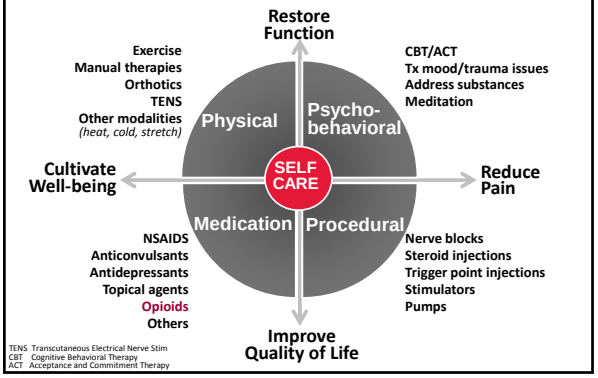
Safe and Competent Opioid Prescribing for Chronic Pain – Part 1
Assessing and Managing Risks

Massachusetts Pain Initiative, Marlborough, MA
October 9, 2014

Daniel P. Alford, MD, MPH
Associate Professor of Medicine
Boston University School of Medicine & Boston Medical Center
dan.alford@bmc.org

Boston University School of Medicine

It's more than medications…

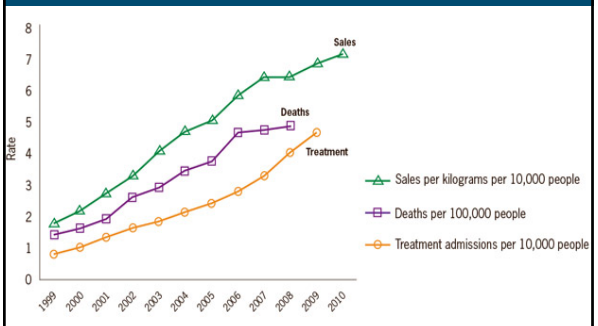


TENS Transcutaneous Electrical Nerve Stim
CBT Cognitive Behavioral Therapy
ACT Acceptance and Commitment Therapy

Agenda

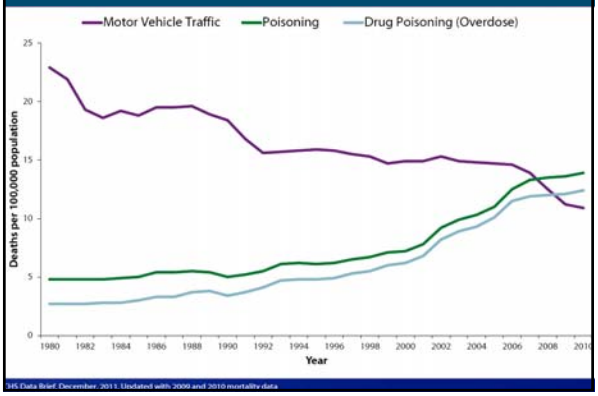
- **Part 1**
  - The scope of the problem
  - Opioid efficacy and safety
  - Assessing opioid misuse risk
  - Initial treatment planning
- **Part 2**
  - Risk/benefit framework
  - Monitoring tools
  - Addressing aberrant medication taking behavior
  - Addressing lack of benefit and/or excessive risk

Troubling Associations

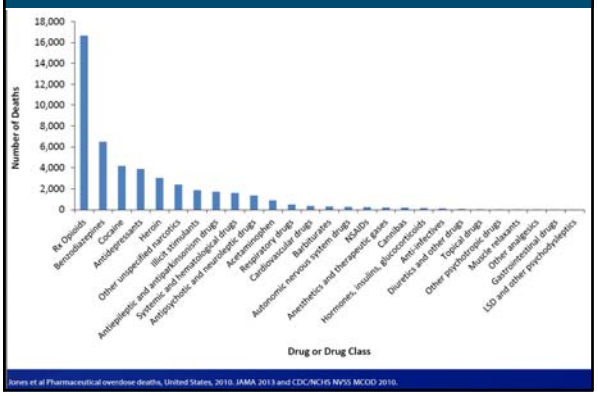


National Vital Statistics System, 1999-2008; Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA), 1999-2010; Treatment Episode Data Set, 1999-2009

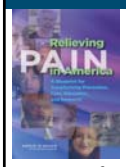
US Drug Overdose Death Rates 1980-2010



Rx Opioids Primary Driver of ODs 2010



Institute of Medicine: A Blueprint for Relieving Pain in America



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

- **Significant barriers to adequate pain care include:**
  - Gaps in pain assessment and management
  - 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**

Institute of Medicine. 2011 Relieving Pain in America. Washington DC

The Problem… chronic pain is complicated

Condition	Prevalence in Patients with Chronic Pain
Major Depression	15% to 56%
Anxiety Disorders	17% to 50%
Somatization Disorder	20% to 31%
Personality Disorders	31% to 81%
PTSD	20% to 34%
Substance Use Disorders	15% to 28%

Dersh J et al. Spine 2006
Trescot AM et al. Pain Physician 2008

Building Trust

Patient Issues

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

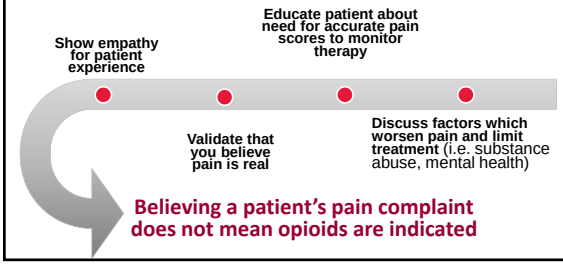
Often demonstrated by **exaggerating…**

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

Building Trust

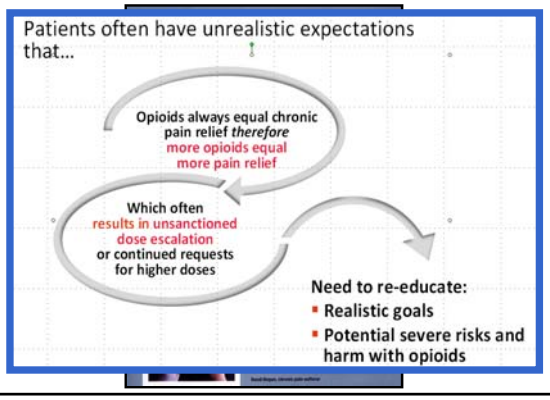
Clinician Issues

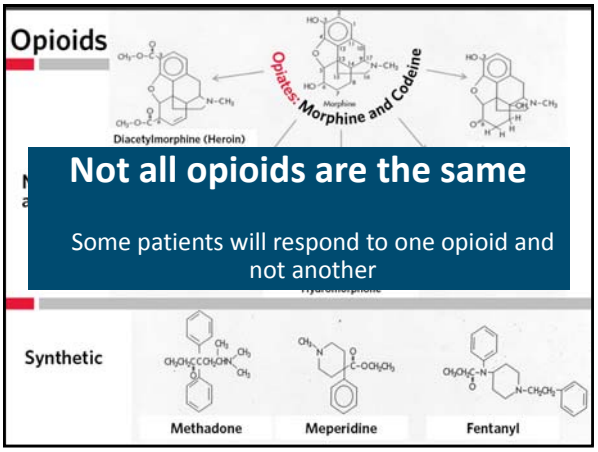
After you take a thorough pain history…



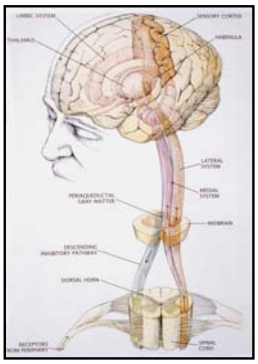
Believing a patient's pain complaint does not mean opioids are indicated

The Problem…unrealistic expectations





Activation of Mu Receptors



- Turn on descending inhibitory systems
- Prevent ascending transmission of pain signal
- Inhibit terminals of C-fibers in the spinal cord
- Inhibit activation of peripheral nociceptors
- **Activate opioid receptors in midbrain ("reward pathway")**

McCleane G, Smith HS. Med Clin N Am 2007

Variable Response to Opioids

Mu Receptor

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

Opioid metabolism

- Differs by individual opioid and by individual patient

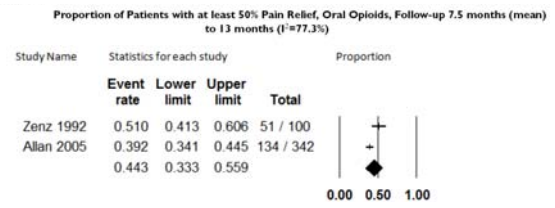
- **Not all pain responds to same opioid in the same way**
- **Trial of several opioids may be needed to find acceptable balance between analgesia and tolerability**

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

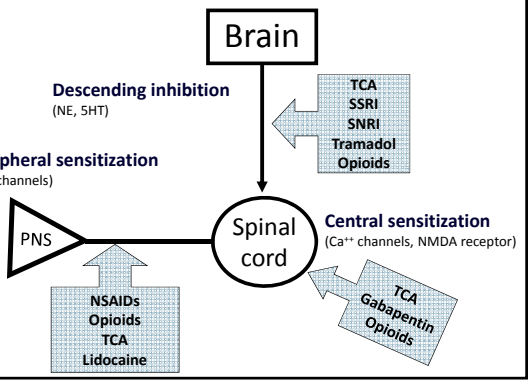
Opioid Efficacy in Chronic Pain



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

Noble M et al. Cochrane Systematic Reviews 2010

Mechanism-Specific Pain Management



Opioid Safety and Risks

- **Allergies** are rare
- **Organ toxicities** are rare
  - Suppression of hypothalamic-pituitary-gonadal axis
  - >50 mg (MSO_4 equivalents) assoc w/ 2X increase fracture risk
- **Side effects** are common
  - Nausea, sedation, constipation, urinary retention, sweating
  - Respiratory depression – sleep apnea

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 Safety and Risks

- **Worsening pain**
  - Hyperalgesia in some patients
  - Withdrawal mediated pain
- **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
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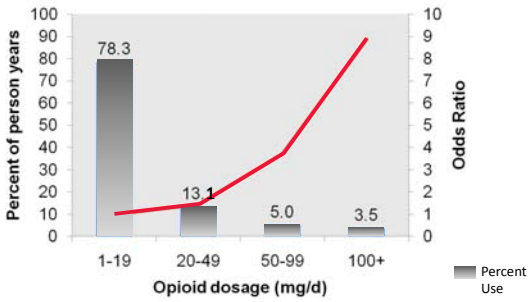
Opioid Overdose Risk



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

Opioid 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 <45 years
  - 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

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 failed
- **Patient agreeable to…**
  - **take opioid as prescribed** (e.g. no dose escalation)
  - **close monitoring** (e.g. pill counts, urine drug testing)

Monitoring Plan
"Universal Precautions"

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

- Agreements "contracts", informed consent
- Assess for opioid misuse risk (e.g., SOAPP, ORT)
- Monitor benefit & harm w/ 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

Agreements ("contracts")

- Educational and informational
- Articulate rationale and risks of treatment
- Articulate monitoring
- Articulates response to aberrant med-taking behaviors
- Takes "pressure" off providers to make individual decisions
  - 'Our clinic policy is…"
- Efficacy not well established (although no evidence of a *negative* impact on patient outcomes)
- No standard or validated form

Fishman SM. Clin J Pain, 2002; Arnold Am J of Medicine, 2006, Starrels Ann Intern Med 2010

Agreements
Potential Components

- One prescriber
- One pharmacy
- No unsanctioned dose increases
- Refill policy
- Patient agrees to consultations as needed
- No illegal drug use
- Patient agrees to urine drug testing and pill counts
- Patient identifies a responsible person to confirm behavior related to medication use

Fishman SM. Clin J Pain, 2002; Arnold Am J of Medicine, 2006

Informed Consent

- Side effects (short and long term)
- Physical dependence, tolerance
- Risk of drug interactions/over-sedation
- Risk of impairment
- Risk of abuse, addiction
- Legal responsibilities (disposing, sharing, selling)
- Opioid medication ***test***

Paterick et al. Mayo Clinic Proc. 2008

Opioid Misuse Risk Screening Tools

- **SOAPP**: Screener & Opioid Assessment for Patients w/ Pain
- **ORT**: Opioid Risk Tool
- **STAR**: Screening Tool for Addiction Risk
- **SISAP**: Screening Instrument for Substance Abuse Potential
- **PDUQ**: Prescription Drug Use Questionnaire

- **No "gold standard"**
- **Lack rigorous testing**

Webster et al. Pain Med. 2005
Butler et al. J Pain. 2008;
Adams et al. J Pain Symptom Manage, 2004

Opioid Risk Tool (ORT)

	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

Assessing Factors Affecting Pain

- **First**
  - Assume patient fears that you think ***the pain is not real or not very severe***
- **Second**
  - Listen to pain history
  - Show empathy for patient experience
  - Validate that you believe pain is real
- **Third**
  - Discuss factors which worsen pain and limit treatment (i.e. substance abuse, mental health)

Discussing Benefits

- Discuss realistic benefits of this treatment
- Long term goals
  - Realistic?
  - Fantasy?
  - Pain free?
- Remind patient
  - Pain unlikely to go away completely
  - Need to manage the problems that pain causes

Setting Goals for Next Visit

- **SMART** goals
  - **S**pecific
  - **M**easurable
  - **A**ction-oriented
  - **R**ealistic
  - **T**ime-sensitive
- Offer prescriptions as a **"test"** of the medication

Discussing Risks

- Discuss medication risks:
  - Sedation, constipation, physical dependence, addiction
  - Dangers of driving and hazardous work
- Discuss monitoring tools used to protect patient
  - Frequent face-to-face visits
  - Urine drug testing
  - Pill counts
  - Prescription monitoring program

Summary

- Not all pain is opioid responsive
- Analgesia and functional improvement may be modest
- Risks include side effects, overdose, addiction but organ toxicity is low
- Assess all patients for opioid misuse risk to set level of monitoring
- Manage all patients using "Universal Precautions"

Safe and Competent Opioid Prescribing for Chronic Pain– **Part 2**

Communication Skills Using a Risk Benefit Framework

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Agenda

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Opioids for chronic pain: 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

Be careful of…
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

Demonstrating Benefits

- Link continuation of opioids to demonstration of benefit
  - Improves patient's realistic expectations
  - Decreases need to prove that pain is terrible
    - "I still have pain, so I still need X"

    versus
    - "My meds allow me to do X, so it is worth it to me to keep taking them"

Monitoring for Harm

- Face to face visits – aberrant behaviors
- Questionnaires/surveys
- Urine drug testing
- Pill counts
- Prescription Monitoring Program (PMP) data

Butler et al. Pain. 2007;
Wu SM, et al. J Pain Symptom Manage. 2006

Addiction
Aberrant Medication Taking Behaviors

- A clinical syndrome presenting as…
  - Loss of Control
  - Compulsive use
  - Use despite negative Consequences

Aberrant Medication Taking Behaviors *(pattern and severity)*

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

Savage SR et al. J Pain Symptom Manage 2003

Aberrant Medication Taking Behaviors
The Spectrum of Severity

O
O
O
O
O
O
O
O
O

- 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

Modified from Portenoy RK. J Pain Symptom Manage 1996

Aberrant Medication-Taking Behaviors

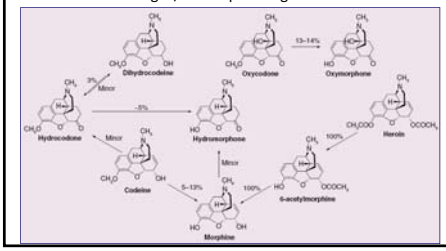
Differential Diagnosis

Pain Relief Seeking	Pain Relief and Drug Seeking	Drug Seeking
▪ Disease progression ▪ Poorly opioid responsive pain ▪ Withdrawal mediated pain ▪ Opioid analgesic tolerance ▪ Opioid-induced hyperalgesia	▪ Likely most common scenario ▪ e.g. pain with co-morbid addiction, patient taking some for pain and diverting some for income	▪ Addiction ▪ Other psychiatric diagnosis ▪ Criminal intent (diversion)

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

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



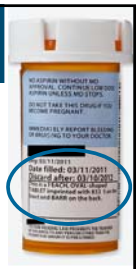
Reisfield GM et al, 2009

Monitoring
Urine Drug Tests

- 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**

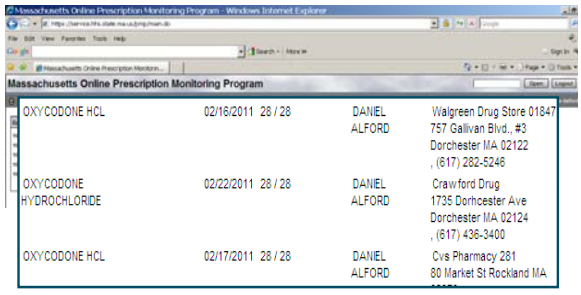
Gourlay DL, Heit HA, Caplan YH. Urine drug testing in primary care. Dispelling myths and designing strategies monograph (www.familydocs.org/files/UDTmonograph.pdf)

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

Prescription Monitoring Program



General Principles

- Maintain risk-benefit model, not a police-offender model
- Reassure patient that you understand pain severity
- Reflect on patient strengths (self-efficacy)
- Partner with patient by sharing control

Continuation of Opioids

- Assess and document benefits and harms
- To continue opioids:
  - There must be actual functional benefit
  - Benefit must outweigh observed or potential harms
- You do not have to prove addiction or diversion, only assess risk-benefit ratio

Lack of Benefit

- Reassess factors affecting pain
- Re-attempt to treat underlying disease and co-morbidities
- Consider escalating dose as a "test"
- No effect = no benefit
- If benefit cannot outweigh risks – STOP opioids

Excessive Risk

- DDx for aberrant medication behavior:
  - Miscommunication of expectations
  - Pseudo-addiction
  - Addiction
  - Diversion
- Match action to most likely cause
  - Not punishment to level of infraction

Matching Action to Ddx

- Tolerance of risk depends on benefit
  - Miscommunication– re-clarify rules once
  - Pseudo-addiction – increase dose as TEST
  - Addiction – stop opioids and refer to addiction treatment. +/- bridge or taper
  - Diversion – stop opioids

Continued Lack of Benefit

- Inadequate analgesia?
- Inadequate improvement in function?
- Not meeting treatment goals?
- Remember:
  - Not all pain is opioid responsive
  - More is not always better

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 the 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 e.g., loss of control, compulsive use, use despite harm
- Remember patients may suffer from both chronic pain and addiction
- May need to "agree to disagree"
- 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" mindset

Exit Strategy
Discussing Possible Diversion

- Discuss why you are concerned about diversion e.g., nonadherence with pill counts, UDT negative for prescribed opioid
- Discuss your inability to prescribe when there is any chance of diversion

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)."

Exit Strategy
Determine Withdrawal Risk

- Exposure to steady state level of medication
  - Neuro-adaptation to opioids
- Higher intensity withdrawal from:
  - Higher steady state levels
  - Longer term exposure
  - Faster rate of medication clearance
    - Long vs. short half life agents

Avoiding "Abandonment"

- You are **NOT** abandoning the patient, you are abandoning an ineffective or risky treatment
- Document risk/benefit discussion and why treatment discontinued
- Restate commitment to continue to work with patient on pain and addiction if needed
  - Refer to specialty pain treatment providers
  - Alert patient to addiction treatment resources
- See patient frequently and monitor for progress and safety
- Copy to patient and to chart

Summary

- Link opioid prescribing to functional benefits
- Present all prescriptions as trials
- Monitor for adverse effects and opioid misuse
- Use a risk-benefit model to stay in caring provider role, even while stopping opioids

www.scopeofpain.com

Upcoming Live Trainings

Tysons Corner, VA…Oct 25th

Boston, MA……Nov 14th

Burlington, VT……Nov 15th

Rocky Hill, CT……Nov 21st