Safe Opioid Prescribing

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American College of Physicians
South Carolina Chapter
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Learning Objectives

- Implement risk assessment tools when prescribing chronic opioid therapy (COT)
- Utilize SCRIPTS (PMP)
- Approach to therapy initiation, titration, rotation, and discontinuation
- Monitoring tools such as drug testing
- Patient education
- Identify specific drug differences among ER/LA opioids

Overdose Death Rates (2008)
COT in Pain Management

- Commonly prescribed
  - Limited evidence supports use for non-cancer pain
- COT goals
  - Improve overall quality of life
  - Improve activity tolerance and physical function
  - Decrease pain intensity
- Among the most abused medications
  - Opioids, benzodiazepines, stimulants
- Significant risk from misuse and drug interaction

COT Risks

- Side effects
- Drug interactions
- Tolerance
- Physical Dependency
- Inadvertent exposure, especially children
- Misuse / abuse
- Addiction
- Diversion by patient or family / household
- Respiratory Depression
- Overdose and Death
### Opioid Side Effects / Management Options

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Management Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea and vomiting</td>
<td>Anti-emetics, Opioid Rotation</td>
</tr>
<tr>
<td>Sedation</td>
<td>Lower dose (if possible); Add nonsedating co-analgesic</td>
</tr>
<tr>
<td></td>
<td>Add stimulant or attention enhancer</td>
</tr>
<tr>
<td>Constipation</td>
<td>Stool softeners, osmotics, diet changes, Relistor, Amitiza, Movantik</td>
</tr>
<tr>
<td>Edema and sweating</td>
<td>Opioid Rotation</td>
</tr>
<tr>
<td>Dizziness</td>
<td>Antivertigo agents</td>
</tr>
<tr>
<td>Confusion</td>
<td>Lower dose, rotate opioid</td>
</tr>
<tr>
<td>Itching</td>
<td>Antihistamines (low efficacy), A / A rotation</td>
</tr>
<tr>
<td>Endocrine dysfunction</td>
<td>Endocrine monitoring</td>
</tr>
<tr>
<td>Reduced libido</td>
<td>Testosterone replacement</td>
</tr>
<tr>
<td>Loss of menstrual period</td>
<td>Endocrine consultation</td>
</tr>
<tr>
<td>Dizziness</td>
<td>Antivertigo agents</td>
</tr>
<tr>
<td>Confusion</td>
<td>Lower dose, rotate opioid</td>
</tr>
</tbody>
</table>

### Opioid Interactions

- **CNS depressants**
  - Alcohol, sedatives, hypnotics, tranquilizers, TCAs, MAOIs
  - Respiratory depression, hypotension, profound sedation, or coma, serotonin syndrome

- **Partial agonists, agonist/antagonist analgesics**
  - Buprenorphine, pentazocine, nalbuphine, butorphanol
  - May reduce analgesic effect or precipitate withdrawal symptoms

- **Skeletal muscle relaxants**
  - Increased respiratory depression

- **Anticholinergic agents**
  - Increased risk of urinary retention and severe constipation, which may lead to paralytic ileus

### Other Interactions

<table>
<thead>
<tr>
<th>Medication</th>
<th>Methadone Effect</th>
<th>Buprenorphine Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZT</td>
<td>Increase in AZT levels; possible toxicity</td>
<td>None</td>
</tr>
<tr>
<td>Lapatinib/Lanoxin</td>
<td>Opiate withdrawal may occur</td>
<td>None</td>
</tr>
<tr>
<td>Rifampin</td>
<td>Opiate withdrawal may occur</td>
<td>Opiate withdrawal may occur</td>
</tr>
<tr>
<td>Fluconazole</td>
<td>Increased methadone plasma concentrations</td>
<td>None</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>Increased methadone plasma concentrations</td>
<td>None</td>
</tr>
<tr>
<td>Sertraline</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Duloxetine</td>
<td>Potentially increases duloxetine exposure</td>
<td>None</td>
</tr>
<tr>
<td>Dextromethorphan</td>
<td>Associated with delirium</td>
<td>None</td>
</tr>
<tr>
<td>Aripiprazole</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>Opiate withdrawal may occur</td>
<td>Not studied</td>
</tr>
<tr>
<td>Methylphenidate</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Diphenhydramine</td>
<td>May have synergistic depressant effect</td>
<td>None</td>
</tr>
</tbody>
</table>
### Risk Factors for RD/OD
- Generally preceded by sedation and decreased respiratory rate
- Risk factors for Respiratory Depression
  - OSA, morbid obesity, snoring
  - Age (>60)
  - CNS depressant polypharmacy
  - Cardiopulmonary disease, organ failure
  - Smoking
  - Post-Surgery – upper abdominal and thoracic

### Aberrant Use Definitions
- **Misuse** - using a medication in a manner other than as specifically directed by a healthcare professional
  - Self titration due to poor pain control or anxiety
- **Abuse** – deliberate nonmedical use
  - Crushing, snorting, injecting
  - Diversion (buying/selling/stealing)
- Both contribute to opioid-related deaths

### Definitions (continued)
- **Tolerance** - adaptive state after drug exposure, increased dose required for clinical effect
  - Alone, does not indicate addiction
- **Dependency** – physiological adaptation wherein discontinuation or reversal of drug causes withdrawal syndrome
  - Occurs in all patients on sufficient doses over time
  - Alone is not indicative of addiction
- **Addiction** – primary, chronic, neurobiological disease with genetic, environmental, and psychosocial elements
  - One or more of the following
    - Impaired control over use, compulsive use, continued use despite harm, craving
Opioid Tolerance

- According to the FDA, a patient is considered opioid tolerant if they are taking, for one week or longer, at least:
  - Morphine (po) – 60 mg/day
  - Hydrocodone – 60 mg/day
  - Oxycodone – 30 mg/day
  - Fentanyl (td) – 25 mcg/h
  - Hydromorphone - 8 mg/day
  - Oxymorphone – 25 mg/ day

Risk Factors for Misuse/Abuse

- Personal history of substance abuse
  - Prescription drugs > illicit drugs > EtOH
- Family History of substance abuse
- Age 16 – 45
- Psychiatric Comorbidity
  - BPAD, ADHD, GAD, MDD, personality d/o
- Preadolescent sexual abuse in women

Risk Stratification Tools

- Use prior to opioid initiation
- Opioid Risk Tool (ORT)
  - www.partnersagainstpain.com
- Screener and Opioid Assessment for Patients with Pain (SOAPP)
  - www.painEDU.org
Opioid Risk Tool (ORT)

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>RISK FACTOR</th>
<th>FEMALE</th>
<th>MALE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family History of Substance Abuse</td>
<td>Alcohol</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Illegal Drugs</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Prescription Drugs</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Personal History of Substance Abuse</td>
<td>Alcohol</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Illegal Drugs</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Prescription Drugs</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Age</td>
<td>Age 16-45 years</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>History of Preadolescent Sexual Abuse</td>
<td>ADHD</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Psychological Disease</td>
<td>OCD</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Schizophrenia</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Depression</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Total Risk Score

<table>
<thead>
<tr>
<th>Total Score Risk Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Risk 0–3</td>
</tr>
<tr>
<td>Moderate Risk 4–7</td>
</tr>
<tr>
<td>High Risk ≥8</td>
</tr>
</tbody>
</table>

Opioid Risk Tool (ORT)

- **Low Risk**
  - No past or current substance abuse
  - Noncontributory family history
  - Psychologically stable

- **Moderate Risk**
  - History of substance abuse, long-term recovery
  - Concerning family history
  - Comorbid psychiatric condition

- **High Risk**
  - Active Substance abuse / addiction
  - Major untreated / unstable psychiatric condition
  - Significant risk to self and prescriber

COT Initiation

- **Step 1: Take a history**
  - Pain / Symptom history
    - Onset, character, duration, severity, relieving/exacerbating factors
    - Prior workup, diagnoses, tests, treatments, surgeries
    - Substance use history, family substance use history
      - Parental addiction is the #1 risk factor for patient addiction
    - Psychiatric History
    - Work History / Disability
COT Initiation

- Physical Exam
  - Multi-organ system
    - Musculoskeletal, neurological
    - Waddell signs
      - Tenderness not related to a particular skeletal or neuromuscular structure; may be either superficial or nonanatomic.
      - Superficial – The skin in the lumbar region is tender to light pinch over a wide area not associated with the distribution of the posterior primary ramus.
      - Nonanatomic – Deep tenderness, which is not localized to one structure, is felt over a wide area and often extends to the thoracic spine, sacrum or pelvis.

PE: Waddell Signs (contd)
- Simulation Tests - These tests give the patient the impression that a particular examination is being carried out when in fact it is not.
  - Axial Loading – Low back pain is reported when the examiner presses down on the top of the patient’s head
  - Rotation – Back pain is reported when the shoulders and pelvis are passively rotated in the same plane as the patient stands relaxed with the feet together

PE: Waddell Signs (contd)
- Distraction Test - A positive physical finding is demonstrated in the routine manner, and this finding is then checked while the patient’s attention is distracted; a nonorganic component may be present if the finding disappears when the patient is distracted.
  - Straight Leg Raising – The examiner lifts the patient’s foot as when testing the plantar reflex in the sitting position; a nonorganic component may be present if the leg is lifted higher than when tested in the supine position.
PE: Waddell Signs (contd)

- **Regional Disturbances** - Dysfunction (e.g., sensory, motor) involving a widespread region of body parts in a manner that cannot be explained based on anatomy; care must be taken to distinguish from multiple nerve root involvement.
  - Weakness – Demonstrated on testing by a partial cogwheel “giving way” of many muscle groups that cannot be explained on a localized neurological basis.
  - Sensory – Include diminished sensation to light touch, pinprick or other neurological tests fitting a “stocking” rather than a dermatomal pattern.

PE: Waddell Signs (contd)

- **Overreaction** (pain behaviors) - May take the form of disproportional verbalization, facial expression, muscle tension and tremor, collapsing, or sweating; judgments should be made with caution, minimizing the examiner’s own emotional reaction.

COT Initiation

- Prior to initiation, discuss/document:
  - Goals of therapy
    - Moderate pain reduction - 30-50%
    - Objective functional goals
  - Risks and Benefits
    - Dependency is not a risk, it is a virtual absolute
    - Side effects, drug / EtOH interactions
    - Impairment – work, driving
    - Risk stratification, potential for aberrancy
  - Start Low and Go Slow
Drug Initiation
- Start low-potency, short-acting, PRN
  - ER/LA formulations are inappropriate for COT initiation and most should only be considered for opioid tolerant patients.
- Follow-up frequently with patients
  - 1-2 weeks until stable
    - Fewer pills dispensed, fewer to discard if ineffective or side effects preclude use
    - Monitor compliance and effectiveness

Controlled Substance Agreement
- Informed consent + treatment "contract"
  - Risks/benefits/alternatives to COT
  - Outlines prescriber expectations of patient
    - Single pharmacy / single prescriber
    - Patient accountability to safeguard medication
      - No refills for lost/stolen/destroyed medication
      - Keep out of reach of children, elderly, etc
    - No selling or sharing of medication with others
    - Take ONLY as prescribed, no self-titration
    - No early refills or nights, weekends, holidays
    - Consent to toxicology testing and pill-counts
    - Refills are contingent upon keeping scheduled appointments
    - Refill requests and appointment rescheduling: 3 days notice
    - 24 hour wait time for Rx refills
    - Privacy waved in the event of law enforcement involvement
    - Therapy may be discontinued at any time for misuse, lack of efficacy, risk > benefit, noncompliance with terms.

Opioid Management / Monitoring
- The 4 A’s
  - Analgesia
    - Numerical or Subjective
  - Activity level
    - Work duties, exercise, domestic chores, leisure
  - Adverse reactions / effects
    - Side effects, affect / personality, family dynamics
  - Aberrant behaviors
    - Misuse/Abuse/Diversion
Other Monitoring Tools

- Current Opioid Misuse Measure (COMM)
  - 17 questions of issues over last 30 days
  - 0 = Never, 4 = Very Often
    - Thinking, memory, task completion
    - Obsessive thoughts, anger, anxiety, self-harm
    - Misuse, diversion, drug seeking, ER visits
  - NPV for opioid misuse = 0.95%
    - www.painEDU.org

Drug Testing

- Saliva, Urine and Blood
  - Urine Point of Care cups, GCMS confirmation
    - POC has substantial false (-) and (+)
    - GCMS is very accurate
  - Saliva testing
    - Takes about 5 minutes to saturate swab
    - No POC, may be more convenient or low-risk patients
  - For POC(+) results, consider waiting for confirmation before making major management decisions
  - Know your metabolites for proper interpretation
    - Codeine to Morphine, OC to OM, HC to HM
    - Parent drug vs metabolite presence, detection window

Prescription Monitoring Program

- SCRIPTS
  - South Carolina Reporting & Identification Prescription Tracking System
  - Created in 2006 (H.3803), started 2008
  - Exclusions
    - Inpatient pharmacies
    - 48 hour supply dispensed from hospital ER
    - Dispensings to long-term care facility residents
    - Five day supply (or 31 days of phenobarb) by a vet
    - FEDERAL DISPENSERS
      - VA / military base pharmacies
      - Methadone clinics
SCRIPTS Sample Report

Prescription Monitoring Program

- 2014
  - S.840 – signed by Gov Haley 6/6/14
    - Daily data submission from dispensers
    - Delegate authorization
      - Individual supervised by authorized prescriber or pharmacist
    - Criminal penalty for delegate use violations
      - Felony – fine < $10k, or prison < 10 years
    - Disciplinary board action for practitioner violations
    - 2 hr prescribing CME per biannual license period
    - Mandatory use was REMOVED from the bill

PDAP Council

- Gov Haley executive order 3/14/2014
  - In response to SCOIG 5/2013 outlining the growing Rx drug abuse problem in SC and the lack of statewide strategy
- 10 members
  - SLED, DHEC, LLR, DHHS, DAODAS, Solicitor’s Office
  - Boards of Medical Examiners, Nursing, Pharmacy, Dentistry
  - Physician advisors in pain management, emergency medicine, family practice
PDAP Council – Joint PM Guide

- **MANDATORY PMP UTILIZATION per Joint Revised Pain Management Guidelines**

- **MED 80 > 3 months = RED FLAG**
  - Re-establish informed consent, review functional status including daily activities, analgesia, aberrant behavior and adverse effects as it relates to progress toward treatment objectives established at the onset of opioid therapy; consult SCRIPTS to verify compliance; re-establish office visit intervals; review frequency of drug screens; and review and execute a new treatment agreement. Relevant information from SCRIPTS should become part of the patient’s medical record.

- Avoid dose escalation without attention to risks and alternatives
- Complete eradication of pain is not an attainable goal
  - “Reasonable level of discomfort” is the best clinical outcome a patient may receive

PDAP Council – Joint PM Guide

- **Pain management in the ER**
  - Utilize SCRIPTS
  - Consult with patient’s opioid prescriber
  - Rx for chronic pain is only rarely indicated in the ER and should limited to supply sufficient for patient to see primary provider
  - No replacement Rx for lost/stolen/destroyed
  - ER/LA opioid should not be routinely Rx
  - Acute pain Rx should rarely exceed 5 days
    - Use SCRIPTS
    - Screen for substance abuse prior to Rx when appropriate

Opioids - Titrate, Rotate, Convert?

- Opioid management frequently requires dose or drug changes to balance efficacy, tolerability, compliance and risk
  - Short vs Long-Acting opioids
  - Abuse Deterrent Formulations (cost / benefit)
  - Breakthrough pain
  - QHS dosing (sleep apnea)
  - Limited formulary options for CMS, Tricare
  - Poor evidence-based management data
Drug Diversion – Warning Signs

### Suspicious History
- Patient referred already taking controlled substances, especially opioid/relaxer/sed
  - Vicmaxanax / Percosomaxanax
- Soft diagnosis based on symptoms
  - COT often contraindicated in FMS, IBS, chronic daily headache, interstitial cystitis, chronic pelvic pain
- Multiple doctors / prescribers
- The Out-of-Towner
- Limited / unobtainable old records from referring doc
- Old, tattered, suspicious records (ash tray smell)
- Request for specific drug

### Suspicious Physical Exam
- Normal exam, exaggerated exam, Waddell
- Symptoms out of proportion to objective findings
  - Severe weakness with normal reflexes
  - Severe numbness with normal Babinski
- Poor Dentition (meth mouth)
- Arm scars (skin popping / track marks)
- Red eyes / nares
- Smoke smell, “Legalize it” T-shirt, etc.

COT Discontinuation

### Reasons
- Lack of objective improvement in physical, functional, and psychosocial activities
- Compliance issues
- Intolerance

- Discontinuation of COT is not patient abandonment but should NOT mark the end of treatment through other modalities or referral to specialists (pain, addiction)
- Structured wean is often safe and effective
  - Reduce dose 30-50% every 3-5 days, >14 days rarely necessary
  - Increased pain is most common complaint
  - Opioid W/D is NOT associated with DT
  - Rapid discontinuation is NOT life threatening
  - Consider inpatient detox and outpatient recovery program
Further Information

- ER/LA REMS program (3 hours CME)
  - In depth instruction on long-acting opioid prescribing / management

- Bibliography
  - Lots of links to cited documents and online resources for further reading

Questions?