SAFE Opioid Prescribing | Strategies. Assessment. Fundamentals. Education
1:30–2pm

Evaluation Is Essential for Safe and Effective Pain Management Using ER/LA Opioids

SPEAKERS
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Presenter Disclosure Information
The following relationships exist related to this presentation:
► Dr Argoff receives advisor/consultant honoraria from Endo, Collegium Pharmaceutical, Depomed, Lilly, Ameritox, ORX Pharma, Pfizer, Daiichi-Sankyo, Tova Pharmaceutical expert investigator honoraria from Endo, Allergan, Janssen, Miller Labs, Lilly and receives grants from Endo/Lilly and Forest Laboratories.
► Dr McCarter receives advisor honorarium from Iroko, NeurogesX, Pfizer, Salix, Sucampo, Teva and Zogenix.
► Dr Stanos receives advisory board/consultant honorarium from Endo Pharmaceuticals, Pfizer, MyMatrixx and GlaxoSmithKline.

Off-Label/Investigational Discussion
► In accordance with ptMCE policy, faculty have been asked to disclose discussion of unlabeled or unapproved use(s) of drugs or devices during the course of their presentations.

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Overall Program Learning Objectives
Sessions I–VI

Upon completion of this initiative, the participants will be better able to:
❖ Implement patient assessment strategies, including tools to assess risk of abuse, misuse, or addiction when prescribing extended-release (ER/LA) opioids
❖ Employ approaches to safely initiate therapy, modify dose, and discontinue ER/LA opioids
❖ Monitor patients by evaluating treatment goals and implementing periodic urine drug testing (UDT)
❖ Employ patient education strategies about the safe use of ER/LA opioids
❖ Identify similarities and differences among ER/LA opioids

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Background: Painkiller Overdoses = Public Health Epidemic

- Overdose deaths from prescription painkillers have increased
  • 16,651 in 2010; >4x # in 1999
  • 43% of all fatal overdoses
- Almost 1 million people ≥12 years old reported nonmedical opioid use ≥200 days in 2009-2010; 4.6 million people reported such use for 30 days or more
  • Highest prescription painkiller overdose rates in middle-aged adults
  • Highest rates in rural counties
  • Highest rates in Whites and American Indians or Alaska Natives
  • Many more Rx opioid overdose deaths in men than women
- In 2009, nearly 500,000 ED/ER visits for Rx painkillers misuse or abuse
- Direct health care costs of nonmedical prescription painkiller use: $72.5 billion annually

The Prevalence of Chronic Pain in the United States Is High

- Approximately 100 million US adults have chronic pain (33%)
- Numerous studies indicate undertreated pain: eg, cancer, older adults, children, minorities
- Goal: define most appropriate analgesic regimen for each pain patient, which may include the use of ER/LA opioids

While improper use of any opioid can result in serious side effects, including overdose and death, risks may be greater with Rx ER/LA Opioids

The Goals of Risk Evaluation and Mitigation Strategy (REMS) CME on ER/LA Opioid Analgesics

- In 2012, the US Food and Drug Administration (FDA) directed all ER/LA opioid companies to provide independent CME grants to educate prescribers and to provide information for patients to:
  • Ensure that the benefits of ER/LA opioids outweigh the risks
  • Help to reduce risk for ER/LA opioid misuse, abuse, and overdose while ensuring access to pain medication
  • Follow FDA “Blueprint” on ER/LA opioids CME to engage and educate prescribers and be in compliance with standards for continuing education for physicians and other health care professionals, including Accreditation Council for Continuing Medical Education (ACCME)

This 6-Session Activity Is FDA REMS-Compliant CME

Goals of This REMS-Compliant Education for ER/LA Opioid Analgesics

- As clinicians, WE are best positioned to balance treatment of pain against risks of serious adverse outcomes, including addiction, unintentional overdose, and death
- In this 6-session curriculum, we will review many best-practice aspects of managing ER/LA opioid analgesic therapy
  • Patient assessment
  • Therapy initiation, dose modification, and discontinuation
  • Therapy management
  • Counseling of patients and caregivers
  • General drug information
  • Product-specific drug information

Evaluation is Essential for Safe and Effective Pain Management Using ER/LA Opioids

learning Objectives for Session I

Upon completion of this module, the participants will be better able to:

- Identify risk factors for opioid-related aberrant behavior
- Differentiate among tolerance, physical dependence, and addiction
Opioid Therapy in Chronic Pain Management

- Opioids ARE commonly prescribed for chronic pain
  - Efficacious for many types of pain
  - Appropriate use is KEY to safety and success
- Goals of chronic opioid therapy:
  - Improve and/or stabilize pain intensity
  - Improve function
  - Improve quality of life (QOL)
- However, significant gaps exist between guideline recommendations for safe prescribing practices of ER/LA opioids and how they are being used in practice
  - Highlights need for further education

But There Are Also Risks

- Opioid analgesics among the most commonly misused or abused pharmaceuticals
  - Over- or under-concern by physicians, patients, and/or caregivers disruptive to physician-patient relationship as well as to effective care
  - Other drugs also commonly abused, eg, stimulants, benzodiazepines
- Misuse:
  - Using a medication other than as directed or indicated, whether intentional or not, and whether harm results or not
    - eg, taking more than recommended dose of an opioid analgesic because pain is poorly controlled
    - eg, offering opioid analgesics to another person who is in pain
- Abuse:
  - Intentionally taking a medication for a nonmedical purpose
    - eg, taking an opioid to get high
- Both misuse and abuse are of concern
  - Can lead to an overdose
  - Common misconception that because opioid is a prescription drug it is safe

Risk Factors Associated With ER/LA Opioids

- Overdose with ER/LA formulations
- Abuse by patient or household contacts
- Misuse and addiction
- Interactions with other medications and substances
- Inadvertent exposure by household contacts, especially children

Who Misuses/Abuses Opioids and Why?

- Nonmedical Use
  - Recreational abusers
  - Patients with disease of addiction
- Medical Use
  - Pain patients seeking more pain relief
  - Pain patients escaping emotional pain

Abuse by Patient or Household Contacts

Source of Prescription Drugs

### Key Concepts

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>Tolerance</td>
<td>State of adaptation. Exposure to a drug induces changes that result in a diminution of 1 or more of the drug's effects over time, indicated by a need for increasing doses to achieve the same effect. Commonly occurs with opioids. Tolerance is not indicative of addiction.</td>
</tr>
<tr>
<td>Physical Dependence</td>
<td>State of adaptation manifested by drug class-specific withdrawal syndrome that can occur with abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence occurs in all patients using opioids for a period of time. Physical dependence is not indicative of addiction.</td>
</tr>
<tr>
<td>Addiction</td>
<td>A primary, chronic, neurobiologic disease with genetic, psychosocial, and environmental components. Characteristic behaviors include 1 or more of the following: impaired control over drug use, compulsive use, continued use despite harm, craving.</td>
</tr>
</tbody>
</table>


### Tolerance, Dependence, and Addiction — Critical Differences

**Behavior that the addicted patient may display:**

“My husband used his entire month’s supply of that extended-release opioid you gave him in 1 week. He seems like a totally different person. I am very concerned.”


### The FDA Definition of Opioid Tolerance

- Opioid naïve vs opioid tolerant
  - Patients are considered opioid tolerant if they are taking, for 1 week or longer, at least:
    - Oral morphine – 60 mg daily
    - Transdermal fentanyl – 25 mcg/h
    - Oral oxycodone – 30 mg daily
    - Oral hydromorphone – 8 mg daily
    - Oral oxymorphone – 25 mg daily
    - Equianalgesic daily dose of another opioid

www.fda.gov.

### Examples of Misuse and Abuse

**What patients will typically say to you:**

“Sometimes in the morning I need to take extra pills just to get going…”

“My friend was visiting this weekend and had terrible back pain. I gave her one of my oxycodone pills. It really helped her. That’s OK, right?”

“Hi, have you ever seen someone eat 400 mg of oxycodone …?”

“Sometimes in the morning I need to take extra pills just to get going…”

“Hi, have you ever seen someone eat 400 mg of oxycodone …?”

Prescribers Can Play an Active Role in Reducing the Risks Associated With Opioids

- Establish diagnosis
  - History and physical
  - Relevant diagnostic tests
- When opioids are being considered as part of acute or chronic pain treatment plan, complete an appropriate risk assessment
  - This is an active and ongoing process


Risk Factors for Opioid-Related Aberrant Behaviors

- Family history of substance abuse
  - Alcohol, illegal drugs, prescription drugs
    - Prescription drug abuse history carries greater risk
- Personal history of substance abuse
  - Alcohol, illegal drugs, prescription drugs
    - Prescription drug abuse history carries greater risk
- Age 16 to 45 years
- History of preadolescent sexual abuse
  - Increases risk for women
- Psychological disease
  - Attention deficit disorder (ADD) or depression
    - ADD carries higher risk

Use of Risk Stratification Tools and Ongoing Monitoring
KEY to Safe and Effective Opioid Use

Risk Stratification and Monitoring Tools

- Risk Stratification Tool:
  - Used before opioids are prescribed
  - Available

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

Opioid Risk Tool (ORT)

<table>
<thead>
<tr>
<th>Category</th>
<th>Risk Factor</th>
<th>Score if Female</th>
<th>Score if Male</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family History of Substance Abuse</td>
<td>Alcohol</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Illegal Drugs</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Prescription Drugs</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Personal History of Substance Abuse</td>
<td>Alcohol</td>
<td>2</td>
<td>2</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>≥16 to 49 years</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>History of Preadolescent Sexual Abuse</td>
<td>OCD, OCS</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Psychological Disease</td>
<td>ADD, OCD, Bipolar Disorder, Schizophrenia</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Total Risk Score

SOAPP — Sample Questions

Please answer the questions below, using the following scale:
0 = Never, 1 = Seldom, 2 = Sometimes, 3 = Often, 4 = Very Often

1. How often do you have mood swings? 0 1 2 3 4
2. How often do you smoke a cigarette within an hour after you wake up? 0 1 2 3 4
3. How often have you taken medication other than the way that it was prescribed? 0 1 2 3 4
4. How often have you used illegal drugs (for example, marijuana, cocaine, etc) in the past five years? 0 1 2 3 4
5. How often, in your lifetime, have you had legal problems or been arrested? 0 1 2 3 4

Consider referring high-risk patients or any patient you have concerns about to a pain specialist.

Meet Peter

- 45-year-old white male, railroad worker for line maintenance and reconstruction
- Spinal lumbar fusion with chronic back and leg pain
- Hx of back pain prior to injury that led to surgery, otherwise healthy

History
- Injured at work, pain on lower right side, radiating down right leg to outside of foot
  - Pain described as aching and throbbing
  - Pain severity 6/10 at rest and 7-9/10 when bending, coughing, or straining with a bowel movement
- NSAIDs, muscle relaxant, and light work duty attempted
- Patient struggled on job, complaints of severe pain

Peter

History (cont)
- Physical therapy (PT), Xray, MRI (L5-S1 disc w impingement of S1 nerve root)
- Failed steroid taper, hydrocodone, epidural steroid, more PT
- Sleep deprived, anxious, withdrawn, financially stressed
- Surgery and rehabilitation – no improvement
- Pain specialist prescribed:
  - Oxycodone CR tablets 40 mg every 12 hours
  - Hydrocodone/acetaminophen 5/500 8/day for breakthrough pain
  - Gabapentin 300 mg/ 2 tablets TID
  - Zolpidem 10 mg/HS
- Returns to your primary care office for ongoing pain management

Next Steps: Make No Assumptions

- Even though the prescriber of the CR oxycodone and hydrocodone/acetaminophen has evaluated Peter’s risk for opioid misuse before initiating these drugs, should you re-assess his level of risk now that the patient is back in your care?

  Yes, because the risk level can change and you want to document you have performed a risk assessment

Peter’s Score on ORT

<table>
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<th>Category</th>
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<td>Alcohol</td>
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<td></td>
<td>Illegal Drugs</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Personal History of Substance Abuse</td>
<td>Alcohol</td>
<td>2</td>
<td>2</td>
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<tr>
<td></td>
<td>Illegal Drugs</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Prescription Drugs</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Age</td>
<td>45-64 years</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>History of Preadolescent Sexual Abuse</td>
<td>OCD, ODD, Bipolar Disorder, Schizophrenia</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Psychological Disease</td>
<td>Abnormal Depression</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total Risk Score</td>
<td></td>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>

Total Score: Risk Category
- Low Risk 0-3
- Moderate Risk 4-7
- High Risk ≥ 8


Peter – Next Steps: Make No Assumptions

- Complete history and physical
- Ask Peter about his goals for treatment:
  - Explain that complete pain relief is rarely achieved
  - Focus on functional goals, eg, return to work, work part-time, able to play golf on weekends, able to walk the dog daily
- Risk for aberrant drug behavior – Moderate (4 on ORT)
- Evaluate mental health status
- Peter’s Rx: oxycodone CR, hydrocodone/APAP, gabapentin, zolpidem – any other Rx? OTC? Drug-drug interactions?
- Re-establish care with new treatment agreement and UDT
- Peter’s household – What is the possibility of inadvertent exposure to the opioids you are prescribing by household contacts, especially children? Have you discussed safe storage?

Opioid Therapy – Ongoing Monitoring

**The 4 A's**

**ADVERSE EFFECTS**

**ACTIVITIES OF DAILY LIVING**

**ABERRANT DRUG-TAKING BEHAVIORS**

Important to remember two other "A's": Assessment and Action (treatment plan)

### Tools for Ongoing Monitoring

**Current Opioid Misuse Measure (COMM) – Sample Questions**
- In the past 30 days, how often have you taken your medications differently than how they are prescribed?
- In the past 30 days, how much of your time was spent thinking about opioid medications (having enough, taking them, dosing schedule, etc.)?
- In the past 30 days, how often have you had to visit the Emergency Room?

Available at [www.painEDU.org](http://www.painEDU.org)

**Pain Assessment and Documentation Tool (PADT) – Sample Questions**
- Is the patient’s functioning with the current pain reliever(s) better, the same, or worse since last assessment?
- Is patient experiencing any side effects from current pain reliever(s)?
- Check-list of potential aberrant drug-related behavior

Available at [www.ucdenver.edu](http://www.ucdenver.edu)

### Summary Session I

- Over the past decade, a significant increase in opioid-related morbidity and mortality
- Unmet needs in pain care remain
- ER/LA formulations of opioid analgesics may pose a greater risk for overdose because of their high opioid content
- Potential for abuse by patients or household contacts must be evaluated when prescribing
- What can prescribers do?
  - Assess each patient’s risk for abuse and obtain a complete history and physical examination
  - Know when to refer patients
  - Understand opioid tolerance criteria (Session II)