Curbing the Opioid Epidemic at Gundersen Health System

IHI Learning Lab – L11
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The presenters have nothing to disclose

Objectives

• Discuss the history of opioid prescribing

• Discuss the results of increased opioid prescribing

• Present 4 patient cases in which opioid medications would be considered in the treatment plan

• Describe Gundersen Health System’s approach to opioid medications and monitoring

• Provide recommendations regarding appropriate opioid prescribing and monitoring of patients with chronic pain
Pain overview

• Pain is a widespread, costly issue
  – Chronic pain affects 50-100 million American adults
  – More than the total affected by heart disease, cancer, and diabetes combined
  – Most common reason people seek medical advice
  – WHO – Pain “number one health problem in America”
  – Huge financial costs – costs the nation up to $635 billion per year in medical treatment and lost productivity
  – Leading cause of disability


History of opioid prescribing in chronic pain

• Opium-derived substances have been around for thousands of years

• Early in 20th century, heroin sold as cough suppressant
  – Heroin addiction became prevalent → Congressional banning in 1924

• Through 1980’s
  – Opioids for chronic pain largely prohibited
  – Physicians risked: medical board sanctions, license restriction
History of opioid prescribing in chronic pain continued...

• 1990’s
  – Small studies demonstrated safety and efficacy of long-term use
    • Drs. Portenoy and Foley published 38 patient case series
      – Maintained on opioids for non-malignant pain
      – Concluded opioid maintenance therapy can be “a safe, salutary and more humane alternative to the options of surgery or no treatment...”
  – Specialty groups advocated for use and change in regulations


1990’s continued...

– 1998 - Federation of State Medical Boards released policy reassuring physicians they wouldn’t face regulatory action for prescribing

– Late 1990’s
  • APS promoted pain be included in every routine assessment
  • Veterans Health Administration - national strategy to improve pain management for its patients
• 2000’s
  – Development of guidelines for pain assessment “Pain as the 5th Vital Sign Toolkit”
    • Later became a Joint Commission standard
  
  – Congress passed and Clinton signed H.R. 3244 declaring 2000-2010 the “Decade of Pain Control and Research”
  
  – With the stroke of a pen, pain management was declared a “patient right”

No opioids for chronic pain  Opioids for all
 Increases in prescribing

• Large increase in non-cancer opioid prescribing over the past 2 decades
  – U.S. opioid sales quadrupled between 1999 and 2010

• Hydrocodone/acetaminophen was the number one prescribed medication 2006-2011


 Increases in prescribing

• Increase from 96 mg OME/person in US in 1997 to 710 mg /person in 2010

• Equivalent to enough to supply every adult American with 5 mg of hydrocodone every 6 hours for 45 days

• Sales increases (1997-2007):
  – 280% for hydrocodone
  – 1,293% for methadone
  – 866% for oxycodone

What were the results?

- Did we cure chronic pain?
- Did we improve patients’ functions?
- Did we improve quality of life for our patients?

Results → Mixed
Opioids are good in the short term, but...

- Several RCTs suggest opioids provide modest pain relief in short to medium term
  - Well established role in severe forms of acute pain and cancer pain
- Much less evidence opioids provide long term pain relief in non-cancer pain
- Systematic review of 39 studies of chronic pain patients treated with opioids
  - Results: No evidence long-term benefit (mainly secondary to paucity of data)
  - Authors did find evidence for increased risk of serious harm that was dose dependent


Many other studies have reported opioid users have:

- Higher pain scores vs non-opioid users
- Decreased quality of life and employment
- Increased disability and healthcare utilization
  - Increased medical costs and subsequent surgery
- Additionally – it is not unusual for chronic opioids to be ineffective or stop working over time

Epidemiologic study from Denmark

- Opioids prescribed liberally
- Study compared a matched cohort of chronic pain patients either using or not using opioids
- Opioid patients had:
  - Worse pain
  - Higher health care utilization
  - Lower activity levels

Study suggested that when prescribed liberally, even if some patients benefit, overall population does not


Adverse effects are common

- Probably 80% of patients suffer at least one adverse effect
  - Sedation, impaired cognition, nausea, constipation, bladder dysfunction, others
- Long term opioid use → other undesirable effects
  - Immune system depression, hormonal disturbances, sleep disordered breathing, hyperalgesia, and others
- Recent systematic review*:
  - Long-term use associated with overdose, abuse, higher rate of fractures, myocardial infarction and markers of sexual dysfunction
  - Risk seems to be dose dependent for some harms


As prescribing increased, so did opioid related deaths

![Graph showing trends in opioid deaths and treatments](image)

*Fig. 3. Rates*° of opioid pain reliever (OPR) overdose death, OPR treatment admissions, and fills were of OPR sold in the United States, 1999-2010.

° Age-adjusted rates per 100,000 population for OPR deaths, create rate per 10,000 population for OPR abuse treatment admissions, and create rate per 10,000 population for fills are of OPR sold.


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Inappropriate use...

- SAMHSA’s (Substance Abuse and Mental Health Services Administration)
  - National Survey on Drug Use and Health 2013 results:
    - 4.3% of adults aged 18-64 used prescription opioids for nonmedical use in the past year
  - DEA – 1 in 10 teenagers report using prescription opioids to get high in the past year
    - 1 in 16 in the past 30 days
  - Opioids now involved in more drug overdose mortalities than cocaine and heroin combined
  - ½ of fatal overdoses involve concomitant use of sedative-hypnotics (especially BZDs)

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National Survey on Drug Use and Health, 2013 results.

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Gundersen Lutheran Medical Center, Inc. | Gundersen Clinic, Ltd.
Opioid danger!

- **44 people per day die** as a result of prescription opioid overdose in the U.S.
  - Highest rate in the 25-54 age group

- Drug overdose was the leading cause of injury death in 2013
  - People 25-64 years old: Overdoses caused > deaths than MVAs


Dependence on opioids has become a gateway to heroin

- According to the National Institute on Drug Abuse:
  - **1 in 15** people who take a prescription opioid for non-medical reasons will try heroin within the next 10 years

• According to the CDC, for every 1 unintentional overdose death related to opioid analgesics...
  - 9 persons are admitted for substance abuse treatment
  - 35 visit EDs
  - 161 report drug abuse or dependence
  - 461 report non-medical use of opioid analgesics


Where did these drugs come from?

- Free from Friend/Relative
- One Doctor
- Bought from Friend/Relative
- Took from Friend/Relative
- Drug Dealer/Stranger
- Bought on Internet

79.4% of these came from ONE doctor

SAMSHA. Results from 2010 National Survey on Drug Use and Health: Summary of Findings.
While we all like to think overdoses just occur in drug seekers/abusers...

![Bar chart showing percentage of patients and prescription drug overdoses, by risk group – United States.](image)


All sides agree...

- There are risks with these medications and not all patients do well with opioids...

- However, there are patients who derive great benefit and do well long-term on opioids
Case 1

- 65 yo female presents with a 6 year history of chronic low back and neck pain
- PMH: Complete L RTC rupture, CTS, known scoliosis and DDD
- SH: Continues to work full time, married, no tobacco/EtOH/substance use
- Past treatments: PT (land and pool), chiropractic care, massage, injections (ESIs, cervical and lumbar facets, MBB/RFA, left shoulder injections)

Past medication trials:
- Gabapentin (side effects)
- Cyclobenzaprine, methocarbamol (side effects)
- Diclofenac patches (helpful – no insurance coverage)
- Multiple opioids
  - Most caused side effects (mainly extreme pruritus)
  - Has tolerated hydrocodone fairly well

Current medications:
- Acetaminophen 3000 mg/day
- Diclofenac 75 mg BID
- Hydrocodone/APAP 5/325 mg tabs – takes 1-2 per day prn
Questions to answer

• Anything else you need/want to know?
• Treatment plan moving forward?
  – Other treatments you want to offer?
• Appropriate to continue opioids?
  – If yes:
    • Do you do any type of opioid agreement/monitoring?
    • How often do you provide refills?
    • How often do you need to see her?

Large Group Discussion
Case 2

- 36 yo male
- Diagnosed with stage IV colorectal cancer with liver metastases

- PMH: Otherwise insignificant
- SH: Married, continues to work full time for a local company, no tobacco/EtOH/substance use

- Cancer treatment: Low anterior resection, chemotherapy, radiation, ablation of liver mets
- Presents with low back and bilateral leg pain

- EMG: severe bilateral L3 radiculopathies and partial involvement of L4 nerves thought secondary to radiation

- Lumbar MRI: far lateral disc at L3-4 compressing left L3 nerve root

- Consults:
  - Neurosurgery and Neurology: recommend conservative treatment

- Treatments: PT, TENS, Medrol Dosepak, OTC topicals, gabapentin, oxycodone 5 mg tabs – takes 3-4 per day
Questions to answer

- Anything else you need/want to know?
- Treatment plan moving forward?
  - Other treatments you want to offer?
- Appropriate to continue opioids?
  - If yes:
    - Do you do any type of opioid agreement/monitoring?
    - How often do you provide refills?
    - How often do you need to see him?

- What if this case were different and he was completely disease free (5 years out from last known disease)...

- Would you monitor this 36 yo male differently?
Large Group Discussion

Case 3

- 62 yo male
- PMH: CAD with history MI, HTN, OSA, history of multiple spinal surgeries (fused T2-sacrum per his report – done elsewhere)
- SH: On disability, history of EtOH abuse, admits to daily marijuana use
- Presents with continued thoracic and lumbar back pain and right lumbar radicular pain
- Past treatments: PT, “aromatherapy and breathing exercises”, and multiple ESIs elsewhere
- Moved to the area from Massachusetts and on Naproxen twice daily and hydrocodone/acetaminophen 10/325 mg tabs – 6 tabs/day
  - Brings bottles with; no outside records available
Questions to answer

• Anything else you need/want to know?
• Treatment plan moving forward?
  — Other treatments you want to offer?
• Appropriate to continue opioids?
  — If yes:
    • Do you do any type of opioid agreement/monitoring?
    • How often do you provide refills?
    • How often do you need to see him?

• Should you address the marijuana use and, if so, how do you address?
Large Group Discussion

Case 4

• 50 yo female

• PMH: Chronic back pain, anxiety, depression, CAD with history MI, HTN, hypothyroidism, and known non-compliance with medical care

• Followed for years regarding her LBP

• History of multiple broken opioid agreements secondary to:
  – Lost prescriptions
  – Overuse of medications
  – Multiple failed UDTs
    • Prescribed medicine not present and non-prescribed substances present
• Presents 7 months following extended hospital stay to treat bilateral lower extremity compartment syndrome requiring fasciotomies, multiple debridements and subsequent split thickness skin grafts

• Patient was non-compliant with medications, became severely hypothyroid → hyponatremia, tissue edema → rhabdomyolysis and compartment syndrome
  — Initial CPK >20,000

• Pain is bilateral legs with right side >> left side

• Past pain medications: NSAIDs (including COX2 – PUD and GI upset), cyclobenzaprine, metaxolone, pregabalin, topiramate, gabapentin, tramadol

• Other treatments: PT – currently undergoing for strengthening

• Current medications: Acetaminophen, oxycodone (10 mg at bedtime)

Questions to answer

• Anything else you need/want to know?
• Treatment plan moving forward?
  — Other treatments you want to offer?
• Appropriate to continue opioids?
  — If yes:
    • Do you do any type of opioid agreement/monitoring?
    • How often do you provide refills?
    • How often do you need to see her?

• How would you address the past broken opioid agreements?
Large Group Discussion

As mentioned earlier, all sides agree...

- There certainly are risks with these medications and not all patients do well with opioids...

- However, there are patients who derive great benefit and do well long-term on opioids

- **Competing public health concerns:**
  - Under-treatment of pain
  - Abuse of prescription drugs

- What is the best way to curb this epidemic while continuing to treat patients’ pain?
Gundersen Health System
Background

Gundersen Lutheran Medical Center, Inc. | Gundersen Clinic, Ltd.
La Crosse, Wisconsin

- Multispecialty group medical practice
- 325 bed teaching hospital
- Level II Trauma and Emergency Center
- 30 Primary Care Clinics
- +700 medical, dental and associate staff
- 5,500 support staff
Disease Registries at GHS

- 9 Disease Registries
  - Asthma
  - CKD 1,2,3
  - CKD 4,5
  - Depression
  - Hypertension
  - Heart Failure
  - Diabetes
  - Chronic Pain
  - Coronary Artery Disease

Chronic Pain Committee Structure

- Primary Care Providers
- Pain Medicine Specialist
- Legal
- Nursing
- Patient Education
- Quality Improvement
- IS/IT
Oversight

Executive Committee

Quality Committee

Disease Management Steering Committee

Chronic Pain Committee

Standard Operating Procedure

Why: Standardize care for patients with chronic pain

How:

– Outline roles and responsibilities of care team
– Define prescribing practices for long term opioid medications
– Establish guidelines for compliance including urine toxicology and agreements
Opioid Agreement Content

- Side effects and contraindications

- Patient responsibility
  - Medication use
  - Refill guidelines
    - Lost or damaged medications
    - Requests for early refills
    - Use of one pharmacy
  - Prescription pick up
    - Only one other person may pick up prescriptions
    - Photo ID required
  - Goals
Content Continued...

• Emergent need for other opioid or increase in dose

• Compliance requirements
  – Urine toxicology screening
  – Pill counts

• Safe storage

Content Related to Agreement Failure

• Missed or same day canceled appointments
• Urine screen reveals illicit/unexpected substance(s) or absence of prescribed opioid
• Criminal charges
• Refusing pill count/urine screens
• Aberrant behavior
• Inappropriate medication use
Standard Patient Education Materials

Chronic Pain Patient Education Bundle:
- Opioids Safe Use and Side Effects
- How to Prevent Opioid Constipation
- A Pain Control Log
- Your Role in Your Care

Chronic Pain Registry

- Registry Population: patients on Schedule II opioids for 6 consecutive months

- Registry Metrics
  - DIRE Score - once in lifetime
  - Urine Toxicology Screening - annually
  - Chronic Pain Agreement - annually

- Number of patients currently enrolled: 2300
Registry View

Standard Medication Refill Template

Pending Prescriptions

- oxycodone CR (OXYCONTIN C.R.) 20 mg controlled release tablet
Sig: Take 1 Tab (20 mg) by mouth 3 times daily.

Refill(s) request received via call from patient.
Chart review completed
Last refill given on 9/21/14. Next refill due 10/19/15.
Last acute visit with RB on 9/14/15. Next appointment scheduled with RB on 1/19/16.

Chronic Pain Registry

Yes

Pain Agreement/Dire Score:

Dire Score: 20

Agreement Status: Renewed

Last compliance urine drug screen:

Please review, edit and authorize pending prescriptions above as appropriate.
System Implementation

- Provider education:
  - By request prn
  - Department chair meeting
- RN/LPN/MA education:
  - Required to complete online module
- Standard operating procedure
  - Guided practices
  - Role checklists

Sustaining Change

- Access to performance outcomes:
- Access to reports: patient level detail
The Opioid Controversy

No opioids for chronic pain

Opioids for all

Reset of pendulum to the center

Curtailing abuse/misuse

- A number of professional societies worldwide have produced guidance advocating/promoting judicious and careful use

- Washington State – developed opioid dosing guidelines which basically recommends limiting dosing to <120 mg/day OMEs
  - Initial guidelines released in 2007
  - Results: 29% decrease in opioid-related deaths between 2008-2013

- UCSD Opioid Dose Threshold*

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<tr>
<td>Fentanyl</td>
<td>100 mcg/hr</td>
<td>50 mcg/hr</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>240 mg/day</td>
<td>80 mg/day</td>
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*Gregory Polston, MD, UCSD Director of Pain Medicine. Presentation at AAPM conference 2013.
• Hooten WM, et al. recently reported 1 in 4 patients prescribed an opioid for the first time progress to episodic or long-term opioid use.

• Patients more likely to progress to longer-term use include those with:
  – History of substance abuse
  – Nicotine use
  – Greater burden of illness

Initial Steps of Opioid Therapy as proposed by ASIPP

- Comprehensive assessment
  - Thorough history and physical exam
  - Other history: general medical, psychosocial
  - Functional status
  - Sleep patterns
  - Psychological evaluation – evaluation for depression, anxiety, somatization
  - Substance use history
  - Addiction risk screening via screening tool
  - Monitoring


Prescribing

- Standard operating procedure/policy/protocol in place
- Opioid agreement/contract
  - Urine Drug Tests (UDT), random pill counts, one pharmacy,…
- Use of state prescription drug monitoring programs (PDMPs)
- Screen for risk factors: depression, anxiety, substance abuse
- Consider using an opioid risk assessment tool
  - Eg. DIRE, ORT, SOAPP, …
- Educate your patients
  - Risks, how to take – don’t assume patients know how to use opioids safely
Opioid agreements (OA)

- Several purposes:
  - Outlines provider expectations of patient
  - Outlines provider is working to provide pain and functional improvement for patient
  - Provides informed consent regarding risks and benefits
  - Potentially improves treatment program adherence and limits abuse

- Recommended by multiple groups:
  - American Academy of Pain Medicine
  - American Society of Interventional Pain Physicians
  - American Pain Society
  - Veterans Health Administration
  - Federation of State Medical Board
  - Multiple Others...

However...

- There is controversy over whether the OA purposes are achieved
- Very limited empirical evidence regarding effectiveness in reducing drug abuse and diversion
- Ethical issues associated with use
  - Paternalistic
  - May impair physician-patient communication/relationship
- If not used universally – unjust, bias

What is the evidence for OA and UDT?

- There are few, well done studies looking at this

- Starrels JL, et al. performed a systematic review looking at treatment agreements and UDT to reduce opioid misuse in patients with chronic pain
  - Only 11 studies met inclusion criteria and all observational (and quality of the studies were fair to poor)
  - Results: in the 4 studies with comparison groups, opioid misuse was modestly reduced (7% to 23%) with OA +/- UDT
  - Conclusion: There is weak evidence supporting the effectiveness of UDT and OA


Continued...

- Authors state...
  - “Even in the absence of strong evidence, several compelling reasons for physicians to consider implementing these strategies exist.”

  - PCPs who use OA report improved satisfaction, comfort, and sense of mastery in managing chronic pain
  - Associated with reductions in ED visits in observational studies
  - Multiple studies demonstrate UDT is valuable tool in detecting non-prescribed drugs and confirming adherence beyond that identified by patient self-report or impression of treating physician
  - Implementing routine UDT may improve provider-patient relationship and clinical morale
Authors evaluated the quality and content of guidelines on the use of opioids for chronic pain.

13 guidelines met selection criteria.
- When assessing mitigation risks, 3 guidelines had little content so the other 10 guidelines were assessed.

Results regarding risk mitigation:
- 9 (of 10) guidelines recommend considering use of risk assessment tools and treatment agreements.
  - “Treatment agreements may improve adherence and providers’ willingness to prescribe opioids, on the basis of a few small, observational studies.”
- 9 (of 10) guidelines recommend urine drug testing.
  - Recommendations vary from consider to mandatory.

My thoughts...

- Although there is limited evidence regarding OAs and UDT, if we are going to continue to provide opioid medications safely to the patients that need these, health care systems need to be designed to support routine opioid monitoring.
Opioid prescribing/monitoring tips

• At each visit, **clear** documentation of:
  – Pain score/intensity
  – Dose of medication(s)
  – Functional status/improvement
  – Progress towards set goals
  – Physical exam
  – Other treatments
  – Adverse effects
  – Adherence with medications and non-pharmacologic treatment
  – Need for continued opioid use

Opioid prescribing/monitoring

• **Visits:** at least every 3-6 months, more frequent if high risk patient or titrating doses

• **Random** urine drug testing, pill counts

• Dose adjustments only made by prescriber

• No early prescriptions

• No refills for lost prescriptions

• Educate patients on proper disposal of unused opioids
Urine drug testing

• A mainstay of adherence monitoring in conjunction with other tools
• Provides baseline information
• Ensures appropriate use of prescribed opioids
• Detects use of non-prescribed medications/illicit substances

• Be cautious about making treatment decisions, though, based on the results of a single UDT
  – Use your experts in the lab for help!

Prescription Drug Monitoring Programs

• **Use** PDMPs
  – Now functioning in almost all states (49)
  – If your state PDMP allows, make your staff delegates under you to assist
  – Hopefully, fully active national database at some point soon
    • National Association of Boards of Pharmacy PMP InterConnect system is currently facilitating exchange of data between 30 states
PDMPs are effective when utilized

- 2010 study found when PDMP data used in ER, 41% of cases had altered prescribing after clinician reviewed PDMP data
  - 61% of patients received fewer or no opioids (compared to what was originally planned by physician prior to reviewing data)
  - 39% received more opioids than previously planned
    - Physician was able to confirm patient did not have recent history of controlled substance use


Limit opioid doses

- Avoid escalating doses/dose restrict
  - <100 mg/day OME
    - Studies show that M&M from overdose increases significantly when OME > 100 mg/day
    - Original studies claiming “safety” of long term opioid use had patients on low doses (majority <40 mg OME)
    - All of the available literature correlates increasing mortality with increasing doses
    - Higher doses = higher rates of side effects

Opioid dosing

- 2011 VA study: 12 month randomized trial of conservative, “hold the line” prescribing strategy vs liberal dose escalation
- Assessed: pain severity, pain relief from meds, functional disability, opiate misuse/noncompliance
- **Results:**
  - Escalating group: 80% increase in opioid dosage
  - Stable group: 16% increase in the 12 month time
  - Escalating group had better immediate pain relief after taking medications
  - **However,** acute effect of medication dose did **not** translate to differences in usual pain scores or functional improvement
  - 27% of patients were discharged over course of study due to opioid misuse/noncompliance (no group differences in rate of misuse)

If you are going to start/continue opioids ensure...

- Clear plan for tapering or discontinuing
- Clonidine for withdrawal
  - 0.1-0.2 mg po every 6-8 hours or 0.1 mg patch weekly

- Bottom-line:
  YOU MAKE THE RULES!

My approach to the cases...

- Obtain all of the history elements noted previously
- Thorough initial physical exam with each patient
- Thorough discussion regarding risks of opioids

- **Case 1**
  - Given significant disease noted, limited other options moving forward, appropriate DIRE score and no other red flags, appropriate to continue hydrocodone
  - Establish OA, baseline UDT with likely yearly screening thereafter
  - 28 day refills
  - Clinic visits every 3 months if remains on stable doses
  - Continue other adjunct treatments that are helpful (injections, etc)
My approach to the cases continued...

- **Case 2**
  - Cancer/palliative care patients are exempt from required OA/UDTs at our institution
  - Give only the amount of medication needed (try not to stock pile the patient)
  - Keep in close contact and adjust dosage/refill amounts as needed
  - Other adjunct medications (neuropathic, etc), consider other treatments as well (ESI, etc)
  - If years out and disease free, I would establish OA and complete regular opioid monitoring with visits every 3 months

- **Case 3**
  - Get outside records, baseline x-rays to confirm patient reports
  - Discuss, in depth, history of EtOH and THC use
    - Express concerns regarding opioid use in his situation
  - Consider adjunct treatments (neuropathic pain medications, pain psychology)
  - Establish OA, UDT
  - THC → I have patients choose one or the other
    - My approach with patients:
      - I believe marijuana has beneficial pain relieving properties...HOWEVER, in its current form and availability, I can not condone its use as an adjunct pain medication
      - We need more research and a better form (i.e. oral pill?) so we know patients are getting consistent doses, etc.
      - Additionally, since it is illegal, I can not support its use
My approach to the cases continued...

**Case 4**
- Find an adjunct neuropathic agent that may help
- Neuropsychology/pain psychology assistance
- Possible help from Addiction Medicine

- This patient needs a frank discussion regarding past opioid use
  - Huge red flags!
- Tough situation – she has a reason for pain but is high risk given past history of possible overusing or selling/diverting drugs
- Plan: OA, UDT baseline with results prior to refill, call in for random pill counts/UDTs
- Close follow up – likely only provide 1 week of opioids at a time initially
- One strike and she’s out!

Future plans at GHS

**Additional education for our patients**
- Short video all patients will view with initiation of new OA/update of OA

**Education for all providers who prescribe opioids**
- Further education regarding:
  - Monitoring
  - UDT results and how to interpret
  - Dose limiting
As mentioned earlier - competing public health concerns...

- Under treatment of pain
- Abuse of prescription drugs

Then, add in healthcare reimbursement tied to patient satisfaction

It all leads to a tough balance...

- Just remember – opioids are dangerous, care must come with prescribing!
- Don’t be the next to make headlines...

Jury convicts California doctor of murder in overdose deaths

By Ed Payne, CNN
11/23/2015
Questions/comments?