Safe and Responsible Opioid Prescribing in an Opioid Epidemic

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United States Pain Paradigm

- USA ~4.5% of world population
- Consume 99% global hydrocodone
- Consume 73% global oxycodone
- Consume 2/3 global illicit drugs





The Increase in Therapeutic Opioids Use in the U.S. (mg/person) from 1997 – 2007

Table 6. The increase in therapeutic opioids use in the U.S. (mg/person) from 1997 to 2007.

Туре	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	% of Change from 1997	
Methadone	1.94	2.60	3.47	5.14*	6.81	9.54	13.26	17.03	19.31	23.84	25.50		1214%
Oxycodone	16.68	24.66	34.99	55.11	71.75	80.56	95.97	105.05	110.27	133.33	154.73		899%
Fentanyl	0.28	0.34	0.39	0.53*	0.67	0.87	1.14	1.33	1.40	1.54	1.67		496%
Hydrocodone	32.49	38.93	43.57	50.83	56.15	67.77	80.44	86.70	92.90	107.49	118.70		265%
Morphine	22.20	24.01	24.50	28.11	31.72	36.95	44.30	51.55	54.20	63.03	68.59		209%
Total	73.59	90.54	106.92	139.72	167.1	195.69	235.11	261.66	278	329.23	369.19		402%

^{*} For year 2000 data is not available, the average of 1999 and 2001 was taken.

Source: Data taken from U.S. Drug Enforcement Administration. Automation of Reports and Consolidated Orders System (ARCOS); www. deadiversion.usdoj.gov/arcos/retail_drug_summary/index.html. Access date: 8/25/2010

Source for 2007 data - http://www.justice.gov/ndic/pubs33/33775/dlinks.htm





Epidemic of Chronic Pain

- Lasting >3 months
- Persists beyond what's expected, given degree of pathology
- Elicited by injury/disease
- Likely perpetuated factors pathogenically & physically remote from original cause
- Prevalence of chronic pain in US
 - **10-25%**
 - Rate increases with age/ chronic illness/obesity
 - Opioids recommended therapies for management of several types of non-cancer related pain

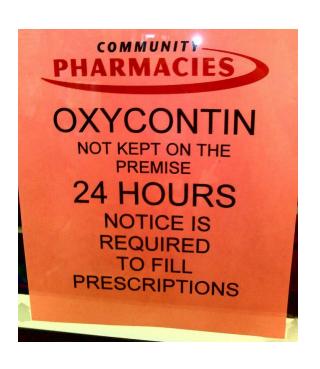


Why the Opioid Increase?

- Liberalization of laws governing opioid prescribing
- Joint Commission Standards 2000
- Growing public awareness of the right to pain relief
- HCAPS- Patient Satisfaction Surveys
- Aggressive marketing



"The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy"



- Unprecedented Marketing
- No studies support benefit over other opioids
- Sales Reps trained "Risk of Addiction <1%"
- Original FDA Label- Risk of Abuse/Addiction
 - 1996 "Very Rare"
- Widely abused- crushed, injected, inhaled
- 2007 Purdue Pharma fined \$634M
- 2009 OxyContin Sales \$3B



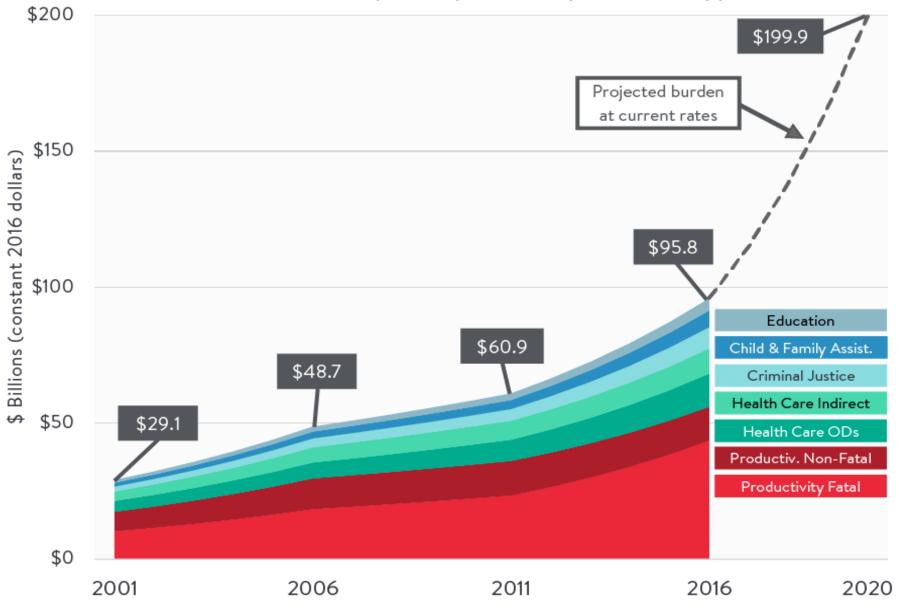
Long Acting/ ER Opioid Evidence



- FDA label LA/ER "the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."
- There are NO studies showing any benefits of long-acting opioids over short acting opioids
- Long acting opioids increase all-cause mortality when treating non-cancer chronic pain
- Oxycontin 2018 FDA package insert

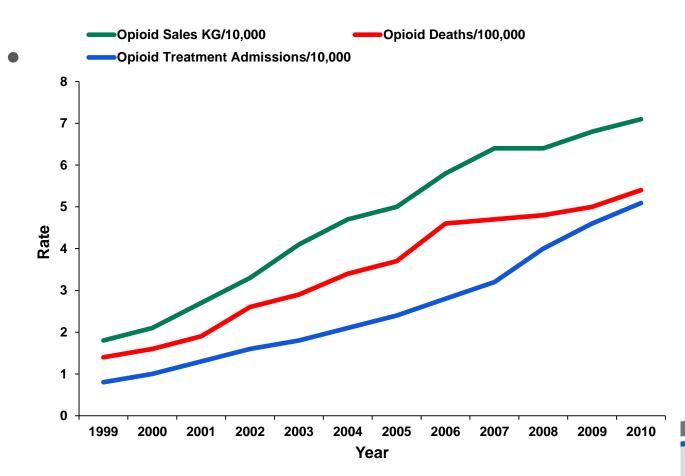
"A double-blind, placebo-controlled, fixed-dose, parallel group, two- week study was conducted in 133 patients with persistent, moderate to severe pain, who were judged as having inadequate pain control with their current therapy. In this study, OXYCONTIN 20 mg, but not 10mg, was statistically significant in pain reduction compared with placebo."

Costs of the Opioid Epidemic by Year and Type



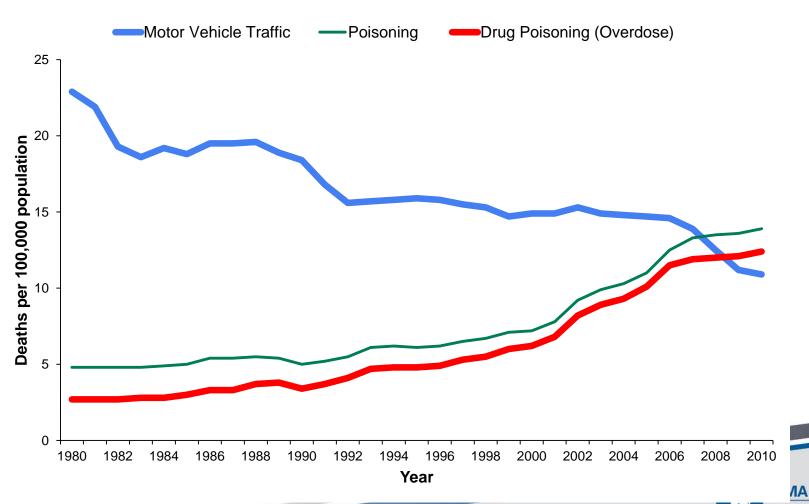
^{*} Data between labeled estimates interpolated using constant growth rates

Rates of Opioid Overdose Deaths, Sales, and Treatment Admissions, United States, 1999–2010

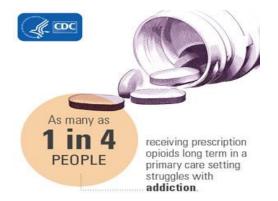




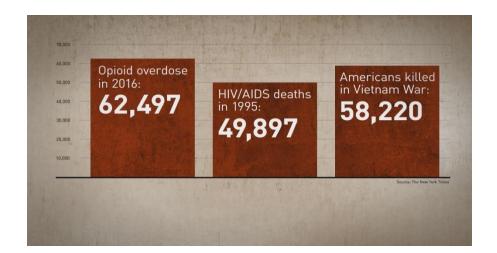
MVA vs. Poisoning Deaths













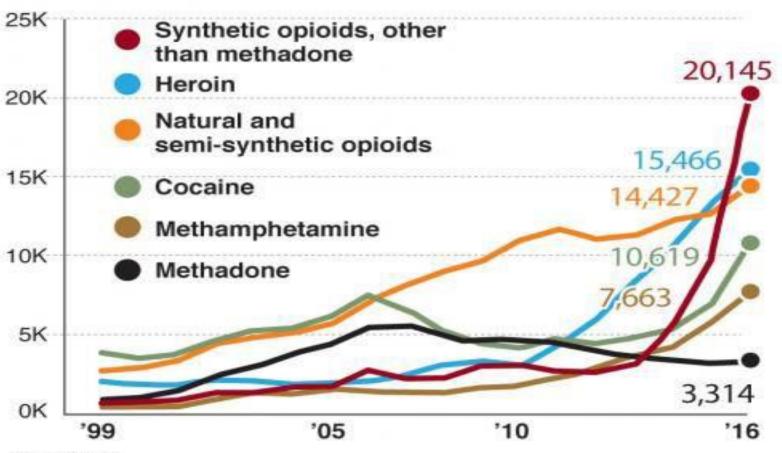


Who Are These People?



U.S. drug overdose deaths

Among the more than 64,000 drug overdose deaths estimated in 2016, the sharpest increase occurred among deaths related to fentanyl and fentanyl analogs (synthetic opioids), more than 20,000 overdose deaths.



Source: CDC Graphic: Staff, TNS

Heroin use is part of a larger substance abuse problem.

Nearly all people who used heroin also used at least 1 other drug.

Most used at least **3** other drugs.

Heroin is a highly addictive opioid drug with a high risk of overdose and death for users.

People who are addicted to...









2x

3x

15x

40x

...more likely to be addicted to heroin.

Evidence & Expert Opinion for Chronic Opioids

2014 AAN- Opioids for chronic non-cancer Pain

"Whereas there is evidence for significant short-term pain relief, there is no substantial evidence for maintenance of pain relief or improved function over long periods of time without incurring serious risk of overdose, dependence, or addiction."

2016 CDC Guideline for prescribing opioids

"Evidence on long-term opioid therapy for chronic pain outside of end-of-life care remains limited with insufficient evidence to determine long-term benefits, though evidence suggests risk of serious harms that appears to be dose — dependent."

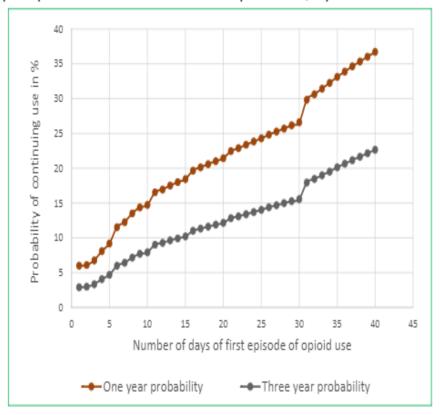
Franklin GM. "Opioids for chronic noncancer pain: A position paper of the American Academy of Neurology". Neurology. 2014 Sep 30;83(14):1277-84

Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e



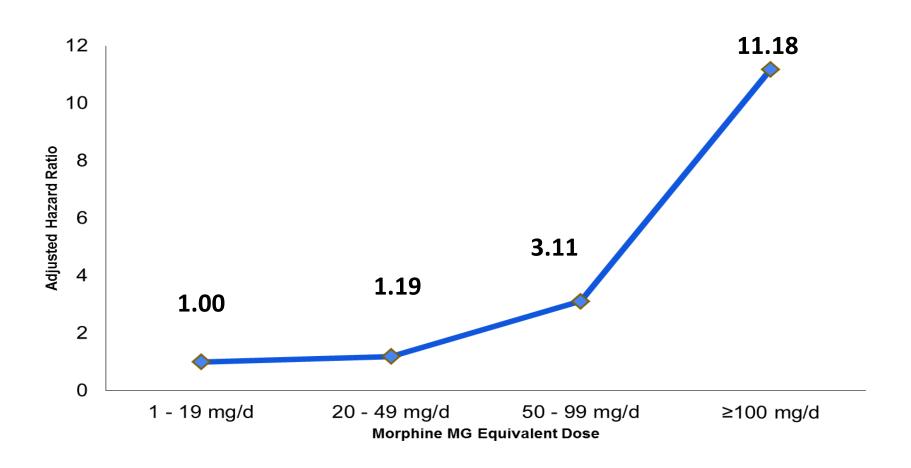
Acute Pain – every day of an opioid matters

FIGURE 2. One- and 3-year probabilities of continued opioid use, by duration of first episode in days (base case)

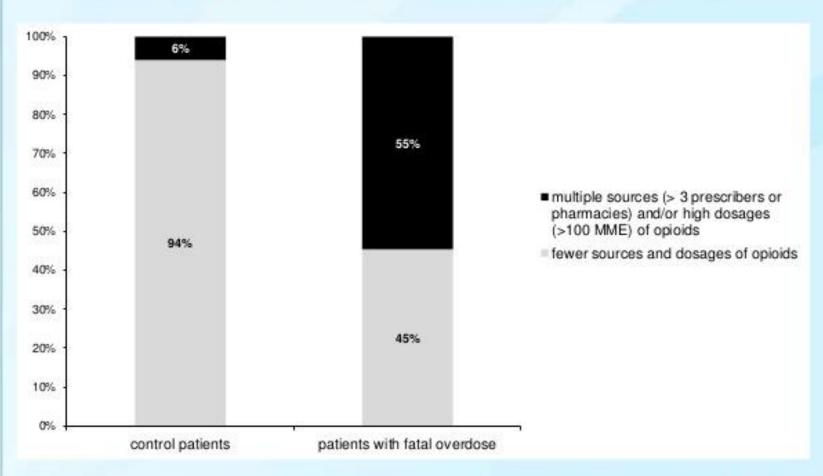


Duration is expressed in terms of days (1-40) with increments of 1 day. Discontinuation is defined as 180 opioid-free days and allowable gap to assess continuous opioid use in first episode was 30 days.

Opioid Dose and Overdose Risk



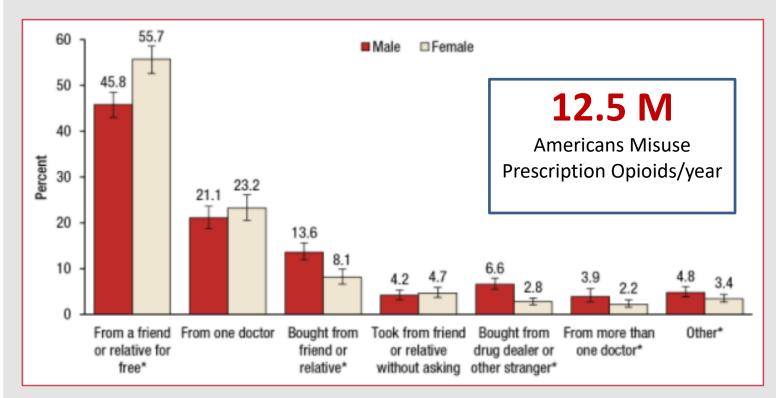
Majority of opioid overdose deaths associated with multiple sources and/or high dosages



Baumblatt JAG et al. High Risk Use by Patients Prescribed Opioids for Pain and its Role in Overdose Deaths. JAMA Intern Med 2014; 174; 796-801.

Diversion (non-medical) Use of Prescription Opioids

Figure 2. Source of prescription pain relievers for the most recent nonmedical use among past year users aged 12 or older, by gender: annual averages, 2013 and 2014





Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain - The SPACE Trial

PRAGMATIC, 12-MONTH, RANDOMIZED TRIAL WITH MASKED OUTCOME ASSESSMENT



chronic back pain, hip or knee osteoarthritis pain that occured ~daily for > 6 months

Opioid Group

N = 119

Step 1: morphine IR, hydrocodone/acetaminophen, oxycodone IR.

Step 2: morphine sustained-action, oxycodone SA.

Step 3: transdermal fentanyl.

max dosage up to 100 morphine-equivalent mg



Non-Opioid Group N = 119

Step 1: acetaminophen, NSAIDs.
Step 2: nortriptyline, amitriptyline, gabapentin
and topical analgesics: capsaicin, lidocaine.
Step 3: pregabalin, duloxetine and tramadol



PAIN RELATED FUNCTION AT 12 MONTHS

BPI Interference Scale (1-10), 10 = worse

Difference: 0.1 (-0.5 to 0.7), p = 0.58

3.3

3.5

PAIN INTENSITY BPI Severity Scale (1-10), 10:

BPI Severity Scale (1-10), 10 = worse

Difference: 0.5 (0.0 to 1.0), p = 0.03

1.8

3.4

MEDICATION RELATED ADVERSE EFFECT OVER 12 MONTHS

Medication related symptom checklist (1-19), 19 = worse

Difference: 0.9 (0.3 to 1.5), p = 0.03

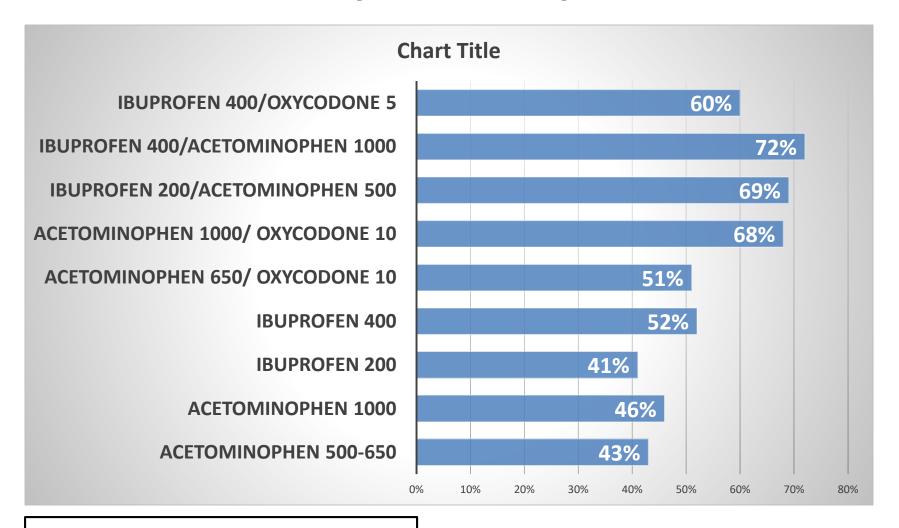
0.9

Single Dose Oral Analgesics for Acute Post-Operative Pain Cochrane System Review 2015

- >50,000 patients, 450 clinical studies
- Randomized, double blind trials
- Percent patients 50% pain relief
- Range of results; 30%-70% people achieved 50% relief
- Range of relief; 2-20h
- Placebo Effect = 5-20%

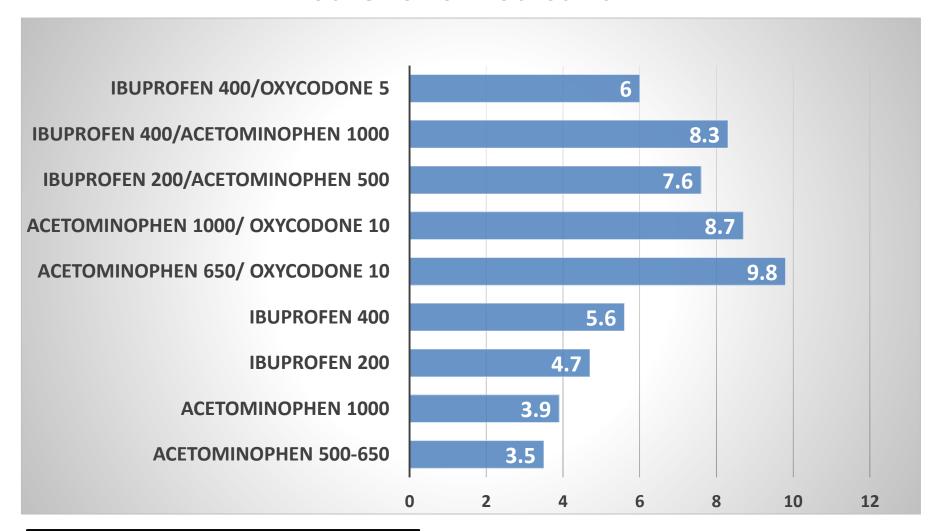


Single Dose Oral Analgesics for Acute Post-Operative Pain Percent of patients 50% pain relief



OXYCODONE 5 = PLACEBO

Single Dose Oral Analgesics for Acute Post-Operative Pain Hours to re-medication



OXYCODONE 5 = PLACEBO

NSAIDS vs. Opioid - Renal Colic

A 2004 Cochran review concluded......

NSAID & Opioids have = effectiveness but opioids have more side-effects



Surgery; A Gateway to Opioid Use

- Claims data 2013-2014, 13 elective surgeries
- Adults 18-64, continuous private prescription & medical insurance
- No opioid scripts 12 months prior to surgery
- N=36,177
- Minor Surgery (80%)- Varicose Vein, Laparoscopic Cholecystectomy, Laparoscopic appendectomy, hemorrhoidectomy, thyroidectomy, transurethral prostate surgery, parathyroidectomy carpal tunnel
- Major Surgery (20%)- ventral hernia, colectomy, reflux surgery, bariatric surgery, hysterectomy
- Primary Outcome- New persistent opioid use 90d post-op
 - **5.9%** Minor Surgery
 - **6.5%** Major Surgery

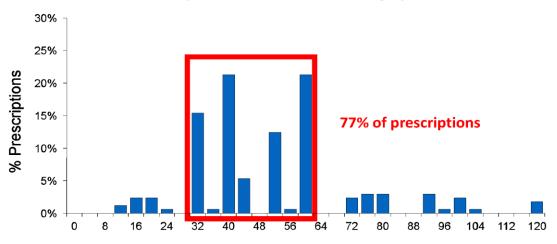
Surgery; A Gateway to Opioid Use

- Risk Factors for New Persistent Opioid use
- Not dependent on severity of surgery
- Tobacco Use
- Alcohol Use Disorder
- Substance Use Disorder
- Anxiety/Depression
- Pre-Operative Pain- Back, neck, arthritis, central pain disorder

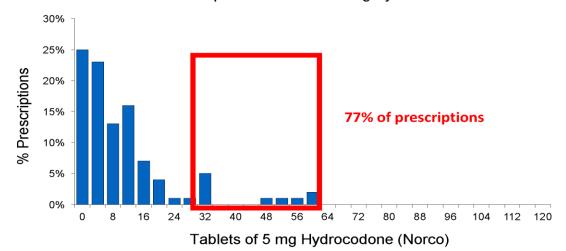


Lap Choly; Opioid Prescribed vs Opioid Used

Opioids Prescribed After Surgery



Opioids **Used** After Surgery

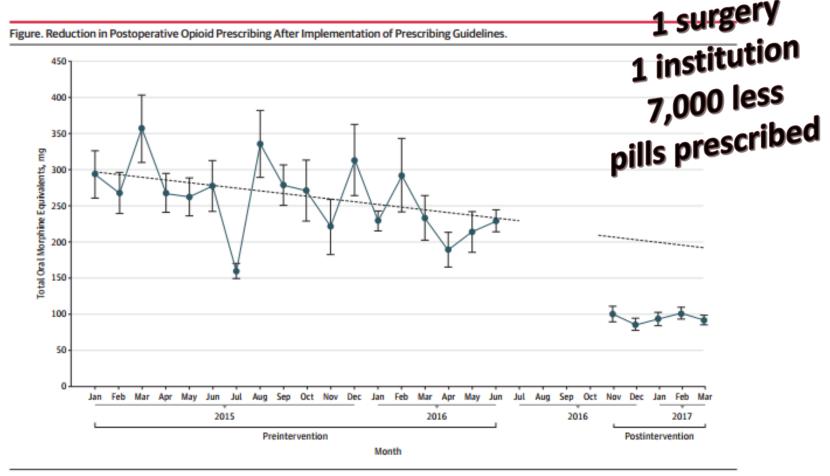


Reduction in Opioids through Evidence Based Guidelines

Laparoscopic cholecystectomy

	Pre- Intervention (N=170)	Post-Intervention (N=200)
Refill requested	4.1%	2.5%
Mean Opioid given	50 hydrocodone	15 hydrocodone
Mean Opioid used	6 hydrocodone	4 hydrocodone
Median Pain Score	5	5

Reduction in Opioid Prescribing through Evidence Based Guidelines



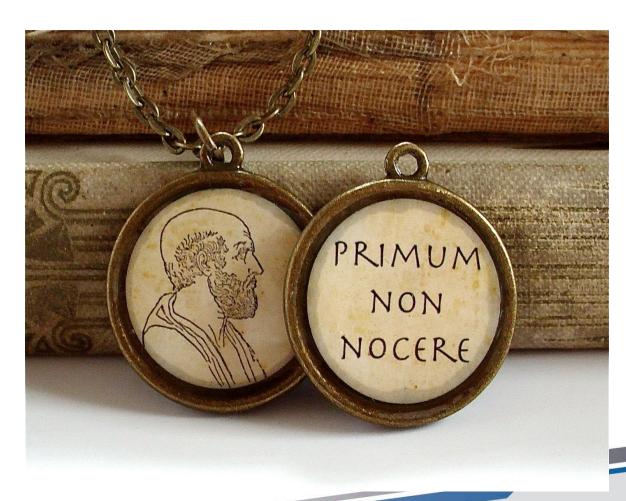
Following the implementation of evidence-based prescribing guidelines, opioid prescriptions were significantly reduced from an equivalent of approximately 45 pills of hydrocodone, 5 mg, to approximately 15 pills (P < .001). The dashed line represents the expected decline in prescribing prior to the study intervention.

Peri-Operative Opioid Recommendations – 3/2018

Procedure	Hydrocodone (Norco) 5 mg tablets Codeine (Tylenol #3)	Oxycodone 5 mg tablets	
Procedure		30 mg tablets	Hydromorphone
		Tramadol	(Dilaudid)
		50 mg tablets	2 mg tablets
Laparoscopic Cholecystectomy		15	10
Laparoscopic Appendectomy		15	10
Inguinal/Femoral Hernia Repair (open/laparo	15	10	
Open Incisional Hernia Repair	30	20	
Laparoscopic Colectomy	30	20	
Open Colectomy	30	20	
Ileostomy/Colostomy Creation, Re-siting, or	40	25	
Open Small Bowel Resection or Enterolysis	30	20	
Thyroidectomy		10	5
Hysterectomy			
Vaginal		20	10
Laparoscopic & Robotic	25	15	
Abdominal		35	25
Breast Biopsy or Lumpectomy Alone	10	5	
Lumpectomy + Sentinel Lymph Node Biops	15	10	
Sentinel Lymph Node Biopsy Alone	15	10	
Simple Mastectomy ± Sentinel Lymph Node	30	20	
Modified Radical Mastectomy or Axillary Ly	45	30	
Wide Local Excision ± Sentinel Lymph Node	30	20	



First, Do No Harm





Indiana Opioid Laws & Opioid Best Practices



Indiana Opioid Laws

- 2014 Chronic Opioid Prescribing Law
- 2017 7 Day Prescribing Law
- 2018 CME requirement
- 2018 INSPECT requirement



2014 Indiana Chronic Opioid Law

Any patient

- Taking >60 opioid pills /month >3mo
- Taking an opioid >15 MME for >3mo
- Using a transdermal opioid patch >3mo
- Taking tramadol (if greater than 600mg/day) for >3mo
- Taking any dose of an Extended release med not in abuse deterrent form for which one exists
- Exemptions

Terminal condition, palliative care, Hospice, NH

Morphine Equivalent Dose (MED) Mg Morphine Dose (MME)

1mg hydrocodone = 1mg morphine
1mg oxycodone = 1.5mg morphine
15mg hydrocodone = 15mg morphine
10mg oxycodone = 15mg morphine
90mg hydrocodone = 90mg morphine
60mg oxycodone = 90mg morphine

2014 Indiana Chronic Opioid Law Perform your own evaluation

- Perform appropriately focused history & physical
- Use objective pain assessment tool
- Order appropriate tests
- Obtain & review records of past care
- Utilize non-opioid options

7) What treatments or medications are you receiving FORM 3.2 Brief Pain Inventory Time: 8) In the Past 24 hours, how much relief have pain 1) Throughout our lives, most of us have had pain treatments or medications provided? Please circle from time to time (such as minor headaches, the one percentage that most shows how much sprains, and toothaches). Have you had pain releif you have received other than these everyday kinds of pain today? 0% 10 20 30 40 50 60 70 80 90 100% No Complete relief 2) On the diagram shade in the areas where you feel pain. Put an X on the area that hurts the most. 9) Circle the one number that describes how, during the past 24 hours, pain has interfered with your: A. General activity 0 1 2 3 4 5 6 7 Does not interfere B. Mood Does not Completely interfere C. Walking ability Completely 3) Please rate your pain by circling the one number that best describes your pain at its worst in the D. Normal work (includes both work outside the past 24 hours. home and housework No pain as bad as 0 1 2 3 4 5 6 you can imagine Does not Completely interfere interferes 4) Please rate your pain by circling the one number that best describes your pain at its least in the E. Relations with other people past 24 hours. 1 2 3 4 5 8 9 10 No pain as bad as Does not Completely you can imagine interfere 5) Please rate your pain by circling the one number F. Sleep that best describes your pain on the average 1 2 3 4 5 6 7 8 9 10 0 1 2 3 4 5 6 Does not Completely pain as bad as interfere interferes you can imagine G. Enjoyment of life 6) Please rate your pain by circling the one number that tells how much pain you have right now. 0 1 2 3 4 5 9 10 1 2 3 4 5 6 7 8 9 10

Does not

pain as bad as

you can imagine

No

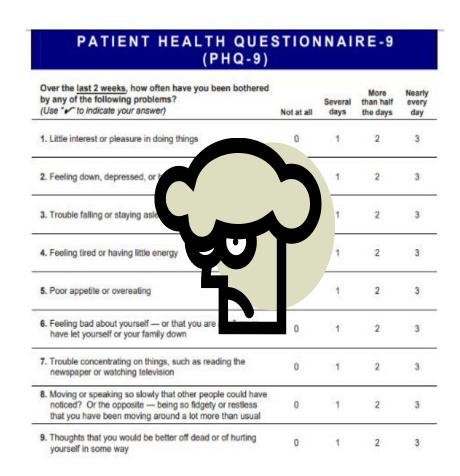
pain

Completely

interferes

2014 Indiana Chronic Opioid Law Mental Health Risk Stratification

- Mental & Physical health are inextricably linked
- Treatment of underlying mental health issues will often improve response to pain treatment
- PHQ-2,PHQ-9, GAD-7 can be useful, quick, validated tools



2014 Indiana Chronic Opioid Law Risk Stratification for Substance Misuse



- Patients with h/o substance use disorder increased risk of harm from opioids
- Ask patients about past or current substance use/abuse (alcohol, prescription medications, illicit drugs or tobacco/e-nicotine) prior to initiating opioids
- Validated tools....
 ORT, Dire, COMM, SOAPP-R,
 DAST

2014 Indiana Chronic Opioid Law Risk Stratification



- UDM has evolved to become a <u>standard</u> of care when prescribing opioids
- Detect illicit substances
- Monitor adherence to prescribed meds
- Interpretation is critical
- "At any time the physician determines that it is medically necessary, whether at the outset of an opioid treatment or anytime thereafter, a physician prescribing opioids for a patient shall perform or order a drug monitoring test, which must include a confirmatory test."

2014 Indiana Chronic Opioid Law

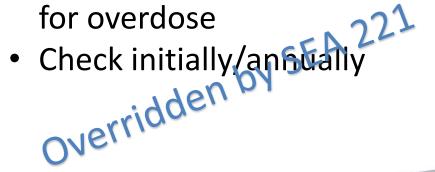
Urine Drug Monitoring- Medical Necessity

- Reason to believe patient not taking meds
- Reason to suspect diversion
- No improvement in pain
- Reason to suspect patient taking other drugs
- Reason to believe patient using other opioids
- Early refills
- Stolen scripts
- Inconsistent INSPECT
- Previous UDT inconsistent

- Aberrant behaviors
- Apparent Intoxication
- Unauthorized dose escalation
- Reluctant to change meds
- Refusal to participate in work-up
- Substance abuse history
- Health status change
- Co-morbid psych issues
- Evidence of abuse
- Any other relevant factor to making professional judgement

2014 Indiana Chronic Opioid Law Risk Stratification

- Review state PDMP before initiating opioid therapy.
- Determine whether patient receiving opioid dosages or dangerous combinations that put him or her at risk for overdose







2014 Indiana Chronic Opioid Law Review & Sign a Treatment Agreement

- Goals of treatment
- Consent drug monitoring / random pill counts
- Prescribing policies, prohibition of sharing medications & requirement to take meds as prescribed
- Information on pain meds prescribed by other physicians / alcohol use
- Reasons that opioid therapy may be changed or discontinued
- Counsel women of child-bearing age about the potential for fetal opioid dependence
 a neonatal abstinence syndrome (NAS).



2014 Indiana Chronic Opioid Law Functional Goals



After initial evaluation, establish working diagnosis

Specific Achievable Functional Goals

Reframe expectations: A realistic "Pain Score" target isn't zero!

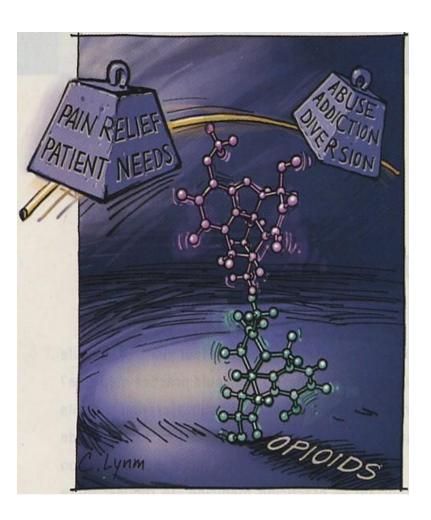
2014 Indiana Chronic Opioid Law Periodic Scheduled Visits

- Evaluate patient progress
- Monitor compliance
- Set clear expectations
- Q 4mo, if stable (minimum)
- Q 2mo, if changing meds;
 more often as needed



Affect • Activities of Daily Living • Analgesia Adverse effects • Aberrant

2014 Indiana Chronic Opioid Law Reassessment is required if MED ≥ 60 mg/d



- Face-to-face review to reassess your patient
- Formulate/document a revised assessment and treatment plan
- Discuss the increased risk for adverse outcomes (including death) with higher opioid doses if that is what you plan to do

2014 Indiana Chronic Opioid Law

- Do your own evaluation
- Risk Stratify
 - Mental health
 - Risk of Substance Misuse
 - INSPECT
 - Urine Drug Testing
- Treatment Agreement/ Functional Goals
- Regular Visits/ Reassess if greater than 60 MED

2017 – 7d Opioid Prescribing Limit

- Physician issuing initial opioid prescription for a patient may not prescribe more than a 7-day supply
 - Note: Limit applies to that physician's first opioid prescription to that patient
 - No specific exception for practitioners in the same practice
- For an adult patient age 18 or older, there are no quantity limits on subsequent opioid prescriptions written by that physician
- For patients < 18yo, all opioid Rx limited to 7-day supply
- Exceptions to Seven-Day Limit
 - Cancer
 - MAT for a substance-abuse disorder
 - Palliative Care
 - Professional Judgment (Must document in the MR that a non-opiate not appropriate and physician is using his or her professional judgment to prescribe for longer than the 7-day limit)

2017 – 7d Opioid Prescribing Limit

Other Provisions

- Physician must comply if patient or patient's authorized representative requests a smaller amount of an opioid than the physician initially planned to prescribe
 - Physician must document the request, as well as who made it, in the patient's MR
- Allows Indiana pharmacies to partially fill a prescription at the request of patient or patient's authorized representative
 - Under a change to federal law (21 U.S.C. 829), the unfilled portion of an original Schedule II prescription may be filled up to 30 days after the date of the original prescription



2018 Indiana 2h Opioid CME requirement

Senate Bill 225 (Effective July 1, 2018)

Beginning July 1, 2019 (next physician renewal):

- All practitioners who apply for or renew Indiana Controlled Substances Registration
- Must have completed 2 hours of CME during the previous 2 years
 - CME must address opioid prescribing and opioid abuse
- For physicians CME courses must be approved by the IN Medical Licensing Board or offered by an approved organization

The Indiana Professional Licensing Agency must list approved CME courses on its website

The law sunsets July 1, 2025



2018 Indiana INSPECT requirement

Senate Bill 221 (Effective July 1, 2018)

Requires checking INSPECT each time before prescribing an opioid or benzodiazepine to any patient (No specific exceptions for hospice, palliative care, or LTC patients)

Effective date <u>depends on situation:</u>

- Applies 7/1/2018 for practitioners with INSPECT integrated into EMR
- Applies 1/1/2019 for practitioners providing services in
 - o The ER; or pain management clinic
- Applies 1/1/2020 to practitioners providing services in a hospital
- Applies 1/1/2021 to all practitioners
- Patients on pain management contract –q 90dPractitioners
- MLB Waiver if no internet



2016 CDC Guideline for Prescribing Opioids

- CBT- small positive effect on disability
- Exercise Therapy- can improve pain and function chronic low back pain
- Exercise Therapy- improve function and reduce pain in OA knee, OA hip
- Exercise Therapy improve fibromyalgia symptoms,
 well being and physical function in fibromyalgia
- Exercise and CBT should be used to reduce pain and improve function in chronic pain

2016 CDC Guideline for Prescribing Opioids

- Opioids should only be continued if there is a meaningful improvement in pain & function (30% improvement)
- Avoid prescribing Opioid & Benzo whenever possible
- UDM initiation & annually
- ER Opioids for Severe pain requiring around the clock, long-term opioid tx for which alternative tx inadequate
- Avoid short and long acting opioids (unless end of life)
- Use lowest dose, additional precaution at 50MED/day
- Avoid dosage >90MED/day (if not improved DC or taper)



2016 - FDA Black Box Warning

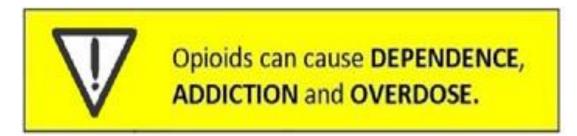
Health care professionals should limit prescribing opioid pain medicines with benzodiazepines or other CNS depressants only to patients for whom alternative treatment options are inadequate. If these medicines are prescribed together, limit the dosages and duration of each drug to the minimum possible while achieving the desired clinical effect. Warn patients and caregivers about the risks of slowed or difficult breathing and/or sedation, and the associated signs and symptoms. Avoid prescribing prescription opioid cough medicines for patients taking benzodiazepines or other CNS depressants, including alcohol.





Opioid Changes

- 508 Opioids Relabeled by January 2019
- Non-Cancer Chronic Pain- Ceiling dose =90MME
- Any Non-Cancer Chronic Pain >90MME off-label
- Acute pain limits 3 days



Universal Precautions Be wary of co-morbid risks with opioids

Patient morbidity/mortality risk is more pronounced for patients...

- Age <25</p>
- Benzodiazepine use/abuse
- Alcohol use/abuse
- Illicit substance use/abuse
- Untreated mental health issues
 (e.g. depression, hx of suicide)
- Chronic respiratory problems
 (e.g. Asthma, COPD, OSA, CHF)



Safe Storage & Safe Disposal





Follow these simple steps to dispose of medicines in the household trash

MIX

Mix medicines (do not crush tablets or capsules) with an unpalatable substance such as dirt, kitty litter, or used coffee grounds;

PLACE

Place the mixture in a container such as a sealed plastic bag;



THROW

Throw the container in your household trash;



SCRATCH OUT

Scratch out all personal information on the prescription label of your empty pill bottle or empty medicine packaging to make it unreadable, then dispose of the container.





Thank you!



Thank you!

