Chronic Pain and Opioid Risk Management

CRIT Program

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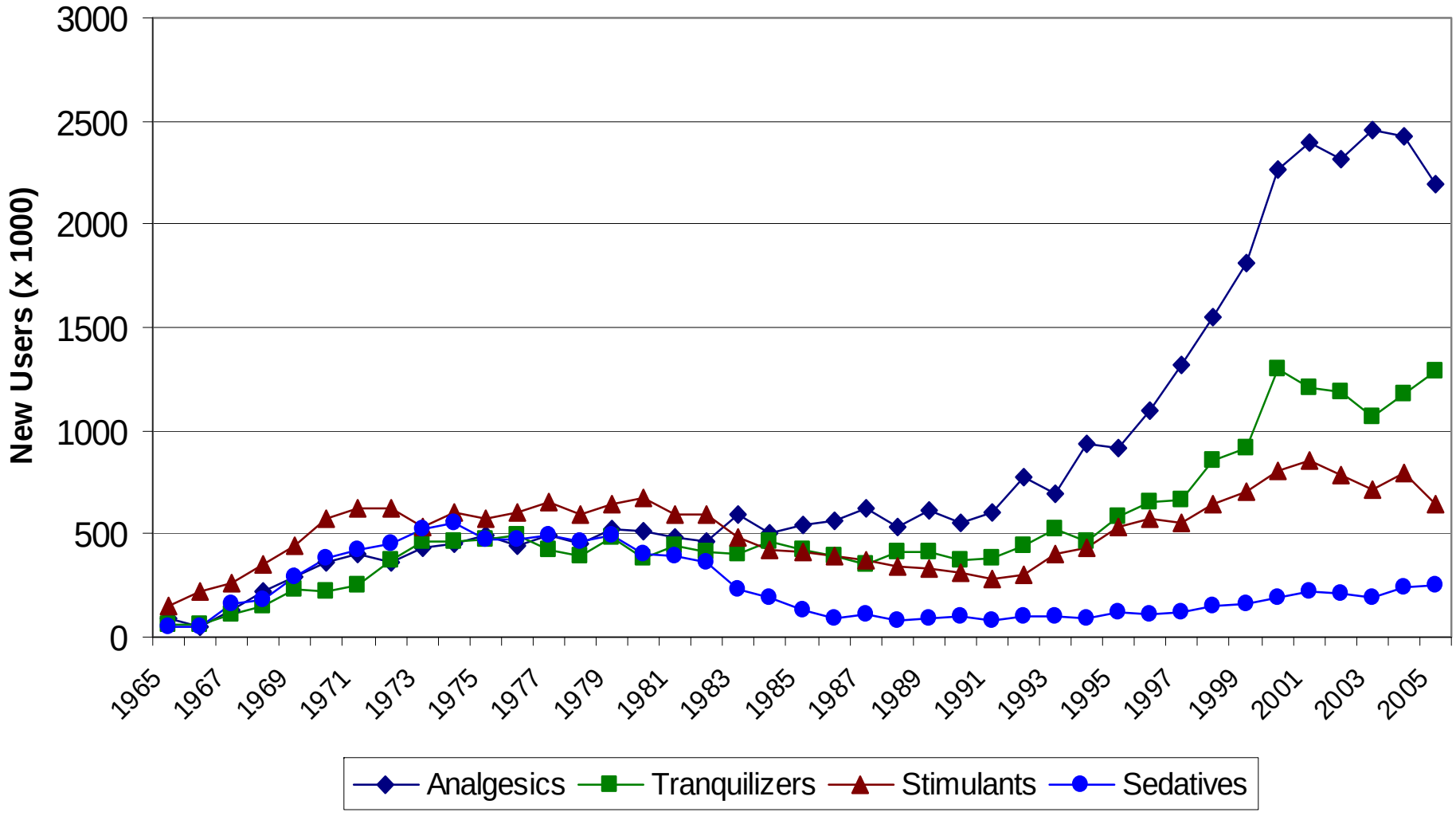
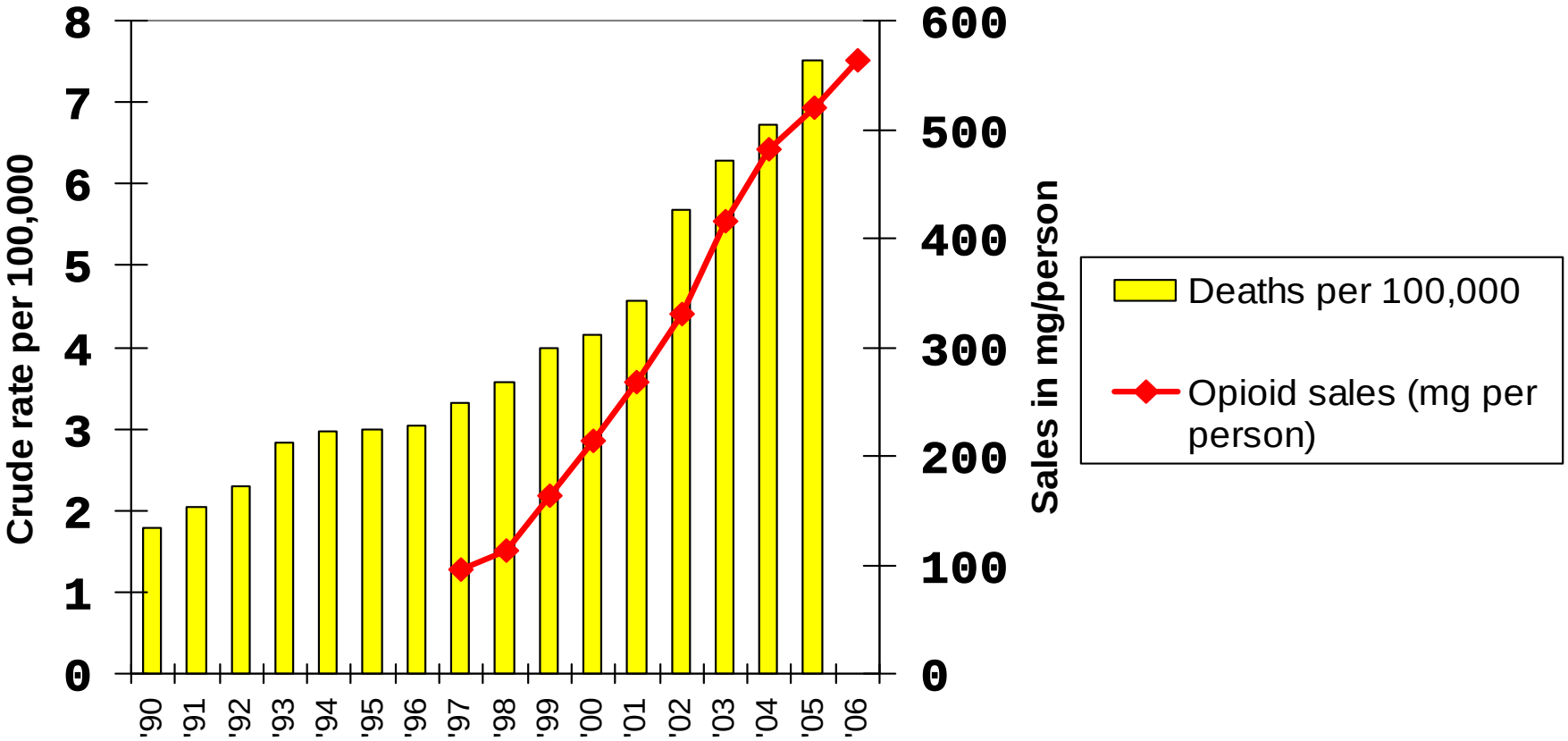
Exhibit 2: Past Year Initiation of Non-Medical Use of Prescription-type Psychopharmaceutics, Age 12 or Older: In Thousands, 1965 to 2005[1]

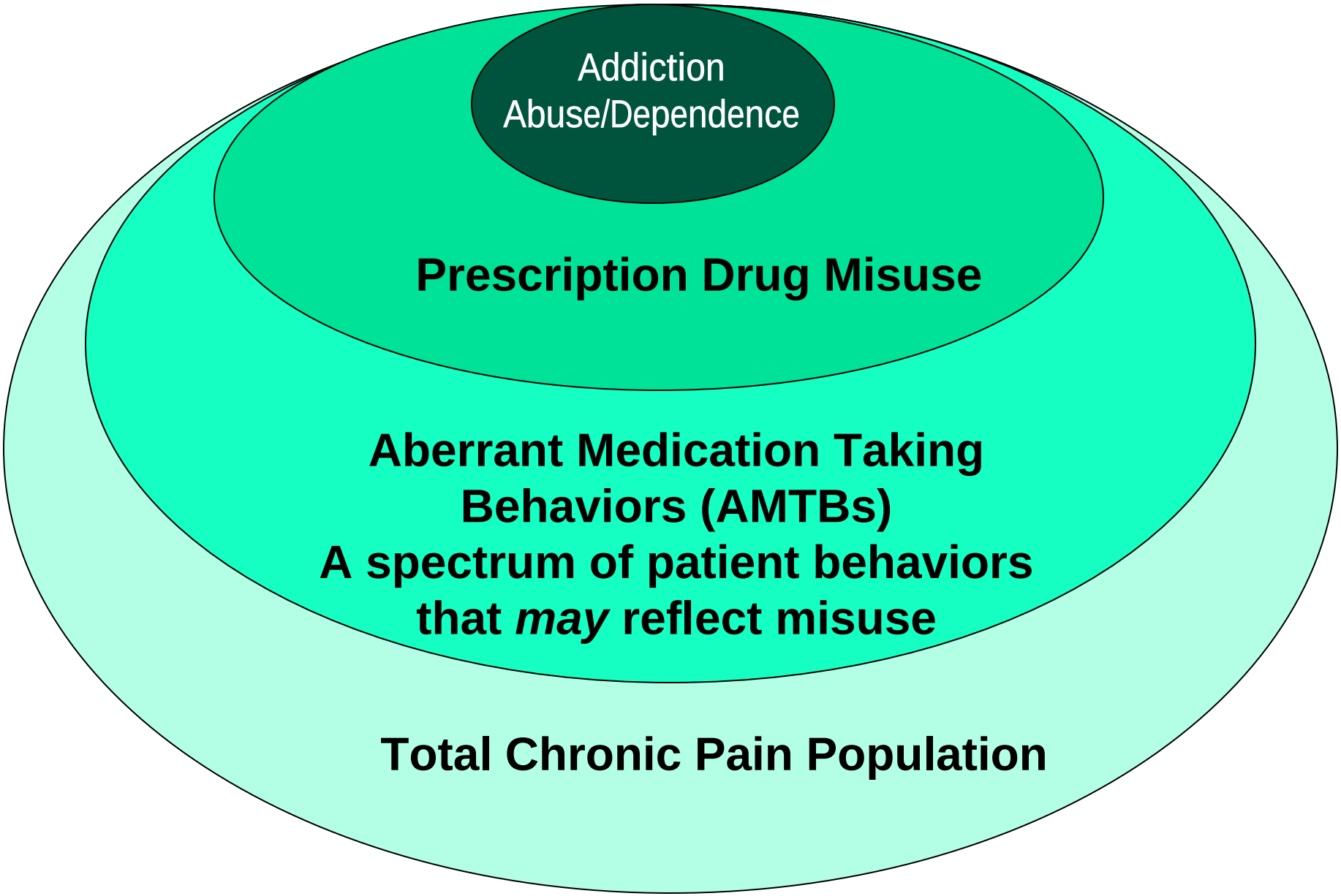


Source: SAMHSA, OAS, NSDUH data , July 2007

Deaths per 100,000 related to unintentional overdose and annual sales of prescription opioids by year, 1990 - 2006

Source: Paulozzi, CDC, Congressional testimony, 2007





Adapted from Passik. APS Resident Course, 2007

Physical Dependence vs. Opioid Dependence vs. Addiction

- Physical dependence
  - *Biological adaptation*
  - Signs and symptoms of withdrawal (e.g., pain) if opioid is abruptly stopped
- Addiction (4 **C’**s)
  - *Behavioral maladaptation*
  - Loss of **C**ontrol
  - **C**ompulsive use
  - **C**ontinued use despite harm
  - **C**raving
- Opioid Dependence (DSM IV)
  - *Behavioral +/- Biological*

Diagnosing Opioid Dependence*

Chronic Pain Patient on Long-term Opioids

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 period - **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

Less Likely *to be Predictive 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

Aberrant Medication Taking Behavior

More Likely *to be Predictive 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 of illicit drugs
- Use of multiple physicians and pharmacies

Opioid Risk Management

- Effort to minimize harms associated with opioid therapy while maintaining appropriate access to therapy
- Federal agencies (FDA, DEA, ONDCP, SAMHSA, NIDA)
- State agencies
- Healthcare payers
- Pharmaceutical Industry
- Healthcare providers

Katz NP et al. Clin J Pain. 2007;23:103-118

Physician Factors

- Duped
- Dated
- Dishonest

- Medication mania
- Hypertrophied enabling
- Confrontation phobia

- Opiophobia
  - Overestimate potency and duration of action
  - Fear of being scammed
  - Often prescribed with too small a dose and too long a dosing interval
  - Exaggerated fear of addiction potential

Morgan, J. Adv Alcohol Subst Abuse, 1985
Smith DE, Seymore RB. Proc White House Conf on Prescription Drug Abuse,1980
Parran T. Medical Clinics of North America 1997

Clinical Opioid Risk Management

- Pain and functional improvements
- “Universal Precautions” -evidence of aberrant medication taking behavior/misuse /addiction/diversion
  - Agreements/contracts
  - Drug testing
  - Pill/patch counts
  - Informed consents
  - Prescribe small quantities
  - Frequent visits
  - Single pharmacy
  - Establish a refill and cross coverage system

FSMB Guidelines 2004 www.fsmb.org,
Gourlay DL, Heit HA. Pain Medicine 2005

Agreements/Contracts

- Educational and informational, articulating rationale and risks of treatment
- Articulates monitoring (pill counts, etc) and action plans for aberrant medication taking behavior
- Takes “pressure” off provider to make individual decisions (Our clinic policy is…)
- Prototype http://www.painedu.org
- Efficacy not well established
- No standard or validated form
- No evidence they are detrimental

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

Informed Consent

Risk: exposure to a chance of injury or loss

- Side effects (short and long term)
  - physical dependence
- 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

Urine Drug Testing

- Purpose: Evidence of therapeutic adherence and evidence of non-use of illicit drugs
- Detailed hx of all medications (prescribed and OTC)
- Know limitations of test and 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

Urine Toxicology Monitoring in Patients on Opioids for Chronic Pain

		BEHAVIOR ISSUES		
		YES	**NO**	**TOTAL**
URINE TOX	**POSITIVE**	10 (8%)	26 (21%)	36 (29%)
	NEGATIVE	17 (14%)	69 (57%)	86 (71%)
	TOTAL	27 (22%)	95 (78%)	122

26/122 (21%) of patients had no aberrant behavioral issues BUT had abnormal drug screen

Katz NP et al. Clinical J of Pain 2002

Pill (and used Patch) Counts
Scheduled vs. Random

My strategy…

Give 4 week (28d) supply with f/u in 3 weeks for pill count

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/acetaminophen (Percocet®) and more recently with ibuprofen.
- Recent extensive reevaluation of his hip pain was negative.

Case continued

- Requested that his orthopedist prescribe something stronger like “Percocet” 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 a history of alcohol, tobacco or drug use.

Case continued

- Meds: Ibuprofen 800mg 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

- 42 year old man on disability with chronic hip pain who is requesting “Percocet”.

- Is he drug seeking?
- Should you prescribe opioid analgesics?
- If so, how should he be monitored?

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

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 have opioid use closely monitored (e.g. pill counts, urine screens)

Opioid Efficacy in Chronic Pain

- Most literature surveys & uncontrolled case series
- RCTs are short duration <4 months with small sample sizes <300 pts
- Mostly pharmaceutical company sponsored
- Pain relief modest
  - Some statistically significant, others trend towards benefit
  - One meta-analysis decrease of 14 points on 100 point scale
- Limited or no functional improvement

Balantyne JC, Mao J. NEJM 2003
Martell BA et al. Ann Intern Med 2007; Eisenberg E et al. JAMA. 2005

Addiction Risk

- Published rates of abuse and/or addiction in chronic pain populations are 3-19%
- 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, h/o alcohol or cannabis use[1]
  - Lifetime history of substance use disorder[2]
  - Family history of substance abuse, a history of legal problems and drug and alcohol abuse[3]
  - Heavy tobacco use[4]
  - History of severe depression or anxiety[4]

[1] Ives T et al. BMC Health Services Research 2006 [2] Reid MC et al JGIM 2002
[3] Michna E el al. JPSM 2004 [4]Akbik H et al. JPSM 2006

1 month later

- He is currently taking Percocet 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 Percocet?

Opioid Responsiveness/Resistance

- Degree of pain relief with
  - Maximum opioid dose
  - In the absence of side effects ie. 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

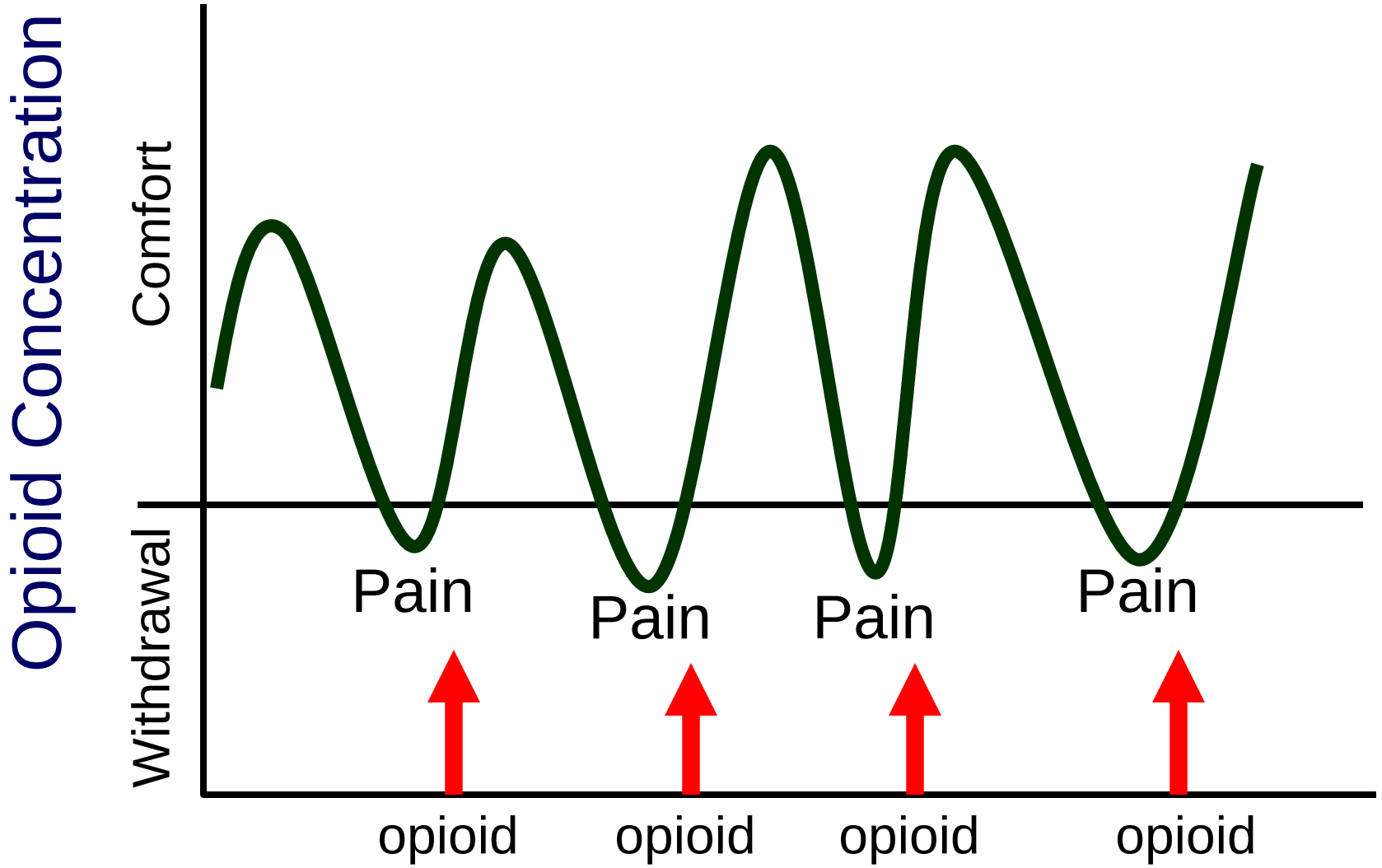
- Transition to sustained release morphine and signed controlled substance agreement.
- After a stable period of several months, he surprises you by presenting without an appointment requesting an an early refill.
- **Is he addicted?**

Aberrant Medication Taking Behaviors
Differential Diagnosis

- Inadequate analgesia – "Pseudoaddiction"[1]
  - Disease progression
  - Opioid resistant pain (or pseudo-resistance)[2]
  - Withdrawal mediated pain
  - Opioid-induced hyperalgesia[3]
- 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 C et al 2007

Withdrawal Mediated Pain



Approaching Patient with Aberrant Drug-taking Behavior

- 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, if not absolute, contraindication to controlled drugs

Passik SD, Kirsh KL. J Supportive Oncology 2005

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

- Prescription opioid misuse and unintentional overdoses have increased
- Opioid physical dependence does not equal opioid dependence or addiction
- Opioid analgesic therapy should be carefully monitored using universal precautions
- Not all aberrant medication taking behavior equals addiction
- Manage lack of benefit by tapering opioids
- Manage addiction by tapering opioids and referring to substance abuse treatment