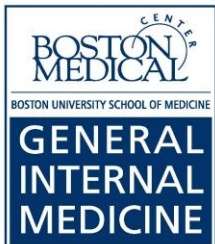


Opioids and Chronic Pain

CRIT/FIT 2013

May 2013

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CRIT/FIT 2013

Boston University School of Medicine



Bad News and Good News

- **Bad News:**

- I changed my talk

- **Good News:**

- It is a better talk

- You will get the better talk on your USB drive

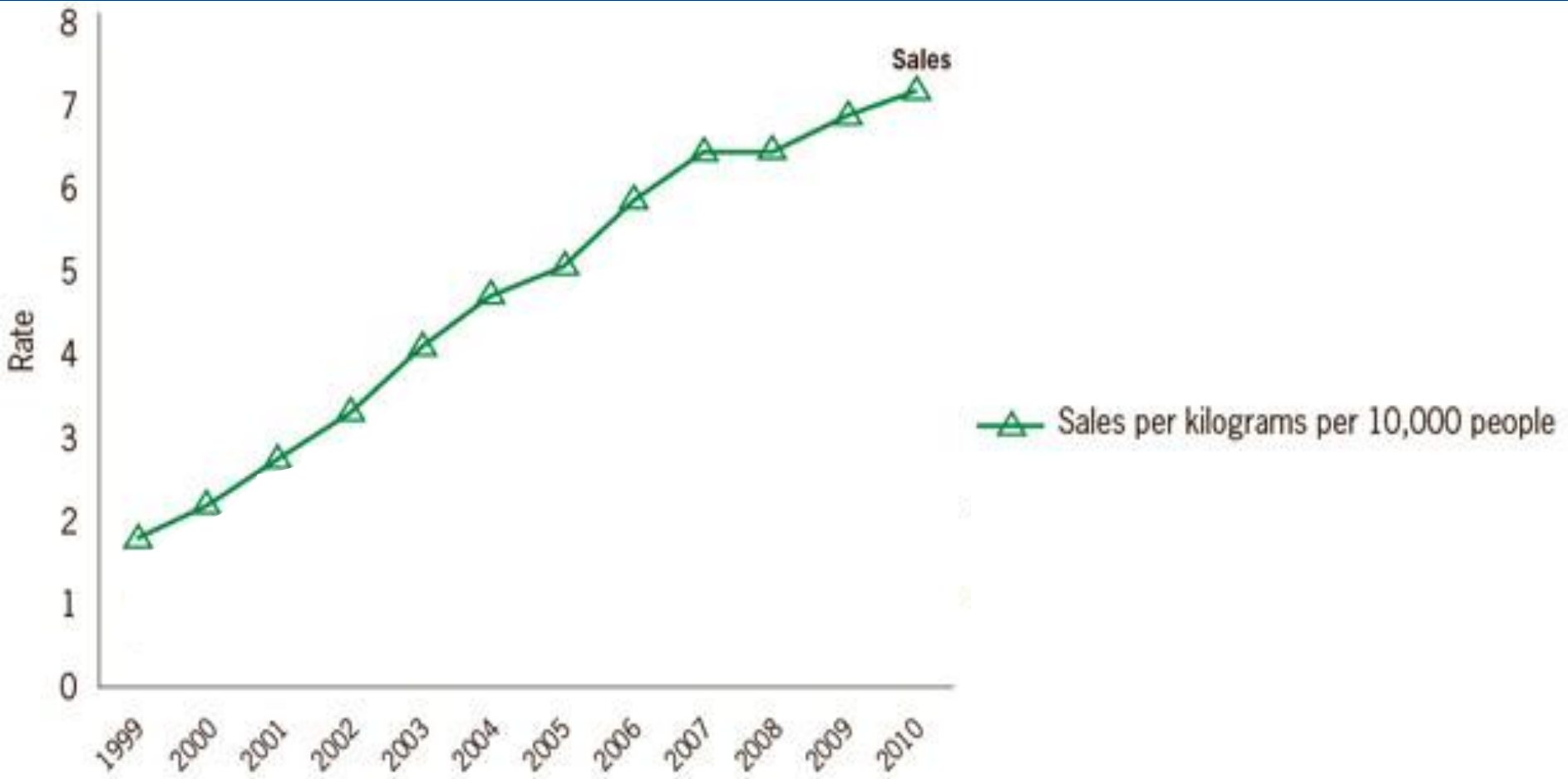
Four Powerful Learning Experiences

- 1. A patient being admitted to a methadone maintenance program**
- 2. A walk down the hall to my first Medical Grand Rounds presentation with the Chair of Medicine**
- 3. A conversation with my aunt Harriet**
- 4. A complement from a primary care patient**

My Biases

- Opioids...
 - can be effective for some
 - can be harmful for some
 - can be prescribed safely
- Providers can be and want to be trained to prescribe opioids for chronic pain safely and competently

Opioid Sales, Deaths and Addiction Treatment Admissions



National Vital Statistics System, 1999-2008; Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA), 1999-2010; Treatment Episode Data Set, 1999-2009
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The Problem...chronic pain is complicated



Variables Affecting Pain Experience

Genetic predispositions

- Structure and function of the nervous system
- Molecular basis for response to pain and/or analgesic

Environmental stressor effects

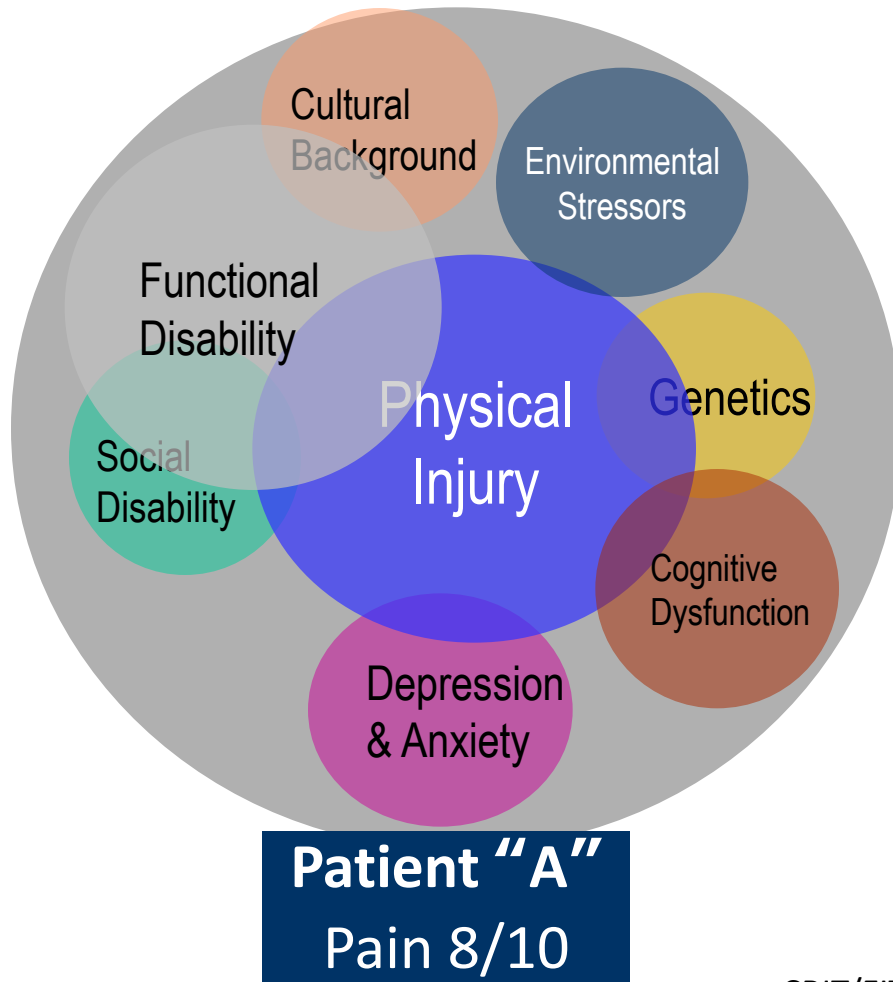
- Work, home

Social and cultural beliefs effects

- Socially determined constructs of pain, suffering and disability
- Beliefs about pain treatment

Psychiatric Co-morbidities

Chronic Pain is Complicated



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The Problem...unrealistic expectations

More UNREALISTIC expectations...

Opioids always = 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 <8 months w/ small samples <300 pts

While we all want better evidence...
*Absence of evidence is
NOT evidence of absence*

- Addiction not assessed

Balantyne JC, Mao J. NEJM 2003

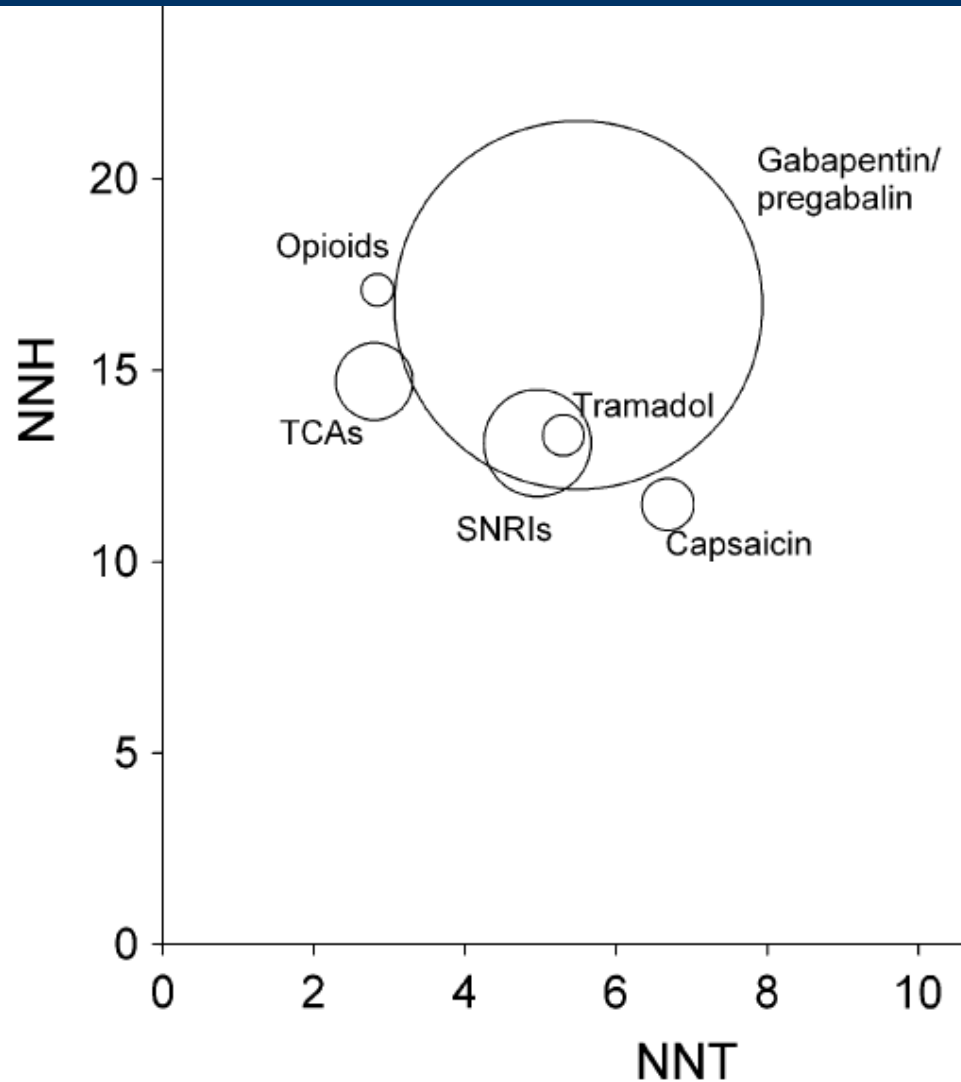
Kalso E et al. Pain 2004

Eisenberg E et al. JAMA. 2005

Furlan AD et al. CMAJ 2006

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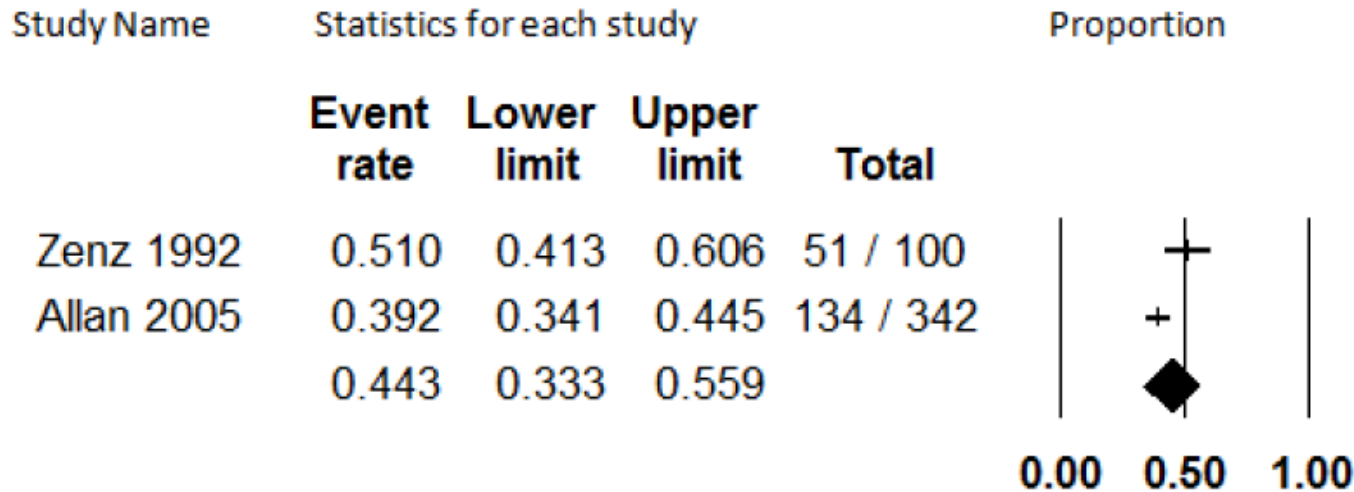
Neuropathic Pain



Medication	NNT	NNH
TCA	2.1	15.9
Opioids	2.6	17.1
Pregabalin	4.5	10.6
Tramadol	4.9	13.3
SNRI	5.0	13.1
Gabapentin	6.4	32.5
SSRI	6.8	-

Opioid Efficacy in Chronic Pain

Proportion of Patients with at least 50% Pain Relief, Oral Opioids, Follow-up 7.5 months (mean) to 13 months ($I^2=77.3\%$)



- N=442
- 44.3% of participants had at least 50% pain relief

The Problem...variable opioid response

Mu Receptor

- G protein-coupled receptor family, signal via second messenger (cAMP)
- Mu receptor subtypes
- >100 polymorphisms in the human MOR gene

Opioid metabolism

- Differs by individual opioid and by individual patient

- **Not all chronic pain responds to opioids**
- **Not all pain responds to same opioid in the same way**
- **Trial of several opioids may be needed to find acceptable balance between analgesia and tolerability**

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%

Opioid Misuse/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
 - Young age
 - Personal history of substance abuse
 - Illicit, prescription, alcohol, nicotine
 - Family history of substance abuse
 - Legal history (DUI, incarceration)
 - Mental health problems

Akbik H et al. JPSM 2006

Ives T et al. BMC Health Services Research 2006

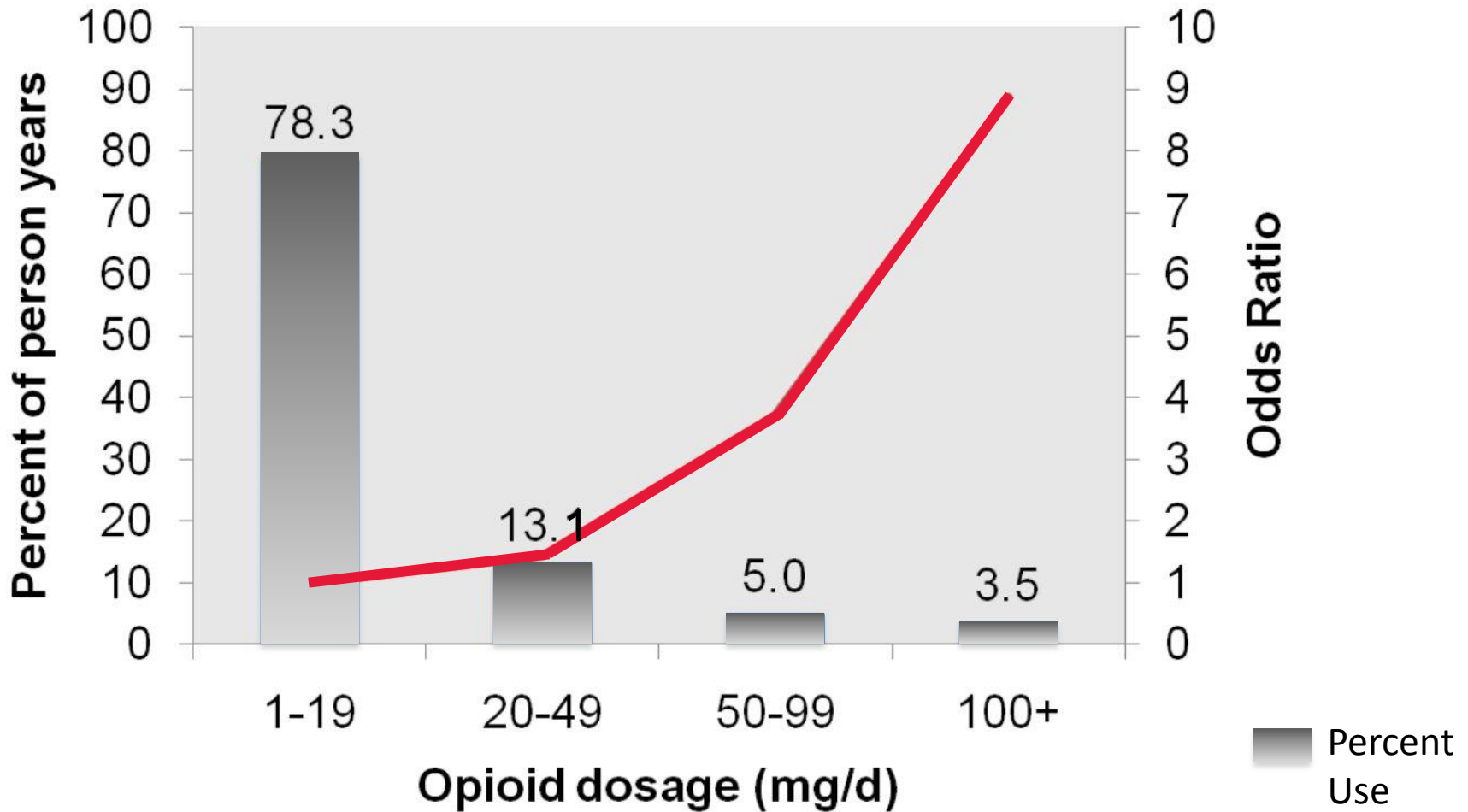
Liebschutz JM et al. J of Pain 2010

Michna E et al. JPSM 2004

Reid MC et al JGIM 2002

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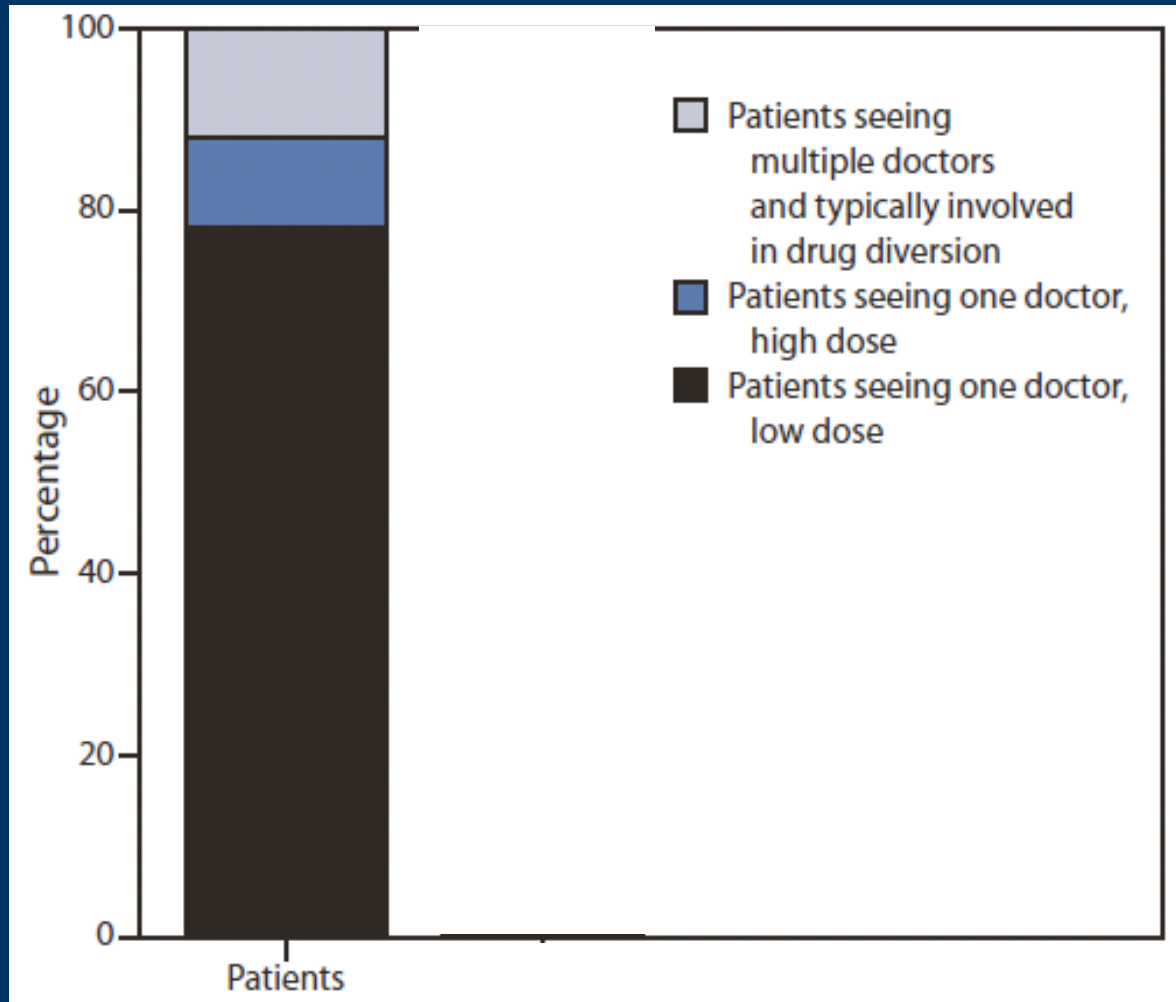
Overdose Risk



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Group Health Consort Study, 1997-2005; Dunn KM, et al. Ann Intern Med. 2010 Jan 19;152(2):85-92.

Percentage of patients and prescription drug overdoses, by risk group




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Is my patient “pain-relief seeking” or “drug seeking” or both?

- There are no “pain meters”
- Vital signs are not reliable in chronic pain
- Pain is subjective to the patient and to the provider
- It is difficult to distinguish **inappropriate** drug-seeking from **appropriate** pain relief-seeking or **both** on the first visit (s)

Is the my patient addicted?

- 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

**Aberrant Medication
Taking Behaviors**
(Pattern & Severity)
- Opioid Dependence (DSM IV)
 - *Behavioral maladaptation+/- Biological*

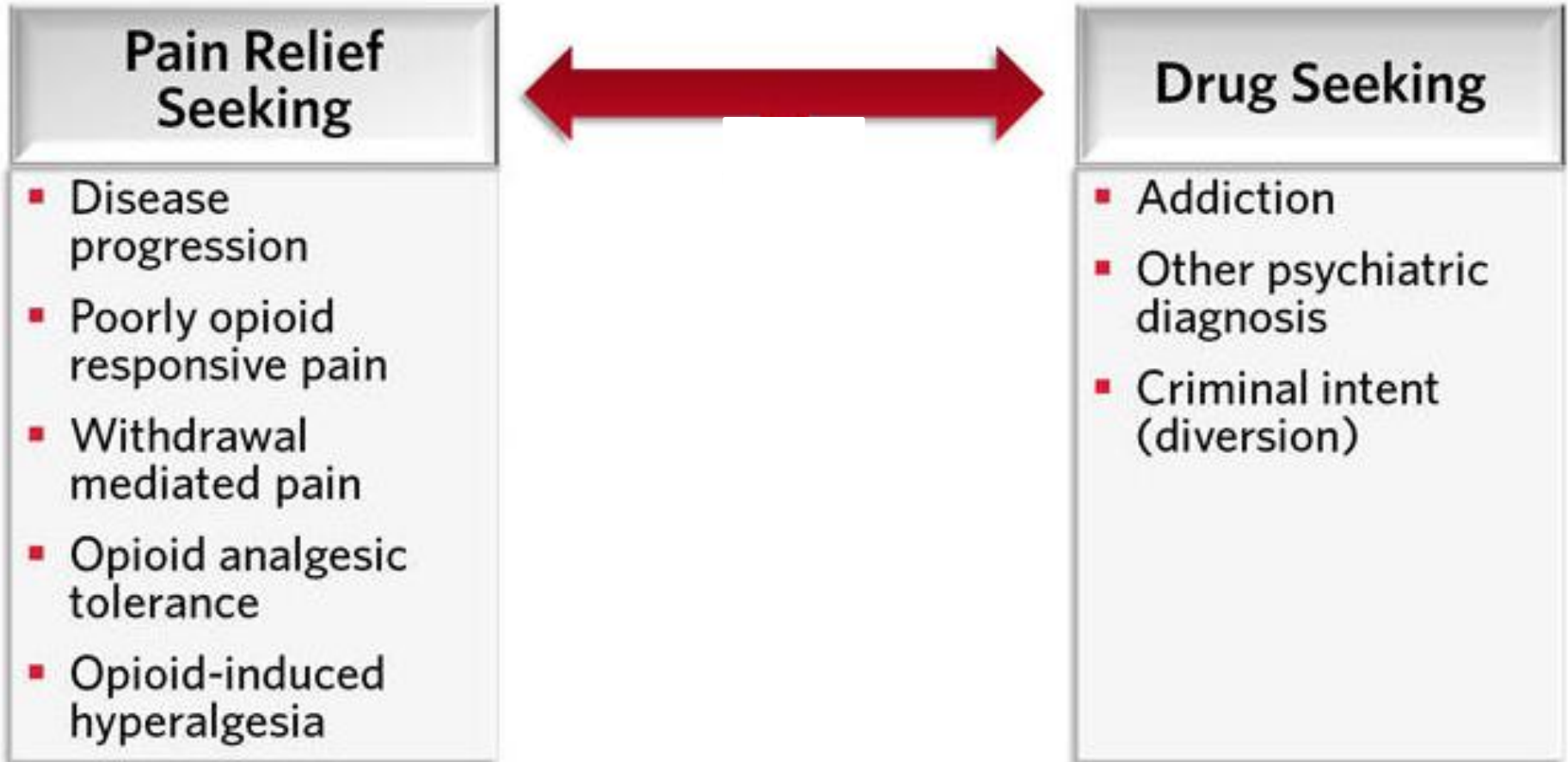
Aberrant Medication Taking Behaviors

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)
- Resistance to change therapy despite AE (e.g. over-sedation)
- Deterioration in function at home and work
- Non-adherence w/ monitoring (e.g. pill counts, urine drug tests)
- Multiple “lost” or “stolen” opioid prescriptions
- Illegal activities – forging scripts, selling opioid prescription

Aberrant Medication-Taking Behaviors

Differential Diagnosis



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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)**

Opioid Safety

- Allergies are rare
- Adverse effects are common
 - Nausea, **sedation**, constipation
 - Urinary retention, sweating, **respiratory depression**
- 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 proven 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

Assessing Benefit: PEG scale

1. What number best describes your pain on average in the past week:

0	1	2	3	4	5	6	7	8	9	10
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?

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

3. What number best describes how, during the past week, pain has interfered with your general activity?

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

Assessing Risk: Opioid Risk Tool

	Female	Male
Family history of substance abuse		
Alcohol	<input type="checkbox"/> 1	<input type="checkbox"/> 3
Illegal drugs	<input type="checkbox"/> 2	<input type="checkbox"/> 3
Prescription drugs	<input type="checkbox"/> 4	<input type="checkbox"/> 4
Personal history of substance abuse		
Alcohol	<input type="checkbox"/> 3	<input type="checkbox"/> 3
Illegal drugs	<input type="checkbox"/> 4	<input type="checkbox"/> 4
Prescription drugs	<input type="checkbox"/> 5	<input type="checkbox"/> 5
Age between 16-45 years	<input type="checkbox"/> 1	<input type="checkbox"/> 1
History of preadolescent sexual abuse	<input type="checkbox"/> 3	<input type="checkbox"/> 0
Psychological disease		
ADHD, OCD, bipolar, schizophrenia	<input type="checkbox"/> 2	<input type="checkbox"/> 2
Depression	<input type="checkbox"/> 1	<input type="checkbox"/> 1

Scoring
 0-3 low risk
 4-7 moderate risk
 >8 high risk

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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

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

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

Two FREE Online Educational Resources

www.scopeofpain.com

www.opioidprescribing.com

Safe and Competent Opioid Prescribing Education (SCOPE) Program

Risk Evaluation and Mitigation Strategy (REMS) Program

- **3 components**
 - *Free* 3 module web-based education
 - 10 Live conference held around the US
 - MA, MI, NE, NC, OR, RI, WI
 - Train-the-trainer workshops



[Overview](#)

[Pre-Assessment](#)

Essential Modules

- ✓ Essential Module 1
 - ✓ CME Information
 - ✓ Activity
 - Post Test
- ✓ Essential Module 2
 - ✓ [CME Information](#)
 - ✓ [Activity](#)
 - [Post Test](#)
- ✓ Essential Module 3
 - ✓ [CME Information](#)
 - ✓ [Activity](#)
 - [Post Test](#)

[Evaluation/Certificate](#)

State Modules

Module 2: Second Visit - One Week Later Initiating Opioid Therapy Safely

Web-based Program

3 Modules

How to:

- determine when opioid analgesics are indicated
- assess for opioid misuse risk
- talk to patients about opioid risks and benefits
- monitor and manage patients on long-term opioid therapy

Case Study: Mary Williams

- 42 year old female
- Hypertension
- Type 2 diabetes with painful neuropathy
- Chronic low back pain



Next



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