ASSESSING PATIENTS FOR TREATMENT WITH ER/LA OPIOID ANALGESIC THERAPY

Unit I
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Disclosure of Relevant Financial Relationships
Content of Activity: ASAM Medical -Scientific Conference 2013

<table>
<thead>
<tr>
<th>Name</th>
<th>Commercial Interests</th>
<th>Relevant Financial Relationships: What Was Received</th>
<th>Relevant Financial Relationships: For What Role</th>
<th>No Relevant Financial Relationships with Any Commercial Interests</th>
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</thead>
<tbody>
<tr>
<td>Melvin Pohl</td>
<td>Las Vegas Recovery Center</td>
<td>Salary Medical Director</td>
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</tr>
</tbody>
</table>

Balance Risks Against Potential Benefits

- Conduct Hx, physical exam, & appropriate testing
- Comprehensive benefit-to-harm evaluation
  - Balance potential benefits on pain & function against potential risks
- Risks include
  - Overdose: ER/LA dosage units contain more opioid than IR drugs
  - Abuse by patient or household contacts
  - Misuse & addiction
  - Physical dependence & tolerance
  - Interactions w/ other medications & substances
  - Inadvertent exposure by household contacts, especially children

Adequately DOCUMENT all patient interactions, assessments, test results, & treatment plans

Clinical Interview: Significant Recent Medical Hx

- Illness relevant to (1) effects or (2) metabolism of opioids
  1. Pulmonary disease, constipation, nausea, cognitive impairment
  2. Hepatic, renal disease
- Illness suggestive of substance abuse; eg:
  - Hepatitis
  - HIV
  - Tuberculosis
  - Cellulitis
  - STD
  - Trauma, burns
  - Cardiac disease
  - Pulmonary disease


Clinical Interview: Pain & Treatment Hx

- Description of pain
  - Location
  - Intensity
  - Quality
  - Onset/duration
  - Variations/patterns/rhythms
- What relieves the pain?
- What causes or increases pain?
- Effects of pain
- Patient’s pain & function goal

Clinical Interview: Pain & Treatment Hx

- Pain medications
  - Past use
  - Current use
    - Query state PDMP* where available to confirm patient report
    - Contact past providers & obtain prior medical records
    - Conduct UDT*
  - Dosage
    - For opioids currently prescribed: opioid, dose, regimen, & duration
      - Important to determine if patient is opioid tolerant†
    - General effectiveness
    - Nonpharmacologic pain relief & effectiveness

Perform Thorough Physical Examination & Assessment of Presenting Pain Condition

- Objective data to confirm Hx & Dx
- Components of physical exam (appropriate to pain location)
  - General physical exam
    - Vital signs: overall health & comorbidities
    - General appearance, posture, gait, & pain behaviors
  - Neurologic exam
  - Musculoskeletal exam
    - Inspection
    - Palpation
    - Percussion
    - Auscultation
    - Provocative maneuvers
    - Cutaneous or trophic findings
  - Order diagnostic tests (appropriate to complaint)

Assess Each Patient's Risk of Abuse, Including Substance Use & Psychiatric Hx

- Obtain a complete Hx of current & past substance misuse
  - Prescription drugs
  - Illegal substances
  - Alcohol & tobacco
    - Substance abuse Hx does not prohibit treatment w/ ER/LA opioids but may require additional monitoring & expert consultation/referral
  - Family Hx of substance abuse & psychiatric disorders
  - Hx of sexual abuse
  - Social history also relevant
    - Employment, cultural background, social network, marital history, legal history, & other behavioral patterns
Assess Each Patient’s Risk, con’t

- Be knowledgeable about risk factors for opioid abuse
  - Personal or family Hx of alcohol or drug abuse
  - Younger age
  - Presence of psychiatric conditions
- Understand & use addiction or abuse screening tools
  - Assess potential risks associated w/ chronic opioid therapy
  - Manage patients using ER/LA opioids
  - Conduct a UDT
  - Understand limitations

Risk Assessment Tools: Examples

<table>
<thead>
<tr>
<th>Tool</th>
<th>No of items</th>
<th>Administered by</th>
</tr>
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<tbody>
<tr>
<td>Opioid Risk Tool (ORT)</td>
<td>5</td>
<td>By patient</td>
</tr>
<tr>
<td>SOAPP® Screener &amp; Opioid Assessment for Patients w/ Pain</td>
<td>24, 14, &amp; 5</td>
<td>By patient</td>
</tr>
<tr>
<td>DRE Diagnosis, Irresponsibility, Risk, &amp; Efficacy Score</td>
<td>7</td>
<td>By clinician</td>
</tr>
<tr>
<td>Characterize misuse once opioid treatments begins:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FMQ Pain Medication Questionnaire</td>
<td>26</td>
<td>By patient</td>
</tr>
<tr>
<td>ZMM Current Opioid Misuse Measure</td>
<td>17</td>
<td>By patient</td>
</tr>
<tr>
<td>PDUG Prescription Drug Use Questionnaire</td>
<td>40</td>
<td>By clinician</td>
</tr>
</tbody>
</table>

Not specific to pain populations:

- CAGE-AID: Cut Down, Annoyed, Guilty, Eye-Opener Tool, Adjusted to Include Drugs
- MFAT: Money, Alcohol, Family, Trouble
- DAST: Drug Abuse Screening Tool
- SBIRT: Screening, Brief Intervention, & Referral to Treatment

Opioid Risk Tool (ORT)

Mark each box that applies

<table>
<thead>
<tr>
<th>Item</th>
<th>Female</th>
<th>Male</th>
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</thead>
<tbody>
<tr>
<td>1. Family Hx of substance abuse</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Illegal drugs</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Prescription drugs</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2. Personal Hx of substance abuse</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Illegal drugs</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Prescription drugs</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3. Age between 16 &amp; 49 yrs</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>4. Hx of preadolescent sexual abuse</td>
<td>1</td>
<td>1</td>
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<tr>
<td>5. Psychologic disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADD, OCD, Bipolar, schizophrenia</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Depression</td>
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<td>1</td>
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</tbody>
</table>

Scoring totals:

• Administer
  - On initial visit
  - Prior to opioid therapy
• Scoring (risk)
  - 0-3: low
  - 4-7: moderate
  - ≥8: high
SOAPP
• Identifies patients as 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

When to Consider a Trial
• Pain is moderate to severe
  • Failed to adequately respond to nonopioid & nondrug interventions
• Continuous, around-the-clock opioid analgesic is needed for an extended period of time
• Potential benefits are likely to outweigh risks
  • Consider referral to pain or addiction specialist for patients where risks outweigh benefits
• No alternative therapy is likely to pose as favorable a balance of benefits to harms

When to Consider a Trial
• 60-yr-old w/ chronic disabling OA pain
  • Nonopioid therapies not effective, IR opioids provided some relief but experienced end-of-dose failure
  • No psychiatric/medical comorbidity or personal/family drug abuse Hx
  • High potential benefits relative to potential risks
  • Could prescribe opioids to this patient in most settings w/ routine monitoring
• 30-yr-old w/ fibromyalgia & recent IV drug abuse
  • High potential risks relative to benefits (opioid therapy not 1st line for fibromyalgia)
  • Requires intensive structure, monitoring, & management by clinician w/ expertise in both addiction & pain
  • Undertake only if risks can be adequately managed
When to Consider a Trial

- Selection of patients between these 2 extremes requires:
  - Careful assessment & characterization of patient risk
  - Structuring of care to match risk
    - In patients w/ Hx of substance abuse or a psychiatric comorbidity, this may require assistance from experts in managing pain, addiction, or other mental health concerns
    - In some cases opioids may not be appropriate or should be deferred until the comorbidity has been adequately addressed
      - Consider referral


Referring High-Risk Patients

- Prescribers should
  - Understand when to appropriately refer high-risk patients to pain management or addiction specialists
  - Also check your state regulations for requirements


Special Considerations: Elderly Patients

- Does patient have medical problems that increase risk of opioid-related AEs?
  - Respiratory depression more likely in elderly, cachectic, or debilitated patients
    - Altered PK due to poor fat stores, muscle wasting, or altered clearance
    - Monitor closely, particularly when
      - Initiating & titrating ER/LA opioids
      - Given concomitantly w/ other drugs that depress respiration
      - Reduce starting dose to 1/3 to 1/2 the usual dosage in debilitated, non-opioid-tolerant patients
    - Titrate dose cautiously
    - Older adults more likely to develop constipation
      - Routinely initiate a bowel regimen before it develops
  - Is patient/caregiver likely to manage opioid therapy responsibly?

Special Considerations: Children

- Safety & effectiveness of most ER/LA opioids* in pediatric patients <18 yrs not established
- Pediatric analgesic trials pose challenges
- Most opioid studies in children focus on inpatient safety
- Opioids are common sources of drug error
- Pediatric opioid indications are primarily life-limiting conditions
  - Few children w/ chronic pain due to non-life-limiting conditions should receive opioids
- Consult pediatric palliative care team or pediatric pain specialist when prescribing opioids to children
- Or refer to specialized multidisciplinary pain clinic


*Transdermal fentanyl approved in children aged ≥2 yrs

CO*RE Case: Peter

25 Year Old Male

Case: Peter

- New to area, presents at 4:45 pm on Friday
  - Chronic left knee pain from a MVA 5 yrs ago
  - Wants oxycodone ER & oxycodone IR for "rescue"
- Hx
  - 3 knee surgeries—last was 18 mo ago
  - Persistent ambulatory dysfunction—granted disability
  - Prior therapies: medications, supporting devices, & PT
    - Only oxycodone ER works
    - Allergy to acetaminophen & NSAIDs
    - Morphine & codeine make him throw up
    - PT sessions not helpful
- Physical examination of knee
  - No erythema, swelling, or bruising; surgical scars present
  - Left quadriceps has signs of atrophy compared to right side
  - Limited ROM on flexion of left knee
Peter: Assess Abuse Risk w/ 5-Q SOAPP

<table>
<thead>
<tr>
<th>How often:</th>
<th>Never=1</th>
<th>Seldom=2</th>
<th>Sometimes=3</th>
<th>Often=4</th>
<th>Very often=4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. do you have mood swings?</td>
<td>☑️</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>2. do you smoke a cigarette within an hr after you wake up?</td>
<td></td>
<td>☑️</td>
<td></td>
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<tr>
<td>3. have you taken medication other than the way that it was prescribed?</td>
<td></td>
<td>☑️</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. have you used illegal drugs (eg. marijuana, cocaine) in past 5 yrs?</td>
<td></td>
<td>☑️</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. in your lifetime, have you had legal problems or been arrested?</td>
<td></td>
<td>☑️</td>
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</tr>
</tbody>
</table>

**TOTAL SCORE:** 7 (cutoff is 4)=high risk for prescription opioid misuse

- On further questioning:
  - Admits smoking 1 cigarette pack/d for 10 yrs
  - Claims occasional marijuana use, not for last 2 yrs

Peter: Assess Abuse Risk

- Ask for contact details of prior regular physician
  - No info w/ him—can get it on Monday if you give him a prescription now
- Ask Peter to provide a urine sample for testing
  - He accuses you of not trusting him
  - Explain it is your office policy for a new patient being considered for a controlled substance
  - He goes w/ your nurse
- Access your state’s PDMP: 6-month report
  - Received 28 prescriptions from 4 physicians, using 5 pharmacies
    - ER & IR oxycodone, IR oxycodone/acetaminophen, & IR hydrocodone/acetaminophen
    - Some paid for w/ insurance, others w/ cash

Peter: UDT & Results

- POC immunoassay cup tests for THC, cocaine, opiates, methamphetamine, & amphetamine
  - Only detects naturally occurring opiates—morphine & codeine
  - Semisynthetic oxycodone not reliably detected
    - Included in some, but not all panels—always check
- POC test positive for THC & negative for other substances
- Second sample sent to laboratory, w/ request for a pain management profile that includes oxycodone
  - Adulterant panel, THC, cocaine, opiates, & oxycodone
Peter: What Now?

A. Write a 4-d supply of ER & IR oxycodone, to last until you contact his previous prescriber on Monday

B. Will not write a prescription today, as he lied about prescribers & drug use. Untreated addiction prevents you addressing his pain; refer to a pain management physician w/ addiction expertise

C. Write 30-d prescriptions for ER & IR oxycodone while you carry out diagnostic tests on his injury, obtain his prior medical records, & review test results

Peter: Case Summary

- Several red flags raised
  - PDMP report revealed probable doctor shopping
  - UDT positive for recent marijuana use, which he denied
  - SOAPP score suggests risk for prescription drug misuse
  - DEA identified modus operandi used by a drug-seeking patient
    - Wants appointment toward end of office hrs
    - Requests specific controlled substance
    - Claims nonopioid analgesics do not work or allergy
    - Reluctant to give name of primary physician
    - Younger age
- Peter may have a pain problem
  - Beyond your scope of practice to manage while his addiction is untreated
  - Refer to pain management or addiction specialist

ASAM Case:
Eleanor
56 Year Old Female
Case: Eleanor

- 56 year-old Caucasian female with fibromyalgia, degenerative disc disease with chronic back pain
- Treated in the past (OxyContin 80mg bid, oxycodone 15mg 6x/day, zolpidem 10mg has, alprazolam 1mg bid, sertraline 100mg daily).
- No history of early refills, nonsmoker, chronic depression and anxiety.
- 5-Q SOAPP score is 2 (no illegal drug use, nonsmoker, no legal hx or meds over prescribed amounts
- ORT score is 2 (no family or personal history of substance abuse, >45yo, + history of sexual abuse and psych disease.

Case: Eleanor

- Complains of severe pain, and wants to restart medications as previously.
- Issues to explore:
  - Benefit vs harm?
  - Opioid trial?
  - No use of sedative/hypnotics?
  - Proper treatment of psych issues?
  - History of treatment for sexual trauma?
  - Exercise, nutrition, sleep hygiene, counseling support, family involvement.

Case: Eleanor

Which of the following would be an important first step prior to starting any new medication?

A. Obtain a comprehensive urine toxicological screen
B. Send the patient for a full psychiatric evaluation
C. Do a comprehensive pain history and physical examination
D. Tell her opiates are bad and we need to focus on her depression