Opioid Prescribing in Primary Care

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October 25, 2013
Disclosures

Attention
Due to the lapse in government funding, the information on this web site may not be up to date, transactions submitted via the web site may not be processed, and the agency may not be able to respond to inquiries until appropriations are enacted. Updates regarding government operating status and resumption of normal operations can be found at USA.gov

I personally have no disclosures but I have an excuse!!
Women Dying of Opioid Overdose at Unprecedented Rates
Megan Brooks July 02, 2013

FDA rewrites opioid narcotic labels to tighten use for pain
September 10, 2013 | By Melissa Healy

"Unreal" Overdose Spike Has Officials Ready to Fight Opioid Drugs
63 people overdosed in Bensalem over the past month, but the drug problem is much larger
By Vince Lattanzio | Tuesday, Oct 8, 2013 | Updated 11:25 AM EDT

"I’ve had it with these drugs and these people that are overprescribing them," he said. "They are a clear threat, as if they were terrorists, they are a threat to this nation. I don’t have an impact nationally, but I’m going to do everything in our power here in Bensalem...to combat these drugs and we’re going to push them back and we’re going to hold the line.”
Objectives

- Determine risks and benefits of prescribing opioids
- Discuss Universal Precautions for Opioid Management
- Introduce/review tools and strategies that might help make opioid prescribing efficient and safer
- Acknowledge responsibility we have as docs in mitigating opioid epidemic
ROUND RED TABLET
Side 1: OC
Side 2: 60

May Cause
Drowsiness, Alcohol
May Intensify This
Effect. Use Care
When Operating A
Car Or Dangerous
Machinery.

May Cause Dizziness

Swallow Whole. Do
Not Chew Or Crush.

OXYCONTIN 60MG TABLETS
MFG PURDUE
TAKE 5 TABLETS BY
MOUTH EVERY 6 HOURS
FOR PAIN

USE BEFORE 03/19/10

QTY 590
NO REFILLS

Walgreens

4 HAMMERHEAD PL, CROMWELL, CT 06416

(860) 613-2324
Scope of Problem

- Since 1999 mortality rates have doubled to quadrupled
- 36 million Americans use opioid drugs illegally (10%)
- 2010 28K people died of opioid involved drug OD in America
- Costs BILLIONS (lost productivity, medical care, etc)
- 2010 2 million people > age 12 reported they tried using rx pain meds for a non medical reason for the first time (5,500 per day)
Just a thought...

Do you remember REZULIN?

- Diabetes drug
- Liver damage to fulminant failure ~ 430 patients
- Death in 391

OPIOIDS

28,000 deaths 2010

For every 1 death there are...

- 10 treatment admissions for abuse
- 32 emergency dept visits for misuse or abuse
- 130 people who abuse or are dependent
- 825 nonmedical users

http://www.cdc.gov/homeandrecreationalsafety/rxbrief/
Which is the highest selling drug in the US?

Vicodin: 131 million rx
For 47 million people
Where do people get opioids?

- 55% free from friend or relative
- 17.30% from 1 doctor
- 11.40% took from friend/relative
- 4.80% bought from friend/relative
- 4.40% got from drug dealer/stranger
- 7.10% other

http://www.cdc.gov/homeandrecreational safety/rxbrief/v
What a Pain!

- Inappropriate prescribing can lead to:
  - Reduced function
  - Addiction
  - Abuse
  - Diversion
  - Death

- Adequate evidence for long term opioid rx is lacking
  - Studies show that quality of life for many is reduced
  - Higher depression and healthcare utilization rates

- SO WHY DO WE DO IT??
But Pain is perfect Misery, the worst
Of evils and, excessive, overturns
All patience…
~ John Milton, *Paradise Lost* 1935
Inadequate pain tx vs inappropriate prescribing of opioids

• Why?
  • Lack of knowledge of best practices
  • Unknown real source/treatment of pain
  • Conflicting guidelines
  • Concern for regulatory authorities
  • Misunderstanding of causes and signs of dependence and addiction
  • Fear of causing addiction
  • Fear of being duped
  • **Mistaken belief that complete pain relief is attainable**
Requirements of some states

- Many state medical boards require prescribers to complete a certain number of CME credits on topics related to appropriate prescribing
  - California: Pain management,
  - California DO: Pain management,
  - Connecticut: risk management,
  - Florida DO: risk management, controlled substances; subsequent renewals: One hour each in risk management,
  - Florida: controlled substances; CME with regard to risk management,
  - Massachusetts: registration in the PMP, 3hrs CME
  - Oklahoma DO: prescribing controlled substances (every 2 yrs)
  - Pennsylvania: risk management or patient safety
  - Pennsylvania DO: risk management and (AOA 1-A) patient safety
  - Rhode Island; 2 credits: pain management
  - Tennessee; 1 credit (every 2 years) in appropriate prescribing
  - West Virginia: pain management
  - West Virginia DO: 2 credits (one-time requirement) in (AOA 1-A or B) end-of-life care, including pain management
Pain Types

A. Nociceptive  Noxious Peripheral Stimuli

B. Inflammatory  Inflammatory

C. Neuropathic  mixed mechanisms

D. Noninflammatory/Nonneuropathic  No mechanical stimuli

- Strains and sprains
- Bone fractures
- Postoperative

- Osteoarthritis
- Rheumatoid arthritis
- Tendonitis

- Diabetic peripheral neuropathy
- Post-herpetic neuralgia
- HIV-related polyneuropathy

- Fibromyalgia
- Irritable bowel syndrome


Central Sensitization

- Disproportionate, non mechanical, unpredictable pain from nonspecific aggravating and palliative factors
- Diffuse tenderness on palpation
- Strong association with maladaptive factors
- Hyperalgesia
- Allodynia
- Pain summation
- Radiation beyond dermatomal distribution

Antidepressants/anti sz help to reduce release of sub P, glutamate and NE producing analgesic and anxiolytic effect (lyrica, NSRI)

Psychiatry vol 10, no 5 May 2010 pg 15-16.
Strategies for Pain and Associated Disability

Pharmacotherapy
- nonopioids
- adjuvant analgesics
- topicals
- opioids

Interventional Approaches
- Injections
- Neurostimulation

Physical Medicine and Rehabilitation
- Assistive devices
- Electrotherapy

Complementary and Alternative Medicine
- Massage
- Supplements

Psychological Support
- Psychotherapy
- Group support

Lifestyle Change
- Exercise
- Weight loss
MU Receptor Activity

- 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")

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 Choice

- Duration and onset of action
  - “Rate hypothesis” - fast on, fast off – most rewarding - addicting
- Patient’s prior experience
  - Mu polymorphisms – differences in opioid responsiveness
- Route of administration
- Side effects and Cost
- Currently there are NO abuse resistant opioids or opioid formulations
<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose available</th>
<th>Usual dose</th>
<th>cost</th>
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<td><strong>Morphine</strong></td>
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<td>immediate-release</td>
<td>15, 30 mg tabs</td>
<td>15-60 mg</td>
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<td>generic</td>
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<tr>
<td>extended-release</td>
<td>15, 30, 60, 100, 200 mg tabs</td>
<td>15-30 mg²</td>
<td>q8-12h</td>
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<tr>
<td>generic</td>
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<td>MS Contin (Purdue)</td>
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<td>Nucynta (Ortho-McNeil Janssen)</td>
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<td>Ultram (Ortho-McNeil Janssen)</td>
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Morphine is King

- Use morphine equivalent as basis for risk of death
- > 100 mg ME increases risk of OD X 2
- >200 mg ME increases risk of OD X 9

- Oxycontin 20 mg bid ~ 40 mg daily = 60 mg ME
- Methadone 10 mg bid ~ 20 mg = 75 mg ME
- Fentanyl 50 mcg/h = 100 mg ME
There’s an app for that…
Weak Opioid Agonist
NE and 5-HT Reuptake Inhibitor

- **Tramadol** (immediate and extended release)
  - Mu-opioid agonist
  - Norepinephrine and serotonin reuptake inhibitor

- **Tapendtadol (Nucynta)**
  - Mu-opioid agonist
  - Norepinephrine reuptake inhibitor
  - Is scheduled as II
Methadone

- NMDA receptor antagonist
- Less euphoria (po)
- 5HT, NE uptake inhibition
- Inexpensive

- Long, variable, unpredictable half-life
  - Analgesia 6-8 hours
  - Serum t½ 20-40 hours
- QTc prolongation, risk of torsades de pointes
Model Policy

- Physician Responsibility
  - Assess patient
  - Establish a clear diagnosis and DOCUMENT this
  - Review old records if available
  - Assess the relative risk for abuse and misuse
  - Written consent and medication agreement
  - Monitor for aberrant behaviors
  - Intervene as appropriate
Model Policy: assessment of pt

- Benefits must outweigh the risks
  - Assessment must be adequate and show opiate treatment is an appropriate course
  - History and Physical!!
  - Imaging for evaluation
- Assess for risk of abuse and misuse
Model Policy: Prescribe Cautiously

- Informed Consent/patient education
  - Co-morbid conditions, other meds
  - Risk of medication to self and others
  - Lock up of meds
- Patient Agreement ("narcotic contract")
  - Regular visits
  - One pharmacy
  - Discuss ED visit/other prescribers
  - Pill counts random
  - Random Urine tox screens
  - Violation plans
Opioid Risk Tool

- Provides 5-item initial risk assessment
- Stratifies risk groups into low (6%), moderate (28%) and high (91%)
  - Family History
  - Personal History
  - Age
  - Preadolescent sexual abuse
  - Past or current psychological disease

Valid?
- 125 pt enrolled
- 112 ADRBs in 53 over 8 months
  - 32 UDS found
  - 7 id’d by physician obs
  - 14 both

Who had ADRB out of ORT
- 41 of 106 (38.7%) low risk
- 8 of 14 (57%) mod risk
- 4 of 5 high risk (80%)

Webster, Webster. Pain Med, 2005
What is addiction risk?

- Published rates of abuse and/or addiction in chronic pain populations are 3-19%\(^1\)

- Suggests that **known risk factors** for abuse or addiction in the general population would be **good predictors** for problematic prescription opioid use

  - Past cocaine use, history of alcohol or cannabis use\(^2\)
  - Lifetime history of substance use disorder\(^3\)
  - Family history of substance abuse, a history of legal problems and drug and alcohol abuse\(^4\)
  - Heavy tobacco use\(^5\)
  - History of severe depression or anxiety\(^5\)

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Opioid Hyperalgesia

• Cellular responses to chronic opioid intake:
  • an increase in neuropeptides such as dynorphin$^{11}$, cholecystokinin,$^{12}$ and substance P$^{13}$
    • all of which have been demonstrated to enhance pain sensitivity
  • the activation of glial cells, producing inflammatory cytokines and resulting in amplified pain.$^{14}$

Monitoring

- Drug screening
- Prescribe small quantities
- Frequent visits
- Single pharmacy
- Pill counts
- Consult PMP if available in state

- FSMB Guidelines, 2004
  (http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf);
Follow up Tools: Pain Assessment and Documentation Tool: (PADT) 4 A’s

- **Analgesia**
  - What was your pain level on average during the past week? 0-10
  - What was your pain level at the worst in last week? 0-10
  - What percentage of your pain has been relieved? 0-100%
  - Is the pain relief enough to make a real difference in your life?
  - (doctor answers: is relief clinically significant??) Yes/No

- **Activities**
  - Physical/function ~ better, worse, same
  - Family relationships
  - Social relationships
  - Mood
  - Sleep patterns
  - Overall Functioning
PADT cont

- Adverse Events
  - Any side effects from the medicine?
    - Nausea
    - Constipation
    - Mental Cloudiness
    - Itching
    - Sweating
    - Fatigue
    - Drowsiness
    - Other

- Aberrant Drug Behavior
  - Appears intoxicated
  - Negative mood change
  - Unkempt/impaired
  - Accidents
  - Early renewal/lost/stolen
  - Increased doses without ok
  - Contact with street culture
  - Abusing etoh or illicits
  - Arrested
  - Hoarding or stockpiling
  - Insists on med by name
  - Uses in response to stressor
  - Gets from other doctor
PEG Tool

• Past week average pain?

• Enjoyment (pain interfering?)

• General activities
Monitoring: urine drug tests

- Implementation Considerations
  - Know limitations of test and your lab
  - Be careful of false negatives and positives
  - Talk with the patient: “If I check your urine right now will I find anything in it?”
  - Random versus scheduled
  - Supervised, temperature strips, check Cr
  - Chain-of-custody procedures

Urine Testing

Purpose

- Evidence of therapeutic adherence
- Evidence of non-use of illicit drugs
- Knowing that they will be tested reinforces use of med ~ may reduce illicit drug use

Results of study from pain medicine practice (n=122)

- 22% of patients had aberrant medication taking behaviors
- 21% of patients had NO aberrant behaviors BUT had abnormal urine drug test

Therefore, aberrant behavior and urine drug test monitoring are both important

The dedicated deceiver...
Pill Counts

- Can give up to 31 day supply to patient
- Can give up to three months with start dates on other rx’s

- 28 day supply
- 24 hour policy
- How about that dedicated deceiver?
  - “rentals”
Multifactor Implementations

Educate: medical students/residents/physicians/patients/Communities
- www.drugabuse.gov/nidamed
- www.pcss-o.org

Follow Best Practice Recommendations
- http://www.nhms.org/resources/Opioid.php

Increase numbers of Rx Return facilities/take back programs

Collaborate: PC, specialities, mental health, pharmacy, law enforcement PDMP
Best Practice

- Use non-opioid pain relieving meds and adjunctive tx
- Start with short acting medicine
- Use a controlled substance agreement/consent
- Avoid other sedating medications
- Monitor A’s (analgesia, activity, adverse effects, aberrant behavior), urine for compliance
- Set up behavioral health for chronic pain
- Consider medication rotation
- Taper if not working
- Stop if concerns for diversion, abuse or addiction
- Refer for further treatment if out of primary care realm
Making changes at a Community Hospital

- Asked to create “guideline”
  - Determine minimum education for docs
  - Develop (or adopt) a controlled substance agreement to be used system wide
  - Be a resource for providers
  - Develop liaison relationship with pain management providers
  - Explore partners in mgt ~ acupuncture, behavioral health, PT, exercise programs, support groups
- Monitor outcomes
  - Physician satisfaction
  - Possibly # of patients on chronic opioids
  - # of patient referrals to pain management for med management
On-line resources

http://www.partnersagainstpain.com/printouts/Opioid_Risk_Tool.pdf

http://www.ucdenver.edu/academics/colleges/PublicHealth/research/centers/maperc/online/Documents/Pain%20Assessment%20Documentation%20Tool%20(PADT).pdf

http://www.painedu.org/soapp.asp

www.PCSS-O.org

www.scopeofpain.org


NHMS Resource Tool:

http://www.nhms.org/resources/Opioid.php