, 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>Status</strong></td>
<td>Licensed</td>
<td>Schedule II-V</td>
<td>Schedule II-V (for terminally ill pts. only)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td>None</td>
<td>None</td>
<td>Required-no amount specified</td>
</tr>
</tbody>
</table>

Initial prescribing limits for acute pain: 7 days for adults, 5 days for minors.

Prescribing Limits, Status & Education Requirements

Physician
- Licensed
- Schedule II-V
- Required-no amount specified

Physician Assistant
- Schedule II-V

Advanced Practice Nurse
- Schedule II-V (for terminally ill pts. only)

PDMP: Prescription Drug Monitoring Program

General
- OARRS (Ohio Automated Rx Reporting System)
  www.ohiopmp.gov
- Administered by the Board of Pharmacy
- Schedule II-V are monitored
- Designers and prescribers are required to register and input data
- Before prescribing, there is an obligation to review under certain circumstances
- Prescribers can authorize a registered delegate

Reporting
- Must be entered into PDMP within 24 hours of dispensing
- Unsolicited reports/alerts are sent to law enforcement and licensing boards
- Ohio does share data with other states’ PDMP
- Out-of-state pharmacies are required to report to the patient’s home state
- Patient will not be notified if their record has been accessed

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 w/ the PDMP
- Whether prescribers are required to access PDMP information in certain circumstances
- Whether unsolicited PDMP reports are sent to prescribers
- Whether unsolicited PDMP reports are sent to law enforcement and licensing boards
- Whether unsolicited PDMP reports are sent to law enforcement and licensing boards
- Whether unsolicited PDMP reports are sent to law enforcement and licensing boards
- Bordering states may be available
- Designated surrogates may have access

PDMPs
- 18 states – mandatory that provider check PDMP prior to writing for opioids
- 13 states – mandates for use of PDMPs under certain circumstances

Not all federally licensed facilities report to PDMPs
### PDMP BENEFITS

Provides full accounting of prescriptions filled by patient

<table>
<thead>
<tr>
<th>RECORD OF A PATIENT'S CONTROLLED SUBSTANCE PRESCRIPTIONS</th>
<th>PROVIDE WARNINGS OF POTENTIAL MISUSE/ABUSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Some are available online 24/7</td>
<td>- Existing prescriptions not reported by patient</td>
</tr>
<tr>
<td>- Opportunity to discuss with patient</td>
<td>- Multiple prescribers/pharmacies</td>
</tr>
<tr>
<td></td>
<td>- Drugs that increase overdose risk when taken together</td>
</tr>
<tr>
<td></td>
<td>- Patient pays for drugs of abuse with cash</td>
</tr>
</tbody>
</table>

---

### Patient RX History Report

**Mary Jones**

Date: 02-18-2012

<table>
<thead>
<tr>
<th>Prescription</th>
<th>Date</th>
<th>Ref.</th>
<th>Pay Code</th>
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</thead>
<tbody>
<tr>
<td>FENTANYL PATCH 100MCG C-II, TRANSDERMAL PATCH</td>
<td>1/20/12</td>
<td>106XX N</td>
<td>04</td>
</tr>
<tr>
<td>OXYCODONE HYDROCHLORIDE, 15 MG, TABLET</td>
<td>1/06/12</td>
<td>123XX N</td>
<td>04</td>
</tr>
<tr>
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<td>134XX N</td>
<td>04</td>
</tr>
<tr>
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<td>12/21/11</td>
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<td>04</td>
</tr>
<tr>
<td>OXYCODONE HYDROCHLORIDE, 30 MG, TABLET</td>
<td>12/08/11</td>
<td>654XX N</td>
<td>03</td>
</tr>
<tr>
<td>FENTANYL PATCH 100MCG C-II, TRANSDERMAL PATCH</td>
<td>11/16/11</td>
<td>221XX N</td>
<td>04</td>
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<tr>
<td>CLONAZEPAM, 1 MG, TABLET</td>
<td>11/19/11</td>
<td>334XX N</td>
<td>01</td>
</tr>
<tr>
<td>OXYCODONE HYDROCHLORIDE, 30 MG, TABLET</td>
<td>11/09/11</td>
<td>645XX N</td>
<td>01</td>
</tr>
<tr>
<td>OXYCODONE HYDROCHLORIDE, 30 MG, TABLET</td>
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<td>533XX N</td>
<td>04</td>
</tr>
<tr>
<td>OXYCODONE HYDROCHLORIDE, 15 MG, TABLET</td>
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<td>491XX N</td>
<td>04</td>
</tr>
<tr>
<td>OXYCODONE HYDROCHLORIDE, 15 MG, TABLET</td>
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<td>04</td>
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<tr>
<td>OXYCODONE HYDROCHLORIDE, 30 MG, TABLET</td>
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<tr>
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<td>01</td>
</tr>
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</tr>
<tr>
<td>FENTANYL PATCH 75MCG C-II, 75MCG TRANSDERMAL PATCH</td>
<td>8/25/11</td>
<td>599XX N</td>
<td>04</td>
</tr>
<tr>
<td>OXYCODONE HYDROCHLORIDE, 15 MG, TABLET</td>
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</tr>
<tr>
<td>OXYCODONE HYDROCHLORIDE, 30 MG, TABLET</td>
<td>8/15/11</td>
<td>705XX N</td>
<td>03</td>
</tr>
<tr>
<td>FENTANYL PATCH 100MCG C-II, TRANSDERMAL PATCH</td>
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<td>784XX N</td>
<td>03</td>
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<tr>
<td>CLONAZEPAM, .5 MG, TABLET</td>
<td>9/20/11</td>
<td>216XX N</td>
<td>01</td>
</tr>
<tr>
<td>OXYCODONE HYDROCHLORIDE TABLETS, 30 MG, TABLET</td>
<td>8/11/11</td>
<td>477XX N</td>
<td>01</td>
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<td>OXYCODONE HYDROCHLORIDE, 30 MG, TABLET</td>
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</tr>
</tbody>
</table>

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**30**
CANNABIS

- DEA Schedule 1 ("high abuse potential") yet state regulations vary
- There is good evidence that cannabis or selective cannabinoids (cannabidiol) are effective for chronic pain treatment in adults
- More research is needed
- Concern for high risk groups: children, adolescents, pregnant women


Marijuana Status

Medical

Medical use of marijuana allowed
Marijuana use with THC products only allowed

Recreational

Not legal for recreational use in Ohio

CONSIDERATIONS FOR CLINICIANS

- Use available scientific evidence, advise patients
- Inform about potential effects: AEs mostly mild and well tolerated (cough, anxiety)
- Screen for potential misuse/abuse, diversion
- Set treatment goals, use PPA
- Encourage patients to keep notes, discuss with them
- Document everything
- Regular re-evaluation
- Consider periodic UDTs
- Discontinue if not helpful moving toward goals
- Edibles are the fastest growing delivery system
- No well controlled studies on the combined use of opioids and cannabis
CHAPTER 8
COUNSELING PATIENTS & CAREGIVERS

USE PATIENT COUNSELING DOCUMENT
DOWNLOAD:
ORDER HARD COPIES:
www.minneapolis.cenveo.com/submitorders.aspx


COUNSEL PATIENTS ABOUT PROPER USE
EXPLAIN
• Product-specific information about the prescribed IR or ER/LA opioid
• Take opioid as prescribed
• Adhere to dose regimen
• How to handle missed doses
• Notify prescriber if pain not controlled
• Call prescriber for info on handling side effects

INSTRUCT PATIENTS/CAREGIVERS TO
• Read the ER/LA opioid Medication Guide received from pharmacy every time an ER/LA opioid is dispensed

Alan P. Agins, Ph.D.
Jody Agins, MSN, RNP, FNP/GNP-BC 2018
COUNSEL PATIENTS ABOUT PROPER USE (continued)

EXPLAIN

OPSIODS CAN CAUSE DEATH EVEN WHEN TAKEN PROPERLY

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

EXPLAIN

• Signs/symptoms are respiratory depression, gastrointestinal obstruction, allergic reactions

COUNSEL PATIENTS ABOUT PROPER USE (continued)

EXPLAIN

OPSIODS SHOULD BE STORED IN A SAFE & SECURE PLACE

• Tell patients and caregivers, medications must be kept in a locked container
• Will periodically assess for benefits, side effects & continued need for IR/ER/LA opioids
• Need for re-evaluation of underlying medical condition if the clinical presentation changes over time

EXPLAIN

• Away from children, family members, visitors and pets
• Safe from theft

Opioids are scheduled under Controlled Substances Act and can be misused & 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 & 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 w/ ER/LA opioids can cause overdose & death

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

Signs and symptoms of Overdose
- Person can not 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

Available as:
- Naloxone kit (w/ syringes, needles)
- Injectable
- Nasal spray

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

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.

Naloxone Regulation

Effective date
- April 2017

Criminal immunity
- Prescribers: Yes
- Dispensers: Yes
- Lay People: Yes

Also Available
- Without Prescription: Yes
- To 3rd Party: Yes
- By Standing Order: Yes

Carried by First Responders
- Yes

SOURCE:

Collaborative for REMS Education

Naloxone Regulation

Effective date
- April 2017

Criminal immunity
- Prescribers: Yes
- Dispensers: Yes
- Lay People: Yes

Also Available
- Without Prescription: Yes
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Carried by First Responders
- Yes

SOURCE:
www.pdaps.org

Alan P. Agins, Ph.D.
Jody Agins, MSN, RNP, FNP/GNP-BC 2018
**ABUSE DETERRENT/TAMPER RESISTANT OPIOIDS**

- Response to growing nonmedical 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

---

**REMEMBER... In the home**

**STEP 1: MONITOR**
- Note how many pills in each prescription
- Keep track of dosage and refills
- Make sure everyone in the home knows

**STEP 2: SECURE**
- Keep meds in a safe place (locked cabinet)
- Encourage parents of your teen’s friends to secure their prescriptions

**STEP 3: DISPOSE**
- Discard expired or unused meds
- Consult PI for best disposal

---

**RX OPIOID DISPOSAL**

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

<table>
<thead>
<tr>
<th>Collection receptacles</th>
<th>Voluntarily maintained by:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Call DEA Registration Call Center/ At 1-800-882-9539 to find a local collection receptacle – or search online for DEA controlled substances disposal</td>
<td>Law enforcement</td>
</tr>
<tr>
<td>Mail-back packages Obtained from authorized collectors</td>
<td>Authorized collectors, including:</td>
</tr>
</tbody>
</table>

- Manufacturer
- Distributor
- Receiver distributor
- Retail or hospital/pharmacy

- Including long-term care facilities

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

---

**DECREASE AMOUNT OF OPIODS INTRODUCED INTO THE ENVIRONMENT PARTICULARLY INTO WATER**
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 w/ undesirable substance
- Place in sealable bag, can, or other container
- Remove identifying info on label

FDA: PRESCRIPTION DRUG DISPOSAL

FLUSH DOWN SINK/TOILET IF NO COLLECTION RECEPTACLE, MAIL-BACK PROGRAM, OR TAKE-BACK EVENT AVAILABLE

- 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 exception: can seal in Patch-Disposal Unit provided & dispose of in the trash

CHAPTER 8 – PEARLS FOR PRACTICE

- Use formal tools (PPAs, counseling documents) to educate patients and caregivers
- Emphasize patients and caregivers safe storage and disposal
- Consider co-prescribing Naloxone
CHAPTER 9

DRUG CLASS CONSIDERATIONS

FOR SAFER USE: KNOW DRUG INTERACTIONS, PK, & PD

Concurrent use with other CNS depressants can increase risk of respiratory depression, hypotension, profound sedation, or coma

Concurrent use with anticholinergic medication increases risk of urinary retention & severe constipation or paralytic ileus

Methadone & 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

Drugs that inhibit or induce CYP enzymes can increase or lower blood levels of some opioids

Concurrent use of partial agonists or mixed agonist / antagonists† may reduce analgesic effect and/or precipitate withdrawal

May enhance neuromuscular blocking action of skeletal muscle relaxants & increase respiratory depression

Use with MAOIs may increase respiratory depression

Certain opioids with MAOIs can cause serotonin syndrome

Can reduce efficacy of diuretics - induce release of ADH

* Buprenorphine; † Pentazocine, nalbuphine, butorphanol

ADDITION OTHER DRUG INTERACTIONS

Use with MAOIs may increase respiratory depression

Certain opioids with MAOIs can cause serotonin syndrome

Can reduce efficacy of diuretics - induce release of ADH
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 w/ water
- Monitor patients w/ 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 any way. Use entire film.

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:

- Drug substance
- Formulation
- Strength
- Dosing interval
- Key instructions
- Use in opioid-tolerant patients
- Product-specific safety concerns
- Relative potency to morphine
- Specific information about product conversions, if available
- Specific drug interactions

For detailed information refer to online PI:
Drugs@FDA at www.fda.gov/drugsatfda
SUMMARY

Prescription opioid abuse & overdose is a national epidemic. Clinicians must play a role in prevention.

- Assess patients for treatment with IR and ER/LA opioids
- Initiate therapy, modify dose & discontinue use of opioids
- Monitor ongoing therapy with IR and ER/LA opioids
- Counsel patients & caregivers about the safe use of opioids, including proper storage & disposal
- Be familiar with general & product-specific drug information concerning opioids

TO OUR LEARNERS

Our Session Stops here, but your review continues...

Refer to Appendix 1 for specific drug information on ER/LA opioid analgesic Products.

YOUR PARTICIPATION IS IMPORTANT

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!