Session III

Evidence-Based Tools for Screening for Patients at Risk and Monitoring for Adherence to Prescribed ER/LA Opioids

Learning Objectives for Session III

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

- * Evaluate and manage adverse effects of ER/LA opioids
- * Differentiate strategies for monitoring patient adherence

Key Principles of Managing Therapy With ER/LA Opioids

Use clinical evidence-based guidelines to:

- * Screen for risk, including assessment of psychiatric comorbidities
- * Establish analgesic and functional goals
- Use Patient Prescriber Agreements (PPAs) and monitor patient adherence
- Anticipate/manage adverse effects and periodically assess benefits and side effects
- Reevaluate patient's underlying medical condition if clinical presentation changes over time
- * Use referral sources for the treatment of abuse and addiction

FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics. www.fda.gov/downloads/drugs/drugsafety/informationbydrugclass/ucm277916.pdf. Accessed August, 2016.

Realistic Individualized Goal-Setting

- * Reach agreement with patient on treatment goals
- Patient-specific goals may include 1 or more of the following
 - Pain reduction: 30% considered clinically significant
 Explain to patient that complete pain relief rarely achieved
 - Improvement in select functional areas:
 eg, ability to work full time at previous or modified job; play golf once a week, walk the dog daily

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Improved mood

Patient Prescriber Agreement (PPA)

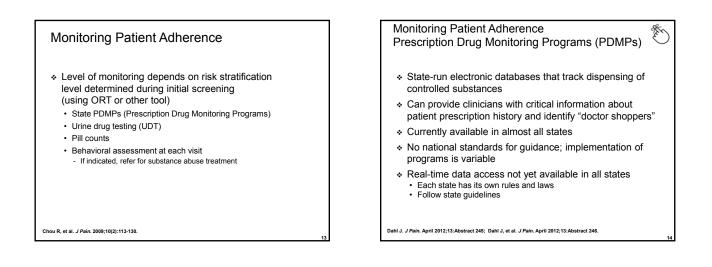
- Clinical evidence and guidelines support use of agreements
- Any of following can be used as a PPA:
 - Informed consent documents
 - Treatment agreement documents
 - · PPA available for download at no cost*
- * Benefits
- Informed decision making with patient
- Enables clear and mutual understanding of goals and expectations and respective responsibilities of patient and
- clinician
- Can be jointly signed during patient visit

*eg, www.caresalliance.org. Chou R, et al. *J Pain.* 2009;10(2):113-130.

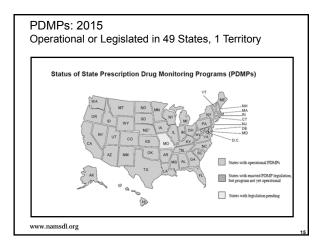
What Is Typically in a Patient Prescriber Agreement (PPA)

- * Understanding of risks and benefits of opioid therapy
- * Taking the opioid exactly as prescribed
- One prescribing doctor and one designated pharmacy and whether or not refills will be called into pharmacy without an office visit
- * Urine/serum drug testing when requested
- Pill counts at each office visit
- * No early refills
- How to safeguard their opioids medication
- * List of behaviors that may lead to discontinuation of opioids
- * Places for signature and dating

Chou R, et al. J Pain. 2009;10(2):113-130.



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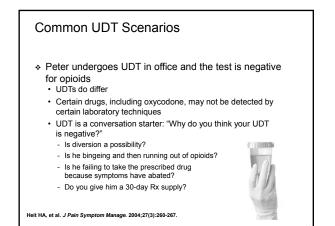
Monitoring Patient Adherence: Urine Drug Testing (UDT)

- Recommended for all patients for reasons of safety and to remove the stigma associated with UDTs
- Testing does not imply a lack of trust; it is a conversation starter
- Self reports of drug use and behavioral monitoring often fail to detect abuse problems
- UDTs can identify use of prescribed opioids as well as illicit drug use
- * Know limitations of UDT or laboratory that you use

Katz NP, et al. Anesth Analg. 2003;97(4):1097-1102; Heit HA, et al. J Pain Symptom Manage. 2004;27(3):260-267.

Urine Drug Testing – KEY POINTS

- Know what to expect and how to interpret results
- Parent compound and or metabolite should show up in the urine
 - Oxycodone \rightarrow oxymorphone
 - Hydrocodone → hydromorphone
 Codeine → morphine
- Is the substance present that you expect?
- ${\boldsymbol{\star}}$ Are there substances present that you do not expect?
- Know what your laboratory does



Common UDT Scenarios

- * Patient on LA morphine undergoes UDT. Test results positive for morphine and hydromorphone

present

- Possible explanations include:
 Patient using another opioid obtained from another physician · Hydromorphone is a trace metabolite
 - of morphine found only when very high morphine concentrations are



Common UDT Scenarios

- Patient being treated with hydrocodone has UDT positive for hydrocodone and hydromorphone
- * After hydrocodone use, urine may be positive for:
 - Hydrocodone only
 - · Hydrocodone and hydromorphone (metabolite)
 - Hydromorphone only

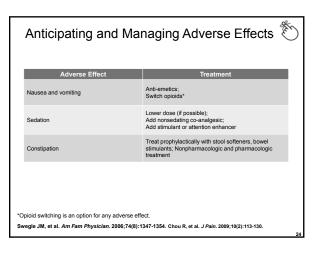
Common UDT Scenarios

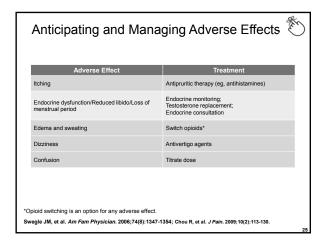
- * Patient reports no relief on codeine and UDT is negative
- * Possible explanations include
 - Laboratory error
 - Diversion
 - · Patient is a slow metabolizer of codeine

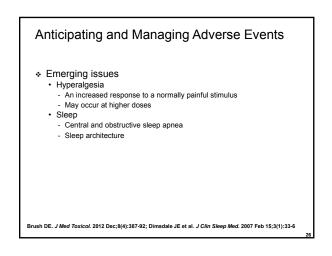
Heit HA, et al. J Pain Symptom Manage. 2004;27(3):260-267.



	SCREENING	CONFIRMATORY		
ANALYSIS TECHNIQUE	Immunoassay	GC-MS or HPLC		
SENSITIVITY (POWER TO DETECT A CLASS OF DRUGS)	Low or none when testing for semi-synthetic or synthetic opioids	High		
SPECIFICITY (POWER TO DETECT AN INDIVIDUAL DRUG)	Varies (can result in false-positives or false-negatives)	High		
TURNAROUND	Rapid	Slow		
OTHER	Intended for a drug-free population. May not be useful in pain medicine.	Legally defensible results		







Respiratory Depression - The Most Serious Adverse Effect

- Most serious adverse effect associated with opioids is RESPIRATORY DEPRESSION
- Occurs when
 - Initial doses are too high
 - Therapy is titrated too rapidly Drug-drug interactions

 - · Opioids combined with other drugs that may potentiate opioid-induced respiratory depression Benzodiazepines
 - Herbals
 - OTC preparations that contain diphenhydramine
- * More common in patients with sleep apnea
- * Respiratory depression may be fatal

OTC over-the-counter

Manchikanti L, et al. Pain Physician. 2012;15(3 suppl):S67-S116.

ER/LA Opioid Analgesics in Pregnancy

- * Be aware of the pregnancy status of your patient
- * There re no adequate and well-controlled studies of ER/LA opioids in pregnant women
- * ER/LA opioids should be used in pregnancy only if the potential benefit justifies the risk to the fetus
- * If opioid use is required, advise the patient of risk of neonatal opioid withdrawal syndrome

Reevaluating the Patient's Condition

- * Reevaluate if the presentation changes to determine if opioid therapy continues to be effective or necessary
- * Reevaluate or refer if there is new pain
- * Continue opioid therapy if appropriate analgesia and functional status improvements are maintained

What to Do if Your Patient Needs Treatment for Abuse and Addiction

- * Know treatment centers in your area
- * Work out a plan with the center you are referring to
- With a clear indication of abuse or addiction, discontinue prescribing of opioids

Chou R, et al. J Pain. 2009;10(2):113-130

Referral Sources for Abuse and Addiction Treatment

- Balancing Pain Management and Prescription Opioid Abuse Available at <u>www.cdc.gov/primarycare/materials/opoidabuse/index.html</u>
- Find Substance Abuse and Mental Health Treatment Available at <u>www.samhsa.gov/treatment</u>
- National Institute on Drug Abuse Available at <u>www.nida.nih.gov</u>
- American Council for Drug Education Available at <u>www.acde.org</u>
- American Academy of Addiction Psychiatry
 Providers' Clinical Support System for Opioid Therapies: www.pcss-o.org
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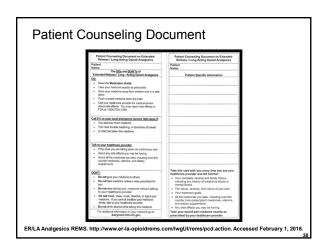
Session IV

Talk to Me: Proven Methods to Counsel Your Patients on ER/LA Opioids and Achieve Positive Outcomes

Learning Objectives for Session IV

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

- Implement counseling strategies to ensure patients know to take ER/LA opioids exactly as prescribed
- Use counseling strategies to explain signs of ER/LA opioid overdose to patients and caregivers



ER/LA, extended-release and long-acting.

Counseling Patients and Caregivers About ER/LA Opioids

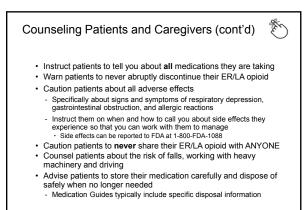
* Use Patient Counseling Document for ER/LA opioids to:

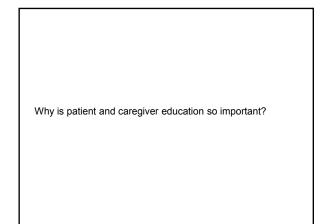
- Explain product-specific information
- Explain how to take and importance of adherence
- Tell patient and/or caregiver they will receive a Medication Guide from the dispensing pharmacy

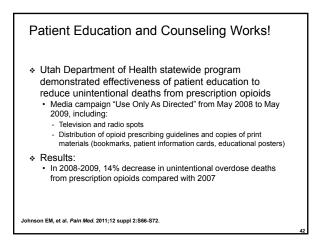
- Stress importance of reading the Guide and getting answers to any questions they may have from the pharmacist or you
- Warn patients not to tamper with ER/LA formulation
- Caution patients about use of other CNS depressants, including alcohol

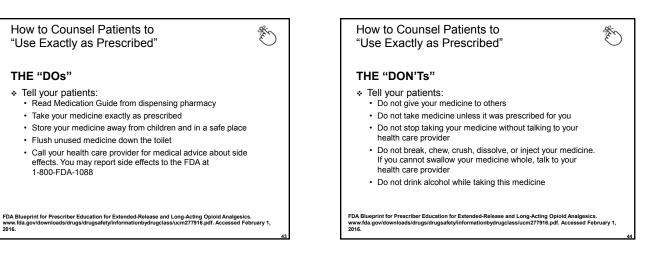
CNS, central nervous system.

FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics. www.fda.gov/downloads/drugs/drugs/ately/informationbydrugclass/ucm277916.pdf. Accessed February 1, 2016.









Patient Counseling Document

- Patient Counseling Document (PCD) on ER/LA opioid analgesics is a tool designed to facilitate important discussions with patients and:
 - Clearly describes "Do's" and "Don'ts" related to safe use
 - Gives clinician area to write patient-specific issues and
 instructions that can be taken by patient from the visit
 - · Helps to consolidate informed consent discussion
- PCD should be provided to and reviewed with patient and/or the caregiver at time of prescribing
- PCD is available at no charge at <u>www.er-la-opioidrems.com/lwgUI/rems/pcd.action</u>

ER/LA Analgesics REMS. http://www.er-la-opioidrems.com/lwgUl/rems/pcd.action. Accessed February 1, 2016.

Case — Joan

- * 62-year-old female with severe right hip osteoarthritis
- Has significant medical issues that prevent her from undergoing total hip replacement
- Started physical therapy, but stopped because of increase
- in pain
- Her pain is significantly affecting her quality of life
 Unable to take NSAIDs because of previous GI bleed
 - Her PCP initiated a trial of Ultram (tramadol), 50 mg, 1-2 TID, with no reported analgesia
 - This was followed by a 2-week course of Nucynta (tapentadol), 50 mg, 1 PO Q 6 hrs
 - Reported pain relief for only 3-4 hours, with VRS decreasing from 8 to 5/10
 Because of less than optimal duration of effect, PCP decides to initiate a trial of Nucynta ER (tapentadol ER), 100 mg PO Q 12 hrs

GI, gastrointestinal; PCP, primary care physician; VRS, verbal rating scale

Ensure Patients Know to Take Opioids ONLY As Prescribed

Instructions need to be product-specific:

- For instance, since Joan is taking Nucynta ER (tapentadol ER); she should be advised to:
- Not crush or chew net metacation
 Place tablet in mouth and take it with enough water to ensure complete swallowing immediately afterward
- Take a dose every 12 hours at same time every day
- But, if you had prescribed Kadian to Joan, you would advise her to
- Swallow capsule intact (whole); never to crush, dissolve or chew the pellets
- If she cannot swallow the capsule whole, contents of the Kadian capsule (peliets) can be sprinkled on applesauce and then swallowed without chewing

www.fda.gov.

Patients Need to Know About Adherence to Prescribed Opioid Regimen

- * Counsel patients and caregivers
- ER/LA opioid medication and dosage is based on their individual needs.
- Doubling up on a dose or taking it sooner than prescribed risks
 overdose with possible life-threatening consequences
- Taking more than prescribed constitutes misuse or abuse
- Missing a dose may result in inadequate pain relief
- · What to do if a dose is missed

FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics. www.fda.gov/downloads/drugs/drugsafety/informationbydrugclass/ucm277916.pdf. Accessed February 1, 2016.

Explain the Dangers of Combining Opioids With Other Substances

- Caution patients and caregivers that overdose or death can occur if ER/LA opioids are used with other CNS depressants, including:
 - Sedative-hypnotics: eg, zolpidem (Ambien); triazolam (Halcion); temazepam (Restoril)
 - Anxiolytics: eg, diazepam, clonazepam
 - Illegal drugs: eg, heroin
- Fatal opioid poisonings have been associated more often with concomitant use of benzodiazepines or alcohol
- Advise patients to use other CNS depressants, including other opioids, only under instruction of their prescriber
- Advise patients to tell all their health care providers about all medications they are taking

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Discuss the Dangers of Abruptly Discontinuing Medication

- Warn patients to not abruptly discontinue or reduce their ER/LA opioid analgesic and to discuss with you, the opioid prescriber, how to safely taper the dose if they wish to discontinue
- Abruptly discontinuing an opioid may lead to withdrawal syndrome
 Stomach cramps, diarrhea, rhinorrhea, sweating, elevated heart rate, increased blood pressure, irritability, dysphoria,

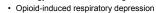
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Inform Patients of Seriousness of Adverse Events Associated With Opioids

 Caution patients and caregivers that opioids can cause serious side effects that may lead to death

2 Con

- Discuss:
 - Signs and symptoms of an overdose, such as: lethargy and somnolence, cognitive impairment



- Risk for severe constipation and gastrointestinal
- obstruction
- Emphasize the importance of healthy bowel habits: keeping hydrated, less sedentary
- · Possibility of allergic reactions

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Opioid Overdose Fatal overdose is not instantaneous—there is usually time for remedial action Naloxone can quickly reverse the effects Both patients and caregivers need to know how to identify opioid overdose, as signs of an overdose are often missed Opioid overdose signs include: Mental depression

- · Hypoventilation (decreased respiration)
- Reduced bowel motility

hyperalgesia, insomnia

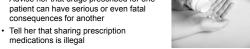
· Miosis (contracted pupils)

Green TR, et al. Addiction. 2008;103(6):979-989; Williams RH, et al. Laboratory Med. 2000;31:334-342.

Update on Joan

- * Joan returns to office after 1 month
- * Reports better pain relief and improved quality of life
- * Tolerating Nucynta ER (tapentadol ER) 100 mg BID and oxycodone 5 mg, 1-2 per day for breakthrough pain
- Urine drug toxicology testing (UDT) is completed
- * She reports running out 2 days early and is requesting early refill
 - She states: "My daughter hurt her back, so I gave her a couple of my pills. It helped her pain, too."
- * What should you do?

Dangers of Sharing Medication: the Legal Responsibilities of the Patient In our society, a commonly held belief among patients and caregivers is that sharing prescription medications is not dangerous or a problem because "prescription medications are safe". * Here's what you should do: · Counsel Joan about importance of not giving her medication to or sharing it with others, even her daughter · Advise her that drugs prescribed for one patient can have serious or even fatal consequences for another

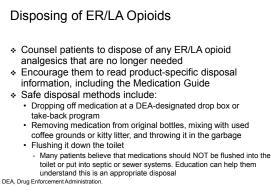


Manchikanti L, et al. Pain Physician. 2012;15(3 suppl):S67-S116; SAMHSA (2010). 2009 National Survey on Drug Use and Health. www.samhsa.gov/data/zk9/zk9Resultsweb/web/zk9results.htm. Accessed Febr 2013.

medications is illegal

Storing ER/LA Opioids Safely * Patients and caregivers must understand importance of storing opioids carefully and protecting them from theft · A secure place away from children, family members, household visitors, and pets - eg, a medication safe, which not only deters theft, but also inadvertent use in children, which could be fatal

Manchikanti L, et al. *Pain Physician.* 2012;15(3 suppl):S67-S116; SAMHSA (2010). 2009 National Survey on Drug Use and Health. www.samhsa.gov/data/2k9/2k9Resultsweb/web/zk9results.htm. Accessed Februar 2013.



FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics. www.tda.govidownloads/drugs/drugsafety/informationby/drugclass/ucm277916.pdf. Accessed February 1, 2016; Practical Pain Management. Opioid Disposal: Dos and Don'ts. www.practicalpainmanagement.com/opioid-dispo dos-don-ts. Accessed January 3, 2016.