Opioids and Chronic Pain

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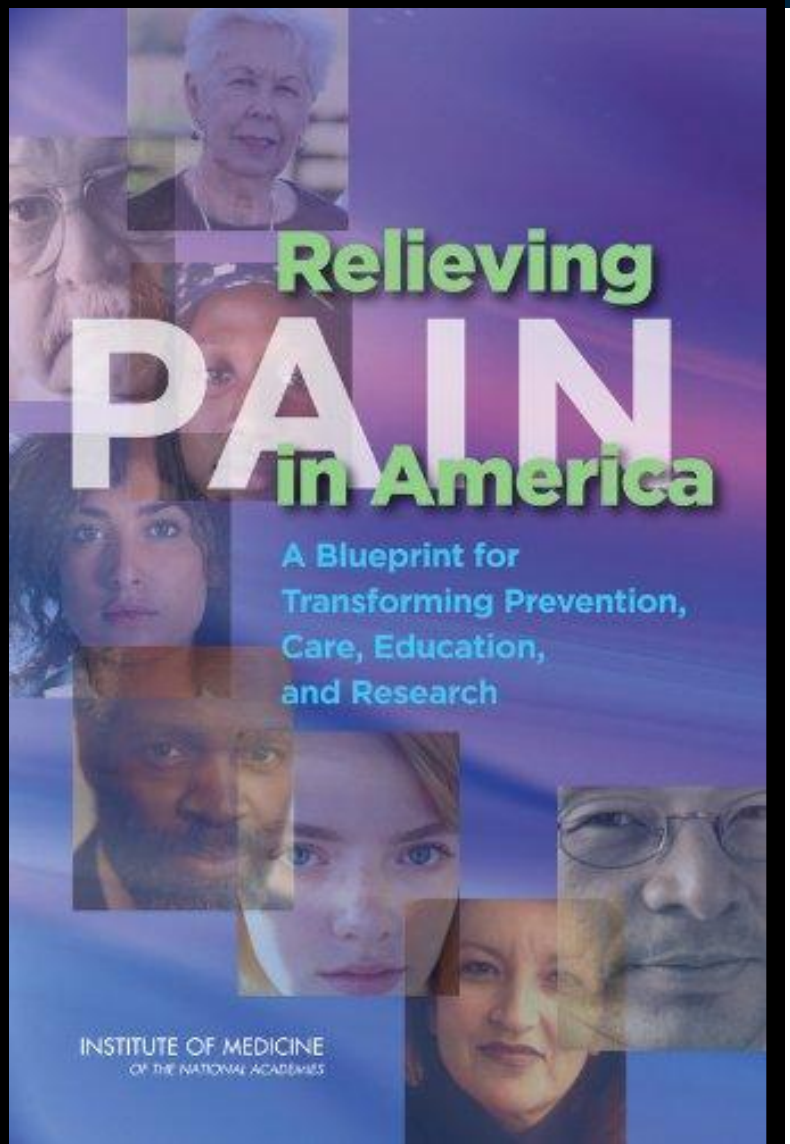
Bad News and Good News

My Biases

- Opioids…
  - can be effective for some
  - can be harmful for some
  - can be prescribed safely

- Physicians **can be** and **want to be** trained to prescribe opioids for chronic pain safely and competently

"To reduce the impact of pain and suffering...require a transformation in **how pain is perceived and judged**...by **people with pain** and by **health care providers** ..."



- Pain care must be tailored to each person's experience
- Chronic pain can be a disease in itself
- **Barriers to adequate pain care**
  - Negative attitudes about people with pain
  - Disparities in pain care due to stereotyping and biases
  - Insurance and reimbursement issues
  - **Regulatory, legal, educational and cultural barriers inhibiting the medically appropriate use of opioid analgesics**

Building Trust

Patient Issues

Patients will assume that you don't believe their pain complaints

Often demonstrated by **exaggerating...**

- **pain scores:** *"on a scale of 0-10…I am a **20**"*
- **functional limitations:** *"I can't do anything"*

Building Trust

Patient Issues

Some patients with adequate pain relief believe it is not in their best interest to report pain relief

Fear that opioid analgesics will be reduced or stopped

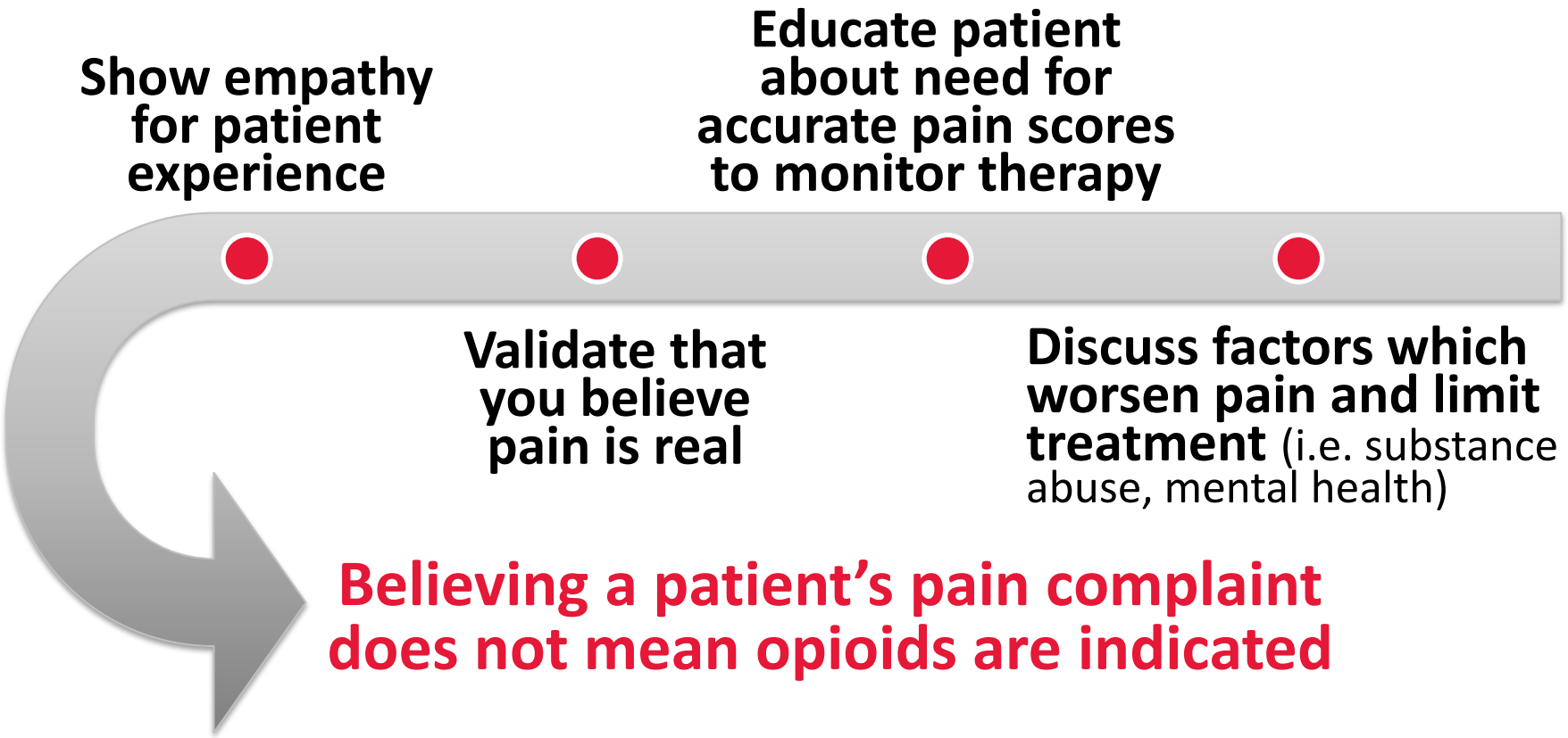
Fear that clinician may decrease efforts to diagnose the cause of the pain

Evers GC, et al. Support Care Cancer. 1997 Nov;5(6):457-60.

Building Trust

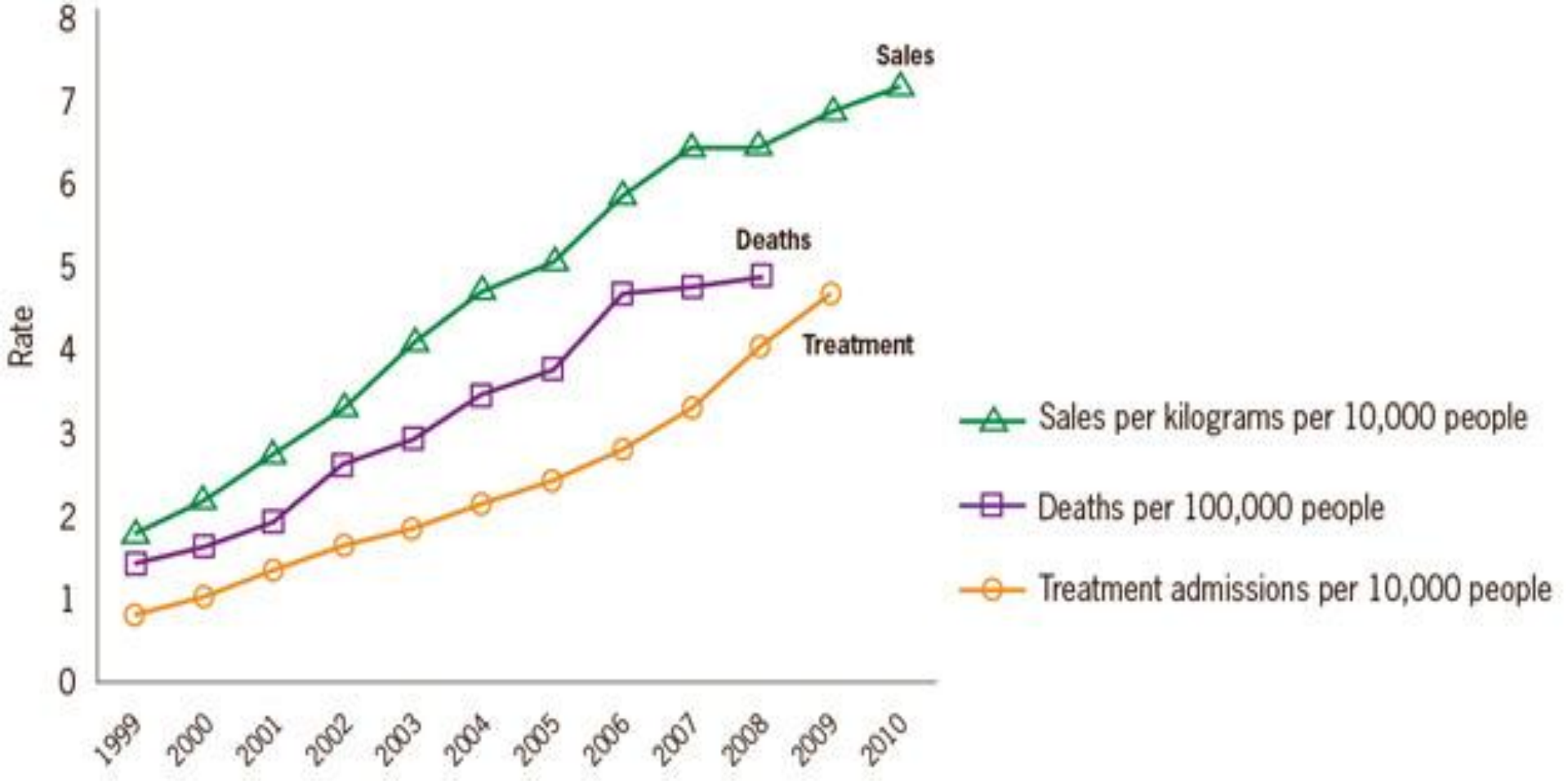
Clinician Issues

- Assume patient fears you think pain is not real or not very severe
- After you take a thorough pain history…



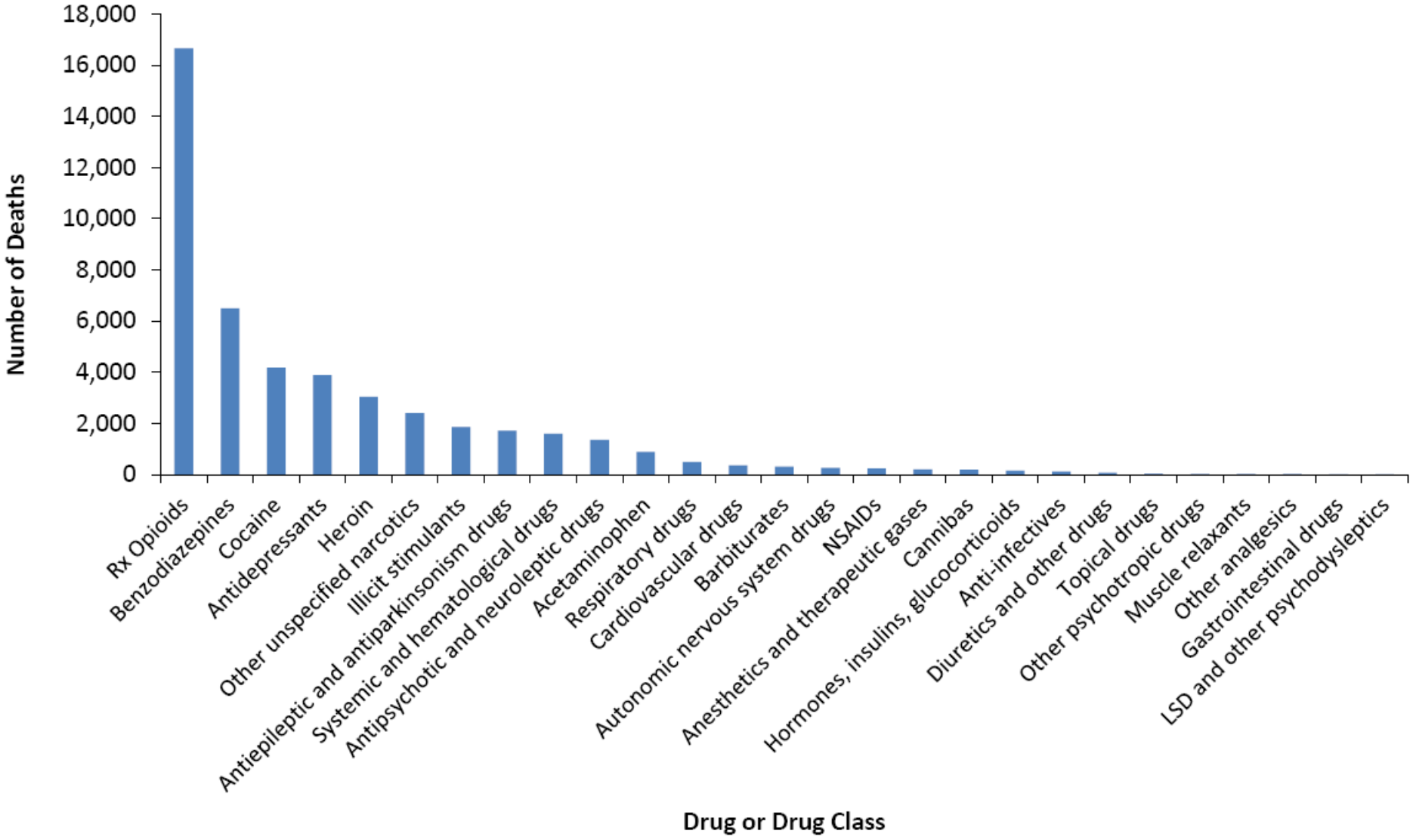
Believing a patient's pain complaint does not mean opioids are indicated

Prescription Opioid Sales, Deaths and Substance Abuse Treatment Admissions



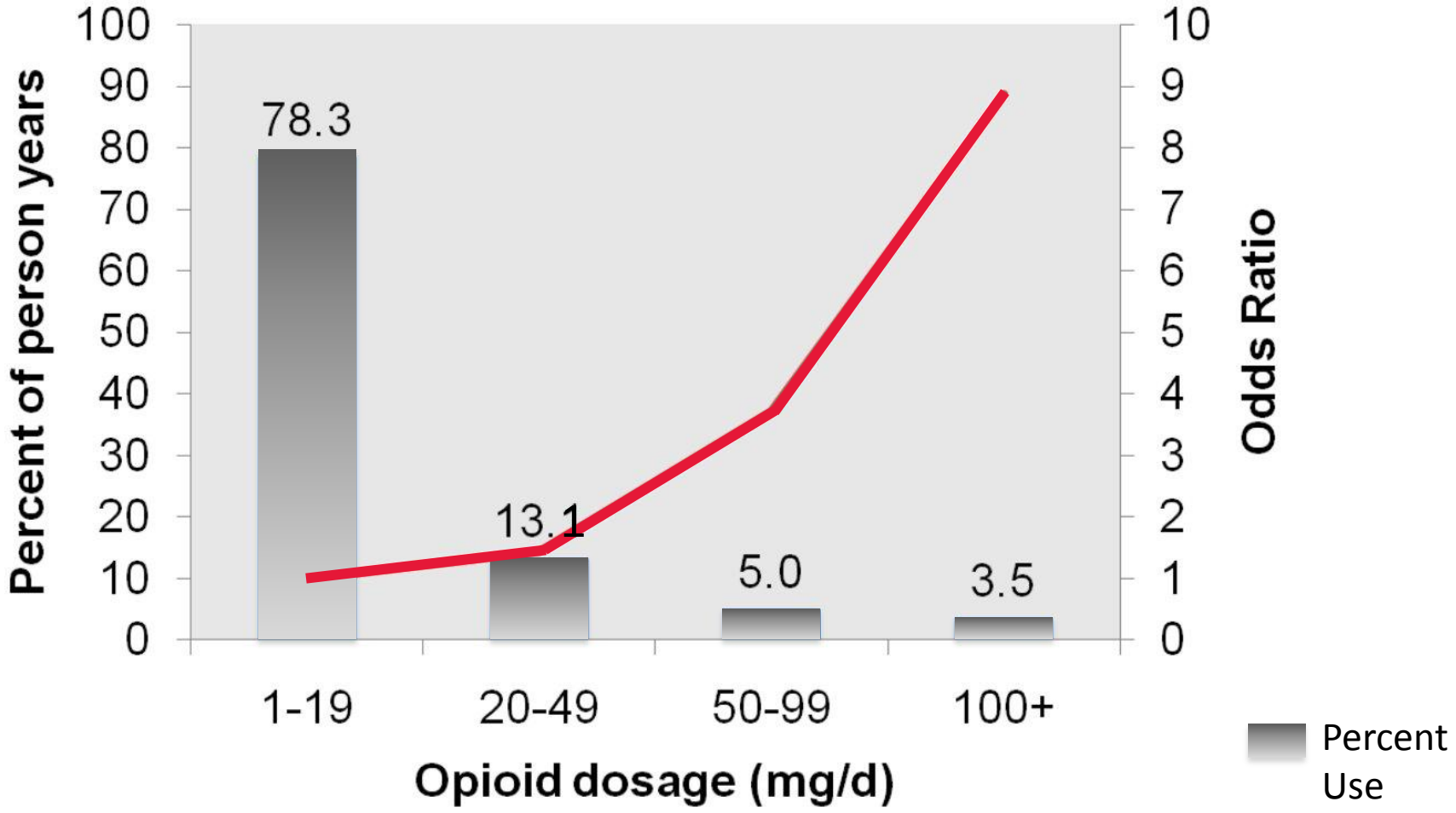
National Vital Statistics System, 1999-2008; Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA), 1999-2010; Treatment Episode Data Set, 1999-2009

Rx Opioids Primary Driver of ODs 2010



Jones et al Pharmaceutical overdose deaths, United States, 2010. JAMA 2013 and CDC/NCHS NVSS MCOD 2010.

Dose and Overdose Risk



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

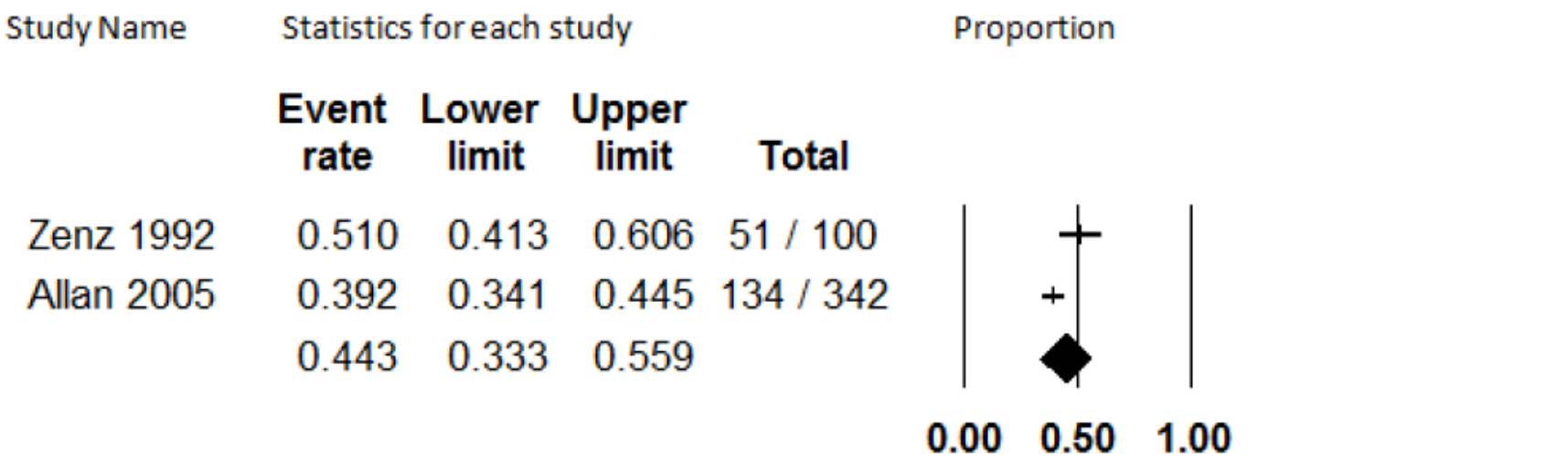
Opioid Efficacy in Chronic Pain

- Most literature surveys & uncontrolled case series
- RCTs are short duration <8 months w/ small samples <300 pts
- Mostly pharmaceutical company sponsored
- Pain relief modest
  - Better analgesia with opioids vs control in all studies (statistically significant)
- Mixed reports on function
- 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

Not all Chronic Pain is Opioid Responsive

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

Noble M et al. Cochrane Systematic Reviews 2010

The Problem...variable opioid response

Mu Receptor

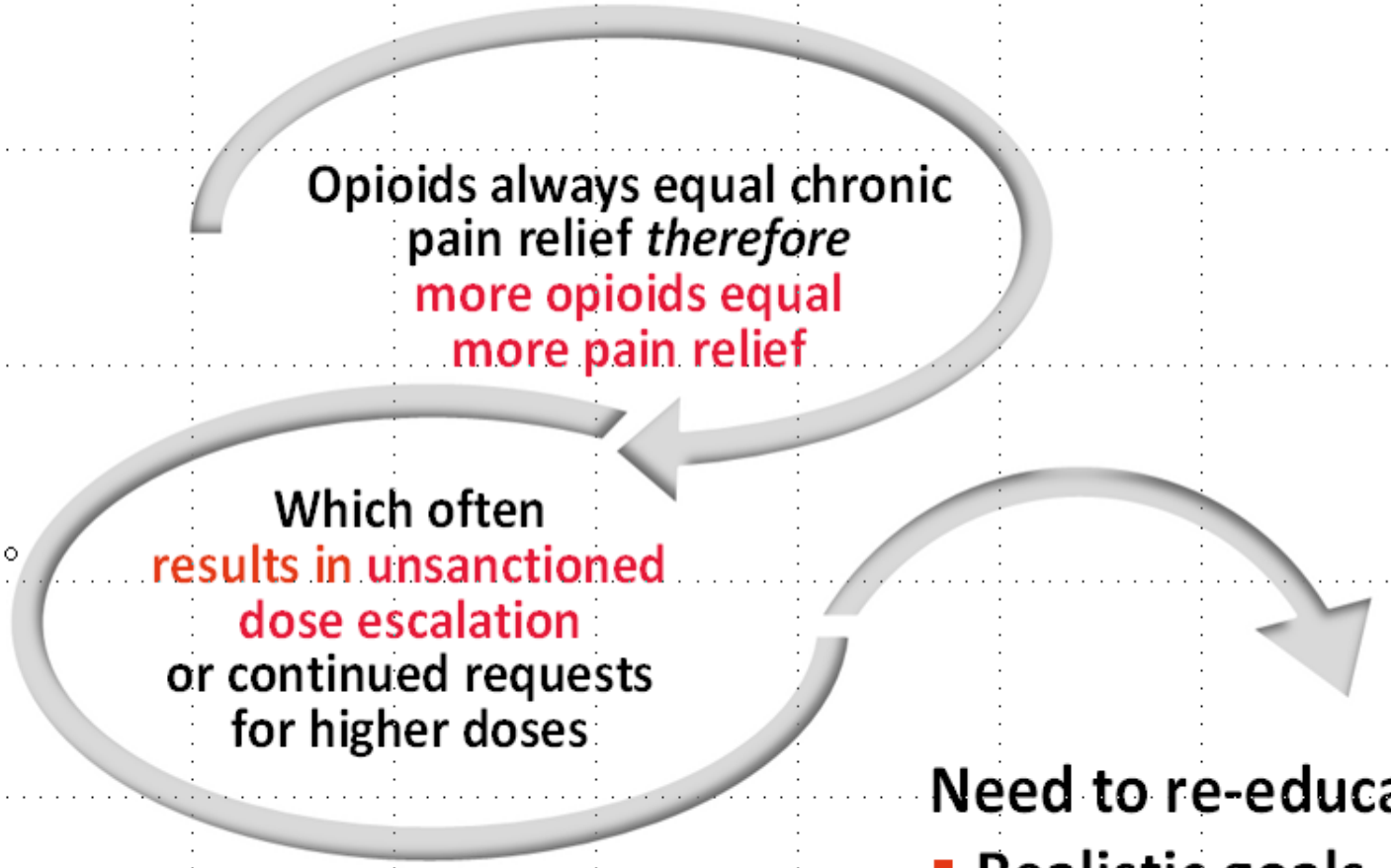
- Mu receptor subtypes
- >100 polymorphisms in the human MOR gene

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**

Patients often have unrealistic expectations that…



Need to re-educate:

- **Realistic goals**
- **Potential severe risks and harm with opioids**

Opioid Safety and Risks

- **Allergies** are rare
- **Side effects** are common
  - Nausea, sedation, constipation, urinary retention, sweating
  - Respiratory depression – sleep apnea
- **Organ toxicities** are rare
  - Suppression of hypothalamic-pituitary-gonadal axis
  - >50 mg (MSO_4 equivalents) assoc w/ 2X increase in fracture risk
- **Worsening pain** *(hyperalgesia in some patients)*
- **Addiction**
- **Overdose**
  - at high doses
  - when combined w/ other sedatives

Saunders KW et al. J Gen Med 2010 , Dunn KM et al. Ann Intern Med 2010
Li X et al. Brain Res Mol Brain Res 2001, Doverty M et al. Pain 2001 , Angst MS, Clark JD. Anesthesiology 2006

Opioid Misuse/Addiction Risk

- Published rates of abuse and/or addiction in chronic pain populations are 3-24%
- 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 el al. JPSM 2004
Reid MC et al JGIM 2002

Is the my patient addicted?

- Physical dependence
  - *Biological adaptation*
- Opioid Use Disorder (DSM V)
  - *Behavioral maladaptation+/- Biological*
- 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)*

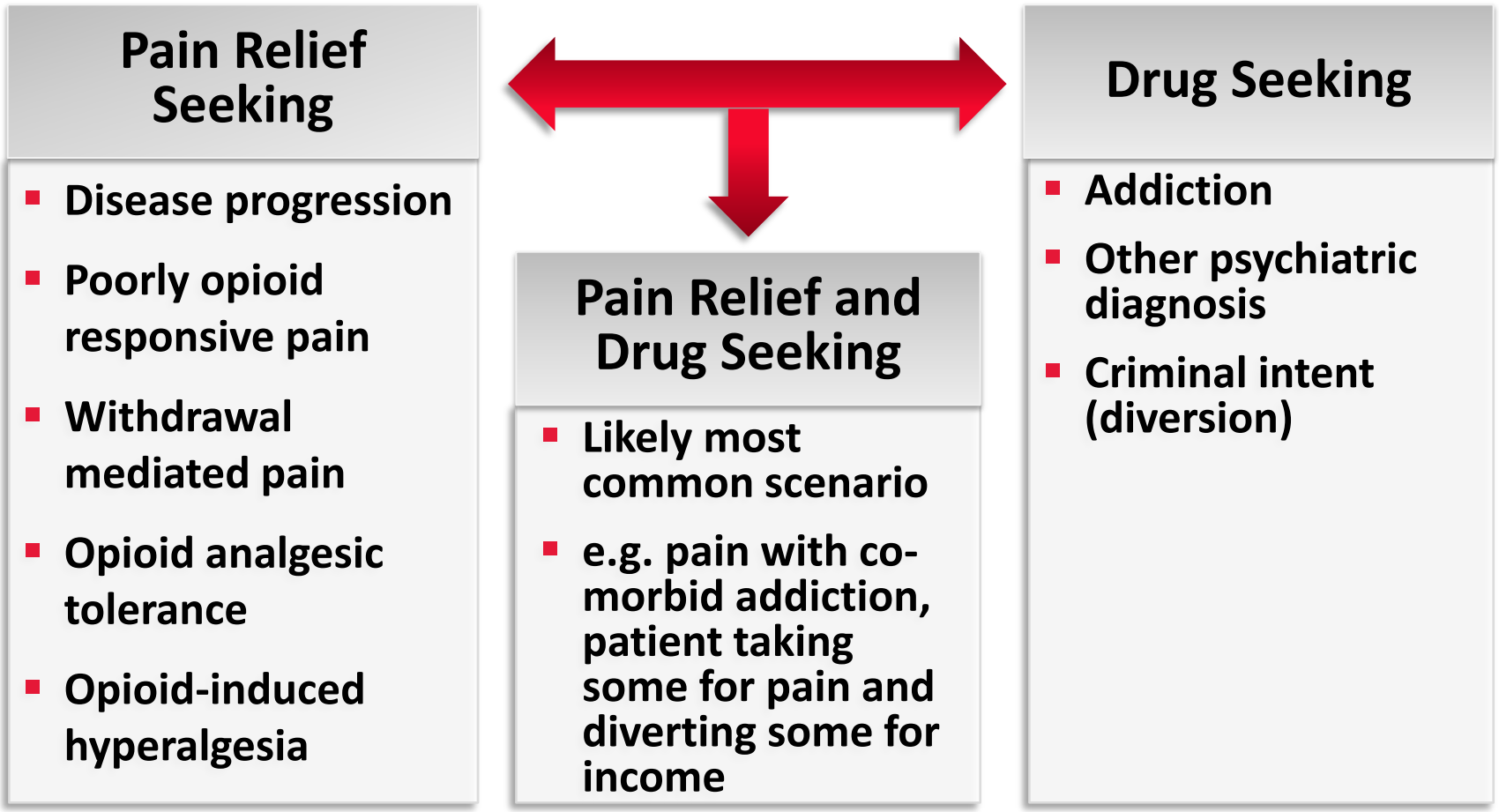
Aberrant Medication Taking Behaviors

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



Alford DP. JAMA. 2013 Mar 6;309(9):919-25.

When Are Opioids Indicated?

- Pain is moderate to severe
- Pain has significant impact on function and quality of life
- Non-opioid pharmacotherapy has been tried and failed
- **Patient agreeable to...**
  - **take opioids exactly as prescribed** (e.g., no unsanctioned dose escalation)
  - **have opioid use closely <u>monitored</u>** (e.g. pill counts, urine drug testing)

Opioid Choice

Short-acting

- Codeine
- Hydrocodone
- Hydromorphone
- Morphine
- Oxycodone
- Oxymorphone

Long-acting

- Fentanyl transdermal
- Extended release morphine
- Extended release oxycodone
- Extended release oxymorphone
- Extended release hydrocodone
- **Methadone**

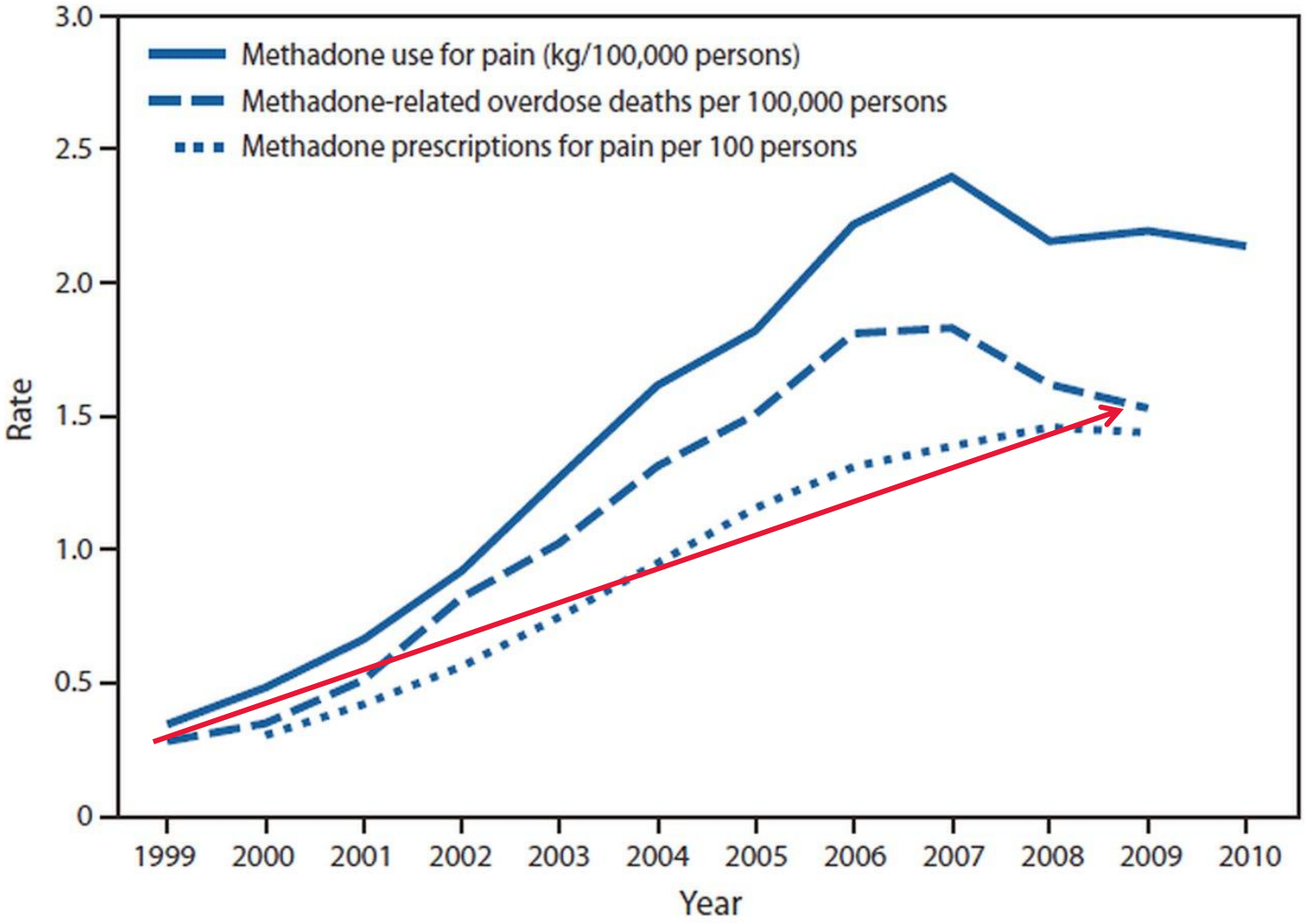
Insufficient evidence to determine whether long-acting opioids are more effective or safer than short-acting opioids

Chou R et al. J Pain Symptom Manage 2003, Argoff C, Silvershein DI. Mayo Clin Proc. 2009

Currently there are NO proven abuse resistant opioids or formulations

Stanos SP et al. Mayo Clin Proc. 2012;87(7):683-694.

Methadone is Different



CDC, Morbidity and Mortality Weekly Report (MMWR) July 6, 2012 / 61(26);493-497.

"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

What is the clinician's role?

VS.

Nicolaidis C. Pain Medicine 2011

The Risk-Benefit Framework

Judge the opioid treatment, not the patient

NOT…

- Is the patient good or bad?
- Does the patient deserve opioids?
- Should this patient be punished or rewarded?
- Should I trust the patient?

RATHER…

Do the benefits of opioid treatment outweigh the untoward effects and risks for this patient (or society)?

Nicolaidis C. Pain Medicine 2011

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

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

Assessing Risk: Opioid Risk Tool

	Female	Male
Family history of substance abuse		
Alcohol	❑1	❑3
Illegal drugs	❑2	❑3
Prescription drugs	❑4	❑4
Personal history of substance abuse		
Alcohol	❑3	❑3
Illegal drugs	❑4	❑4
Prescription drugs	❑5	❑5
Age between 16-45 years	❑1	❑1
History of preadolescent sexual abuse	❑3	❑0
Psychological disease		
ADHD, OCD, bipolar, schizophrenia	❑2	❑2
Depression	❑1	❑1

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

Webster LR, Webster RM. Pain Medicine, 2006

Opioid Misuse Risk Stratification

Discuss level of concern with patient

- "Despite being in recovery from alcoholism, you are at higher risk for developing problems with the opioid pain medication."

Level of monitoring that should be implemented

- Frequency of visits, urine drug testing, etc.
- High risk patients may need to agree to random call-backs

Need for pain and/or addiction consultant

- If available

Some patients may be too risky for opioids analgesics

- e.g., patient with recent opioid addiction

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)

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

Using Risk Benefit Framework

Benefits

Pain
Function
Quality of Life

Risks/Harm

Misuse
Addiction, Overdose
Adverse Effects

Useful to Avoid Pitfalls...

- **"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?"**

RESPONSE:

"I cannot a prescribe a medication that is not helping you (or is hurting you)."

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.scopeofpain.com

SCOPE of Pain
Safe and Competent Opioid Prescribing Education

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BOSTON UNIVERSITY

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

Videos

SCOPE of Pain
Safe and Competent Opioid Prescribing Education

I: Starting opioids, discussing monitoring

II: Assessing aberrant opioid taking behavior, increasing monitoring

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

IVa: Inherited Patient on High Dose Opioids, Part A

IVb: Inherited Patient on High Dose Opioids, Part B

V: Established Patient with Evidence of Illicit Drug Use

VI: PDMP Questionable Activity in an Established Patient

VII: PDMP Questionable Activity in a New Patient

Paul Russo

- 48 year old man with chronic posttraumatic knee and ankle pain s/p infected compound fractures after a motorcycle accident 5 years ago.
- **Current Pain Medications:**
  - Hydrocodone 5 mg/acetaminophen 325 mg 2 tablets 3x/day
  - Ibuprofen 800 mg 3x/day
- His pain is always 4-5 out of 10.
- His cashier job allows him to sit most of the day.

- **Despite denying illicit drug use, his urine drug test was positive for cocaine** (and hydrocodone)…
  - Should you "fire" the patient for lying about his cocaine use?
  - Should you discontinue his opioids?