Patient Assessment for Treatment with ER/LA Opioid Analgesia

Module I

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Key Learning Points

1. A complete and thorough H&P including pain assessment is first step in the development of a treatment strategy for all pain patients
2. A variety of risk assessment tools are available for use in your practice, pick one you are comfortable with using that is appropriate in your practice environment
3. Special populations such as the elderly and children may require additional assessment monitoring
4. DOCUMENT all assessments, test results, patient interactions and treatment plans in your chart or EMR

Overall Program Learning Objectives

Upon completion of this initiative, prescribers will be better able to:

- **Identify and define how to assess patients for treatment with ER/LA opioid analgesics**
- Demonstrate how to initiate therapy, modify dose and discontinue use of ER/LA opioid analgesics
- Recognize how to manage ongoing therapy with ER/LA opioid analgesics
- Employ patient and caregiver counseling about the safe use of ER/LA opioid analgesics, including proper storage and disposal
- Recall general and product-specific drug information concerning ER/LA opioid analgesics

Patient Assessment

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Who Should Receive Opioid Therapy?

- More long-term success has been reported in patients who are stable psychosocially and whose pain is well controlled on low-to-moderate doses of opioids
- However, the success of opioid therapy cannot be reliably predicted by type or history of pain

Breivik H. *Eur J Pain*. 2005;9(2):127-130.

Initial Evaluation and Assessment of Pain

- Comprehensive clinical interview
  - Patient history
  - Physical examination
- Diagnostic studies
- Determination of nature of pain
  - Pain location, duration, intensity, type, patterns
  - Nociceptive, neuropathic, idiopathic components
    - Factors that reduce or intensify pain
- Assessment of comorbid states
- Impact of pain on function, mood, sleep
- Patient's expectations of treatment

Chou R, et al. *J Pain*. 2009;10(2):113-130.; Fishman S. *Responsible opioid prescribing: a physician's guide*. 2007.

Assessment of Risk of Abuse Including Substance Use and Psychiatric History

- Thorough assessment of psychosocial and family history
- Current and prior medical/psychiatric conditions; history of chemical dependence
- Previous use of pain medication
- Social environment and home situation
- Pain-related litigation/other legal issues

Fishman S. *Responsible opioid prescribing: a physician's guide*. 2007.

Factors Predicting Likelihood of Opioid Overuse/Misuse OR Abuse

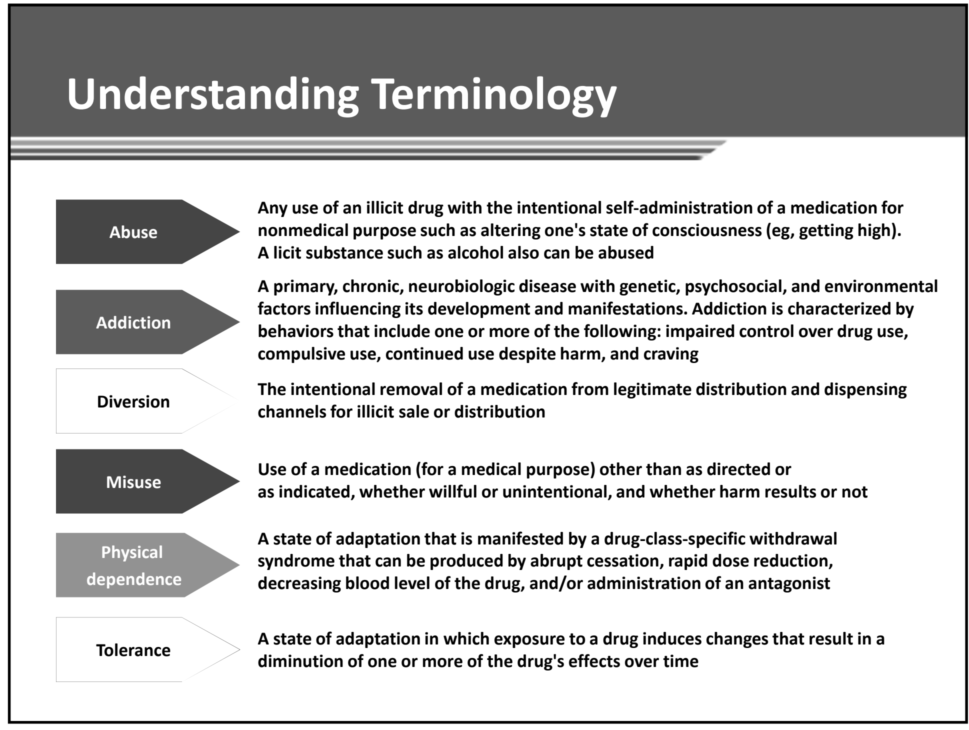
- Nonfunctional status due to pain[1]
- Exaggeration of pain[1]
- Unclear etiology for pain[1]
- Age[2]
- Smokers[2]
- Poor social support[3]
- Polysubstance abuse[3]
- Psychological stress[4]
- Psychological disease[2]
- Focus on opioids[1]
- Preadolescent sexual abuse[2]

[1]Alturi S, et al. *Pain Physician*. 2002;5(4):447-448. [2]Webster LR, et al. *Pain Med.* 2005;6(6):432-442. [3]Dunbar SA, et al. *Pain Symptom Manage*. 1996;11(3):163-171. [4]Savage SR. *Clin J Pain*. 2002;18(4 Suppl):S28-S38.

Audience Response Question

By definition, which of the following behaviors is not categorized as misuse?

A. Unsanctioned use (running out early; bingeing)
B. Accessing drugs from other sources (friend, the street, other doctors)
C. Reluctance to use other methods of pain management
D. Self-administration of medications to alter one’s state of consciousness (“get high”)



Chronic Use of Opioids: Associated Risks

- Overdose
- Abuse
- Misuse
- Addiction
- Physical dependence
- Tolerance
- Interactions with other medications and substances
- Inadvertent exposure by others in household, especially children

Rosenblatt RA, et al. *Ann Fam Med*. 2012;10(4)300-301.

Opioid Overdose

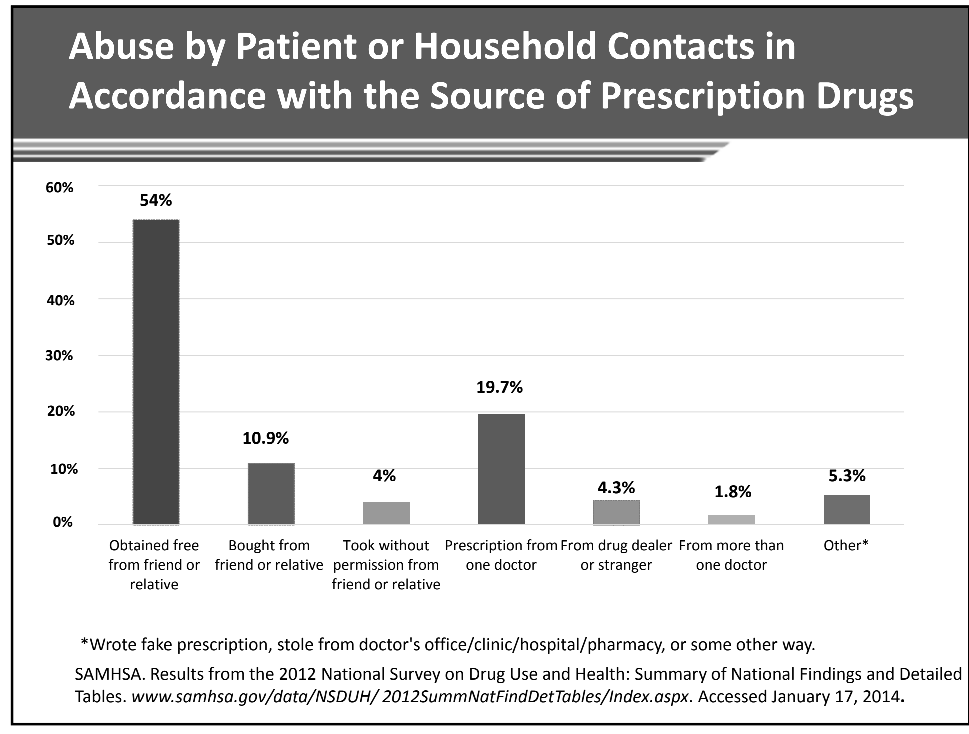
- Overdose with ER/LA formulations is a particular concern as most dosage units contain more opioid than immediate-release formulations

Paulozzi L. Epidemiology of the overdose epidemic. Common Threads in Pain and Addiction. Pain and Addiction Common Threads XIII. 43rd Annual Meeting of the American Society of Addiction Medicine, Atlanta, GA, April, 19, 2012.

Opioid Naïve versus Opioid Tolerance: FDA Definition

- 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

Refer to prescribing information on which products and which doses are indicated for use only in opioid tolerant patients.
www.fda.gov. Accessed February 12, 2014.



Inadvertent Exposure: Children

- In 2011, over 67% of Emergency Department visits for accidental drug ingestion involved children aged 5 and under
  - 6.7% of visits in children under 5 involved narcotic pain relievers
- Importance of counseling on safe storage/disposal
- Children are especially vulnerable

Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits *www.samhsa.gov/data/2k13/DAWN2k11ED/DAWN2k11ED.htm.* Accessed February 12, 2014.

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Risk Assessment Tools

- Risk assessment tools can be useful in evaluating potential risks of drug abuse, misuse, addiction, and diversion
- The tools differ in their formats, ease with which they may be administered, target populations, and the points during treatment when they may be most valuable

Audience Response Question

What tool do you currently use in your practice for risk assessment?

A. ORT
B. SOAPP
C. COMM
D. PHQ-9
E. I do not currently use a risk assessment tool

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Opioid Risk Assessment Tools:
Questionnaires for Patients Considered for Chronic Opioid Therapy

Opioid Risk Tool (ORT)	• 5 question; self-administered • Risk scoring: ***0-3 low; 4-7 moderate; ≥8***
Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R)	• 24 questions; usually self-administered • May be completed as part of an interview with a health care professional • Risk scoring: **Identifies patients as high, moderate or low risk for misuse of opioids**
Diagnosis, Intractability, Risk and Efficacy Score (DIRE)	• 7 questions; administered by health care professional • Risk scoring**: total score of 7-13 not suitable for long-term opioid therapy; score of 14-21 indicate patient may be candidate for long-term opioid therapy**

Butler SF, et al. *J Pain.* 2008;9(4):360-372.; Katz NP, et al. *Clin J Pain.* 2007;23(2):103-118.; Webster LR, Webster RM. *Pain Med*. 2005;6(6):432-442.; Manchikanti L, et al. *J Opioid Manag*. 2007;3(2):89-100.

Opioid Misuse Assessment Tools:
Questionnaires for Patients Once Opioid Treatments Begin

Pain Medication Questionnaire (PMQ)	• 26-item questionnaire; self-administered • Risk scoring: A total score of ≥25 is indicative of problematic use; a total score of ≥30 is indicative that patient should be monitored when prescribed opioid therapy
Current Opioid Misuse Measure (COMM)	• 17-item questionnaire; self-administered • Risk scoring: **A total score of ≥9 is positive for Current Opioid Misuse Measure (COMM); a total score of <9 is negative for Current Opioid Misuse Measure (COMM)**
Prescription Drug Use Questionnaire (PDUQ)	• 42-item questionnaire; administered by clinician • Risk scoring: **The patient answers yes and no questions about his or her pain condition, opioid use patterns, social and family factors, family history of pain and substance abuse syndromes, patient history of substance abuse, and psychiatric history** • **A score <11 'did not meet criteria for a substance disorder,' while those with a score of ≥15 'had a substance use disorder**

COMM. *www.etsu.edu/com/cme/documents/kptt2012/7-COMM_Final_SAMPLE.pdf.* Accessed February 12, 2014.; Butler SF, et al. *Pain*. 2007; 130(1-2): 144-156.

Opioid Risk Tool

Mark each box that applies	Female	Male
1. Family history of substance abuse		
Alcohol	❑ 1	❑ 3
Illegal drugs	❑ 2	❑ 3
Prescription drugs	❑ 4	❑ 4
2. Personal history of substance abuse		
Alcohol	❑ 3	❑ 3
Illegal drugs	❑ 4	❑ 4
Prescription drugs	❑ 5	❑ 5
3. Age (mark box if between 16 and 45 years)	❑ 1	❑ 1
4. History of preadolescent sexual abuse	❑ 3	❑ 0
5. Psychological disease		
ADD, OCD, bipolar, schizophrenia	❑ 2	❑ 2
Depression	❑ 1	❑ 1
Scoring totals	____	____

Administration
- ☐ Initial visit
- ☐ Prior to opioid therapy

Scoring
- ☐ 0-3 (6%): low risk
- ☐ 4-7 (28%): moderate risk
- ☐ ≥8 (91%): high risk

Percentages indicate proportion of classified patients who exhibited an aberrant behavior

ADD=attention-deficit disorder; OCD=obsessive-compulsive disorder.
Webster LR, Webster RM. *Pain Med.* 2005;6(6):432-442.

Monitoring Aberrant Behaviors and Adherence

Aberrant drug-related behaviors consist of a range of behaviors that suggest misuse by the patient and possibly a substance use disorder. Examples of aberrant drug-related behaviors are illustrated below

Behaviors that are weaker indicators ⟷ **Behaviors that are stronger indicators**

Behaviors that are weaker indicators
- Aggressively complaining about the need for medications/higher doses
- Drug hoarding during periods of reduced symptoms
- Requesting specific drugs
- Acquisition of similar drugs from other medical sources
- Unsanctioned dose escalation 1-2 times
- Unapproved use of the drug to treat another symptom
- Reporting psychic effects not intended by the clinician

Behaviors that are stronger indicators
- Injection of an oral formulation
- Selling prescription drugs
- Stealing or borrowing another patient’s drugs
- Obtaining prescription drugs from nonmedical sources
- Concurrent abuse of related illicit drugs
- Multiple unsanctioned dose escalations
- Recurrent prescription losses

Passik SD, et al. *Oncology (Williston Park).* 1998;12:517-521, 524.

Risk Factors for Aberrant Behaviors/Harm

Biological	Psychiatric	Social
Age ≤ 45 years Gender Family history of prescription drug or alcohol abuse Cigarette smoking	Substance use disorder Preadolescent sexual abuse (in women) Major psychiatric disorder (eg, personality disorder, anxiety or depressive disorder, bipolar disorder)	Prior legal problems History of motor vehicle accidents Poor family support Involvement in a problematic subculture

Katz NP, et al. *Clin J Pain.* 2007;23(2):103-118.; Manchikanti L, et al. *J Opioid Manag*. 2007;3(2):89-100.; Webster LR, Webster RM. *Pain Med*. 2005;6(6):432-442.

Risk Groups for Therapy

Low Risk	Moderate Risk	High Risk
• Mild-to-moderate pain • Absent mental health problems • Absent SA history • Strong self- esteem	• Intractable pain • Unrelieved stress • Poor coping skills • Inadequate social support	• Major mental health concerns • Personal and/or family history of SA • Age <50 • Smoker

Webster LR, Webster RM. *Pain Med* 2005;6(6):432-442.

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Special Considerations for the Elderly Patient

- Pain in the elderly population is especially difficult given the myriad of physiological, pharmacological, and psychological aspects of caring for the geriatric patient
- Challenges related to
  - Alterations in opiate pharmacokinetics which occur with normal physiologic aging
  - Polypharmacy
  - Comorbid conditions
  - Higher risk of opioid related adverse events
  - Respiratory depression is more likely
- Requires close monitoring during treatment:
  - Initiating and titrating ER/LA opioids (starting dose should be reduced to 1/3 to 1/2 of usual dosage in debilitated non-opioid tolerant patients)
  - Special attention to development of constipation
- Pay special attention to who will be managing patient's pain

Starting does should be reduced to 1/3 to 1/2 of usual dosage in debilitated non-opioid tolerant patients

Institute bowel prep pro-actively at the initiation of treatment

Chau DL, et al. *Clin Interv Aging.* 2008;3(2):273-278.

Special Considerations in Choosing to Treat Children: Pediatric Patients <18 Years Old

- The safety and effectiveness of most ER/LA opioids in children younger than 18 years have not been established, and most of these agents are not indicated for children
- An exception is transdermal fentanyl, which is approved in *opioid-tolerant* children ages 2 years of age and older*
- Pediatric pain specialists should be consulted when prescribing opioids to children for chronic pain or refer to a specialty multidisciplinary pain clinic

*Please refer to PI for complete prescribing information. Transdermal fentanyl is approved for children ages 2 years and older who are opioid tolerant.
Berde CB, et al. *Pediatrics*. 2012;129:354-364.

Treating a Chronic Pain Patient with a History of Substance Abuse, Psychiatric Issues and/or Drug Related Aberrant Behaviors

- History does not prohibit treatment with ER/LA opioid analgesics but may require additional monitoring and a clinician experienced in the management of this patient population
- May consider consultation with mental health professional and or addiction specialist

Von Korff M, et al. *Ann Intern Med.* 2011;155:325-328.

Stratify Patients with Chronic Pain to Determine Need for Referral

Risk Level	Management
Low	• Can be managed by PCP • If aberrant behaviors are observed, consider increasing risk category
Medium	• PCP co-manages with addiction and/or pain specialists • If aberrant behaviors are observed or persistent, consider assigning to high-risk category
High	• Opioids may not be appropriate in the PCP setting • Refer patient to specialists in management of patients with comorbid pain and addictive disorders • Continue to manage patient's medical care and monitor specialized care

Gourlay D, et al. *Pain Med*. 2005;6(2):107-112.; Gourlay D, et al. *Pain Med*. 2006;7:210-211;author reply 212.

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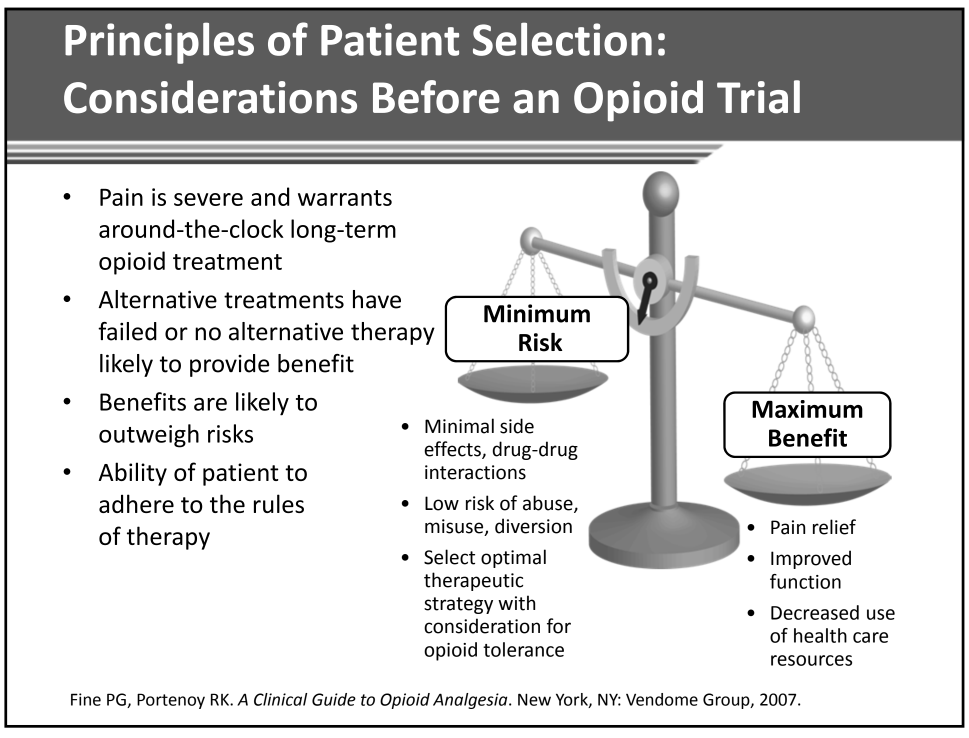
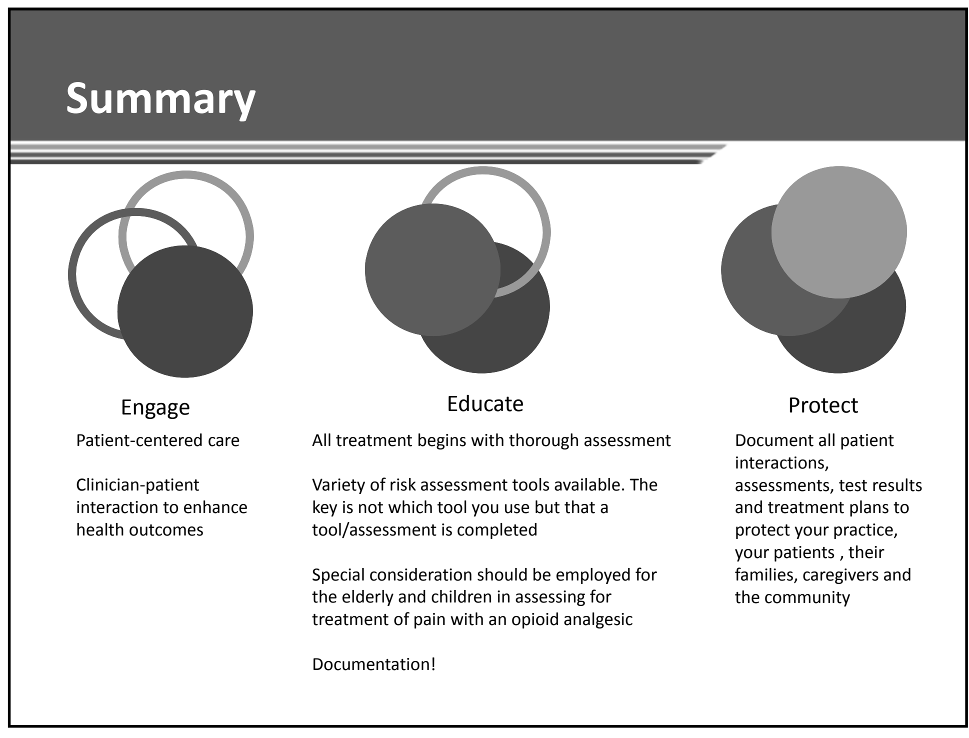


Importance of Proper Documentation

- Adequately document all patient interactions, assessments, test results and treatment plans



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You must answer the post-test questions at the end of this module before moving on to Module 2

You must complete all six modules in order to print your CE certificate