MEDICAL SCHOOL AND RESIDENCY PROGRAM
CURRICULUM RESOURCES ON DRUG ABUSE AND ADDICTION

# Prescription Drug Abuse: An Introduction

## Massachusetts NIDA Consortium

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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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NIDA Centers of Excellence for Physician Information

# 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

American Psychiatric Association. DSM IV-TR, 2000; Savage et al. J Pain Symptom Manage, 2003; Addiction Science and Clinical Practice, 2008; Weaver, Schnoll. J Addiction Medicine, 2007.

# Prescription Drug Misuse (Definitions)

- Additional notes provided for slide 4 (see below)

American Psychiatric Association. DSM IV-TR, 2000; Savage et al. J Pain Symptom Manage, 2003; Addiction Science and Clinical Practice, 2008; Weaver, Schnoll. J Addiction Medicine, 2007.

# 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**

American Psychiatric Association. DSM IV-TR, 2000.

# Aberrant Medication-Taking Behavior

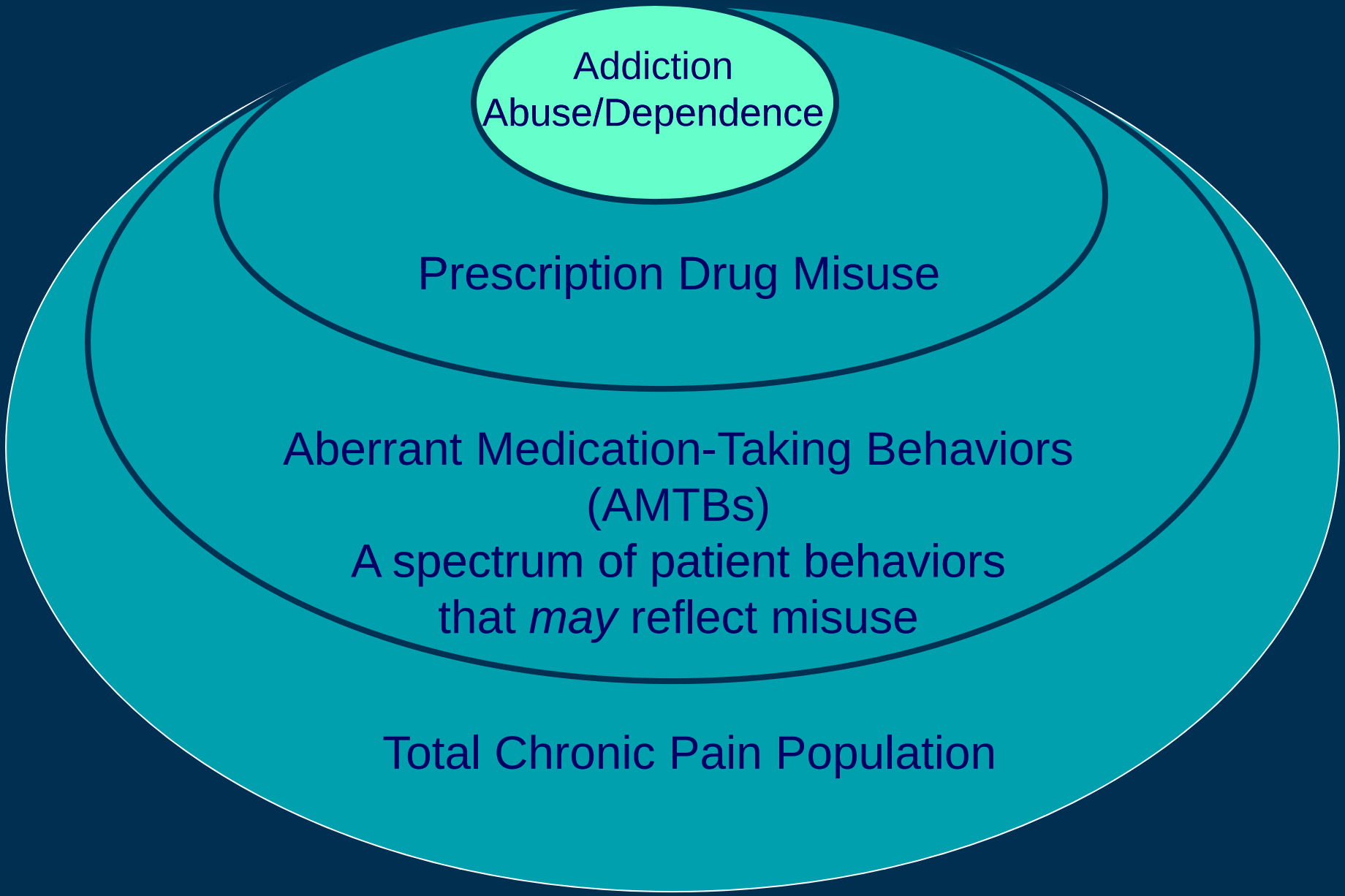
A spectrum of patient behaviors that may reflect misuse

- 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

Butler et al. Pain, 2007.


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

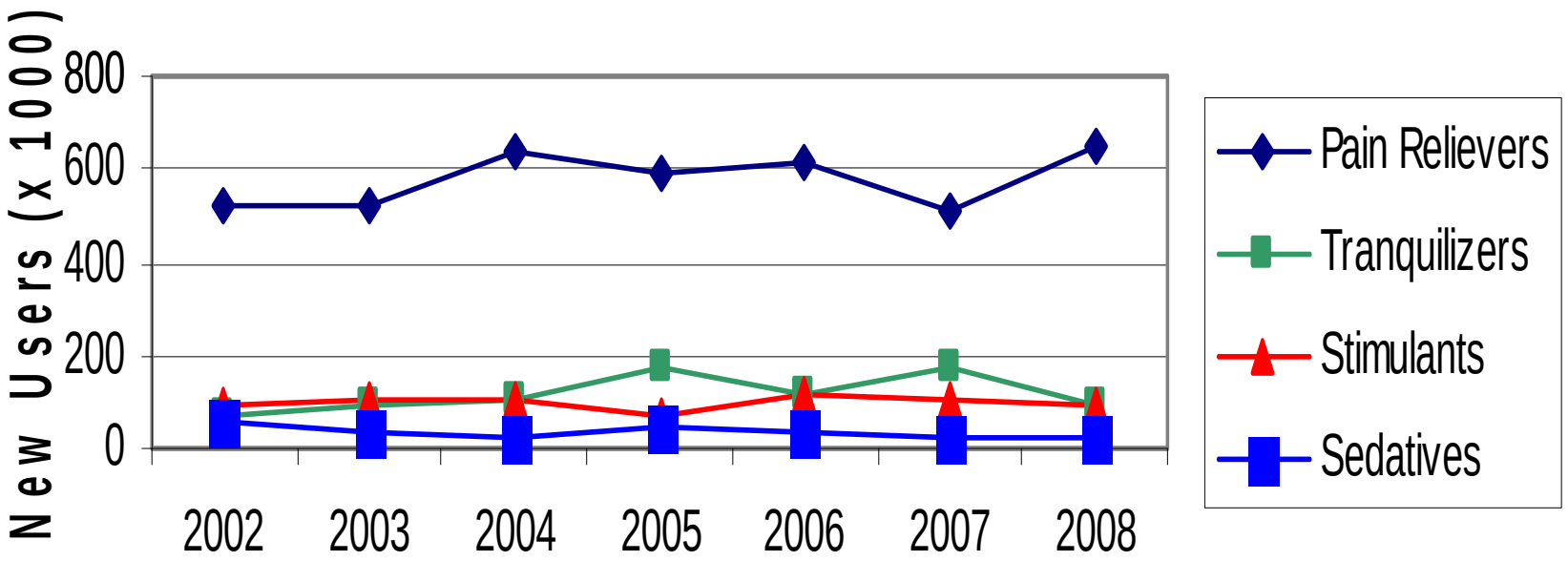
- Opioids
- CNS depressants
  - Benzodiazepines
  - Barbiturates
- Stimulants
- Others

# 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

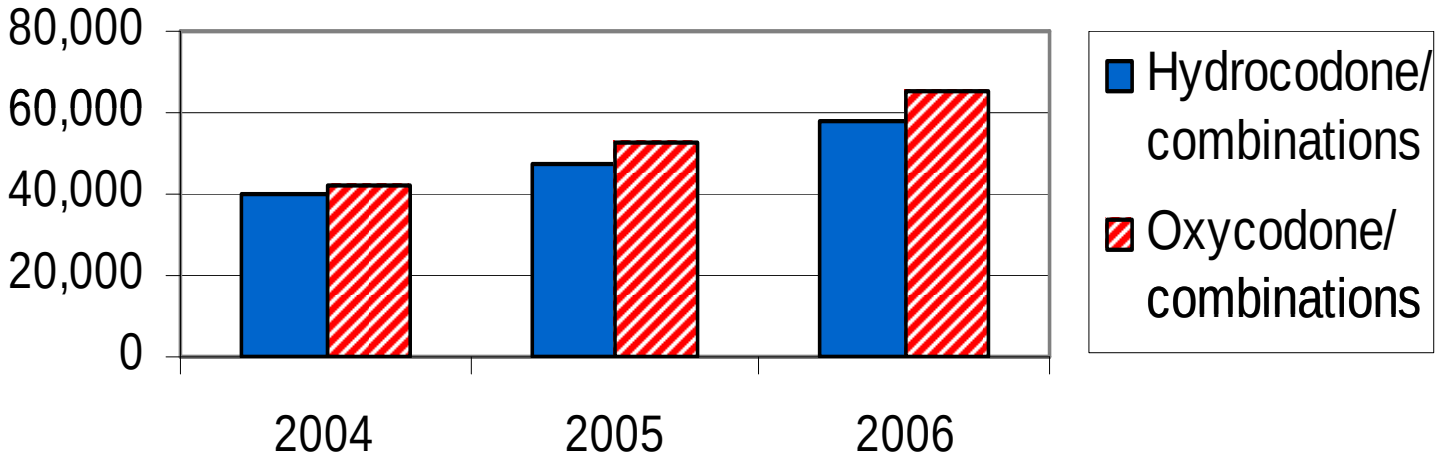
# Past Year Initiation of Non-medical Use of Prescription-type Psychopharmaceutics, Age 12 or Older: In Thousands, 2002-2008




SAMHSA Office of Applied Studies, NSDUH data, 2009.

# Consequences of Prescription Opioid Abuse

**Trends in drug abuse related ED visits involving hydrocodone and oxycodone, coterminous U.S. 2004-2006**




SAMHSA Office of Applied Studies, Drug Abuse Warning Network, 2008.

# 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

Smith DE, Seymore RB. Proc White House Conf on Prescription Drug Abuse,1980.
Parran T. Medical Clinics of North America, 1997.

# 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

Morgan, J. Adv Alcohol Subst Abuse, 1985.

# 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

Balantyne JC, Mao, J. N Engl J Med, 2003.
Martell et al. Ann Intern Med, 2007; Eisenberg et al. JAMA, 2005.

# 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]

[1] Fishbain et al. Clin J Pain, 1992; [2] Ives et al. BMC Health Services Research, 2006; [3] Reid et al. JGIM, 2002; [4] Michna el al. JPSM, 2004; [5]Akbik H., et al. JPSM, 2006.

# 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
- www.emergingsolutionsinpain.com

Webster, Webster. Pain Med, 2005.

# 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?

Mayfield et al. Am J Psych, 1974; Brown RL, Rounds LA. Wisconsin Med J, 1995.

# 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)*

NIAAA. Clinicians Guide to Helping Patients Who Drink Too Much, 2007.
Smith et al. Alcohol Clin Exp Res, 2007.

# 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**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

**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

Passik et al. Clin Ther, 2004.

# 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

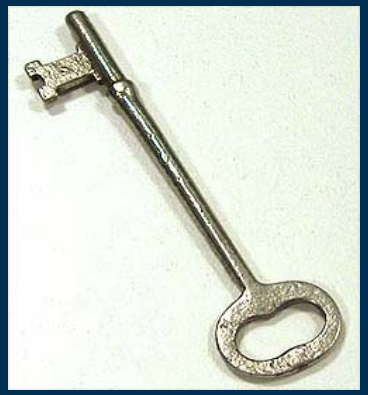
- Clinician-generated
- Four domains over past month
  - Social functioning (marital, family, friends, etc.)
  - Analgesia (intensity, frequency, duration)
  - Physical functioning (work, ADLs, home, etc.)
  - Emotional functioning (stress, mood, etc.)
- Each scored on 5 point scale
  - 1 (Excellent)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

Smith HS. J Cancer Pain Symptom Palliation, 2005.

# 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 (≥ 17)
  - Change treatment

Smith HS. J Cancer Pain Symptom Palliation, 2005.



# 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); Gourlay DL, Heit HA. Pain Med, 2005.

# 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

Fishman SM, Kreis PG. Clin J Pain, 2002; Arnold et al. Am J of Medicine, 2006.

# 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 (http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/patient-physician-relationship-topics/informed-consent.shtml).

# 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)

Paterick et al. Mayo Clinic Proc, 2008.

# 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.

Katz et al. Clinical J of Pain, 2002.

# 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

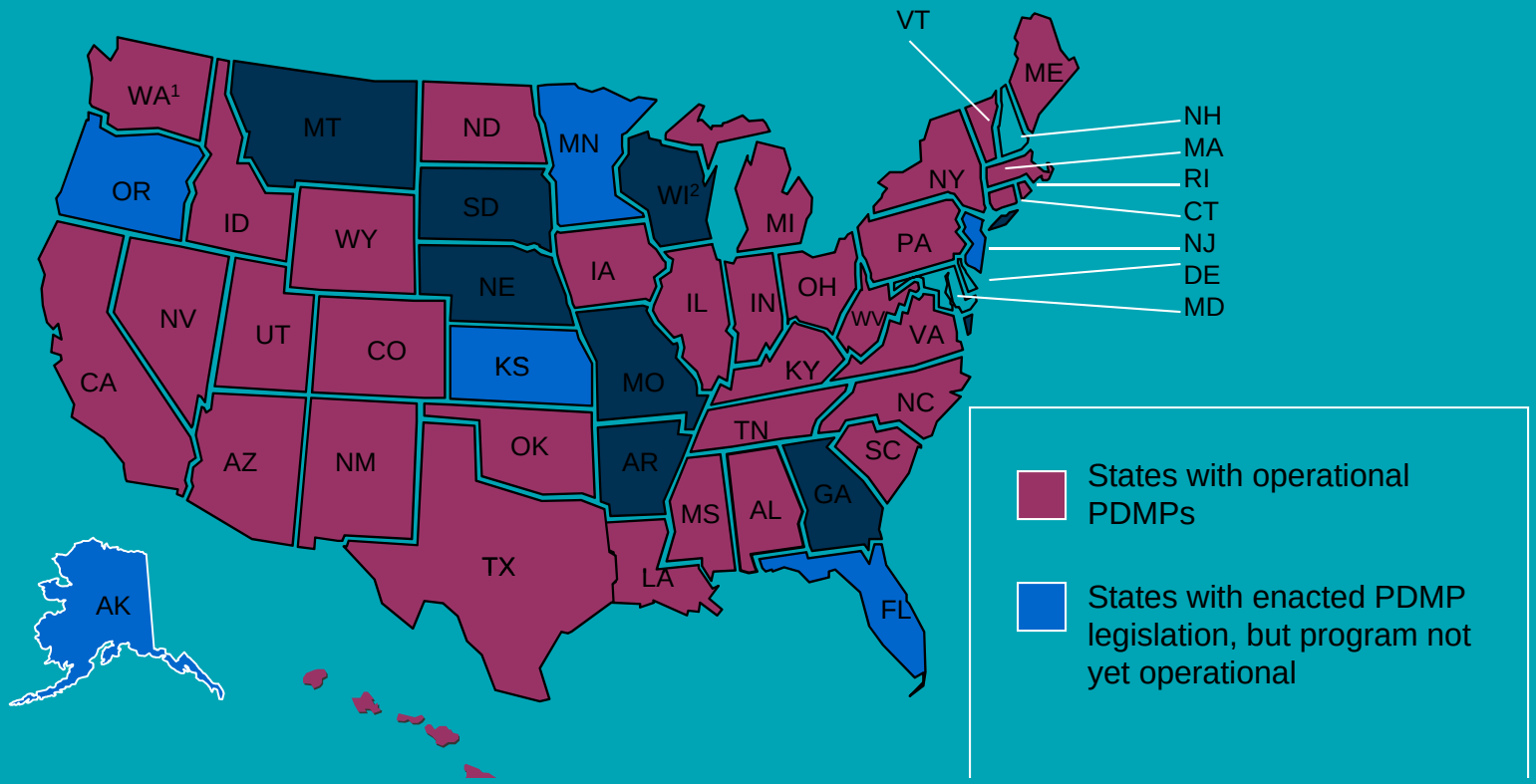
Gourlay DL, Heit HA, Caplan YH. Urine drug testing in primary care: Dispelling myths and designing strategies monograph (www.familydocs.org/files/UDTmonograph.pdf).

# 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)




[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.



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# 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

Vukmir RB. Am J Drug Alcohol Abuse, 2004.

# 3. Identifying Prescription Drug Abuse

# Aberrant Medication-Taking Behavior
## ***more likely*** *to be Suggestive of Addiction*

**Red Flags**

- 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*

**Yellow Flags**

- 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

Butler et al. Pain, 2007.

# 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

Evers GC. Support Care Cancer, 1997.

## 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 tolerance[3]
- 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