Opioids and Chronic Pain

CRIT/FIT 2012

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CARE
Clinical Addiction Research and Education

Preamble

- "Treating pain is neither an absolute science nor risk free" *(Scott M. Fishman, MD Anesthesia & Analgesia. 2007)*
- For the past decade increases in opioid prescribing have coincided with increases in unintentional opioid overdoses
- **WARNING**…A controversial statement follows…
  - I strongly believe that physicians can be trained to prescribe opioids for chronic pain **safely** and **effectively**

The Problem...unrealistic expectations

More unrealistic expectations…

Opioids = Pain Relief

therefore

More Opioids = More Pain Relief

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David Bogan, chronic pain sufferer

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 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

Issues Preventing Opioid Prescribing

n=111

Potential for patients to become addicted	**89%**
Potential for patients to sell or divert	**75%**
Opioid side effects	**53%**
Regulatory/law enforcement monitoring	**40%**
Hassle and time required to track/refill	**28%**

Upshur CC et al. J Gen Intern Med 2006

What is the Addiction Risk?

- Published rates of abuse and/or addiction in chronic pain populations are 3-19%
- Known risk factors for addiction to any substance are good predictors for problematic prescription opioid use
  - Past cocaine use, h/o alcohol or cannabis use
  - Lifetime history of substance use disorder
  - Family history of substance abuse, a history of legal problems and drug and alcohol abuse
  - Tobacco dependence
  - History of severe depression or anxiety

Akbik H et al. JPSM 2006
Ives T et al. BMC Health Services Research 2006
Liebschutz JM et al. J of Pain 2010
Michna E el al. JPSM 2004
Reid MC et al JGIM 2002

What is the Overdose Risk?

Risk of fatal overdose seems directly related to the maximum prescribed daily opioid

- Doses (MSO_4 equivalents) 50-99 mg/d had a **3.7-fold increase** in overdose risk
- Doses ≥100 mg/d had an **8.9-fold increase** in overdose risk with a 1.8% annual overdose rate

Dunn KM et al. Ann Intern Med 2010
Braden JB et al. Arch Intern Med 2010
Bohnert ASB et al. JAMA 2011

Is my patient's chronic pain real?

- There are no "pain meters" & vital signs are not reliable
- Pain is subjective to the patient & to the examiner
- It is difficult to distinguish **inappropriate** drug-seeking from **appropriate** pain relief-seeking
- **There is no way on the first visit(s) to know for certain if the patient's pain is real or not**

Is the my patient addicted?

- Physical dependence
  - *Biological adaptation*
  - Signs and symptoms of withdrawal (e.g., pain) if opioid is abruptly stopped

- Addiction (3 **C**'s)
  - *Behavioral maladaptation*
  - Loss of **C**ontrol
  - **C**ompulsive use
  - **C**ontinued use despite harm

} **Aberrant Medication Taking Behaviors** *(Pattern & Severity)*

- Opioid Dependence (DSM IV)
  - *Behavioral maladaptation+/- Biological*

Aberrant Medication Taking Behaviors

The Spectrum of Severity

- Requests for increase opioid dose
- Requests for specific opioid by name, “brand name only”
- Non-adherence w/ other recommended therapies (e.g., PT)
- Running out early (i.e., unsanctioned dose escalation)

Aberrant Medication Taking Behaviors
Differential Diagnosis

- Inadequate analgesia – “Pseudoaddiction”
  - Disease progression
  - Withdrawal mediated pain
  - Opioid-induced hyperalgesia
- Addiction
- Opioid analgesic tolerance??
- Self-medication of psychiatric and physical symptoms other than pain
- Criminal intent - diversion

Weissman DE, Haddox JD. 1989
Evers GC. 1997
Chang C et al 2007

When Are Opioids Indicated?

- Pain is moderate to severe
- Pain has significant impact on function and on quality of life
- Non-opioid pharmacotherapy has been tried and failed
- **Patient agreeable to…**
  - **take opioid as prescribed (e.g. no dose escalation)**
  - **close monitoring (e.g. pill counts, urine drug testing)**

Variability in Response to Opioids

Mu Receptor

- G protein-coupled receptor family, signal via second messenger (cAMP)
- >100 polymorphisms in the human MOR gene
- Mu receptor subtypes
  - Not all patients respond to same opioid in same way
  - Not all pain responds to same opioid in the same way
  - Incomplete cross-tolerance between opioids

Opioid Safety

- Allergies are rare
- Side effects are common
  - Nausea, **sedation**, constipation
  - Urinary retention, sweating
- Organ toxicities are rare
  - Hypothalamic-pituitary-gonadal axis - ↑prolactin, ↓ LH, FSH, testosterone, estrogen, progesterone
- Overdose especially when combined w/ other sedatives

Opioid Choice

- Duration and onset of action
  - "Rate hypothesis" - fast on, fast off – most rewarding – addicting
  - Short-acting opioids increase risk of opioid-withdrawal mediated pain
- Patient's prior experience
  - *Mu* polymorphisms – differences in opioid responsiveness
- **Currently there are NO abuse resistant opioids or opioid formulations!!**

Key Principles

- Maintain benefit-risk (harm) framework
- Judge the treatment NOT the patient

Assessing Benefit - Risk/Harm
"Universal Precautions"
(not evidence-based but has become "standard" of care)

- Agreements "contracts", informed consent
- Monitor for benefit and harm with frequent face-to-face visits
- Monitor for adherence, addiction and diversion
  - Urine drug testing
  - Pill counts
  - Prescription monitoring program data

FSMB Guidelines 2004 www.fsmb.org
Gourlay DL, Heit HA. Pain Medicine 2005
Chou R et al. J Pain 2009

Assessing Benefit

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

What number best describes your Pain on average in the past week? *(No pain - Pain as bad as you can imagine)*

What number best describes how, during the past week,

- **pain has interfered with your Enjoyment of life?** *(Does not interfere-Completely interferes)*
- **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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Discussing Monitoring with Patients

- 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
  - Thiazide diuretic - K monitoring analogy
- Use consistent approach, but set **level of** monitoring to match risk

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, but necessary, patient-physician communication
  - If I send your urine right now, what will I find in it…
  - Your urine drug test was abnormal, can you tell me about it…
- Document time of last medication use
- Inappropriate interpretation of results may adversely affect clinical decisions

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

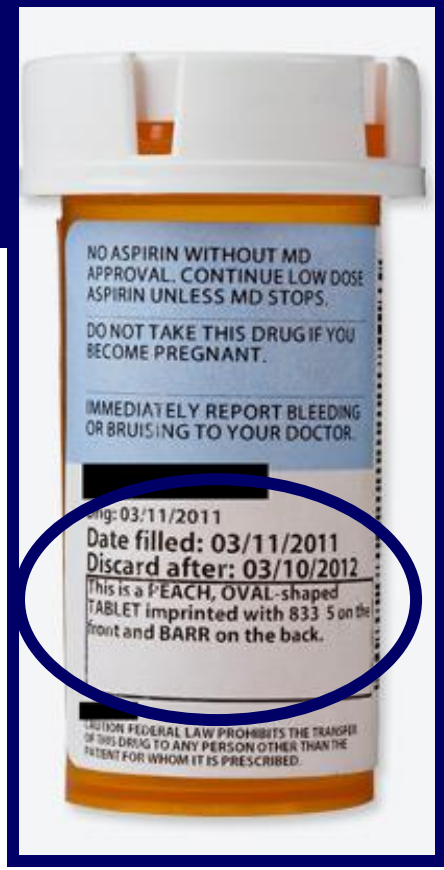
Urine Toxicology Monitoring in Patients on Opioids for Chronic Pain

		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
  - All patients expected to bring remaining pills at each visit
    - If patient “forgets” pills, schedule return visit with in a week
  - For “high risk” patient, use random call-backs

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 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 i.e., you are abandoning (discharging) an ineffective treatment, **not** the patient
- Schedule close follow-ups during and after taper

Lindsey Beecher

Boston University School of Medicine

Age: 43

Marital status: Married

Children: 1 son age 22, 1 granddaughter age 2

Occupation: Elementary school teacher

Pain issue: Chronic painful diabetic neuropathy

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This is an early follow-up visit scheduled after the patient was seen in an outside ER over the weekend

Lindsey Beecher

Boston University School of Medicine

Current Pain Medications:

Methadone 20mg 3 times per day

Neurontin 600mg 3 times per day

She has an up-to-date controlled substances agreement that outlines the need for adherence with close monitoring, including urine drug tests, pill counts and taking her medications exactly as prescribed including NOT increasing her dose without first discussing it with her primary care physician.

Lindsey Beecher

Boston University School of Medicine

She went to an ER on Saturday night after running out of her methadone after doubling her dose because her pain was unbearable. The ER physician scheduled a follow up visit with her primary care physician the following week.

A review of the State on-line prescription monitoring program data confirmed that she was prescribed 30 tablets of methadone 20 mg by the ER physician which she did not disclose to her primary care physician during the visit.

Lindsey Beecher

Boston University School of Medicine

Clinician Tasks:

- Discuss patient's aberrant medication taking behaviors (unsanctioned dose escalation, lack of compliance with pill count)
- Discuss the apparent lack of benefit (9-10 out of 10 pain) and increased risk (over-sedation) of methadone
- Discuss the need for tapering patient's methadone and treating pain with nonopioids and nonpharmacotherapy

Exit Strategy
Discussing Possible Addiction

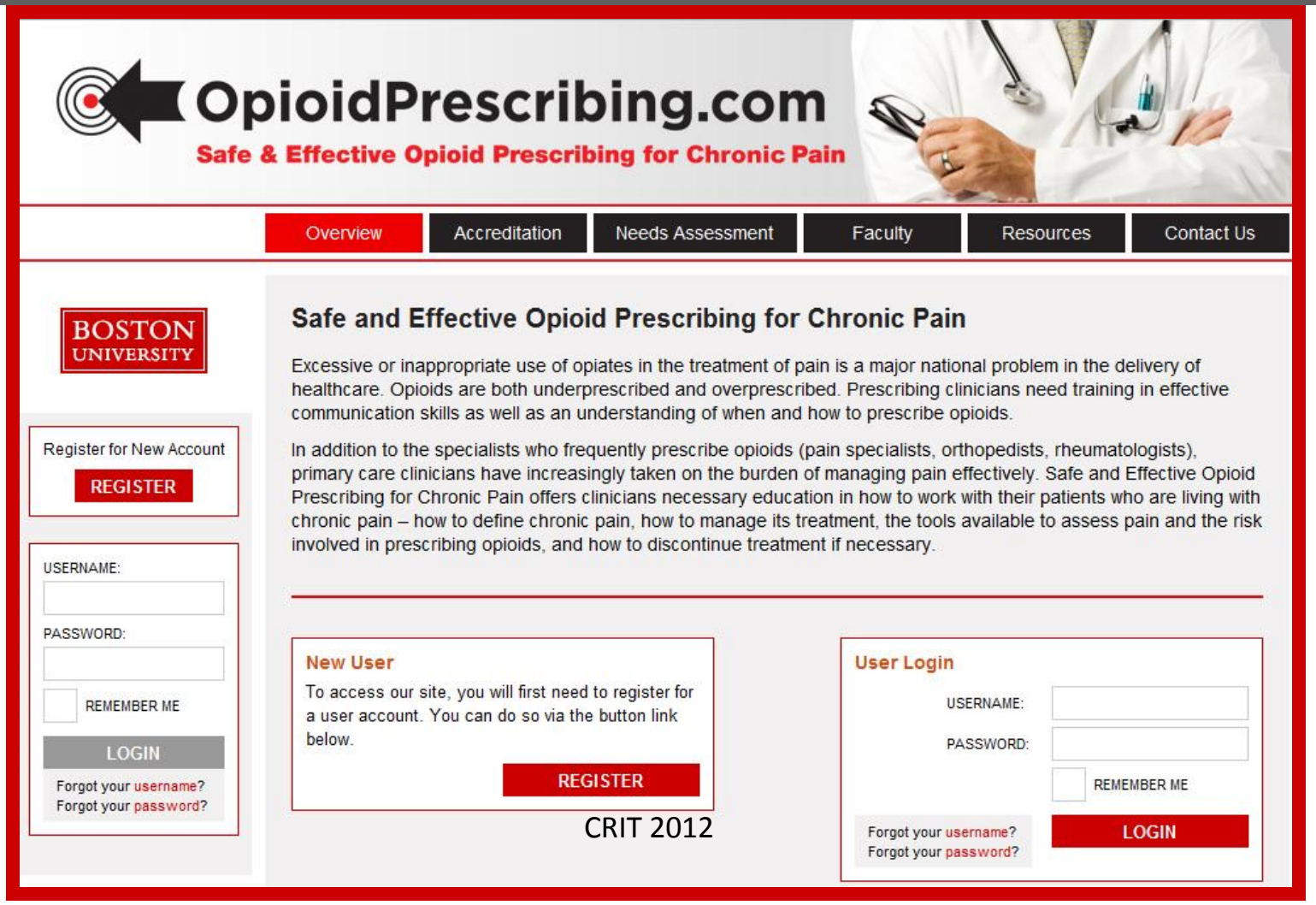
- Give specific and timely feedback why patient's behaviors raise your concern for possible addiction
- Benefits no longer outweighing risks
  - "I cannot responsibly continue prescribing opioids as I feel it would cause you more harm than good."
- Always offer referral to addiction treatment
- Stay 100% in "Benefit/Risk of Med" mindset

Summary

- Opioids can be effective and safe but are imperfect
- Use risk/harm - benefit framework
- Use consistent approach, but set level of monitoring to match risk
- Judge the treatment and not the patient
- If there is benefit in the absence of harm, continue opioids
- If there is no benefit or if there is harm, discontinue opioids

www.opioidprescribing.com

4 *AMA PRA Category 1 Credits™* available, plus risk management and opioid education credits



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www.opioidprescribing.com

- **Module 1:** Opioid efficacy & safety, assessment & monitoring tools
- **Module 2:** Communicating w/ patients & psychiatric co-morbidities
- **Module 3:** Case study
- **Module 4:** Three video vignettes (5-7 minute interview) followed by "roundtable" discussion
  - **Starting opioids, discussing monitoring**
  - **Assessing aberrant opioid taking behavior, increasing monitoring**
  - **Addressing lack of benefit and excessive risk, discontinuing opioid**

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Module 1 Video

Opioid Efficacy and Safety, Daniel P. Alford, MD, MPH, FACP
Assessment and Monitoring Tools, Jeffrey Baxter, MD

DOWNLOAD EFFICACY SAFETY TRANSCRIPTION | DOWNLOAD TOOLS TRANSCRIPTION

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Chat

: For more information, please visit:http://www.bu.edu/cme
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Controlled Substance Policy

- Consistent application ("universal precautions")*
  - Takes pressure off provider
  - Reduces stigmatization
- Increases compliance with expert guidelines
- Standardizes practice
  - Frequency of face to face visits
  - Prescription refills
  - Monitoring for benefits and harms
  - Actions for aberrant medication taking behaviors
  - Documentation

*Gourlay DL, Heit HA. Pain Medicine 2005

Click the balloon to see details.

Opioid Efficacy 00:24:19

Assessment Tools 00:33:46

Assessment Tools

Total 00:58:05
00:02:08 / 00:33:46

Cue Pause Skip

Module 4: The Interview

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- Module 1
- Module 2
- Module 3
- Module 4

In Practice: Applying Principles of Safe Opioid Prescribing

- Information
- Introduction

Cases

- Case I
- Case II
- Case III

Certification

- CME Post-Test
- Evaluation

Supplemental Info

- Massachusetts PMP
- Panel Discussion
- Q & A Sessions

Looking to Logout?

SCENARIO 3: Addressing lack of opioid benefit and excessive risk, discontinuing opioids

The role of the "patient" is performed by a professional actor. The "doctor" is a fully credentialed physician and not an actor.

Clinician Tasks:

- Discuss aberrant medication taking behaviors (unsanctioned dose escalation, lack of adherence with pill counts)
- Discuss the lack of apparent benefit (9-10 out of 10 pain and worsening function) and increased risk (over-sedation) of her methadone use
- Discuss the need for tapering her methadone and treating her pain with nonopioids and nonpharmacotherapy

Module 4: “Roundtable” Discussion