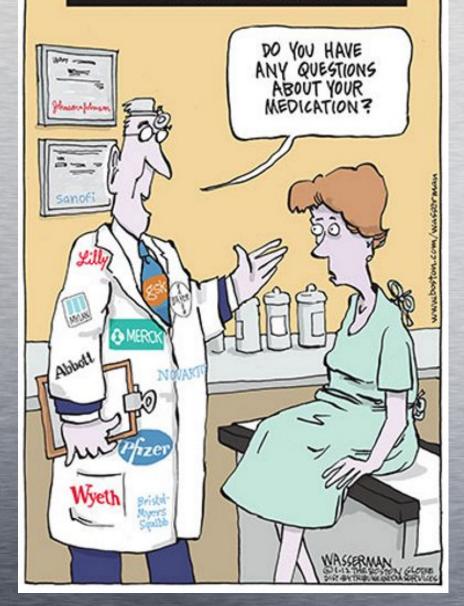
Chronic Pain 2020

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Knowledge that will change your world

NEW DISCLOSURE RULES TAKE EFFECT ON DOCTORS' TIES TO DRUG COMPANIES



Disclosures

Dr. Bailey has no relevant financial conflicts of interest or disclosures.

Objectives

- Increase awareness of the scope/magnitude of chronic pain in the population of patients.
- Explore the extents and trends of the current 'Opioid Epidemic'
- Exposure to some of the increasing regulatory requirements in treating pain.



PAIN IN AMERICA



More than 30% of Americans are living with some form of chronic or severe pain.

MORE PEOPLE LIVE WITH Chronic Pain Than Cancer, Heart Disease, AND DIABETES, COMBINED.



Sources: National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Institute of Medicine

Prevalence 2016

- In 2016, an estimated 20.4% of U.S. adults (50.0 million) had chronic pain and 8.0% of U.S. adults (19.6 million) had high-impact chronic pain with higher prevalence associated with advancing age.
- Age-adjusted prevalence of both chronic pain and high-impact chronic pain were significantly higher among women, adults who had worked previously but were not currently employed, adults living in or near poverty, and rural residents.
- In addition, the age-adjusted prevalence of chronic pain and high-impact chronic pain were significantly lower among adults with at least a bachelor's degree compared with all other education levels.

Dahlhamer J, Lucas J, Zelaya, C, et al. Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults — United States, 2016. MMWR Morb Mortal Wkly Rep 2018;67:1001–1006.

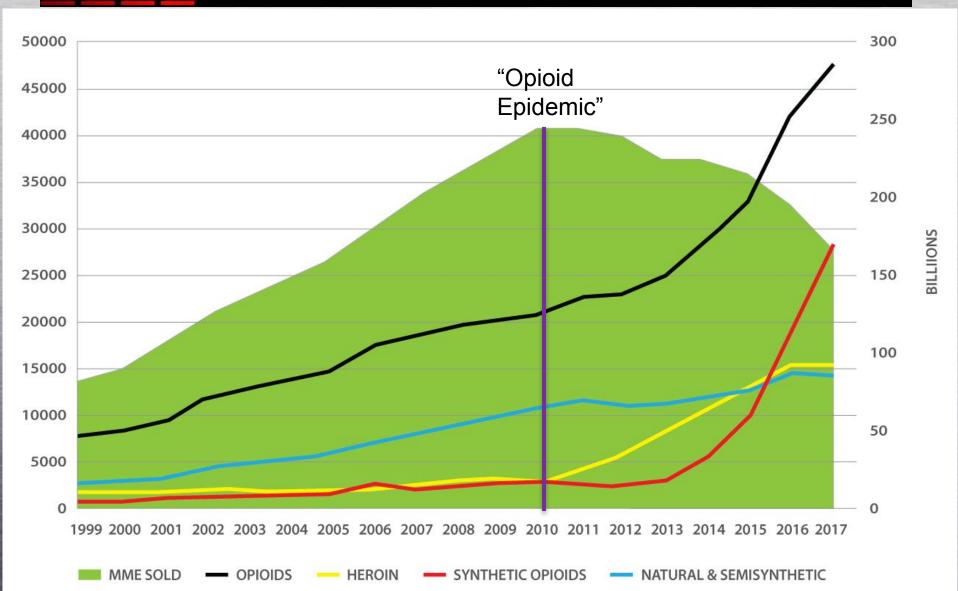
Harsh Truths

- We have an opioid overdose epidemic in the USA with a 33% overall increase in the last 5 years (per CDC – nation wide)
- Deaths from synthetic opioids like illicit fentanyl are up 73% while oxycodone and hydrocodone are up 4%.
 - Heroin related deaths are up 50%

US citizens are about 5% of the worlds population, yet use 80% of the global supply of opioids

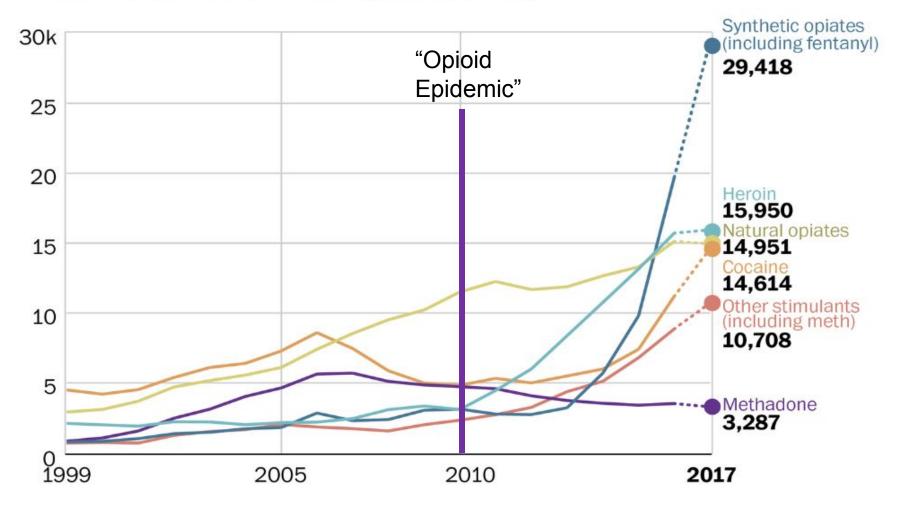
Our patients want a pill for everything and seem minimally willing to participate in their own health care – other than take pills

Rx Opioids Sold vs OD Deaths



Synthetic opiate deaths continue to surge

Annual overdose deaths involving selected drugs

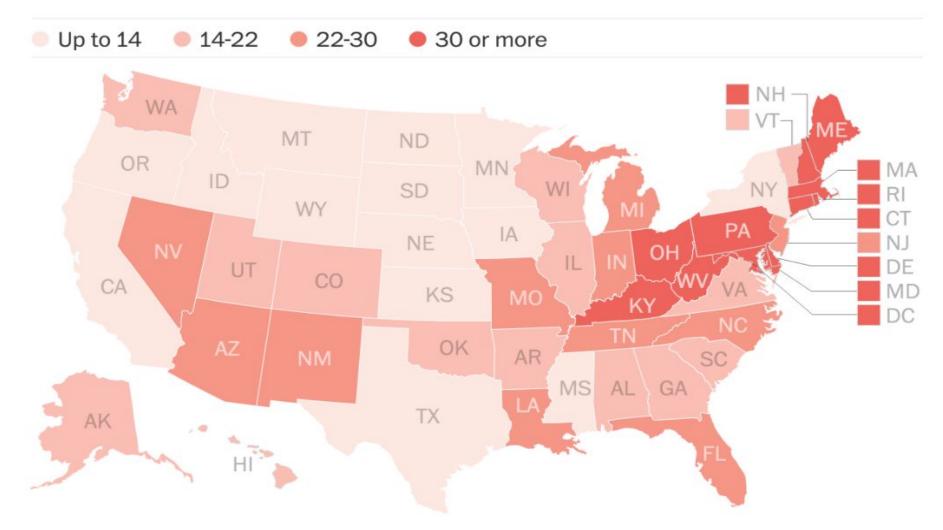


Note: 2017 figures are provisional. Many overdose deaths involve multiple drugs.Source: Centers for Disease Control and PreventionWAPO.ST/WONKBLOG

Overdose estimates for selected drug types in 2017.

The geography of overdose deaths

Drug overdose deaths per 100,000 in 2017

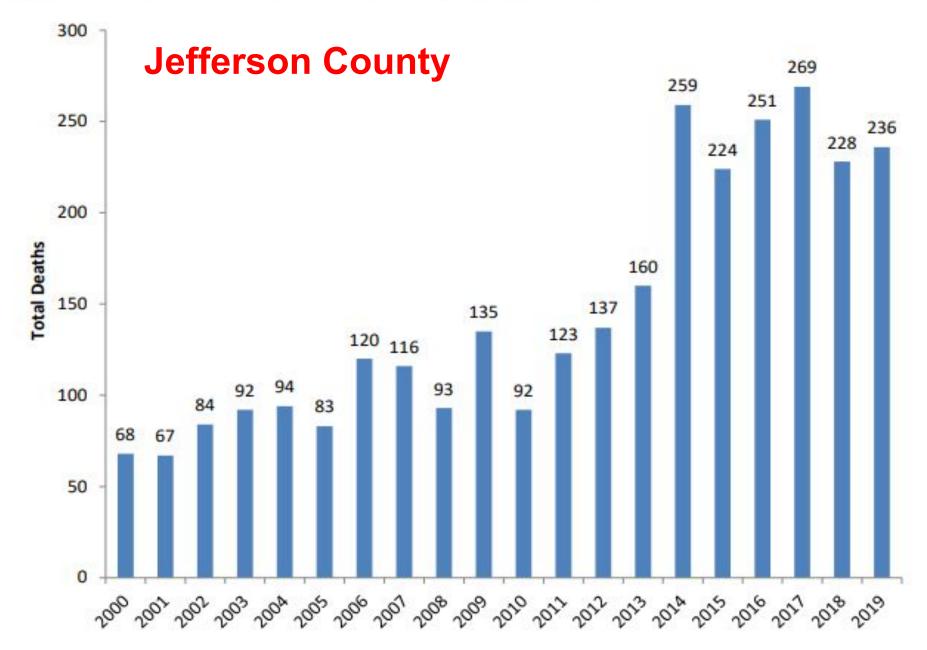


Estimates are preliminary and subject to revision

Source: CDC

WAPO.ST/WONKBLOG

Total Number of Overdose Deaths by Year of Death 2000-2019 Figure 6.1: represents all overdose deaths investigated by the JCCMEO.



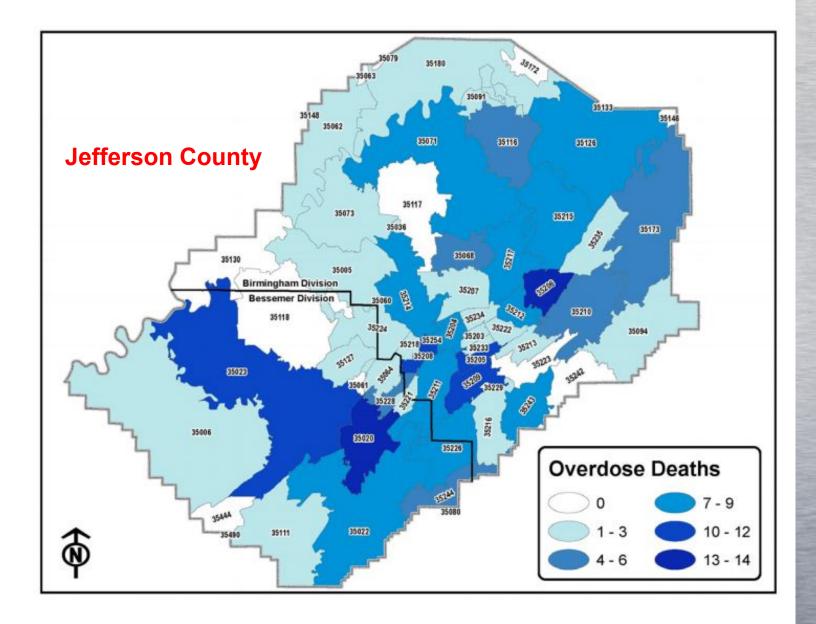
Historical Summary: Illicit Drugs/Poisons, 2010-2019

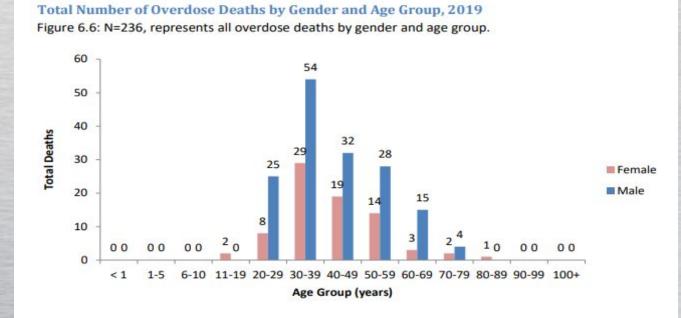
Jefferson County

Figure 6.4: represents illicit drugs and poisons.

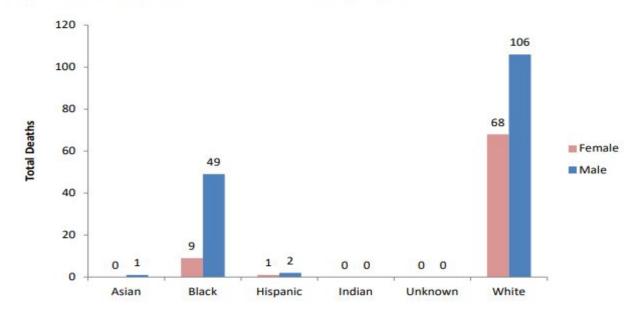


Total Number of Overdose Deaths by Place of Injury Zip Code, 2019 Figure 6.5: N=236, represents all overdose deaths by place of injury zip code.





Total Number of Overdose Deaths by Gender and Race, 2019 Figure 6.7: N=236, represents all overdose deaths by gender and race.



Prescription Medications	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Opioids:			Jeff	erso	n Co	ounty	/			1
Hydrocodone	8	7	8	12	28	11	13	15	12	11
Hydromorphone (Dilaudid)	0	0	0	2	0	1	0	1	1	1
Fentanyl	3	1	1	3	25	49	106	104	68	95
Methadone	22	13	11	21	21	17	16	7	9	8
Morphine	10	17	12	5	7	3	5	3	0	2
Oxycodone	4	8	4	13	21	11	12	11	8	13
Tramadol	2	0	1	6	5	3	3	9	5	5
Benzodiazepines:										
Alprazolam (Xanax)	5	3	7	12	32	8	31	28	15	16
Clonazepam (Klonopin)	0	0	0	1	0	0	0	0	0	2
Diazepam (Valium)	3	1	2	7	11	5	3	6	4	2
Barbiturates:						1.0				
Butalbital	0	0	0	1	1	0	0	0	0	1
Phenobarbital	0	0	0	0	1	0	0	0	0	0
Antidepressants:										
Citalopram (Celexa)	4	2	1	1	2	0	1	5	1	2
Nortriptyline (Palmelor)	2	1	0	1	0	0	0	1	0	0
Velafaxine (Effexor)	0	0	0	2	0	0	0	0	0	0
Other:				· · · · · · · · · · · · · · · · · · ·						
Acetaminophen (Tylenol)	2	1	2	1	1	0	0	0	0	0
Amphetamine	3	0	1	0	2	1	2	0	2	1
Carisoprodol (Soma)	1	3	0	2	4	0	0	0	1	0
Fluoxetine (Prozac)	3	2	1	1	1	4	1	3	0	1
Gabapentin	0	0	0	0	1	0	0	0	0	3
Promethazine (Phenergan)	0	0	1	3	4	1	0	2	1	1
Quetiapine (Seroquel)	1	0	0	2	2	1	1	1	2	7
Sertraline (Zoloft)	0	0	0	0	3	0	1	1	1	0
Trazodone (Oleptro)	0	0	0	1	1	0	1	1	0	2
Gamma-Hydroxybutyrate (GHB)	1	0	1	0	1	0	0	0	2	0

Prescription Opioid Analgesics Commonly Unused After Surgery - A Systematic Review

- Review of 6 studies involving 810 unique patients who underwent orthopedic, thoracic, obstetric, and general surgical procedures, 67% to 92% of patients reported unused opioids.
- Most patients stopped or used no opioids owing to adequate pain control, and 16% to 29% of patients reported opioid-induced adverse effects
- In 2 studies examining storage safety, 73% to 77% of patients reported that their prescription opioids were not stored in locked containers. All studies reported low rates of anticipated or actual disposal, but no study reported US Food and Drug Administration—recommended disposal methods in more than 9% of patients.

"Postoperative prescription opioids often go unused, unlocked, and undisposed, suggesting an important reservoir of opioids contributing to nonmedical use of these products, which could cause injuries or even deaths."

JAMA Surg. Published online August 2, 2017. doi:10.1001/jamasurg.2017.0831

Post-Op Opioid Recommendations	Hydrocodone (Norco) 5 mg tablets Codeine (Tylenol #3)	Oxycodone 5 mg tablets
https://opioidprescribing.info/	30 mg tablets	Hydromorphone
Last updated 3/12/2018	Tramadol	(Dilaudid)
	50 mg tablets	2 mg tablets
Laparoscopic Cholecystectomy	15	10
Laparoscopic Appendectomy	15	10
Inguinal/Femoral Hernia Repair (open/laparoscopic)	15	10
Open Incisional Hernia Repair	30	20
Laparoscopic Colectomy	30	20
Open Colectomy	30	20
Ileostomy/Colostomy Creation, Re-siting, or Closure	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 Biopsy	15	10
Sentinel Lymph Node Biopsy Alone	15	10
Simple Mastectomy ± Sentinel Lymph Node Biopsy	30	20
Modified Radical Mastectomy or Axillary Lymph Node Dissection	45	30
Wide Local Excision ± Sentinel Lymph Node Biopsy	30	20

Fentanyl



- 2 mg of Fentanyl: Potentially lethal dose
- 50x stronger than heroin
- Very small amount can be deadly, and can be inhaled or absorbed through skin
- Danger if the bag opens and powder becomes airborne
- Danger if package opens and drug is exposed to skin

Gabapentin, opioids, and the risk of opioid-related death: A population-based nested case-control study.

CONCLUSIONS: In this study we found that mong • patients receiving prescription epic ds. concomitant treatment with gabapentin was associated with a substantial increase (n/arly 66 10) in the lisk of opioid-related deat. Ginicial s should consider carefully whether to continue rescribing this combination of products and, when the combination is deemed necessary, should closely monitor their patients and adjust opioid lose accordingly. Future research should investigate whether a similar interaction exists between pregabalin and opioids.

On May 15, 2019, the Alabama State Committee of Public Health voted to make Gabapentin a Scheduled V medication, effective November 18, 2019.

PLoS Med. 2017 Oct 3;14(10):e1002396:

l get it

- Most of us are not pain docs and don't write much pain medicine.
- But that isn't the same as writing none and the possible repercussions of improper documentation can be severe.
- It's a good idea to know where we are and where we might be heading in the treatment of chronic pain.

So LISTEN UP!



Definitions

- Chronic pain lasting over one month
- Acute pain lasting less than a week
- Morphine Equivalent Dosage (MEQ) the mg of drug your patient takes / day converted to equianalgesic morphine dosage
- Opioid Risk how likely your patient is to use opioids in a non-prescribed manner or for a non-medical purpose.

Pain

- #1 reason people seek medical attention
- Is an Experience
- Multifactorial
 - Nociceptive / physical
 - Psychological / mood



Recommended Elements

- Patient Information about Opioids
- Medication Agreement
- Opioid Consent Form
- Intake forms with appropriate elements
- Documented Abnormality
- Opioid Risk Assessment
- Rx Drug Monitoring Program Use
- Documented Treatment Plan
- **Drug Screening Policy / Practices**
- Discharge letter (when/if necessary)

Opioid Risk Tool (ORT)

Female Male

D4

D4

D2

Mark each box that applies

- 1. Family history of substance abuse
 - Alcohol **D**2 **Illegal drugs** • **4** Prescription drugs Personal history of substance 3 abuse Alcohol Illegal drugs Prescription drugs Age (mark box if 16-45 years) History of preadolescent sexual abuse **Psychological disease** 2
 - ADD, OCD, bipolar, schizophrenia
 - Depression

2.

3.

4.

- •Exhibits high degree of sensitivity and specificity
- •94% of low-risk patients did not display an aberrant behavior
- •91% of high-risk patients did display an aberrant behavior

Risk Level Scoring 0 - 3 Low	
0-3 Low	
4 - 7 Moderate	
0 - 3 Low 4 - 7 Moderate > 8 High	No.

Webster LR, Webster RM. Pain Med. 2005;6:432-442.

Overall Opioid Risk

Adjust ORT upwards for:

- Age >70
- Respiratory Compromise
- MME > 90
- Methadone use for pain
- Gabapentin use
- Benzodiazepine use
- OSA
- Suicide Ideation

- Hepatic or Renal Impairment
- Aberrant behaviors
- Alcohol or THC use
- Soma
- Sleepers
- Smoking
- Use the adjusted risk level to decide how often to RTC and drug screen

Managing Chronic Pain

- Document an abnormality with a clear diagnosis
- Gather old records
- Good History with attention to:
 - Previous treatments and their outcomes
 - Addiction
 - Drug-related crimes
 - Methadone clinic participation
- Complete Exam with emphasis on the neurologic and musculoskeletal components

Managing Chronic Pain

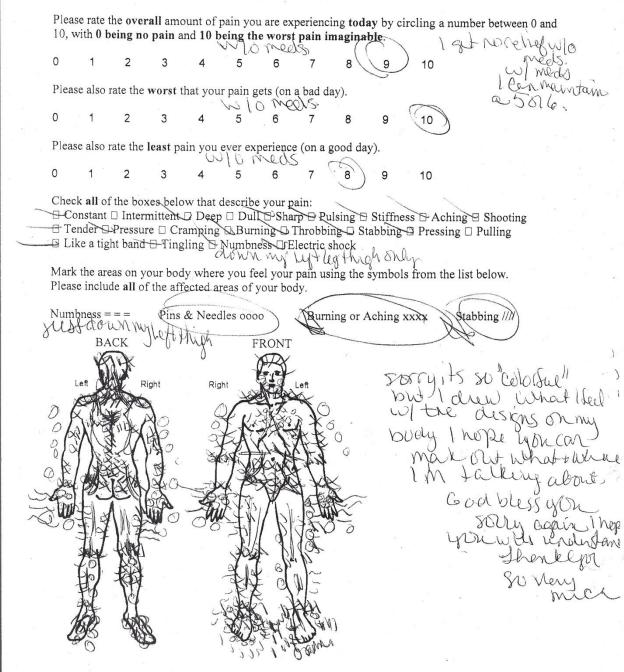
- Try to identify 'pain generators'
- Assess risk for opioid risk diversion ORT
- Formulate and document a Treatment plan
- Consents
 - Opioid use
 - Medication management agreement
 - Procedures
- Make certain that your treatment is justified by your diagnosis.

'Overdone' Paperwork

- Writing in margins and on back of pages.
- Entire Pain Drawing 'colored in'.
- Often with colorful and detailed descriptions of pain.
- Typically a sign of psychiatric involvement.

"Overdone" Paperwork

B. DESCRIBE IN MORE DETAIL YOUR PAIN FOR US



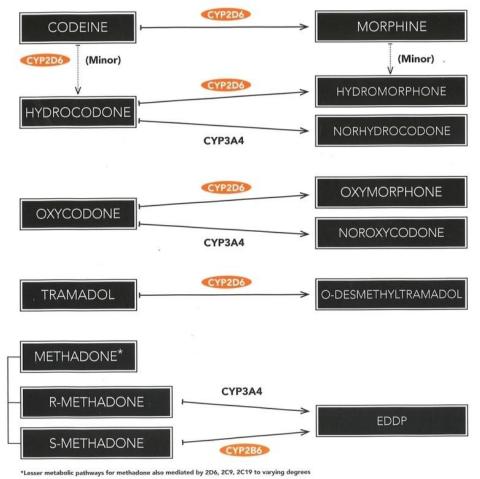
Drug Screen Detection Times

Amphetamines	• 48 hours
Barbiturates	 Short-acting (eg, secobarbital), 24 hours Long-acting (eg, phenobarbital), 2–3 weeks
Benzodiazepines	 3 days if therapeutic dose is ingested Up to 4–6 weeks after extended dosage (≥ 1 year)
Cannabinoids	 Moderate smoker (4 times/week), 5 days Heavy smoker (daily), 10 days Retention time for chronic smokers may be 20–28 days
Cocaine	• 2–4 days, metabolized
Ethanol	• 2–4 hours
Methadone	Approximately 30 days
Opiates	• 2 days
Phencyclidine	 Approximately 8 days Up to 30 days in chronic users (mean value = 14 days)
Propoxyphene	• 6–48 hours

Gourlay DL, Heit HA. Pain Med. 2009;10 Suppl 2:S115-123.

Opioid Metabolism

PRIMARY OPIOID METABOLIC PATHWAYS^{2,3}



Major metabolic pathway Minor metabolic pathway

CYP = cytochrome P450

= Tested by Millennium PGT

EDDP = 2-Ethylidene-1, 5-Dimethyl-3, 3-Diphenylpyrrolidine

PARENT DRUG	PRIMARY METABOLITES
CODEINE	Morphine, Hydrocodone (minor)
HYDROCODONE	Hydromorphone; Norhydrocodone
OXYCODONE	Oxymorphone, Noroxycodone
TRAMADOL	0-Desmethyltramadol
METHADONE (R- AND S-ISOMERS)	EDDP

(2) Adapted from Smith HS. Opioid Metabolism. Mayo Clin Proc. 2009; 84(7):613-624. (3) Adapted from Trescot AM, et al. Opioid Pharmacology. Pain Physician. 2008;11(suppl):1355-1535.

Benzos and Opioids

- This is an extremely 'hot-button' item in the area of medical-legal scrutiny. It is a metric that is being calculated on all of us.
- If one of your patients is on chronic opioids *please* do not start benzos.
- If all other treatment modalities fail and the patient requires benzos, please put that in your note.
- Otherwise, it is likely the patients opioids will be tapered and discontinued.

Alabama Pain Management Laws Effective March 9th, 2017

- Calculation of MME is a necessary metric
 - Using approved conversion tables (my advice use the PDMP values)

Must adopt risk and abuse mitigation strategies

To include but not limited to:

- Pill Counts
- Urine Drug Screens
- PDMP Checks
- Consideration of abuse-deterrent medications
- Monitoring the patient for aberrant behavior
- Using validated risk-assessment tools
- Patient education concerning opioid risks

Querying the PDMP

- MME less than 30 "in a manner consistent with good clinical practice"
- MME more than 30 but less than 90 at least twice a year
- MME more than 90 each time an Rx is written (checked on same day as Rx)

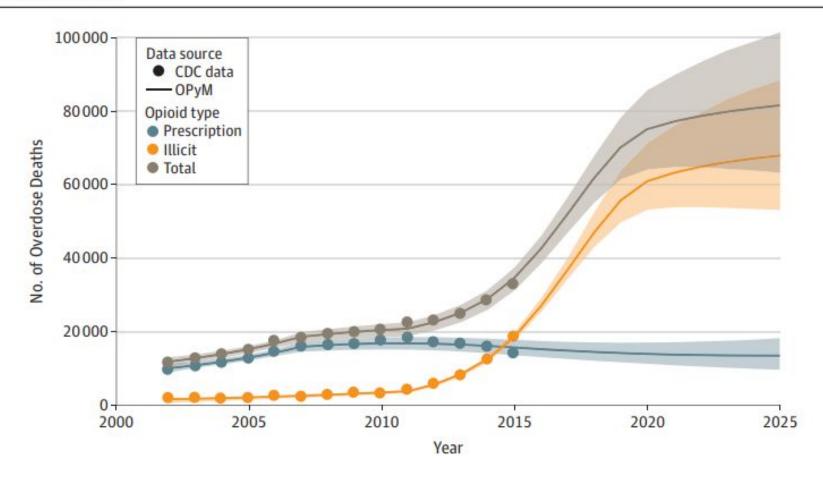
Effective January 1, 2018 - 2 hours of CME related to controlled substance prescribing every 2 years (This lecture can count as one of those)

Prognostications



Projected OD Deaths

Figure 2. Overdose Deaths From Prescription and Illicit Opioids From 2002 to 2025 Under the Base-Case Projection Scenario



JAMA Network Open. 2019;2(2):e187621. doi:10.1001/jamanetworkopen.2018.7621

In My Opinion

- More and more opioids must be viewed as a treatment of last resort – to be used only when all else fails.
- Non-opioid treatment is going to have to assume a much more prominent role in chronic pain management – and our patients are going to have to buy into this.
- Both patients and physicians are going to have to get past the 'pill for every symptom' mentality
- Patients are going to have to become more active participants in their own health care
 - Naloxone rescue is standard of care and should be prescribed for at least all high-risk patients.
- Our present strategies for dealing with the opioid crisis is not reducing opioid-related overdose deaths. Rather, it seems to be shifting the drugs used in them.

Summary

- Chronic pain is a widespread, and expensive medical problem.
- Because of skyrocketing opioid overdose deaths, many new regulations are in place.
- There are a growing number of requirements and regulations; particularly when writing ER/LA opioids.
 Patient participation in their own health care is going to become more and more necessary in the current 'opioids are last resort' mentality.
- The role of non-pharmacologic treatment is going to have to increase.

Save the Pangolins!

TIM MASSON

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