Prescription Drug Abuse: An Introduction
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These curriculum resources from the NIDA Centers of Excellence for Physician Information have been posted on the NIDA Web site as a service to academic medical centers seeking scientifically accurate instructional information on substance abuse. Questions about curriculum specifics can be sent to the Centers of Excellence directly, http://www.drugabuse.gov/coe.

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Prescription Drug Abuse Outline

1. Overview of Prescription Drug Abuse (PDA)

2. Framework for Safe Prescribing

3. Identifying PDA
1. Overview
Prescription Drug Misuse
(Definitions)

- Includes
  - Non-medical use
  - Substance abuse/PDA
  - Dependence
  - Addiction
  - Diversion

- Does NOT include physical dependence

Prescription Drug Misuse (Definitions)

- Additional notes provided for slide 4 (see below)

Opioid Dependence vs. Chronic Pain Managed with Opioids?

The diagnosis of Opioid Dependence requires 3 or more criteria occurring over 12 months:

1. Tolerance – **YES**
2. Withdrawal/physical dependence – **YES**
3. Taken in larger amounts or over longer periods – **MAYBE**
4. Unsuccessful efforts to cut down or control – **MAYBE**
5. Great deal of time spent to obtain substance – **MAYBE**
6. Important activities given up or reduced – **MAYBE**
7. Continued use despite harm – **MAYBE**

Aberrant Medication-Taking Behavior

A spectrum of patient behaviors that may reflect misuse

- Health care use patterns (e.g., inconsistent appointment patterns)
- Signs/symptoms of drug misuse (e.g., intoxication)
- Emotional problems/psychiatric issues
- Lying and illicit drug use
- Problematic medication behavior (e.g., noncompliance)

Implications
- Concern comes from the “pattern” or the “severity”
- Differential diagnosis

Addiction
Abuse/Dependence

Prescription Drug Misuse

Aberrant Medication-Taking Behaviors (AMTBs)
A spectrum of patient behaviors that may reflect misuse

Total Chronic Pain Population
Which Prescription Medications Are Most Likely to Be Abused?

Commonly Abused Medications

- Opioids
- CNS depressants
  - Benzodiazepines
  - Barbiturates
- Stimulants
- Others
Which Prescription Medications are Most Likely to Be Diverted?

Important Drug Characteristics

- Onset of action
- Intensity of effect
- Trade name > generic
- Cost and availability of illicit equivalent
Past Year Initiation of Non-medical Use of Prescription-type Psychopharmaceutics, Age 12 or Older: In Thousands, 2002-2008

Consequences of Prescription Opioid Abuse


[Bar chart showing trends in ED visits for hydrocodone and oxycodone combinations from 2004 to 2006.]

Another Factor Leading to Prescription Drug Misuse

• Physician Over-Prescribing
Why Do Some Physicians Over-Prescribe?

- Duped
- Dated
- Dishonest
- Medication mania
- Hypertrophied enabling
- Confrontation phobia

Why do some Physicians Under-Prescribe? “Opiophobia”

• Overestimate potency and duration of action
• Fear being scammed
• Often prescribe too small of a dose and too long of a dosing interval
• Exaggerate addiction potential

2. Framework for Safe Prescribing
What Is the Physician’s Role?

VS.
When Are Opioids Indicated?

- Pain is moderate to severe
- Pain has significant impact on function
- Pain has significant impact on quality of life
- Non-opioid pharmacotherapy has been tried and failed
- Patient agreeable to close monitoring of opioid use (e.g., pill counts, urine screens)
Opioid Efficacy in Chronic Pain

• Pain relief modest
  – Some statistically significant, others trend toward benefit
  – One meta-analysis decrease of 14 points on 100 point scale

• Limited or no functional improvement

• Most literature surveys & uncontrolled case series

• Randomized clinical trials (RCTs) are short duration < 4 months with small sample sizes < 300 pts

• Mostly pharmaceutical-company sponsored

The Risk-Benefit Framework: Judge the Treatment, not the Patient

**INAPPROPRIATE**

- Is the patient good or bad?
- Does the patient deserve pain meds?
- Should this patient be punished or rewarded?
- Should I trust him/her?

**APPROPRIATE**

Do the benefits of this treatment outweigh the untoward effects and risks in this patient or to society?
Assess Potential Benefit of Opioids

- Assess current function
- What can patient expect to do with opioids that s/he cannot do now?
- Set Specific, Measurable, Action-oriented, Realistic, Time-dependant (SMART) goals for next visit
- Think of opioid prescription as a TEST

Nicolaidis, C. Oregon Health and Science University, SGIM precourse, 2008.
Assess Potential Risks of Opioids

• Potential risks
  – Sedation, confusion, constipation, etc.
  – Addiction or diversion

• Characteristics that affect risk

• Use consistent approach, but set level of monitoring to match risk

Nicolaidis, C. Oregon Health and Science University, SGIM precourse, 2008.
What Is the Addiction Risk?

- Published rates of abuse and/or addiction in chronic pain populations are 3-19%\(^1\)

- Suggests that known risk factors for abuse or addiction in the general population would be good predictors for problematic prescription opioid use
  - Past cocaine use, history of alcohol or cannabis use\(^2\)
  - Lifetime history of substance use disorder\(^3\)
  - Family history of substance abuse, a history of legal problems and drug and alcohol abuse\(^4\)
  - Heavy tobacco use\(^5\)
  - History of severe depression or anxiety\(^5\)

Screening Instruments for Addiction Risk

- Specific for opioid prescription abuse
- Specific for other addictions (CAGE, “single” question for alcohol, NIDAMED, etc.)
Opioid Risk Tool

• Provides 5-item initial risk assessment
• Stratifies risk groups into low (6%), moderate (28%) and high (91%)
  – Family History
  – Personal History
  – Age
  – Preadolescent sexual abuse
  – Past or current psychological disease

• [Website Link]

Screening for Substance Use Disorders

CAGE

• Have you ever felt you should Cut down on your drinking?

• Have people Annoyed you by criticizing your drinking?

• Have you ever felt bad or Guilty about your drinking?

• Have you ever taken a drink first thing in the morning (Eye-opener) to steady your nerves or get rid of a hangover?

CAGE-AID

• Or drug use?

• Or drug use?

• Or drug use?

• Or used drugs?

Screening for Substance Abuse Disorders Using “Single” Questions

• “Do you sometimes drink beer, wine, or other alcoholic beverages? How many times in the past year have you had 5 (4 for women) or more drinks in a day?” (+ answer: > 0)

• “How many times in the past year have you used an illegal drug or used a prescription medication for non-medical reasons?” (+ answer: > 0)

Comprehensive Drug Use Screening and Assessment: NIDA-Modified ASSIST

- Interactive online screening tool, includes tobacco, alcohol, prescription, and illicit drugs

- Pre-screens patients for lifetime use
  - 4 questions about substance use in past 3 months; and
  - 2-3 follow-up questions for each substance used in lifetime

- Generates a numeric Substance Involvement score that suggests the level of medical intervention necessary

- NM\textsc{ASSIST} Clinicians Resource Guide, includes:
  - Step by step instructions for screening tool
  - Scripts on how to discuss drug use with patients; and
  - Information on biological specimen screening, sample progress notes/worksheets, additional resources, and links to treatment facility locators

\url{http://www.drugabuse.gov/nidamed/screening/}
Setting Goals: the Four A’s

• Analgesia
• Activities of daily living
• Avoid Adverse events
• Avoid Aberrant medication-related behaviors

Management of Opioid Therapy

• Assess and document benefits and harms

• To continue opioids:
  – There must be actual functional benefit
  – Benefit must outweigh observed or potential harms

• You do not have to prove addiction or diversion, only assess risk-benefit ratio

Nicolaidis, C. Oregon Health and Science University, SGIM precourse, 2008.
SAFE Score

• Clinician-generated
• Four domains over past month
  – Social functioning (marital, family, friends, etc.)
  – Analgesia (intensity, frequency, duration)
  – Physical functioning (work, ADLs, home, etc.)
  – Emotional functioning (stress, mood, etc.)
• Each scored on 5 point scale
  – 1 (Excellent) to 5 (Poor)
  – Total score 4 - 20
• Not validated

SAFE Score

• Green Zone (4-12)
  – Continue current medical regimen
  – Consider reducing total dose

• Yellow Zone (13-16 or 5 in any category)
  – Monitor closely
  – Reassess frequently

• Red Zone (&gt; 17)
  – Change treatment
Monitoring, Monitoring, Monitoring…

“Universal Precautions”

- Contracts/Agreement form
- Drug screening
- Prescribe small quantities
- Frequent visits
- Single pharmacy
- Pill counts

FSMB Guidelines, 2004
(http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf);
Contracts/Agreements/Informed Consent

PURPOSE:
• Educational and informational, articulate rationale and risks of treatment
• Articulate monitoring (pill counts, etc.) and action plans for aberrant medication-taking behavior
• Take “pressure” off provider to make individual decisions (Our clinic policy is…)
• Prototype: http://www.painedu.org

LIMITATIONS:
• Efficacy not well established (although no evidence of a negative impact on patient outcomes)
• No standard or validated form

Informed Consent

**PURPOSE:** A process of communication between a patient and physician that provides patients with the opportunity to ask questions to elicit a better understanding of the treatment or procedure, so that he or she can make an informed decision to proceed or to refuse a particular course of medical intervention.

American Medical Association. Office of General Counsel, March 2008
Informed Consent

SPECIFIC RISKS OF THE TREATMENT (long-term opioid use):

• Side effects (short and long term)
• Physical dependence, tolerance
• Risk of drug interactions or combinations (respiratory depression)
• Risk of unintentional or intentional misuse (abuse, addiction, death)
• Legal responsibilities (disposing, sharing, selling)

Monitoring: Pill (and Used Patch) Counts
Monitoring: Urine Drug Tests

Purpose
• Evidence of therapeutic adherence
• Evidence of non-use of illicit drugs

Results of study from pain medicine practice (n=122)
• 22% of patients had aberrant medication taking behaviors
• 21% of patients had NO aberrant behaviors BUT had abnormal urine drug test

Therefore, aberrant behavior and urine drug test monitoring are both important.

Monitoring: Urine Drug Tests

- Implementation Considerations
  - Know limitations of test and your lab
  - Be careful of false negatives and positives
  - Talk with the patient: “If I check your urine right now will I find anything in it?”
  - Random versus scheduled
  - Supervised, temperature strips, check Cr
  - Chain-of-custody procedures

Prescription Monitoring Programs

- State-instituted programs
- Electronic access to history of prescribed (and filled) scheduled drugs
  - Required pharmacy data reporting
- States vary
  - Reporting of Schedules (II or II-IV)
  - Response to inquiries: reactive or proactive
- Safeguards for patient confidentiality

www.deadiversion.usdoj.gov/faq/rx_monitor.htm
Status of State Prescription Drug Monitoring Programs (PDMPs)

- States with operational PDMPs
- States with enacted PDMP legislation, but program not yet operational

1 Washington has temporarily suspended its PMP operations due to budgetary constraints.
2 Legislation has been proposed in Wisconsin that, if passed, would establish a PDMP.

Not Enough Benefit?

- Reassess factors affecting pain
- Re-attempt to treat underlying disease and co-morbidities
- Consider escalating dose as a “test”
- No effect = no benefit; hence, benefit cannot outweigh risks – so STOP opioids (Okay to taper and reassess)

Nicolaidis, C. Oregon Health and Science University. SGIM precourse, 2008.
Too Much Risk?

Differential dx for aberrant medication – taking behavior, then match action to cause:

- Miscommunication of expectations: patient education
- Unrelieved pain: change of dosage or medication
- Addiction: referral to addiction treatment
- Diversion: STOP medication

Nicolaidis, C. Oregon Health and Science University. SGIM precourse, 2008.
Case

- 42-year-old male with h/o total hip arthroplasty (THA) presented for 1st time visit with c/o hip pain
- One year ago displaced left femoral neck fracture requiring THA with subsequent chronic hip pain
- Pain managed by his orthopedist initially with oxycodone and more recently with ibuprofen
- Recent extensive reevaluation of his hip pain was negative
Case continued

• Requested that his orthopedist prescribe something stronger like “oxys” for his pain as the ibuprofen was ineffective

• Told to discuss his pain management with his primary care physician (you)

• On disability since his hip surgery and lives with his wife and 2 children

• Denies current or past alcohol, tobacco, or drug use
Case continued

• Meds: Ibuprofen 800 mg TID

• Walks with a limp, uses a cane, vitals normal, 6 ft, 230 lbs

• Large, well-healed scar over the left lateral thigh/hip with no tenderness or warmth over the hip, full range of motion

• Doesn’t want to return to his orthopedist because “he doesn’t believe that I am still in pain”
Case continued

• In summary, 42-year-old man on disability with chronic hip pain who is requesting “oxycodone”

• Is he drug seeking?

• Are opioid analgesics indicated?
Is the Patient “Drug Seeking?”

• Directed or concerted efforts to obtain medication

• It is difficult to distinguish…

  …inappropriate drug-seeking from…

  …appropriate pain relief-seeking
3. Identifying Prescription Drug Abuse
Aberrant Medication-Taking Behavior more likely to be Suggestive of Addiction

- Deterioration in functioning at work or socially
- Illegal activities – selling, forging, buying from nonmedical sources
- Injection or snorting medication
- Multiple episodes of “lost” or “stolen” scripts
- Resistance to change therapy despite adverse effects
- Refusal to comply with random drug screens
- Concurrent abuse of alcohol or illicit drugs
- Use of multiple physicians and pharmacies
Aberrant Medication-Taking Behavior

*less likely* to be Suggestive of Addiction

- Complaints about need for more medication
- Drug hoarding
- Requesting specific pain medications
- Openly acquiring similar medications from other providers
- Occasional unsanctioned dose escalation
- Nonadherence to other recommendations for pain therapy
Current Opioid Misuse Measure (COMM™)

- 17-item self report for ongoing risk assessment
- Questions based on 6 primary concepts underlying medication misuse
- Helps to identify patients at high risk for current aberrant medication-taking behavior
- A high score raises concern for PDA but is NOT diagnostic

One Month Later

• He is currently taking oxycodone 5 mg 1 tablet every 6 hours (120/month) as you prescribed

• He rates his pain as “15” out of 10 all the time and describes no improvement in function

• Should you increase his dose of oxycodone?
Opioid Responsiveness/Resistance

- Degree of pain relief with
  - Maximum opioid dose
  - In the absence of side effects, e.g., sedation
- Not all pain is opioid responsive
  - Varies among different types of pain
    - Acute > Chronic
    - Nociceptive > Neuropathic
  - Varies among individuals
Pseudo-Opioid Resistance

- Some patients with adequate pain relief believe it is not in their best interest to report pain relief
  - Fear that care would be reduced
  - Fear that physician may decrease efforts to diagnose problem

Case continued

• Transition to sustained release morphine and signed controlled substance agreement

• After a stable period of several months, he surprises you by presenting without an appointment requesting an early refill

• Is he addicted?
Aberrant Medication-Taking Behavior
Aberrant Medication-Taking Behaviors
Differential Diagnosis

- Inadequate analgesia – “Pseudoaddiction”¹
- Disease progression
- Opioid resistant pain (or pseudo-resistance)²
- Addiction
- Opioid analgesic tolerance³
- Self-medication of psychiatric and physical symptoms other than pain
- Criminal intent – diversion

¹ Weissman DE, Haddox JD. 1989; ² Evers GC. 1997; ³ Chang et al. 2007.
Approaching Patient with Aberrant Medication-Taking Behavior

- Take non-judgmental stance
- Use open-ended questions
- State your concerns about the behavior
- Examine the patient for signs of flexibility
  - More focused on specific opioid or pain relief
- Approach as if they have a relative contraindication to controlled drugs (if not absolute contraindication)

Passik SD, Kirsh KL. J Supportive Oncology, 2005.
Discussing Lack of Benefit

• Stress how much you believe in/empathize with patient’s pain severity and impact
• Express frustration re: lack of good pill to fix it
• Focus on patient’s strengths
• Encourage therapies for “coping with” pain
• Show commitment to continue caring about patient and pain, even without opioid rx
• Schedule close follow-ups during and after taper
Discussing Possible Addiction

• Explain why aberrant behavior raises your concern for possible addiction

• Benefits no longer outweigh risks
  – “I cannot responsibly continue prescribing opioids as I feel it would cause you more harm than good.”

• Always offer referral to addiction treatment

• Stay 100% in “Benefit/Risk of Med” mindset
Stopping Opioid Analgesics

• Patient is not improving and may have opioid-resistant pain
• Some patients experience improvement in function and pain control when chronic opioids are stopped
• Patient may have a new problem – “opioid dependence (addiction)” and may need substance abuse treatment
• Be clear that you will continue to work on pain management using non-opioid therapy
• Taper patient slowly to prevent opioid withdrawal
Summary

• The use of opioid analgesic therapy requires careful assessment and tailored monitoring approaches.
• Diagnosing addiction during pain management is difficult and requires careful monitoring.
• Usual substance abuse risk factors probably apply to prescription opioid abuse.
• Manage lack of benefit by tapering opioids.
• Manage addiction by tapering opioids and referring to substance abuse treatment.