Opioids and Chronic Pain

CRIT/FIT 2015

May 2015

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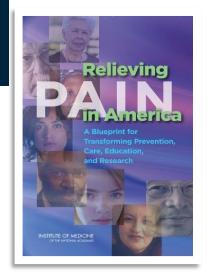


Bad News and Good News



Chronic Pain in Perspective

- 100 Million* in U.S. with chronic pain
- Chronic pain can be a disease in itself
- Care must be tailored to each person's experience



Significant barriers to adequate pain care include:

- Negative attitudes and disparities in pain care
- Lack of decision support for chronic pain management
- Financial misalignment favoring use of medications
- Poor support for team-based care and specialty clinics
- Over-burdened primary care providers
- Regulatory, legal, educational and cultural barriers inhibiting the medically appropriate use of opioid analgesics

Institute of Medicine. 2011 Relieving Pain in America. Washington DC *Dzau VJ, Pizzo PA. *JAMA* 2014; 312 (15):1507-1508 Reuben DB et al. NIH: The Role of Opioids in Treatment of Chronic Pain. *Ann Intern Med*. 2015

"My chronic pain isn't a crime"

Opinion The Boston Globe

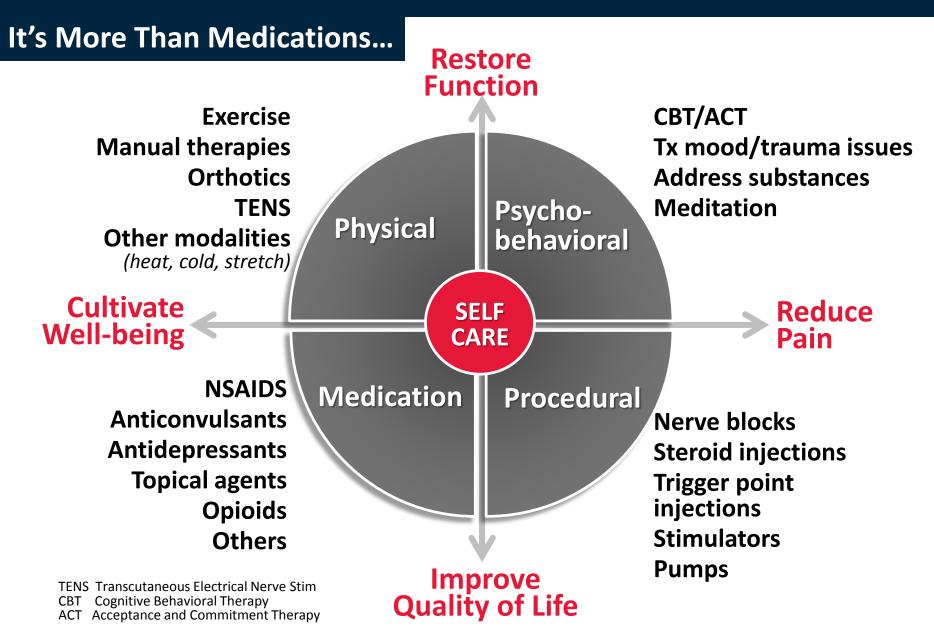
- I will be in chronic pain until I die...I accept it.
- Pain medication is inadequate. But with it I am more consistently functional (homeowner, spouse, parent, teacher, writer, editor).
- Abuse of prescription pain medications is a serious problem; people are dying.
- Ever-tighter regulations...are of dubious value in reducing [abuse] while causing grave harm to those of us in chronic pain, to the overwhelming majority who take medications for appropriate reasons.
- Increasingly I am a suspect, treated less as a patient and more as a criminal.

Donald N.S. Unger, MFA, PhD, English Department, College of the Holy Cross February 03, 2015

Opioids in Perspective

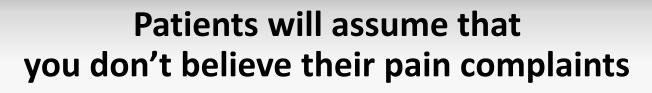
- The efficacy and safety of chronic opioid therapy for chronic pain has been inadequately studied
- Opioids for chronic pain...
 - help some patients
 - harm some patients
 - are only one tool for managing severe chronic pain
 - are indicated when alternative safer treatment options are inadequate

Multidimensional Care



Building Trust

Patient Issues





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

Provider Issues

After you take a thorough pain history...

Show empathy for patient experience Educate patient about need for accurate pain scores to monitor therapy

Discuss factors which worsen pain and limit treatment (i.e. substance use, mental health) Validate that you believe pain is real

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

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 (l²=77.3%)

Study Name	Statistics for each study				Proportion			
	Event rate	Lower limit	Upper limit	Total				
Zenz 1992	0.510	0.413	0.606	51 / 100		+		
Allan 2005	0.392	0.341	0.445	134 / 342		+		
	0.443	0.333	0.559			•		
					0.00	0.50	1.00	

• N=442

• 44.3% of participants had at least 50% pain relief

Noble M et al. Cochrane Systematic Reviews 2010

Variable Opioid Response

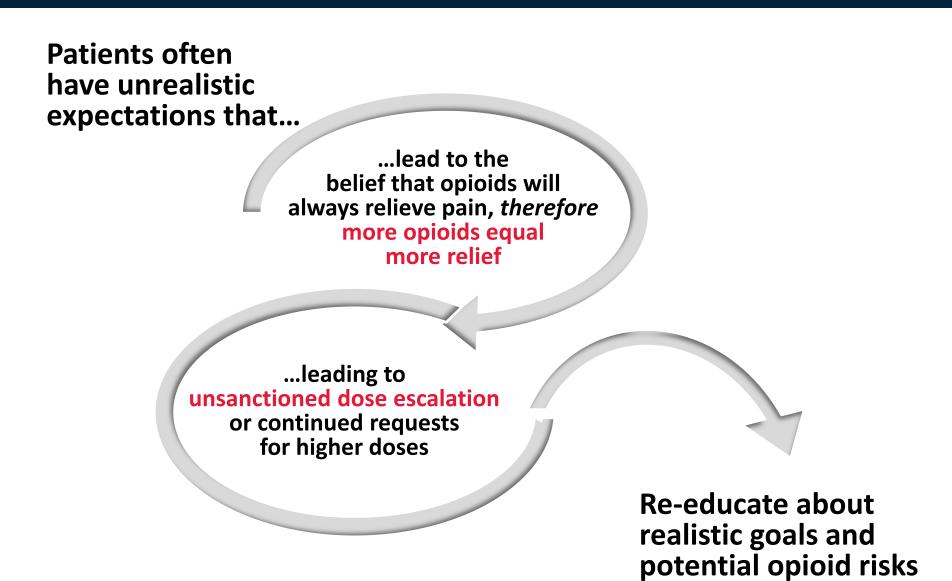
Mu Receptor

- 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

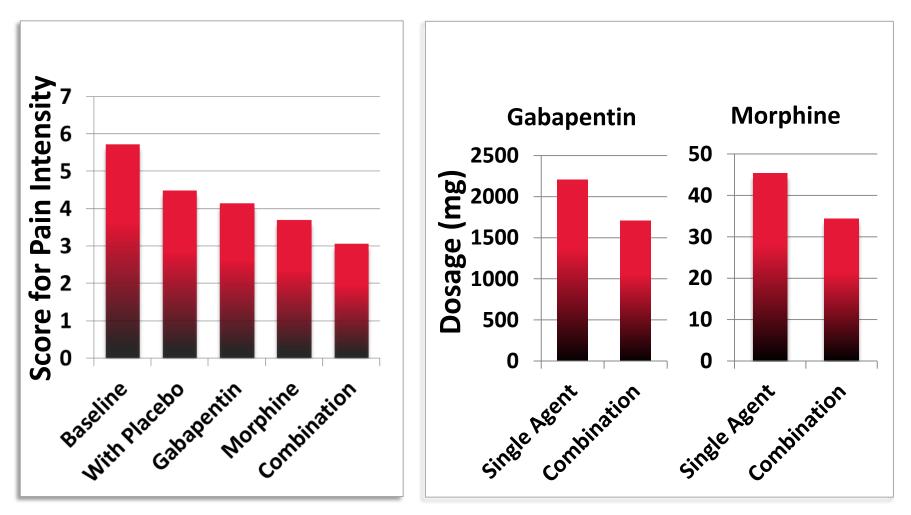
Unrealistic Expectations



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

Exploit Synergism

Morphine, Gabapentin, or their Combination for Neuropathic Pain

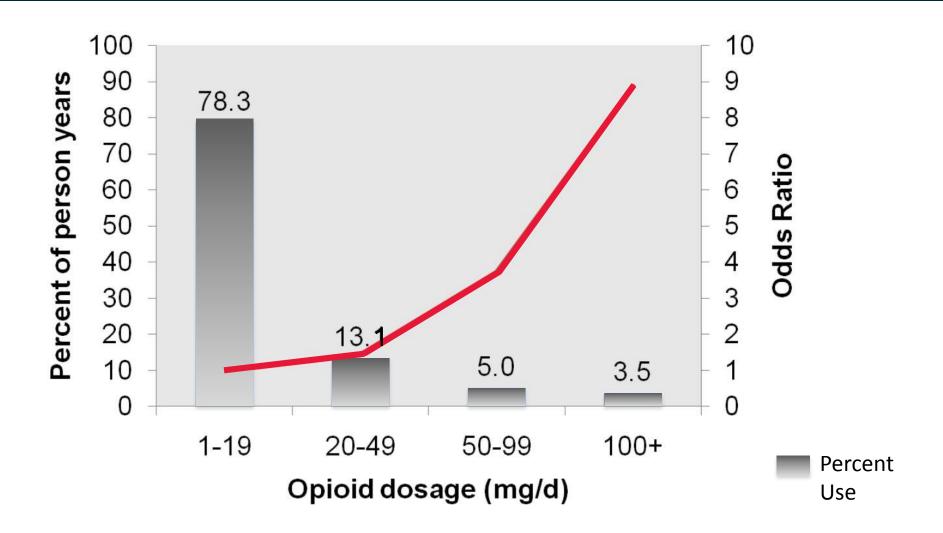


Opioid Safety and Risks

- 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
- Worsening pain (hyperalgesia in some patients)
- Addiction
- Overdose
 - when combined w/ other sedatives
 - at high doses

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

Dose and Overdose Risk



Collateral Opioid Risk

• Risks

- Young children's ingestion and overdose
- Adolescent experimentation leading to overdose and addiction

• Mitigating risk

- Safe storage (i.e., lock box)
- Safe disposal
- Naloxone distribution (if available)*

* Beletsky L, Rich JD, Walley AY. JAMA 2012; 308(18):1863-4

* SAMHSA Overdose Toolkit http://store.samhsa.gov/shin/content/SMA13-4742/Toolkit_Patients.pdf)

Opioid Misuse/Addiction Risk

- Published rates of abuse and/or addiction in chronic pain populations are 3-24%
- <u>Known risk factors</u> for addiction to any substance are <u>good</u> <u>predictors</u> 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

Does my patient have an OUD?

- ✓ *Tolerance
- ✓ *Withdrawal
- Use in larger amounts or duration than intended
- ✓ Persistent desire to cut down
- ✓ Giving up interests to use opioids
- Great deal of time spent
 obtaining, using, or recovering
 from opioids

*This criterion is not considered to be met for those individuals taking opioids solely under appropriate medical supervision

- Craving or strong desire to use opioids
- ✓ Recurrent use resulting in failure to fulfill major role obligations
- ✓ Recurrent use in hazardous situations
- ✓ Continued use despite social or interpersonal problems caused or exacerbated by opioids
- Continued use despite physical or psychological problems

Mild OUD: 2-3 Criteria Moderate OUD: 4-5 Criteria Severe OUD: <u>></u>6 Criteria

American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.)

Is the my patient addicted?

Clinical syndrome presenting as...

- Loss of Control
- Compulsive use
- Continued use despite harm
- Aberrant Medication Taking Behaviors (pattern and severity)

Addiction is **NOT** the same as Physical Dependence

Savage SR, et al. J Pain Symptom Manage. 2003;26:655-667.

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

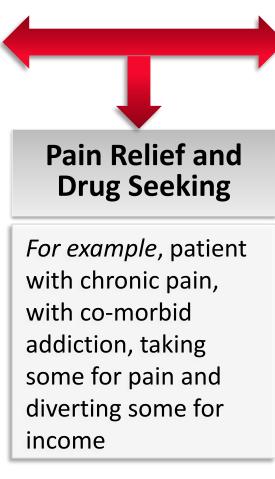
Illegal activities – forging scripts, selling opioid prescription

Aberrant Medication-Taking Behaviors

Differential Diagnosis (DDx)

Pain Relief Seeking

- Disease progression
- Poorly opioid responsive pain
- Withdrawal mediated pain
- Opioid analgesic tolerance
- Opioid-induced hyperalgesia



Drug Seeking

- Opioid use disorder/Addiction
- Other psychiatric diagnosis
- Criminal intent (diversion)

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 monitored
 - e.g. pill counts, urine drug testing



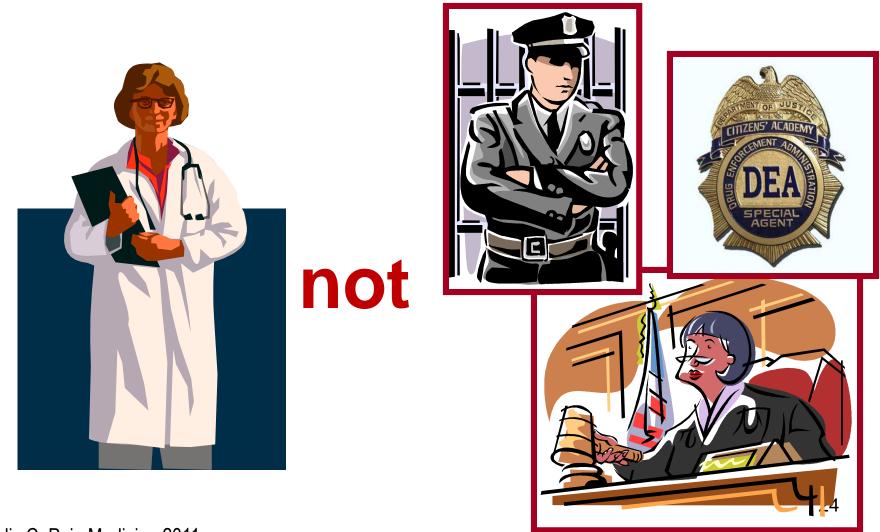
"Universal Precautions"

(not evidence-based but has become "standard" of care)

- Agreements "contracts", informed consent
- Monitor for benefit and harm with frequent face-toface 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?



Nicolaidis C. Pain Medicine 2011

Implementing Universal Precautions in Pain Medicine

Use a Health-Oriented, Risk Benefit Framework

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)?

Judge the opioid treatment NOT the patient

Assessing Benefit: PEG scale

1. What number best describes your <u>pain on average</u> in the past week:										
0	1	2	3	4	5	6	7	8	9	10
Nop	ain									Pain as bad as you can imagine
2. What number best describes how, during the past week, pain has interfered with your <u>enjoyment of life</u> ?										
0	1	2	3	4	5	6	7	8	9	10
Doe inter	s not fere									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
Doe inter	s not fere									Completely interferes

Assessing Risk: Opioid Risk Tool

	Female	Male	
Family history of substance abuse			
Alcohol	D 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	D 1	D 1	
History of preadolescent sexual abuse	□3	D 0	
Psychological disease			Scoring 0-3 low risk
ADHD, OCD, bipolar, schizophrenia	2	2	4-7 moderate risk
Depression	D 1	D 1	>8 high risk

Webster LR, Webster RM. Pain Medicine, 2006

Discussing Monitoring with Patients

- Discuss risks of opioid medications
- 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

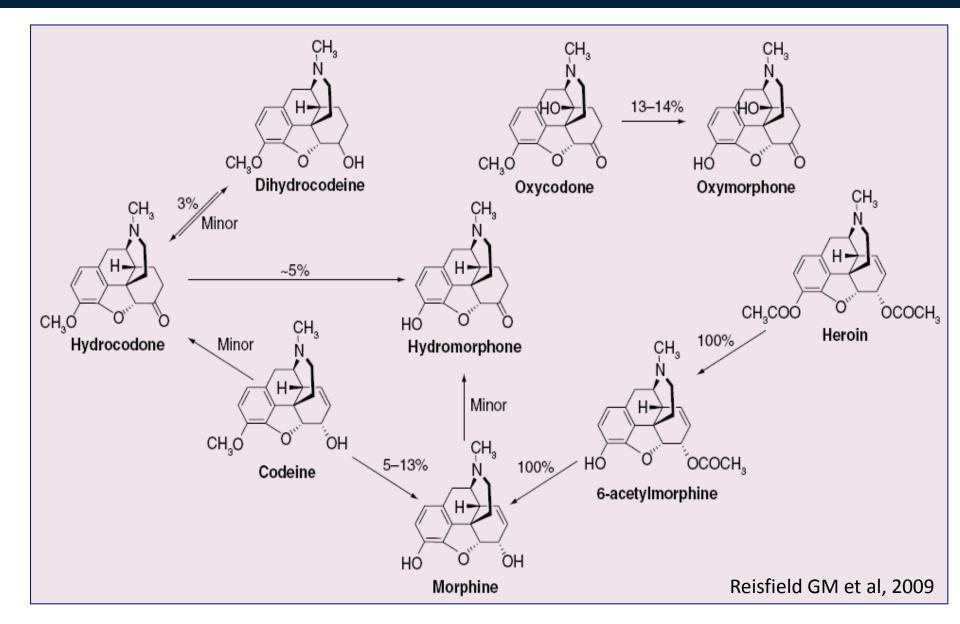
Use consistent approach (Universal Precautions) BUT apply it individually to match risk

Monitoring Urine Drug Tests

- Evidence of therapeutic adherence
- Evidence of non-use of illicit drugs
- Know limitations of test and your lab
- 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
- Know a toxicologist/clinical pathologist

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 Drug Tests



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



Prescription Drug Monitoring Programs (PDMP)

 Statewide electronic database on dispensed controlled substance prescriptions



- Prescription data (usually for the past year, and including information on date dispensed, patient, prescriber, pharmacy, medicine, and dose) are made available to prescribers and pharmacists
- A substantially underutilized resource
 - 22 states now mandate use before writing for controlled substances
- Several studies* suggest association between PDMP use and positive outcomes related to improving prescribing and reducing prescription drug abuse

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"

Discontinuing Opioids

- Do not have to prove addiction or diversion only assess and reassess the risk-benefit ratio
- If patient is unable to take opioids safely or is nonadherent with monitoring then discontinuing opioids is appropriate even in setting of benefits
- Need to determine how urgent the discontinuation should be based on the severity of the risks and harms
- Document rationale for discontinuing opioids
- Determine if the opioid needs to be tapered due to physical dependence

You are abandoning the opioid therapy <u>NOT</u> the patient

Using Risk Benefit Framework



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

https://www.scopeofpain.com/



What is the SCOPE of Pain?

SCOPE of Pain is a series of continuing medical education/continuing nursing education activities designed to help you safely and effectively manage patients with chronic pain, when appropriate, with opioid analgesics. Our program consists of:

- A 3-module cased-based online activity; and
- · Live conferences held around the US

Live conferences Online training

Trainer's Toolkit

A resource to facilitate safe opioid prescribing training of physicians, NPs, PAs, nurses and other clinicians in your institution or practice.



Access the toolkit