Chronic Pain and Opioid Risk Management

CRIT Program

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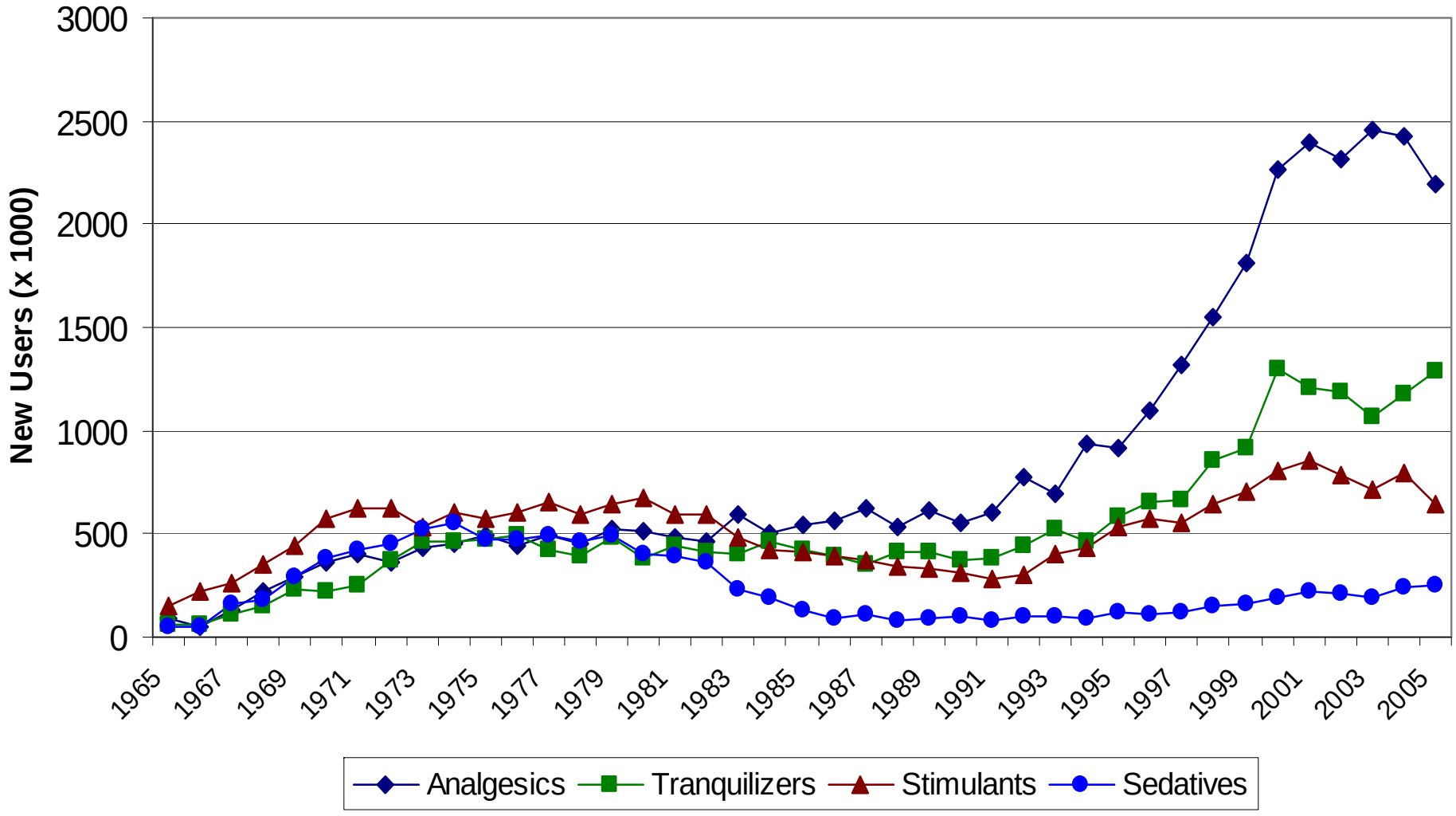
GENERAL INTERNAL MEDICINE

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

Physician Factors

- Duped
- Dated
- Dishonest

- Medication mania
- Hypertrophied enabling
- Confrontation phobia

- Opiophobia
  - Overestimate potency and duration of action
  - Fear of being scammed
  - 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

Addiction is…

- A clinical syndrome presenting as…
  - Loss of **C**ontrol
  - **C**ompulsive use
  - **C**ontinued use despite harm
  - **C**raving

  } **Aberrant Medication Taking Behaviors**

- **NOT** physical dependence
  - Biological adaptation with signs and symptoms of withdrawal (e.g., pain) if opioid is abruptly stopped

Aberrant Medication Taking Behavior

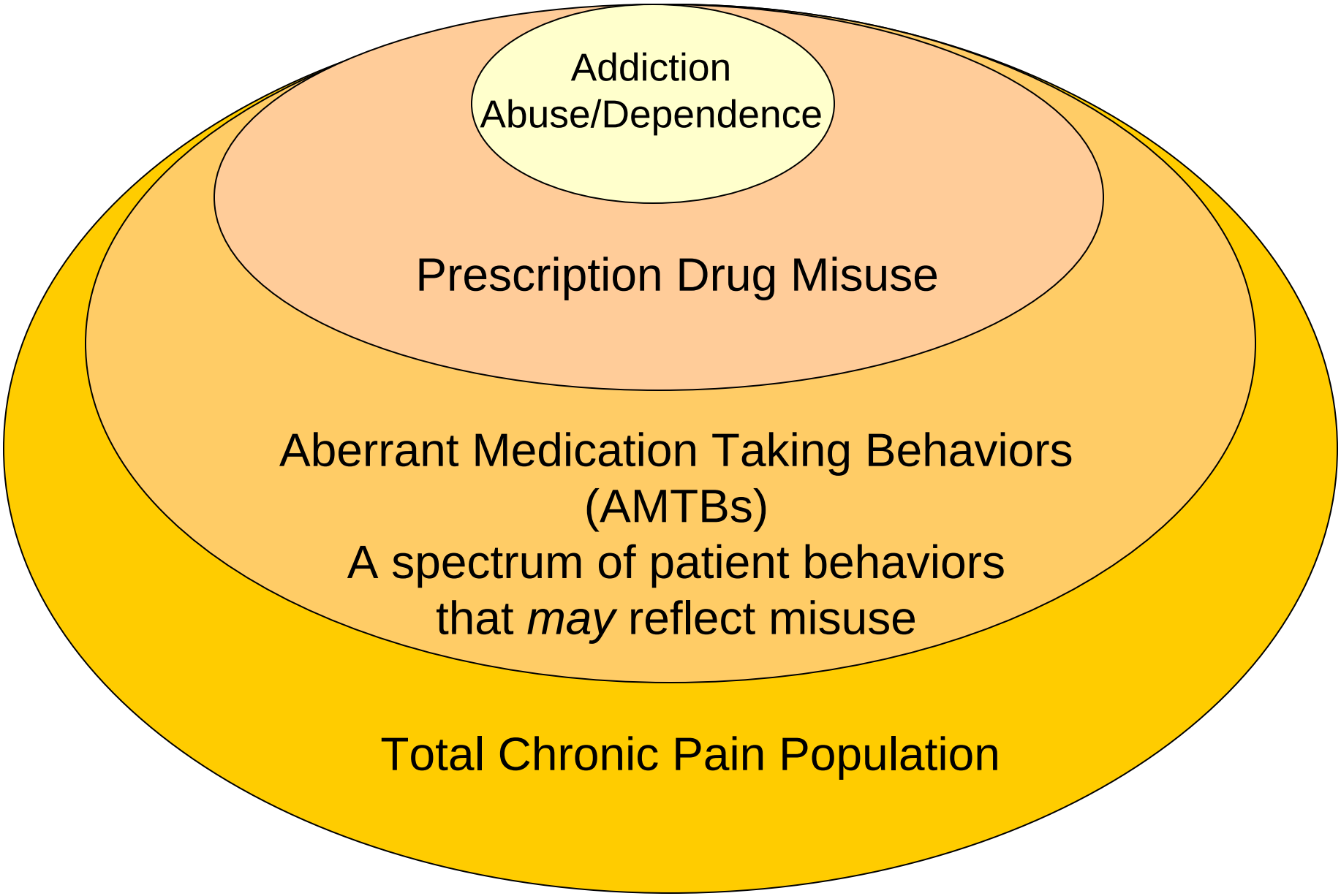
A spectrum of patient behaviors that may reflect misuse:

- 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

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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

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

Monitoring for Benefit & Risk

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

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

Discussing Monitoring

- Discuss risks of opioid medications
- Assign responsibility to look for early signs of harm
- Discuss agreements, pill counts, drug tests, etc. as ways that you are helping to protect patient from getting harmed by medications
  - Statin - LFT monitoring analogy
- Use consistent approach, but set **level of** monitoring to match risk

Would you manage hypertension without measuring blood pressure?

Benefit Assessment

PEG (Pain, Enjoyment, General activity) scale (0-10)

1. What number best describes your Pain on average in the past week? *(No pain - Pain as bad as you can imagine)*
2. What number best describes how, during the past week, pain has interfered with your Enjoyment of life? *(Does not interfere-Completely interferes)*
3. What number best describes how, during the past week, pain has interfered with your General activity? *(Does not interfere – Completely interferes)*

Krebs EE, et al. J Gen Intern Med. 2009

Opioid Risk Assessment: **SOAPP® - SF**

Screener & Opioid Assessment for Patients with Pain

- Evaluate for relative risk for developing problems (e.g. aberrant medication taking behaviors) – 86% sensitive, 67% specific

0=Never, 1=Seldom, 2=Sometimes, 3=Often, 4=Very often

1. How often do you have **mood swings**?
2. How often do you **smoke a cigarette** within an hour after you wake up?
3. How often have you taken **medication other than the way it was prescribed**?
4. How often have you used **illegal drugs** (for example, marijuana, cocaine, etc) in the past 5 years?
5. How often, in your lifetime, have you had **legal problems** or been arrested?

≥ 4 is POSITIVE

< 4 is NEGATIVE

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Agreements/Contracts

- Educational and informational, articulating rationale and risks of treatment
- Articulates monitoring (UDT, pill counts) & action plans for aberrant medication taking behavior
- Takes “pressure” off provider to make individual decisions (Our clinic policy is…)
- 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

- Side effects
  - physical dependence
  - sedation
- Drug interactions
- Risk of misuse
  - abuse, addiction, death
- Legal responsibilities
  - disposing, sharing

Monitoring…

Yellow Flags

Aberrant Medication Taking Behavior

<u>Less Likely</u> to be Predictive 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

Monitoring…

Red Flags

Aberrant Medication Taking Behavior

<u>More Likely</u> to be Predictive 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 of illicit drugs
- Use of multiple physicians and pharmacies

Monitoring
Urine Drug Tests

- **Evidence of therapeutic adherence**
- **Evidence of non-use of illicit drugs**

- Know limitations of test and your lab
- Know a toxicologist/clinical pathologist
- Complex patient-physician communication
- My strategies
  - Try to avoid sending the test… *"If I check your urine right now will I find anything in it?"*
  - Keep it open ended… *"Your urine was positive for drugs, what happened?"*

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

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 test

Katz NP et al. Clinical J of Pain 2002

Monitoring
Pill Counts

- Confirm medication adherence
- Minimize diversion
- My strategies…
  - 28 day (rather than 30 day) supply
  - If patient “forgets” pills, schedule return visit with in a week

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 a history of alcohol, tobacco or drug use.

Case continued

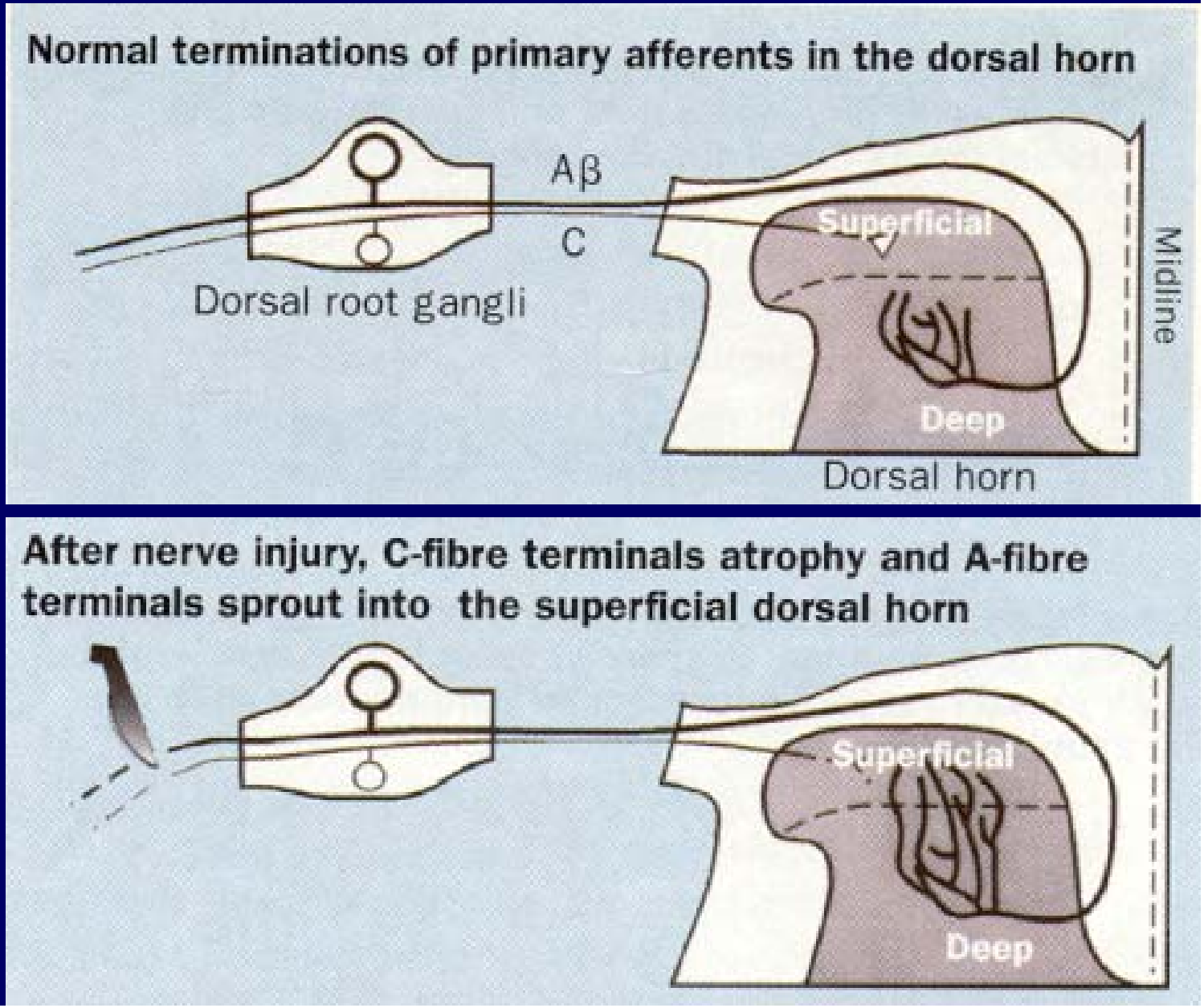
- Meds: Ibuprofen 800mg TID
- Walks with a limp, uses a cane, vitals normal, 6 ft, 230 lbs.
- Large well-healed scar over the left lateral thigh/hip with no tenderness or warmth over the hip, full range of motion.
- Doesn’t want to return to his orthopedist because “he doesn’t believe that I am still in pain.”

Case summary

- 42 year old man on disability with chronic hip pain who is requesting oxycodone.

- **Is his pain real? Is he pain relief seeking?**
- **Is he addicted? Is he drug seeking?**
- Should you prescribe opioid analgesics?
- If so, how will you know if they are helping him?

Is his pain real?



Woolf CJ. Lancet 1999

Is the patient “drug seeking?”

- 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 drug tests)

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
- Limited or no functional improvement

Balantyne JC, Mao J. NEJM 2003
Kalso E et al. Pain 2004
Eisenberg E et al. JAMA. 2005
Furlan AD et al. CMAJ 2006
Martell BA et al. Ann Intern Med 2007

Opioid Test/Trial

- We lack strong accurate predictors:
  - Who will experience lasting benefit
  - Who will be harmed

- We do have good evidence that a 3-month trial is safe (*with no contraindications*)
  - If not continued past the point of obvious failure

Opioid Choice

- Duration and onset of action
  - "Rate hypothesis" - fast on, fast off – most rewarding - addicting
- Patient's prior experience
  - *Mu* polymorphisms – differences in opioid responsiveness
- Route of administration
- Side effects and Cost
- **Currently there are NO abuse resistant opioids or opioid formulations!!**

1 month later

- He signed controlled substance agreement.
- He is currently taking oxycodone 5 mg 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

- 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
  - Varies among individuals
- Emerging research – allelic variants in the genes involving opioid and nonopioid systems, drug-metabolizing enzymes and transporters

Smith HS. Pain Physician 2008

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

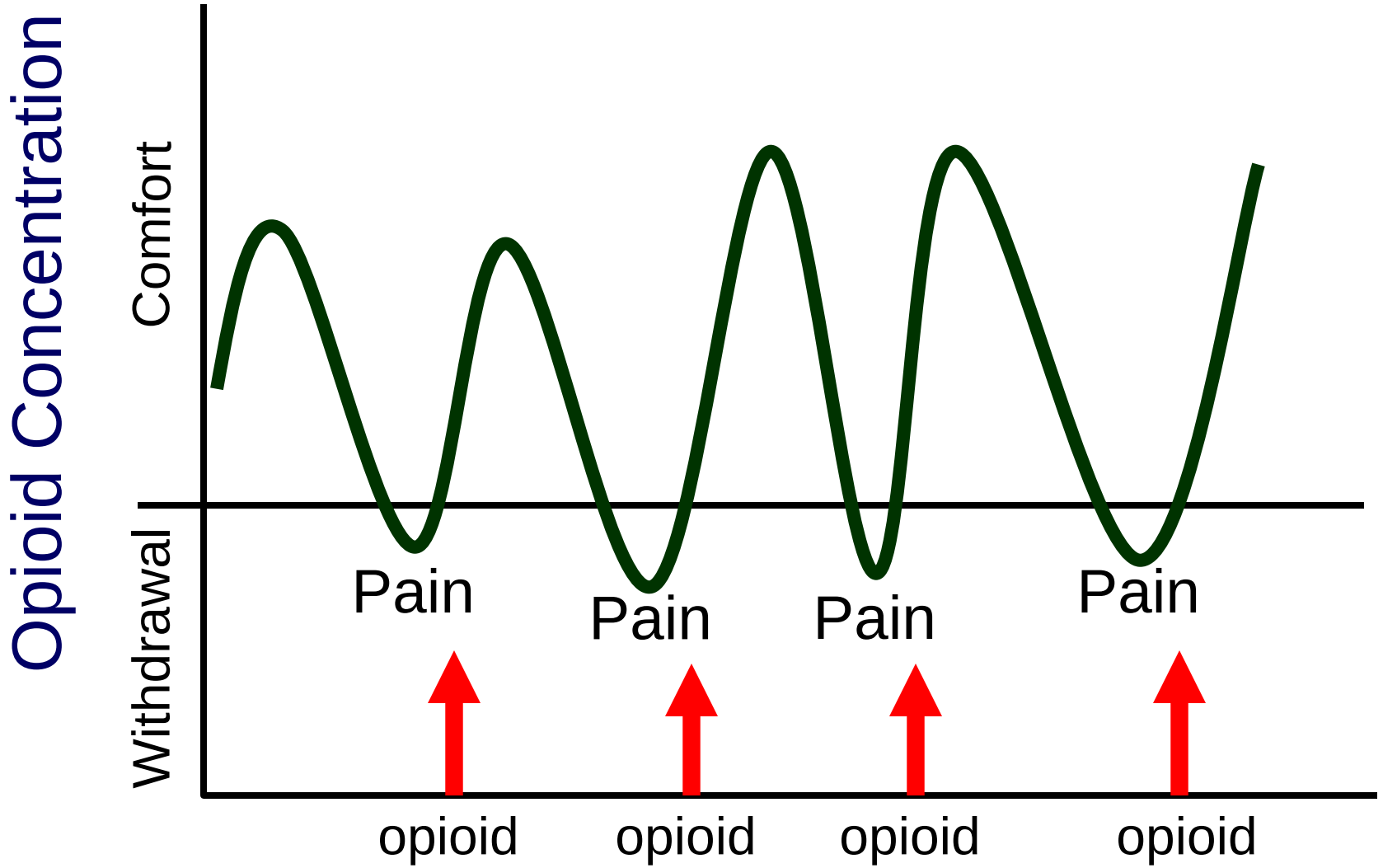
- Transition to sustained release morphine
- After a stable period of several months, he surprises you by presenting without an appointment requesting an an early refill.
- **Is he addicted?**

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 Medication-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 more 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

Continuation of Opioids

- You must convince yourself that there is benefit
- Benefit must outweigh observed harms
- If small benefit, consider increasing dose as a **“test”.**
- If no effect = no benefit, hence benefit cannot outweigh risks – so STOP opioids. (Ok to taper and reassess.)
- You do not have to prove addiction or diversion – only assess Risk-Benefit ratio

Exit Strategy
Discussing Lack of Benefit

- Stress how much you believe / 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 opioids
- Schedule close follow-ups during and after taper

Exit Strategy
Discussing Possible Addiction

- Give feedback: Explain why patient's behaviors raises your concern for possible addiction.
- Benefits no longer outweighing 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

- Some patients experience improvement in cognitive function and pain control when chronic opioids are stopped
- Patient has a new problem – “opioid dependence (addiction)” and should be treated or referred for 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

Exit Strategy
Avoiding Pitfalls

- How can you use framework to respond to?
  - But I really, really need opioids.
  - Don’t you trust me?
  - I thought we had a good relationship / I thought you cared about me?
  - If you don’t give them to me, I will drink / use drugs / hurt myself.
  - Can you just give me enough to find a new doc?

Summary

- Prescription opioid misuse has increased
- Opioids can be effective and safe but are imperfect
- Opioid physical dependence does not equal opioid dependence (addiction)
- Use consistent “universal” approach
- Not all aberrant medication taking behavior equals addiction
- If there is benefit in the absence of harm, continue opioids
- Manage lack of benefit by tapering opioids
- Manage addiction by tapering opioids and referring to addiction treatment