

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

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
 - 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.

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

Monitoring Patient Adherence

- ❖ Level of monitoring depends on risk stratification level determined during initial screening (using ORT or other tool)
 - State PDMPs (Prescription Drug Monitoring Programs)
 - Urine drug testing (UDT)
 - Pill counts
 - Behavioral assessment at each visit
 - If indicated, refer for substance abuse treatment

Monitoring Patient Adherence

Prescription Drug Monitoring Programs (PDMPs)

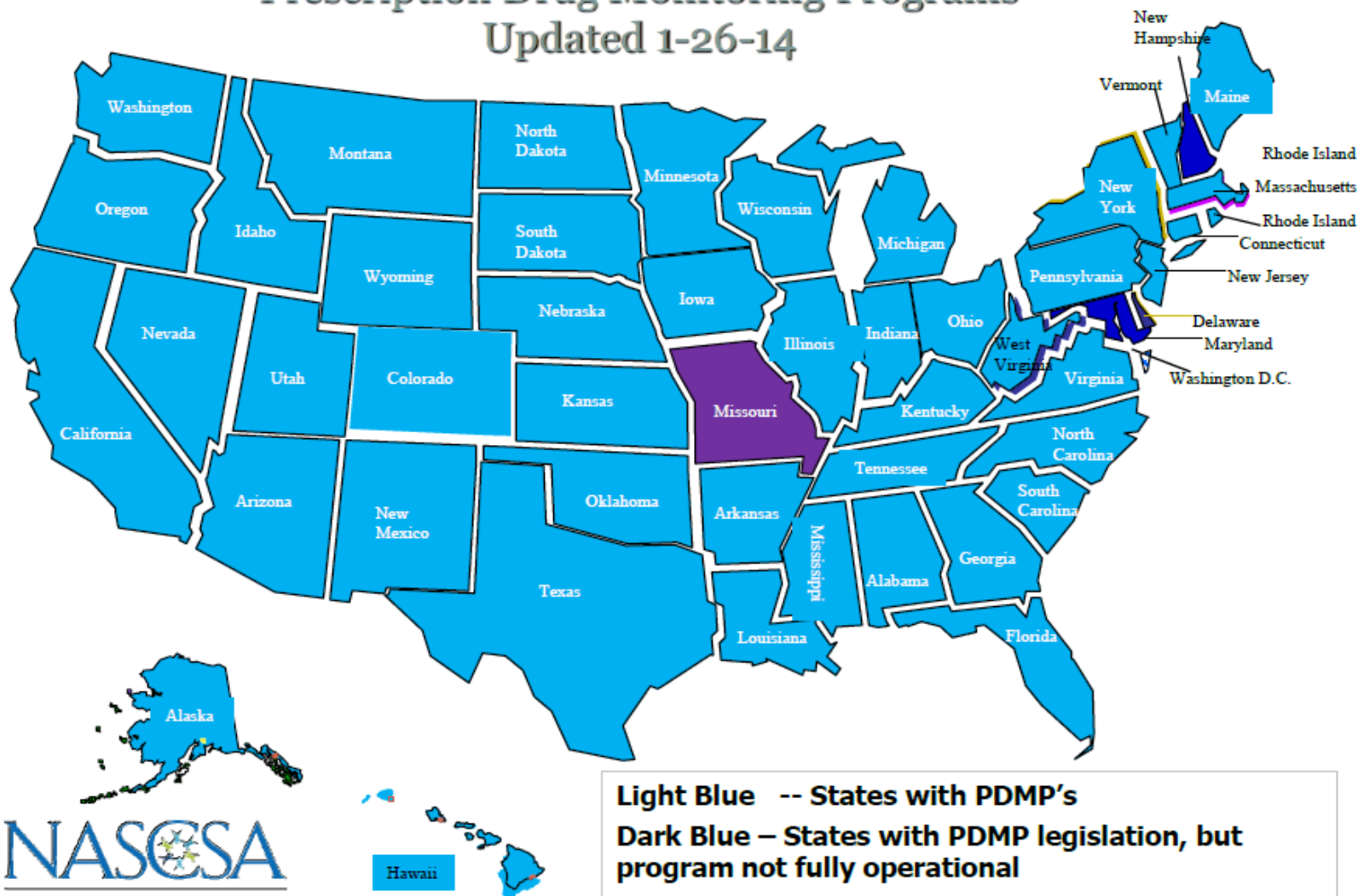


- ❖ State-run electronic databases that track dispensing of controlled substances
- ❖ Can provide clinicians with critical information about patient prescription history and identify “doctor shoppers”
- ❖ Currently available in almost all states
- ❖ No national standards for guidance; implementation of programs is variable
- ❖ Real-time data access not yet available in all states
 - Each state has its own rules and laws
 - Follow state guidelines

PDMPs: 2014

Operational or Legislated in 49 States, 1 Territory

Prescription Drug Monitoring Programs Updated 1-26-14



A Sample PDMP Report:

West Virginia = Board Of Pharmacy – Patient Profile

- ❖ Date 4/15/2012 Date of Birth 12-10-1966
Beginning Date: 04-01-11 =nbsp Ending Date: 04-15-12
- ❖ First Name: MIKE Last Name: =OWEN

First Name	Address	Zip	Fill date	Rx no.	Product Name	Strength	Qty	Doctor Name	Doctor DEA	Pharm Name	Pharm DEA	Ph Zip
MIKE	319 LOWER	25526	4/2/2011	11222	APAP/HYDRO	500MG-10MG	180	SMITH JOE	DH0267890	TOM'S PHARM	GF1234567	25526
MIKE	319 LOWER	25526	5/3/2011	19976	APAP/HYDRO	500MG-10MG	180	SMITH JOE	DH0267890	TOM'S PHARM	GF1234567	25526
MIKE	319 LOWER	25526	5/27/2011	23466	APAP/HYDRO	500MG-10MG	180	SMITH JOE	DH0267890	TOM'S PHARM	GF1234567	25526
MIKE	319 LOWER	25526	6/4/2011	31111	APAP/HYDRO	500MG-10MG	180	JOHN JOHN	DH0267890	BILL'S PHARM	AF1245687	25526

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

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 → oxymorphone
 - Hydrocodone → hydromorphone
 - Codeine → morphine
- ❖ Is the substance present that you expect?
- ❖ Are there substances present that you do not expect?
- ❖ Know what your laboratory does

Common UDT Scenarios

- ❖ Peter undergoes UDT in office and the test is negative for opioids
 - UDTs do differ
 - Certain drugs, including oxycodone, may not be detected by certain laboratory techniques
 - UDT is a conversation starter: “Why do you think your UDT is negative?”
 - Is diversion a possibility?
 - Is he bingeing and then running out of opioids?
 - Is he failing to take the prescribed drug because symptoms have abated?
 - Do you give him a 30-day Rx supply?



Common UDT Scenarios

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



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



Screening vs Confirmatory UDTs

	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

GC-MS, gas chromatograph mass spectrometer; HPLC, high performance liquid chromatography.
www.opioidrisk.com.

Anticipating and Managing Adverse Effects



Adverse Effect	Treatment
Nausea and vomiting	Anti-emetics; Switch opioids*
Sedation	Lower dose (if possible); Add nonsedating co-analgesic; Add stimulant or attention enhancer
Constipation	Treat prophylactically with stool softeners, bowel stimulants; Nonpharmacologic measures

*Opioid switching is an option for any adverse effect.

Swegle JM, et al. *Am Fam Physician*. 2006;74(8):1347-1354. Chou R, et al. *J Pain*. 2009;10(2):113-130.

Anticipating and Managing Adverse Effects



Adverse Effect	Treatment
Itching	Antipruritic therapy (eg, antihistamines)
Endocrine dysfunction/Reduced libido/Loss of menstrual period	Endocrine monitoring; Testosterone replacement; Endocrine consultation
Edema and sweating	Switch opioids*
Dizziness	Antivertigo agents
Confusion	Titrate dose

*Opioid switching is an option for any adverse effect.

Swegle JM, et al. *Am Fam Physician*. 2006;74(8):1347-1354; Chou R, et al. *J Pain*. 2009;10(2):113-130.

Anticipating and Managing Adverse Events

❖ Emerging issues

- Hyperalgesia
 - An increased response to a normally painful stimulus
 - May occur at higher doses
- Sleep
 - Central and obstructive sleep apnea
 - Sleep architecture

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 are 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

Referral Sources for Abuse and Addiction Treatment

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

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

Patient Counseling Document on Extended-Release / Long-Acting Opioid Analgesics	Patient Counseling Document on Extended-Release / Long-Acting Opioid Analgesics
Patient Name:	Patient Name:
The DOs and DON'Ts of Extended-Release / Long - Acting Opioid Analgesics	Patient Specific Information
DO: • Read the Medication Guide • Take your medicine exactly as prescribed • Store your medicine away from children and in a safe place • Flush unused medicine down the toilet • Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.	
Call 911 or your local emergency service right away if: • You take too much medicine • You have trouble breathing, or shortness of breath • A child has taken this medicine	
Talk to your healthcare provider: • If the dose you are taking does not control your pain • About any side effects you may be having • About all the medicines you take, including over-the-counter medicines, vitamins, and dietary supplements	
DON'T: • Do not give your medicine to others • Do not take medicine unless it was prescribed for you • Do not stop taking your medicine without talking to your healthcare provider • Do not break, chew, crush, dissolve, or inject your medicine. If you cannot swallow your medicine whole, talk to your healthcare provider. • Do not drink alcohol while taking this medicine	Take this card with you every time you see your healthcare provider and tell him/her: • Your complete medical and family history, including any history of substance abuse or mental illness • The cause, severity, and nature of your pain • Your treatment goals • All the medicines you take, including over-the-counter (non-prescription) medicines, vitamins, and dietary supplements • Any side effects you may be having
For additional information on your medicine go to: dailymed.nlm.nih.gov	Take your opioid pain medicine exactly as prescribed by your healthcare provider.

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/drugsafety/informationbydrugclass/ucm277916.pdf. Accessed February 23, 2013.

Counseling Patients and Caregivers (cont'd)



- Instruct patients to tell you about **all** medications they are taking
- Warn patients to never abruptly discontinue their ER/LA opioid
- Caution patients about all adverse effects
 - Specifically about signs and symptoms of respiratory depression, gastrointestinal obstruction, and allergic reactions
 - Instruct them on when and how to call you about side effects they experience so that you can work with them to manage
 - Side effects can be reported to FDA at 1-800-FDA-1088
- Caution patients to **never** share their ER/LA opioid with ANYONE
- Counsel patients about the risk of falls, working with heavy machinery and driving
- Advise patients to store their medication carefully and dispose of safely when no longer needed
 - Medication Guides typically include specific disposal information

Why is patient and caregiver education so important?

Patient Education and Counseling Works!

- ❖ Utah Department of Health statewide program demonstrated effectiveness of patient education to reduce unintentional deaths from prescription opioids
 - Media campaign “Use Only As Directed” from May 2008 to May 2009, including:
 - Television and radio spots
 - Distribution of opioid prescribing guidelines and copies of print materials (bookmarks, patient information cards, educational posters)
- ❖ Results:
 - In 2008-2009, 14% decrease in unintentional overdose deaths from prescription opioids compared with 2007

How to Counsel Patients to “Use Exactly as Prescribed”



THE “DOs”

- ❖ Tell your patients:
 - Read Medication Guide from dispensing pharmacy
 - Take your medicine exactly as prescribed
 - Store your medicine away from children and in a safe place
 - Flush unused medicine down the toilet
 - Call your health care provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088

How to Counsel Patients to “Use Exactly as Prescribed”



THE “DON’Ts”

- ❖ Tell your patients:
 - Do not give your medicine to others
 - Do not take medicine unless it was prescribed for you
 - Do not stop taking your medicine without talking to your health care provider
 - Do not break, chew, crush, dissolve, or inject your medicine. If you cannot swallow your medicine whole, talk to your health care provider
 - Do not drink alcohol while taking this medicine

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 www.er-la-opioidrems.com/lwgUI/rems/pcd.action

Patient Counseling Document on Extended-Release / Long-Acting Opioid Analgesics	Patient Counseling Document on Extended-Release / Long-Acting Opioid Analgesics
Patient Name:	Patient Name:
The DOs and DON'Ts of Extended-Release / Long - Acting Opioid Analgesics	Patient Specific Information
<u>DO:</u> - Read the Medication Guide - Take your medicine exactly as prescribed - Store your medicine away from children and in a safe place - Flush unused medicine down the toilet - Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.	
<u>Call 911 or your local emergency service right away if:</u> - You take too much medicine - You have trouble breathing, or shortness of breath - A child has taken this medicine	
<u>Talk to your healthcare provider:</u> - If the dose you are taking does not control your pain - About any side effects you may be having - About all the medicines you take, including over-the-counter medicines, vitamins, and dietary supplements	
<u>DON'T:</u> Do not give your medicine to others Do not take medicine unless it was prescribed for you Do not stop taking your medicine without talking to your healthcare provider Do not break, chew, crush, dissolve, or inject your medicine. If you cannot swallow your medicine whole, talk to your healthcare provider. Do not drink alcohol while taking this medicine	Take this card with you every time you see your healthcare provider and tell him/her: - Your complete medical and family history, including any history of substance abuse or mental illness - The cause, severity, and nature of your pain - Your treatment goals - All the medicines you take, including over-the-counter (non-prescription) medicines, vitamins, and dietary supplements - Any side effects you may be having
For additional information on your medicine go to: dailymed.nlm.nih.gov	Take your opioid pain medicine exactly as prescribed by your healthcare provider.

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 her medication
 - 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 Avinza 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 Avinza capsule (pellets) can be sprinkled on applesauce and then swallowed without chewing

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

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

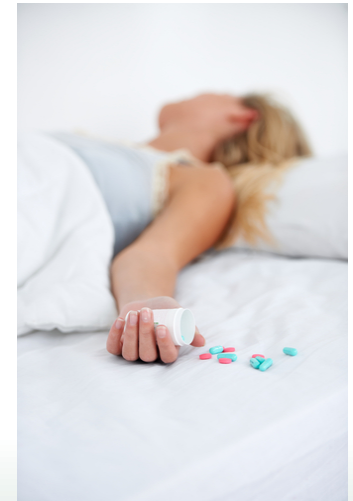
Discuss the Dangers of Abruptly Discontinuing Medication

- ❖ 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, hyperalgesia, insomnia

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
- ❖ Discuss:
 - Signs and symptoms of an overdose, such as: lethargy and somnolence, cognitive impairment
 - Opioid-induced respiratory depression
 - Risk for severe constipation and gastrointestinal obstruction
 - Emphasize the importance of healthy bowel habits: keeping hydrated, less sedentary
 - Possibility of allergic reactions



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
 - Miosis (contracted pupils)

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: 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
 - Tell her that sharing prescription medications is illegal



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/2k9results.htm. Accessed February 22, 2013.

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/2k9results.htm. Accessed February 22, 2013.

Disposing of ER/LA Opioids

- ❖ Counsel patients to dispose of any ER/LA opioid analgesics that are no longer needed
- ❖ Encourage them to read product-specific disposal information, including the Medication Guide
- ❖ Safe disposal methods include:
 - Dropping off medication at a DEA-designated drop box or take-back program
 - Removing medication from original bottles, mixing with used coffee grounds or kitty litter, and throwing it in the garbage
 - Flushing it down the toilet
 - Many patients believe that medications should NOT be flushed into the toilet or put into septic or sewer systems. Education can help them understand this is an appropriate disposal

DEA, Drug Enforcement Administration.

FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics. www.fda.gov/downloads/drugs/drugsafety/informationbydrugclass/ucm277916.pdf. Accessed February 23, 2013; Practical Pain Management. Opioid Disposal: Dos and Don'ts. www.practicalpainmanagement.com/opioid-disposal-dos-don-ts. Accessed January 8, 2013.