The Opioid Crisis and the Management of Orofacial Pain

Course Material

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Outline

Introduction Miller

Objectives MacKie

Definitions MacKie

Data (Mortality, Morbidity, and SUD) MacKie

Risk Factors MacKie

Responses MacKie

Managing Pain (Considerations) MacKie

Lessons for Dentists Miller & Berman

Cases Studies MacKie & Miller & Berman

Introduction

This course will present information about the opioid crisis and how this crisis impacts the management of orofacial pain by oral health care providers.

Introduction (cont.)

- Many resources are becoming available on guidelines for prescribing medications for the management of acute and chronic pain.
- These resources are readily available online, some of which may be mentioned in this course.
- This course is not designed to recapitulate these guidelines, but more to give an overview of the opioid epidemic and what a dentist needs to consider before prescribing medication for the pain management of patients

Introduction (cont.)

- At the end of the material by Dr. MacKie, Drs. Miller and Berman added a "lessons learned" section that summarizes some of the main points of this material
- Finally, Drs. MacKie, Miller, and Berman prepared hypothetical cases to illustrate some of the issues that are involved in pain management of patients, given the current opioid epidemic

Objectives

- Review <u>DEFINITIONS</u> pertaining to the opioid crisis (epidemic)
- Review <u>DATA</u> about mortality and morbidity associated with the opioid crisis and data on substance use disorders (SUD) and the opioid use disorder (OUD)
- Review <u>RISK FACTORS</u> for SUD and OUD, including demographic factors associated with these disorders
- Review <u>RESPONSES</u> to this crisis by health care providers, legislatures, medical and dental boards, and organizations
- Review <u>CONSIDERATIONS FOR MANAGING PAIN</u> in the context of the current opioid crisis

Definitions

- Addiction
 - v. Dependence
 - · v. Tolerance
- Substance Use Disorder (SUD)
 - Opioid Use Disorder (OUD)

What is Drug Addiction?

- Addiction is a chronic relapsing brain disease
- Characterized by compulsive drug seeking and use, despite harmful consequences
- Drugs of abuse change the structure and function of the brain
- These brain changes can be long-lasting, and can lead to harmful behaviors

Addiction

Neurobehavioral condition with genetic and environmental factors

- Chronic
- Craving
- Compulsive
- Continues despite harm



Addiction

Neurobehavioral syndrome with genetic and environmental influences that result in psychological dependence for psychic effects. Chronic, Craving, Compulsive and Continuous despite harm

<u>Dependence</u>

Neuro-adaptation characterized by withdrawal syndrome if substance is stopped or lowered abruptly

Tolerance

Physiologic state resulting from regular use of drug in which the dose must be increased to achieve the same clinical response

* Duration then magnitude *

Pseudo-addiction (totally discredited notion)

Behavior pattern exhibited "drug seeking" by patient who is receiving inadequate pain management/too little opioids.

What is a Substance Use Disorder?

- Problematic pattern leading to clinically significant impairment or distress, including at least 2 of the following and occurring within 12 months:
 - > Larger amounts than and longer than intended
 - > Persistent desire or unsuccessful efforts to cut/control use
 - > Seeking time and energies increases
 - Craving/desire for substance
 - Use associated with failure to fulfill roles, work, interpersonal/social, family, school
 - Giving up important activities due to use
 - > Hazardous situations related to use

Substance Use Disorder DSM-V

Maladaptive pattern leading to clinically significant impairment or distress within a year including two or more of:

- 1. <u>Tolerance**</u> **= not a criteria when on Rx opioids
- 2. Withdrawal signs**

Motivational Injury

- 3. Substance taken in larger amounts/longer period of time than intended
- 4. Unsuccessful efforts to quit/cut back
- 5. Energy, time and effort to obtain, use or recover from substance
- 6. Strong desire/craving for substance
- 7. Use interferes with major role obligations: work/school/home
- 8. Continues despite impact on social and interpersonal relationships
- 9. Used in situations where it may be physically hazardous
- 10. Social, occupational, recreational activities reduced or eliminated
- 11. Use despite knowledge of medical or psych, problem resulting from use

Data

Mortality
Morbidity

Data

Mortality Deaths from drug overdose

Figure 3. National Drug Overdose Deaths Involving Any Opioid, Number Among All Ages, by Gender, 1999-2018

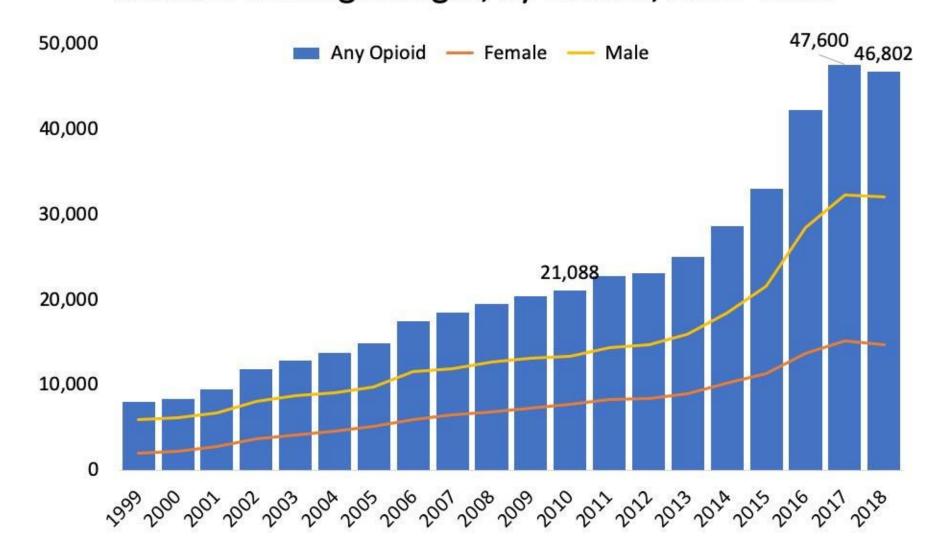


Figure 4. National Drug Overdose Deaths Involving Prescription Opioids, Number Among All Ages, 1999-2018

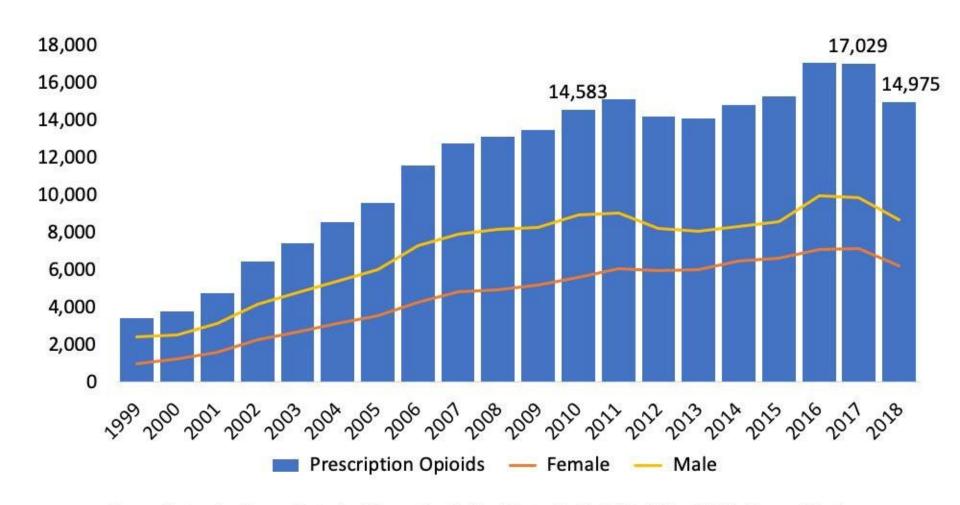
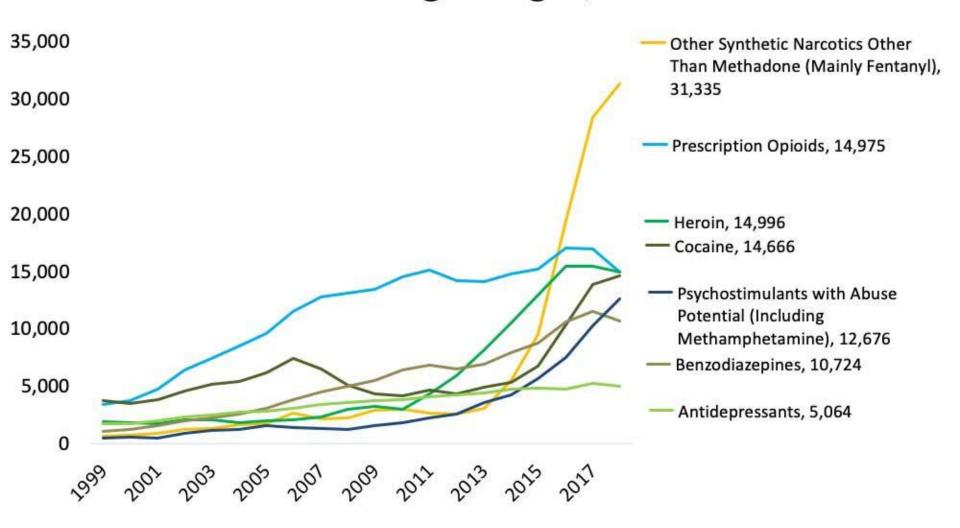
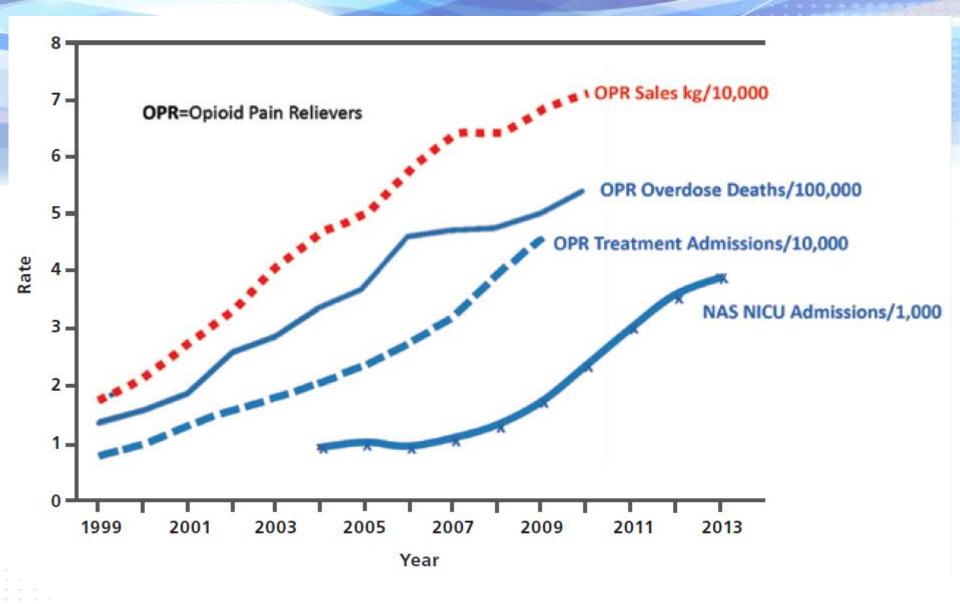


Figure 2. National Drug Overdose Deaths Number Among All Ages, 1999-2018

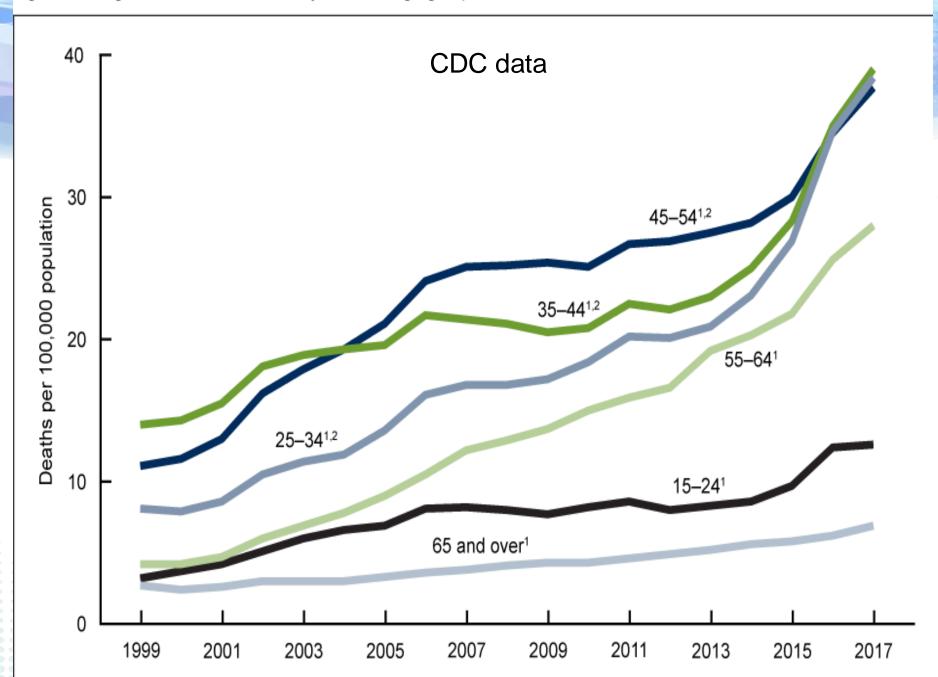


Source: : Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2018 on CDC WONDER Online Database, released January, 2019



latrogenic Opioid Epidemic

Figure 2. Drug overdose death rates, by selected age group: United States, 1999–2017



Years of Life Lost (YLL) From Opioid-Related Deaths in the United States in 2016

Sex and Age	US Population, No.	Opioid-Related Deaths, No.	Rate of Opioid- Related Deaths, No./1 000 000 Population	YLL, No.	YLL, No./1000 Population
Överall					
0-14 y	61 037 347	83	1.4	6180	0.1
15-24 y	43 612 557	4027	92.3	230 694	5.3
25-34 y	44 864 505	11 552	257.5	576 676	12.9
35-44 y	40 577 537	9747	240.2	400 611	9.9
45-54 y	42 864 368	9074	211.7	290 153	6.8
55-64 y	41 618 831	6321	151.9	154 065	3.7
≥65 y	49 420 383	1441	29.2	22 979	0.5
Total	323 995 528	42 245	130.4	1 681 359	5.2

JAMA Network Open. 2018;1(2):e180217. doi:10.1001/jamanetworkopen.2018.0217

Highest Mortality Ever

- June 2019-June 2020
- Over 81,000 deaths attributable to drug OD
- > 70 % of OD deaths opioid related
 - Synthetic opioids (primarily illicitly manufactured fentanyl) likely the primary driver of the increases in OD deaths, increasing 38.4 %
 - cocaine OD deaths increased by 26.5 %
 - Psychostimulants OD deaths, such as methamphetamine, increased by 34.8 %
 - Psychostimulant OD deaths now exceeds cocaine related deaths

Overdoses in Children

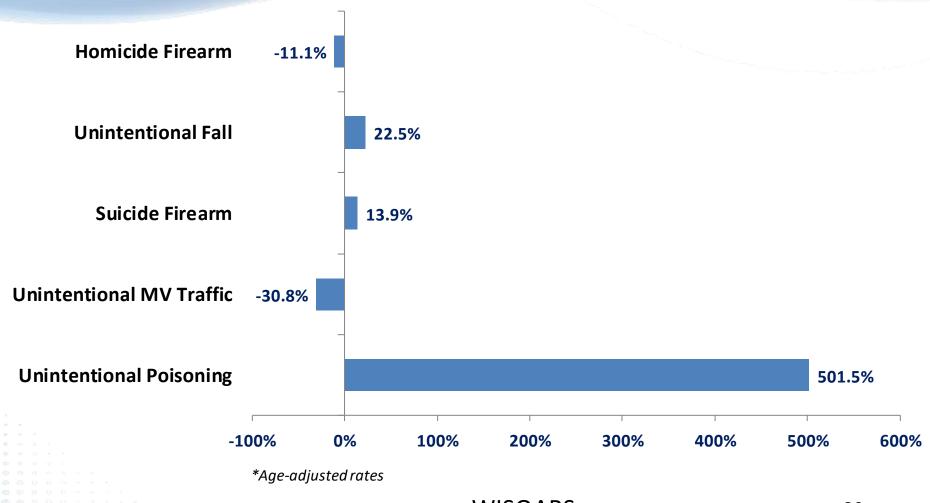
Pediatric Opioid Rx Overdoses: 2001-2008

- Emergency department visits for opioid overdose rose 101%
- Admissions related to Rx opioid overdoses rose 86%

Data

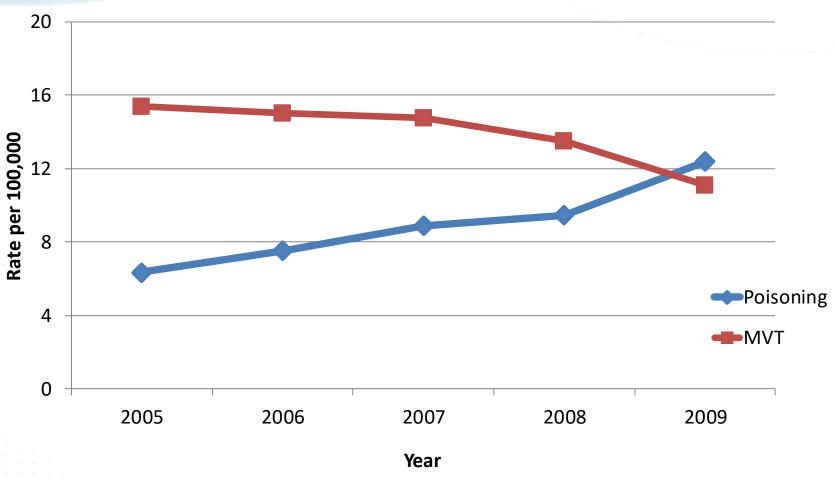
INDIANA Deaths from drug overdose

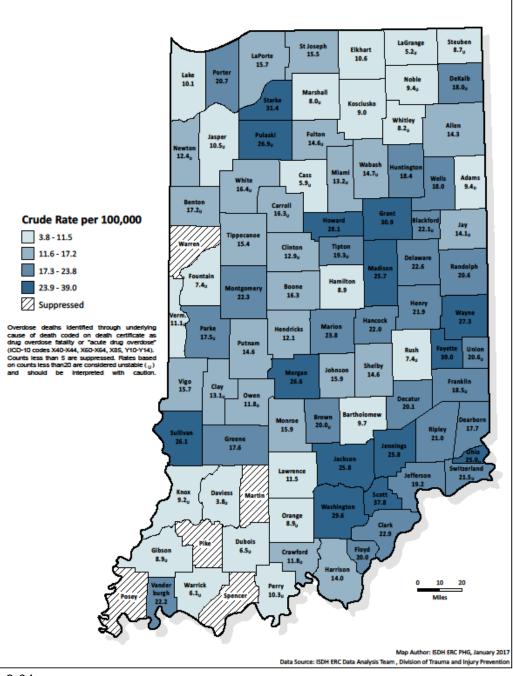
Percent Change in Leading Causes of Injury Death*— *Indiana*, 1999–2009



Source: WISQARS

Unintentional Poisoning and Motor Vehicle Traffic Death Rates, Age-Adjusted, *Indiana*, 2005 – 2009





DEATH CERTIFICATES

Overdose as cause of death (Jan 2017)

- GREATER THAN 60% of all recent deaths in IN are opioid related
- 13 or more counties had the highest rate (24-39 per 100,000)

2018 Opioid Deaths in Indiana

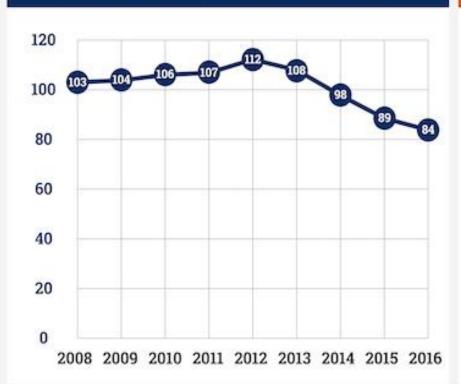
Location 💠	0-24 💠	25-34 💠	35-44 💠	45-54 💠	55+ ♦
Indiana	103	328	295	197	181

https://www.kff.org/other/state

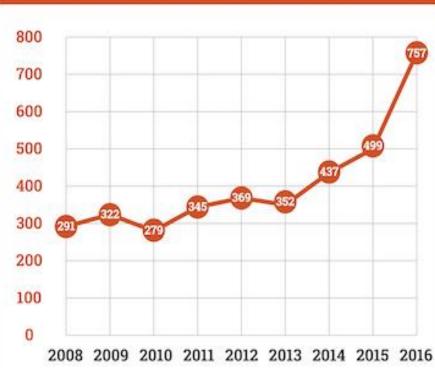
<u>Year</u>	OD Deaths		
2017	1852		
2018	1629		
2019	1699		

The Opioid Epidemic in Indiana

Prescriptions per 100 Residents



Opioid Deaths



2020 Opioid Poisoning Deaths Per 100,000 Residents

Deaths by County of Occurrence, Regardless of State or County of Residence

1,526

Opioid Deaths in Indiana

23.5
Opioid Deaths in
Indiana per
100,000
Residents

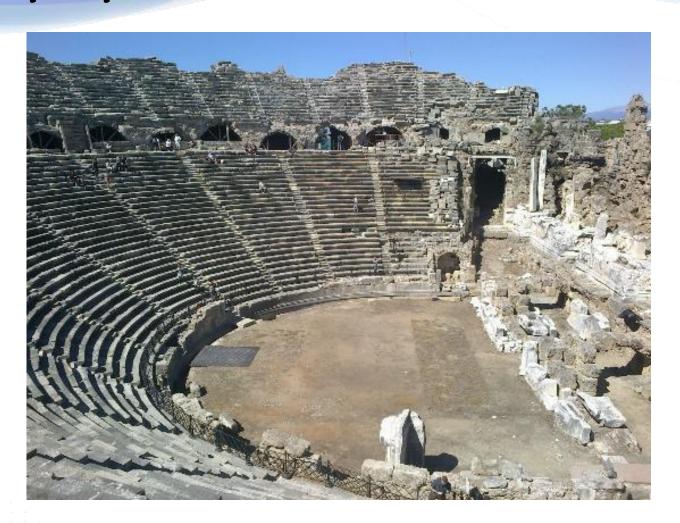


Opioicentric Pain Care: Medicine's Greek Tragedy



Good intentions gone astray

Opiophilia: Morbidia & Mortalicus



The Cast and Stage

The Chorus Providers, Advocacy, Patients

Hero Dr. A. Skip Aleze

Heroin Ann O. Dyne

Titans Big Pharma, Medicalization,

Pain "Experts"

The Plague latrogenic Opioid Epidemic

Period 1992-202_?

Ann – A tragic case

- 17 drinking and weed
- 17-19 aches and pains from motor vehicle accident and soccer
 - Soma and Vicodin from Dr. Skip Aleze
 - Percocet from friend and college MD

Why did she keep getting refills?

HOMETOWN CLINIC

John Doe, M.D. Family Practice 1234 Your Address YourCity, GA 98765 (987) 654-3210 Fax (987) 654-3211

Lic. #: A12345 DEA #: AA7654321 NPI #: 789456123

110922A12345 #00001

Ann O. Dyne

ров 6/06/84

Address

Name

123 Diversion Way

Date 1/16/03_{AF}

R

Vicodin 5 mg

Sig.- 1-2 po each 6 hrs prn pain **Disp.- 84**

Refil NR 1 2 3 4 5 Void After

Spanish

Do Not Substitute-Dispense As Written

Skip Aleze, MD

Signature



Ann - More Meds, Less Help

- 17 Drinking and weed
- 17-19 Aches and pains from MVA and soccer
 - Soma and Vicodin from Dr. Skip Aleze
 - Percocet from friend and college MD
- 21 Fatigue, pain and dysfunction
 - Anxiety worse & leave of absence
 - Xanax added to mix by Dr. Holly Trinity
- Unintended pregnancy
 - Dr. Skip delivers her daughter, Sophia

Note: This combination of drugs would have a euphoric effect which is desirable by drug abusers

Ann and Sophia – New Beginnings...

- Sophia in Hospital 6 days, crying, not eating
- Ann and Sophia move home with her mom



Ann – Hibernation then Relapse

- Counseling helps Ann adjust to life
- Age 25 Stable Job, good daycare and new boyfriend
 - Xanax (2-4/wk) & just social Etoh
- Fell while being "social", fractured wrist
 - Norco from ED and post-op Percocet
- Hibernation Ended
 - ** latrogenic Relapse **



Ann – Guided further down the wrong path

- 2008-2011 Ann remained on opioids and Xanax
- Saw Dr. Skip Aleze and others
 - Norco 10 mg 4-5/day, Xanax 1 prn #90/mo
- 2010- Sales Rep. showed him convenience,
 - point of care (poc) Urines --\$ and benefit to urine toxicology done in office
 - Dr. Aleze began poc Urine Drug Monitoring (UDM) in 2010
- 2011 he sent urine for confirmation to Ameritox
 - Morphine, hydrocodone & alprazolam

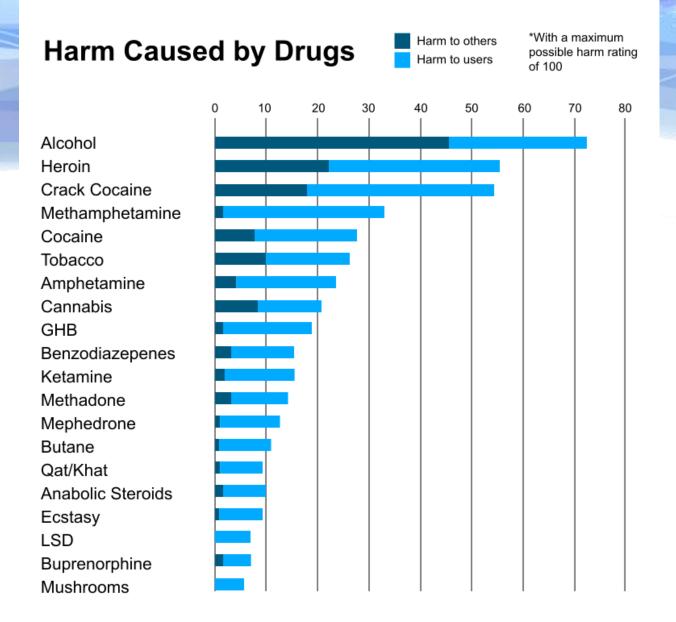
What does this likely mean?

Athens, Indiana



Data

Morbidity with SUD / OUD



We treat, but do we help?

Aggressive use of opioids and interventional technologies has been brought to bear between 1997 and 2005 (~ 65 % increase in expenditures) without evidence of improvement in self-assessed health status and pain. Many outcomes were worse.

JAMA 2008; 299(6):656-664

Points to Note

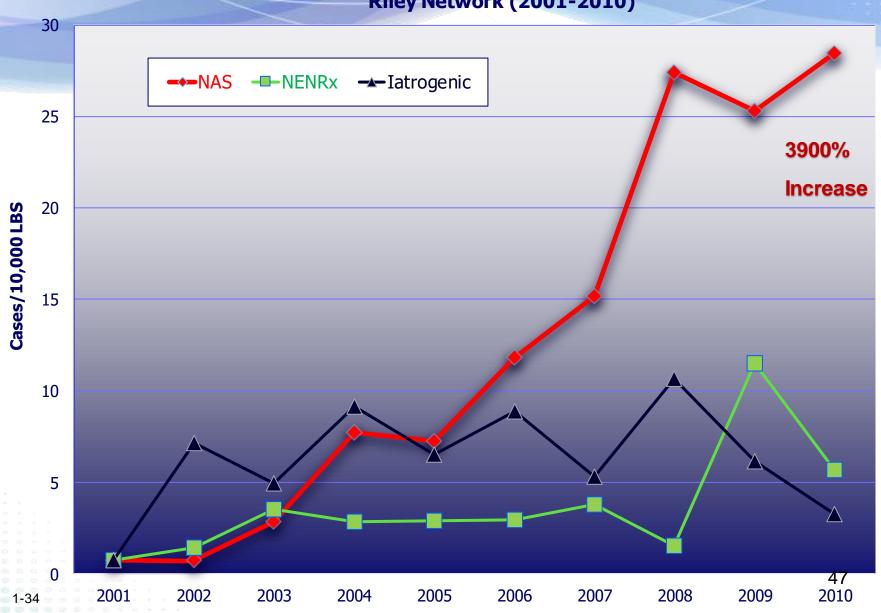
- Pain care and opioid use did not seem to help people have less pain or improvements
- Practices were not evidence based
- Opioid Rx 112/100 Hoosiers in 2012
- "Pseudo-addiction" was introduced and drove increases in use. There is <u>NO</u> evidence that pseudo-addiction is real.
- Many teenagers take opioids illicitly

Data

Morbidity
with SUD / OUD

Harm to Neonate

Neonatal Opiate Withdrawal Riley Network (2001-2010)



Human epidemiological studies have reported an association between opioid use during pregnancy and an increased risk of neural tube defects and other birth defects. The opioid system is implicated in bonding between mother and infant —for example, mice that lack the gene coding for the mu opioid receptor, the main target of opioid analgesics and heroin, show deficits in attachment toward their mothers. Opioid use during pregnancy could theoretically disrupt attachment between women and their babies Cognitive impairments have also been reported in children and young people born to women who misused opioids during pregnancy, although the relative contributions of other drugs or lifestyle factors to such deficits are unclear. BMJ 2016; 352

Much remains to learn on this. Opinions vary. 48

Perspective and Wisdom

"The possibility that health care might cause net harm is increasingly important given the sheer magnitude of the modern health care enterprise...these issues will likely challenge assumptions about the value of many current health care practices."

Data





Prevalence (Burden)

Prescription Drug Misuse

- USA <5% of world population</p>
- > consumes 99% global hydrocodone
- consumes >80% global opioid



Source: NSDUH 2009

Note: These statistics raise "safety issues" related to prescribing controlled substances:

- 1. What we wish to prescribe, based on our assessment
- 2. What the patient may be receiving from other MDs and dentists
- 3. What the patient may be using illicitly

Number of Americans on Long-term Opioids

10 Million

Opioid overdose deaths rose 28 percent in 2016, to 42,000 men, women and children

Ann Intern Med 2017; 167:181-191

NSDUH (SAMSHA) Data 2015

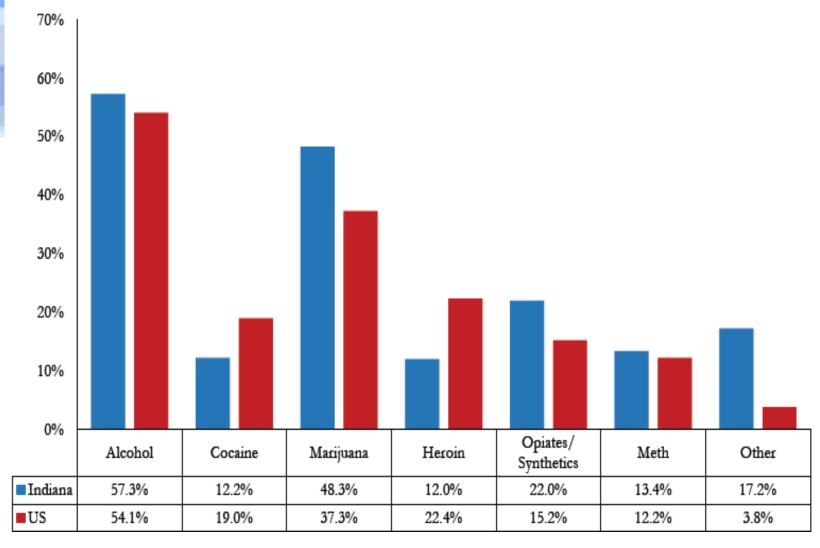
- National survey of 51,200 people from 50 states and D.C. in 2015
- Survey results indicated that 38% of U.S. population used an opioid in 2015 (i.e. approx. 91.8 million people)
- Among Adults with opioid Rx
 - 12.5% reported misuse
 - Among these 12.5%, 16.7% indicated they had a OUD
- Of all adults who reported misusing opioids
 - 40% with a Rx, and 60% without an Rx
 - Among the 60%, 41% <u>obtained opioids illicitly</u> for free from friends and family
- Among adults who misused opioids 63% reported <u>relief</u> of pain as motivation

Lifetime Prevalence of SUD

- 12-15% of Americans
- 30% of children of alcoholics
- 28-33% of people on chronic opioids

J Addictive Dis 2011; 30:185-194

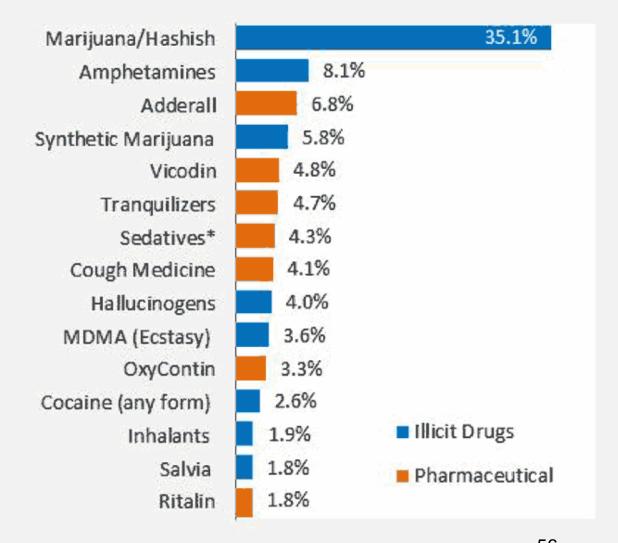
Figure 4. Percentage of Treatment Admission with Reported Use of Substances (TEDS-A, 2013)



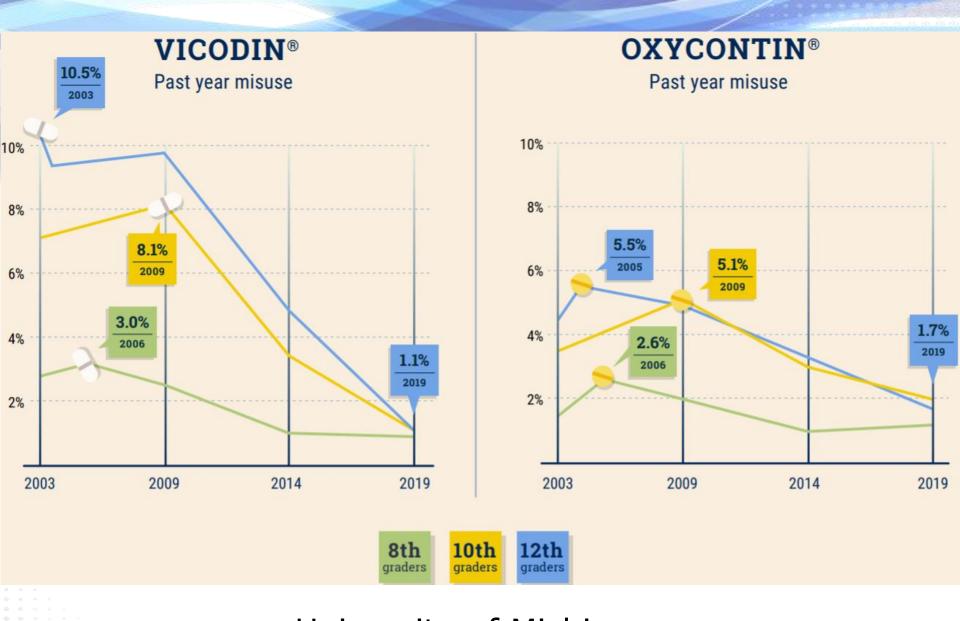
Note: Reported use of various substances by individuals admitted for treatment to hospitals (Indiana vs. U.S.)

SUD in 12th Graders

Past-Year Use of Various Drugs by 12th Graders (Percent)



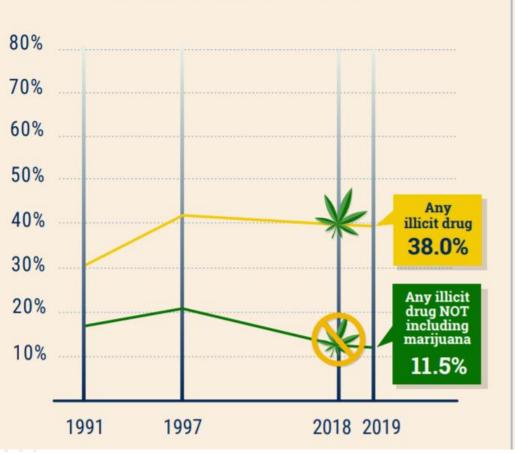
SOURCE: University of Michigan, 2014 Monitoring the Future Study



University of Michigan:
Monitoring the Future 2019 Survey Results

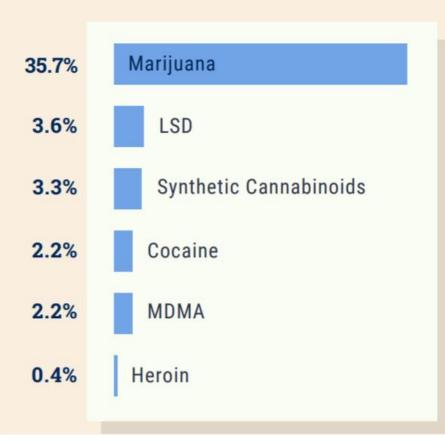
ILLICIT DRUG USE STEADY

Past year use among 12th graders



PAST YEAR ILLICIT DRUG USE

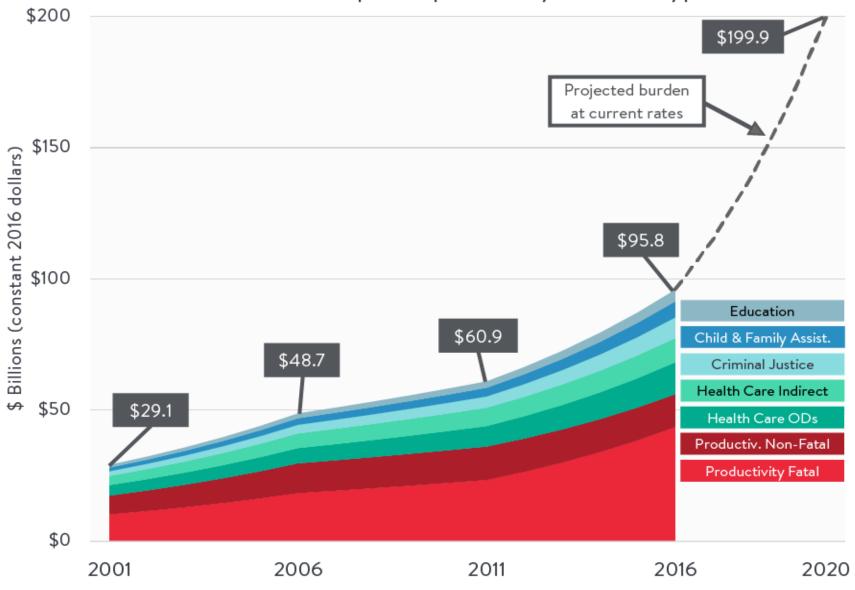
Past year use among 12th graders



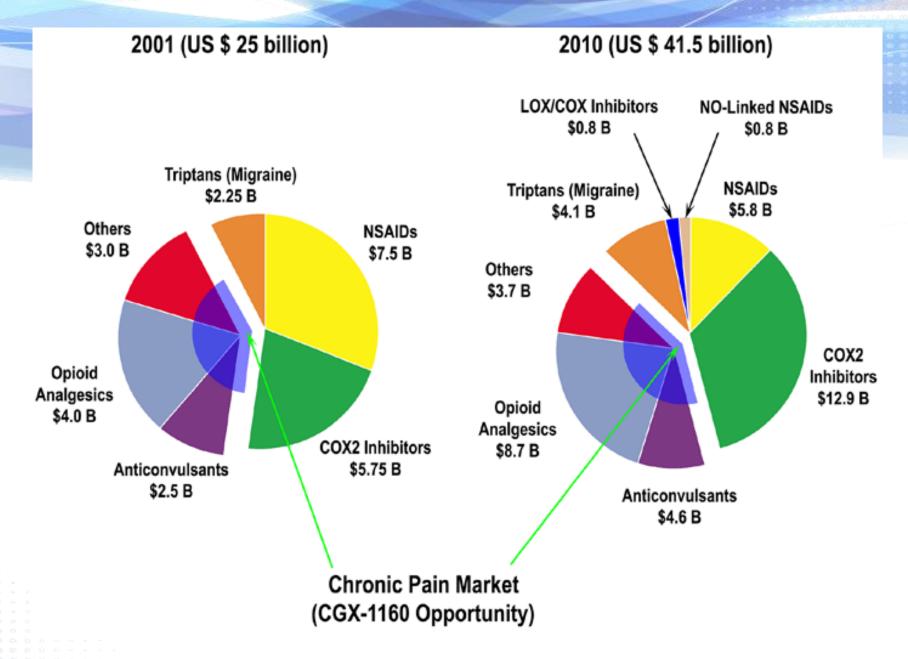
Cost of Opioid Prescriptions in US

- 2006 estimated total cost nonmedical use prescription opioids was \$53.4 billion
- \$42 billion (79%) to lost productivity
- \$8.2 billion (15 %) to criminal justice costs
- \$2.2 billion (4%) to drug abuse treatment
- CDC's estimate for 2009 is \$ 72 billion

Costs of the Opioid Epidemic by Year and Type



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



Points to Note

 Addiction, morbidity and morality data were not seriously addressed until 2012-2013

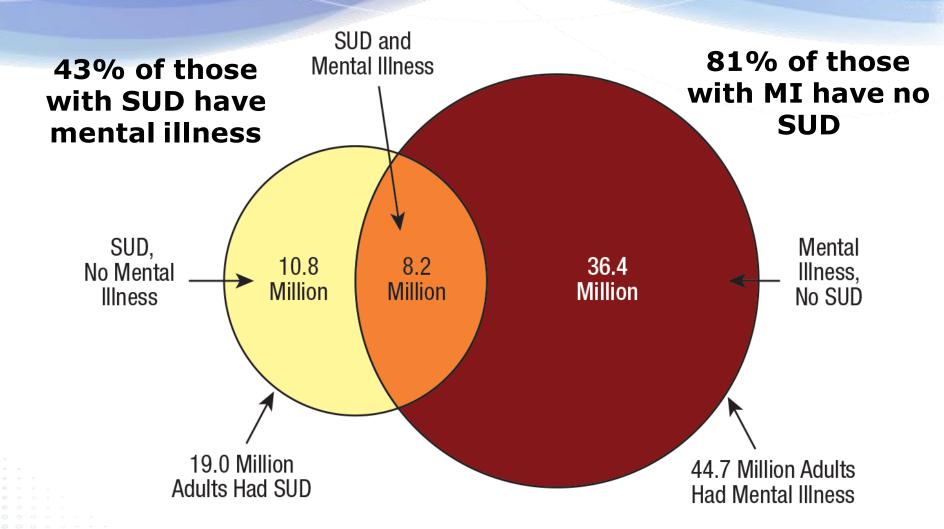
Ignoring harm, OD is dose related

- Rx opioid use clearly hurting our economy by 2006
- Chronic strong opioid use associated with lower quality of life scores, all 8 domains in SF-36
- Neonatal Abstinence Syndrome rose > 1000 fold in Indiana over a decade
- National Organizations attention and regulations arrived too late
- Over 640,000 people lost from Rx opioid related death since 1999

Risk Factors for

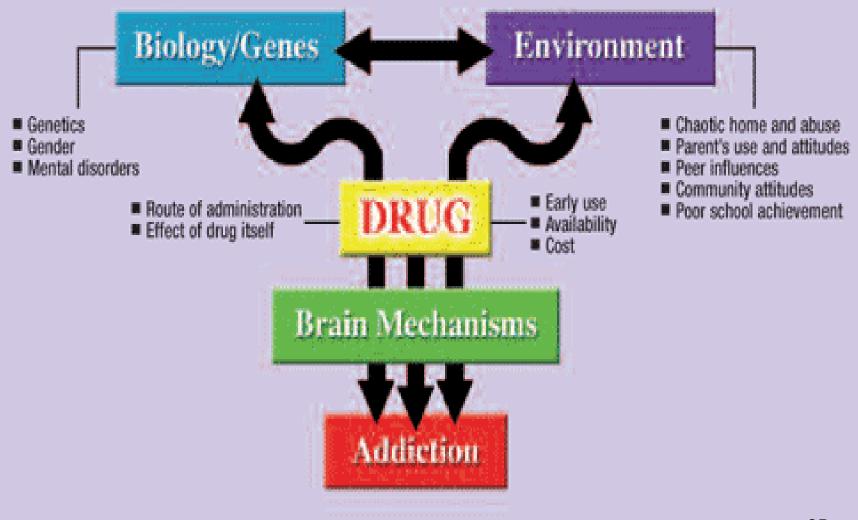
- Substance Use Disorders (SUD)
 - Opioid Use Disorder (OUD)
- Addiction
- Death from Overdose

Overlap of Mental Illness and SUD



2016 NSDUH

RISK FACTORS



Risk Factors

"Feel Good"

Why folk try exogenous chemicals

- To feel good and to have "novel"
 - Feelings, sensations, experiences and to share
 - Positive re-enforcement
- To feel less/less bad
 - Anxiety, worries, fears, depression, hopelessness
 - Negative re-enforcement

Risk Factors

Alleviate Pain

What is Pain

 An unpleasant sensory and emotional experience associated with actual or <u>potential</u> tissue damage, or <u>described</u> in terms of such damage

Pain: Big Take Home Point

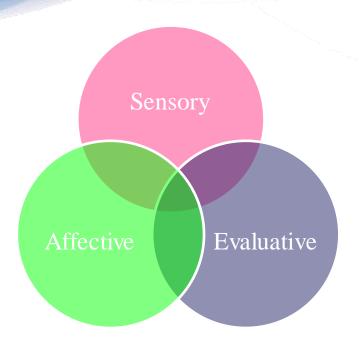
Pain is a *Perceptual Experience* formed in the brain

- Similar to other experiences with flexible biological associations:
 - Hunger, tickle, itch, urinary urgency and orgasm
- A complex experience embracing physical, mental, social, and behavioral processes, compromising the life of many individuals
 - -SSI Commission For Evaluation of Pain

Increase in opioid medications to manage pain

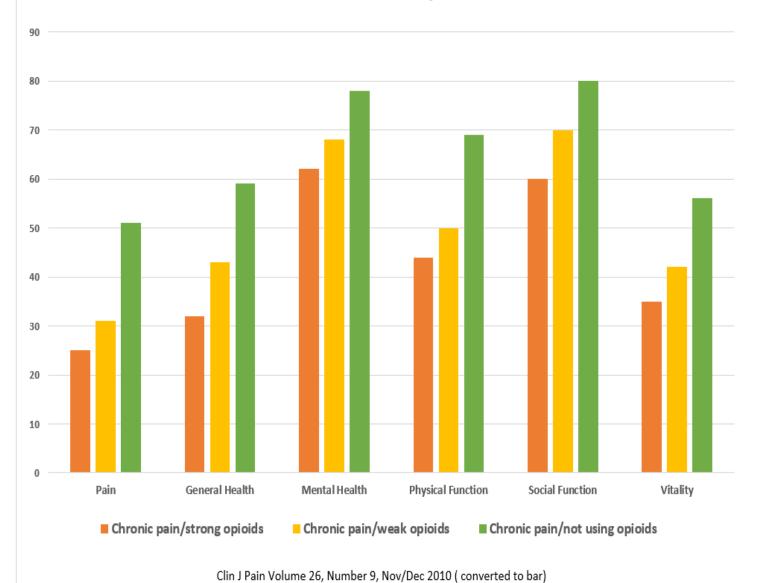
- > Growing public awareness of the right to pain relief
- > Joint Commission Standards 2000
 - New pain standards
- <u>Liberalization of laws governing opioid prescribing</u>
- Aggressive marketing of long-acting opioids by the pharmaceutical industry

Chronic Pain



Chronic pain is more complex than acute pain and can be difficult to manage

Quality of Life Scores According to Chronic Pain Status and the use of Opioids

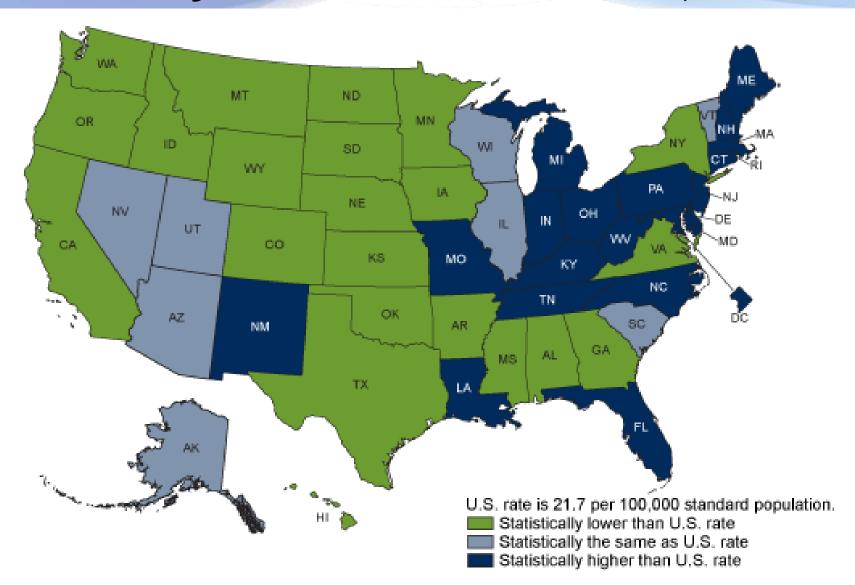


Predictors of Opioid Misuse in Patients with Chronic Pain

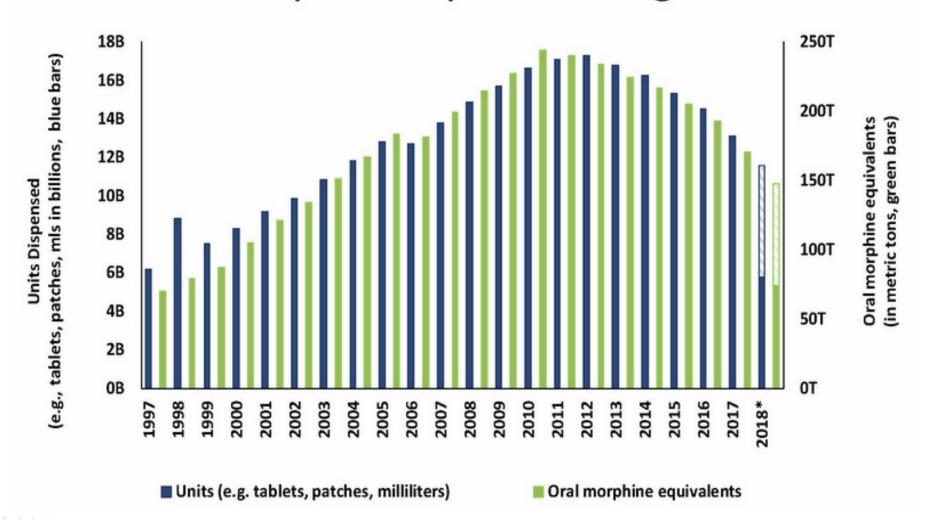
- 196 patients in Academic Chronic Pain Venue (Int. Med)
- Monitored for 12 months
- Misuse criteria
 - 1. UTS
 - 2. + UTS (too much)
 - 3. Multiple providers
 - 4. Diversion
 - 5. Rx forgery
 - 6. Stimulants

74% participants were depressed on screening

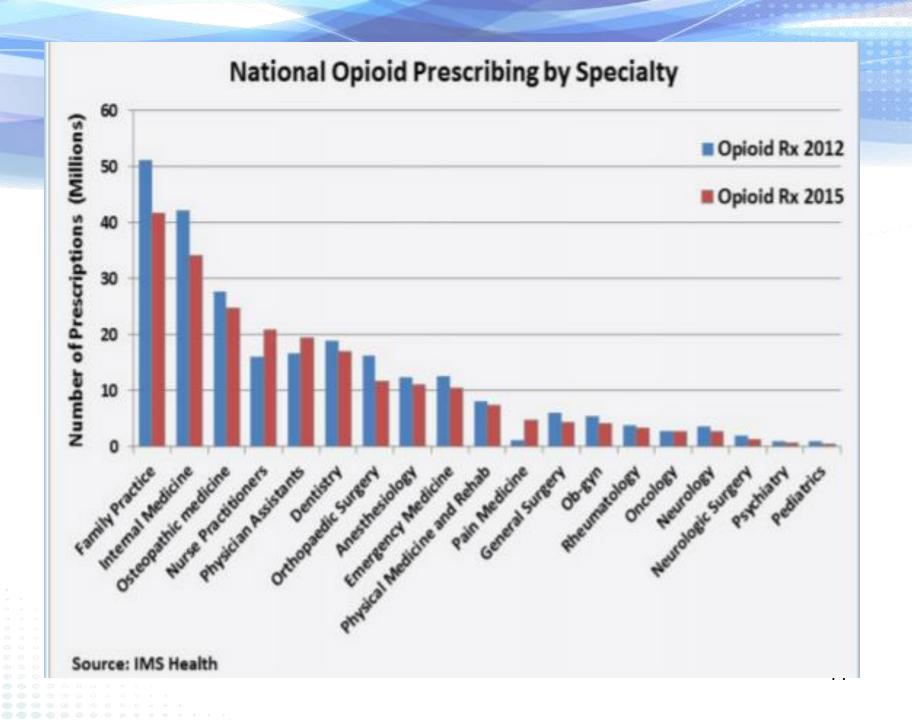
Age-adjusted drug overdose death rates, by state: United States, 2017



Prescription Opioid Analgesics

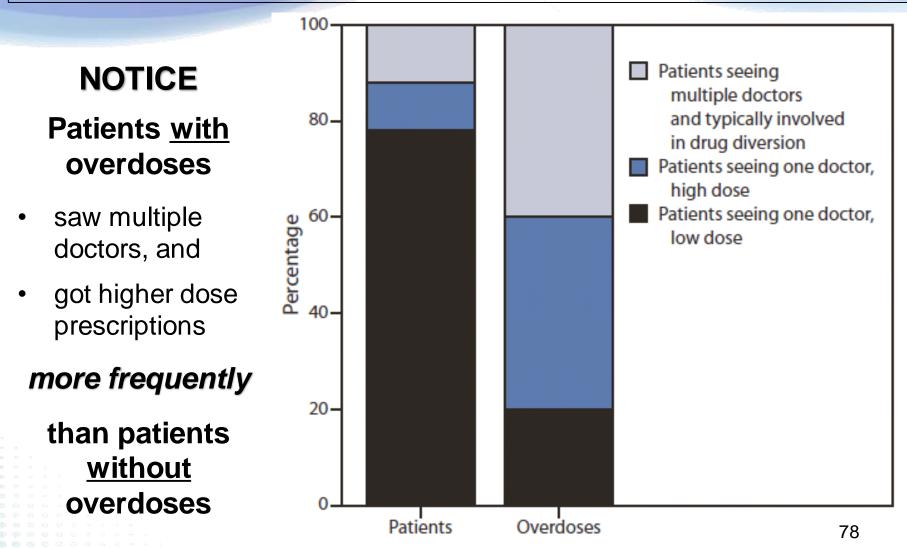


SOURCE: FDA AND IQVIA



Percentage of patients seeing multiple doctors

(Patients w/ Hx overdose vs. Patients w/o Hx overdose)



Points of Note

- Experts over-stated opioid safety
- Pharma mislead providers and consumers
- Providers felt compelled to increase opioid use despite no solid evidence for chronic pain
- CMS and Joint Commission forced "standards" without evidence
 - Pain as 5th Vital Sign and survey questions
- Providers wrote for ever increasing amounts of opioids until 2013

AAN - Position paper "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."

A position paper of the American Academy of Neurology" Neurology 2014; 83(14):1277-84

What is the Addiction Risk?

- Published rates of abuse and/or addiction in chronic pain populations are 3-19%
- Suggests that <u>known risk factors</u> for abuse or addiction in the general population would be <u>good predictors</u> for future aberrant behavior as well
 - Past cocaine use, h/o alcohol or cannabis use¹
 - Lifetime history of substance use disorder²
 - Family history of substance abuse, a history of legal problems and drug and alcohol abuse³
 - Heavy tobacco use⁴
 - History of BAD and severe depression or anxiety⁴

¹ Ives T et al. BMC Health Services Research 2006 ² Reid MC et al JGIM 2002

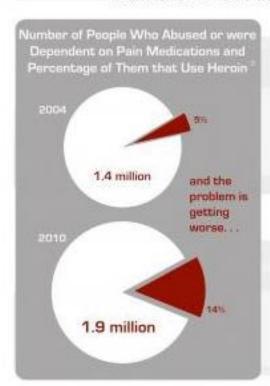
³ Michna E el al. JPSM 2004 ⁴Akbik H et al. JPSM 2006

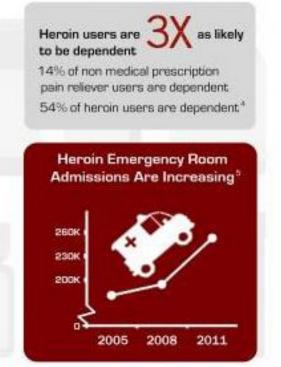
ABUSE OF PRESCRIPTION PAIN MEDICATIONS RISKS HEROIN USE

In 2010 almost 1 in 20 adolescents and adults – 12 million people – used prescription pain medication when it was not prescribed for them or only for the feeling it caused. While many believe these drugs are not dangerous because they can be prescribed by a doctor, abuse often leads to dependence. And eventually, for some, pain medication abuse leads to heroin.

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PEOPLE WHO TAKE NON MEDICAL PRESCRIPTION PAIN RELIEVERS WILLTRY HEROIN WITHIN 10 YEARS





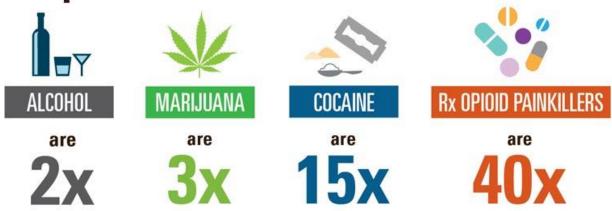
Heroin use is part of a larger substance abuse problem.

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.

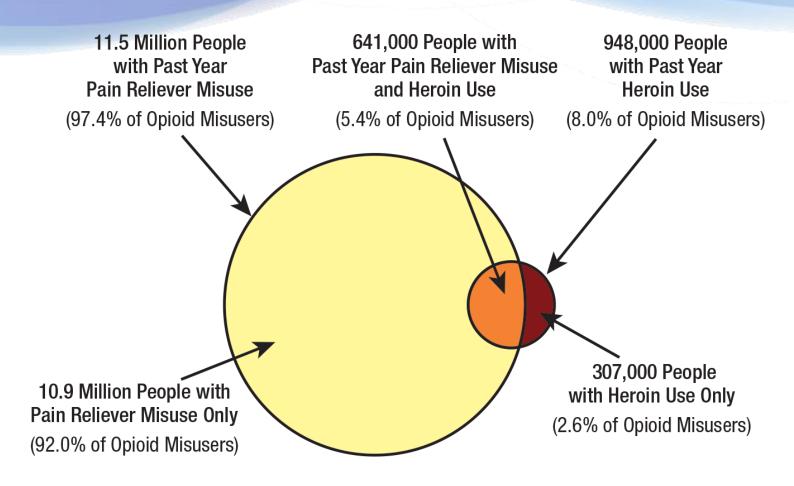
People who are addicted to...



...more likely to be addicted to heroin.

SOURCE: National Survey on Drug Use and Health (NSDUH), 2011-2013.

Overlap of Pain Reliever Use and Heroin Use



11.8 Million People Aged 12 or Older with Past Year Opioid Misuse

84

Select the true statements

- A. People suffer not because their discomfort is untreatable but because physicians are reluctant to prescribe morphine.
- B. When patients take morphine for pain, addiction is rare.
- C. Addiction seems to arise only in those who take it for psychological effects. e.g., euphoria or to relieve tension.
- D. Patients who take morphine for pain do not develop the rapid tolerance that is often a sign of addiction.

Ronald Melzack: Scientific American, 1990

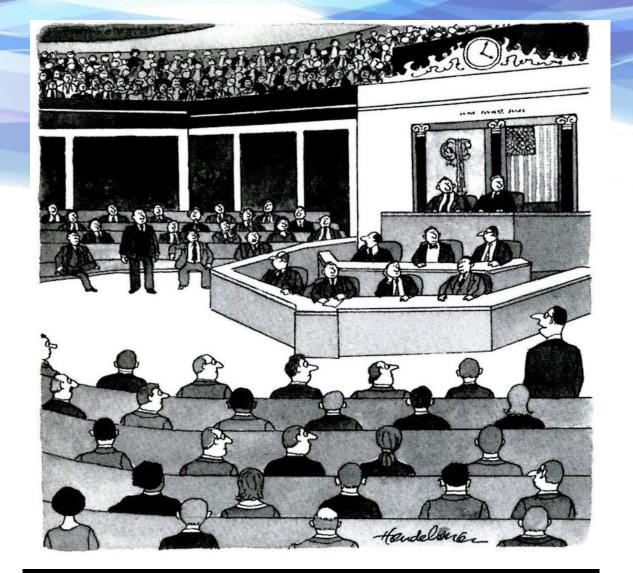
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- D. To take morphine for pain do not develop and tolerance that is often a sign of addiction.

Ronald Melzack: Scientific American, 1990

Points to Note

- Over 15 % of people using opioids with an Rx feel they have an OUD
- Most people who report using Rx opioids w/o an Rx report doing so to control pain
- 40-60% of illicit Rx opioid use comes from friends or family
- Majority of nonmedical Rx opioid use that comes from a provider comes from a single provider
- Many current heroin users began with Rx opioids
- Polysubstance abuse is very common in those with SUDs



Pain Business Overshadows Health

"Mr. Speaker, will the gentleman from Big Imaging yield the floor to the gentleman from Big Opioid?"

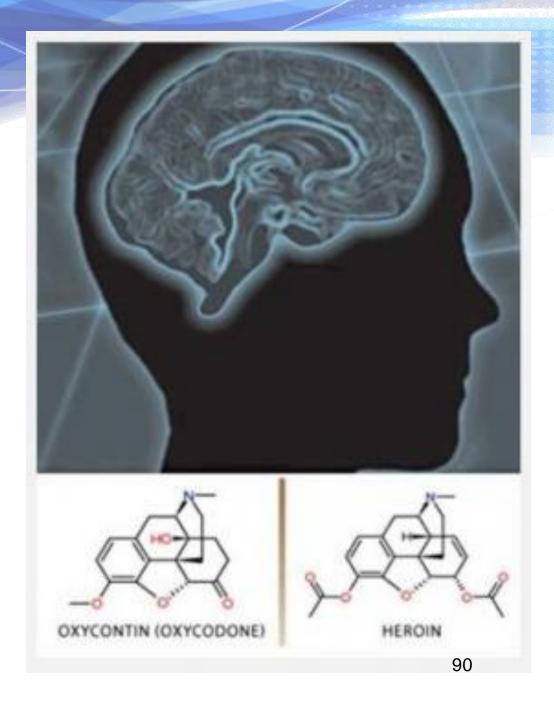
"The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy"

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



Which is heroin and which is oxycodone?

Similar chemical structure leads to similar biological effect



A Population-based Study on Chronic Pain – All-Cause Mortality and Treatment with Opioids

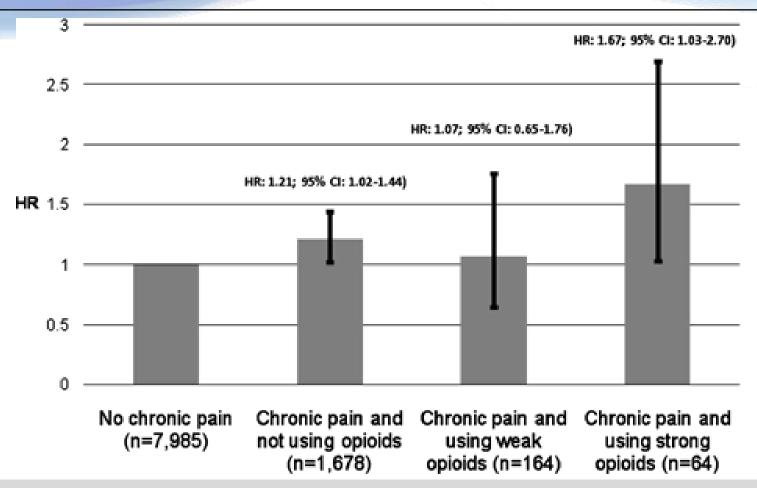
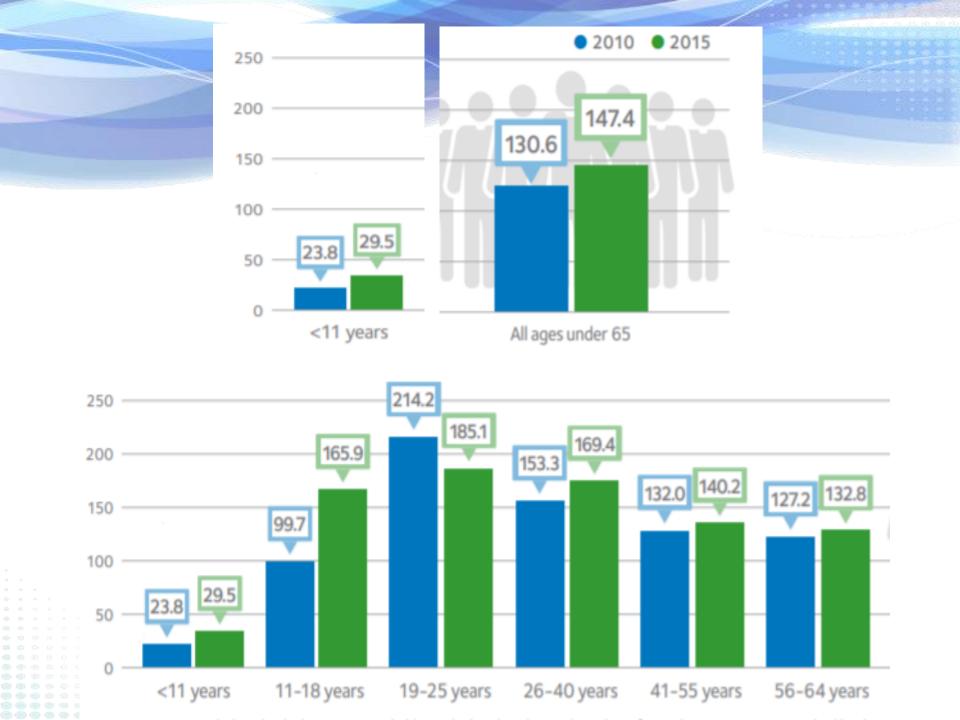


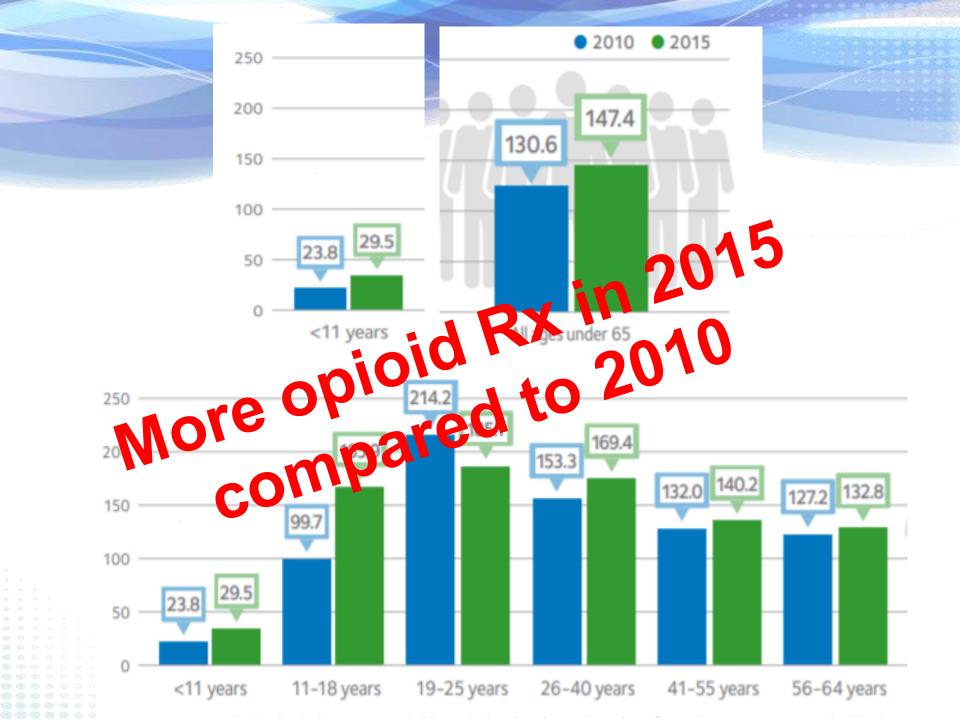
FIGURE 1. Hazard Ratios (HR) and 95% confidence intervals for <u>all-cause mortality</u> according to the chronic pain status and the use of opioids in 2000. Clin J Pain 2010; Volume 26, Number 9

Points of Note

- No increase in opioid education for providers
 - e.g. how to write an Rx
- Experts over-simplified opioid use
- Morbidity and mortality data related to opioid use and mis-use was largely ignored 2004-2012
 e.g. opioid related deaths overtaking MVA related deaths (occurred in IN 2008)

In 2012 DENTISTS wrote about 20,000,000 prescriptions for opioid pain medications ~ 105 opioid prescriptions *per* dentist





More opioid Rx in 2015 compared to 2010

 Studies in the United States show dentists recommend and prescribe opioids over nonsteroidal antiinflammatory drugs, in greater quantities, and for longer than necessary to control dental pain. An estimated 1 million opioid pills prescribed following tooth extractions remain unused in the United States. Furthermore, dentists are responsible for onethird of opioid prescriptions to adolescents, a vulnerable population for opioid misuse.

JAMA Netw Open. 2019;2(5):e194303. doi:10.1001/jamanetworkopen.2019.4303

Perspective and Wisdom

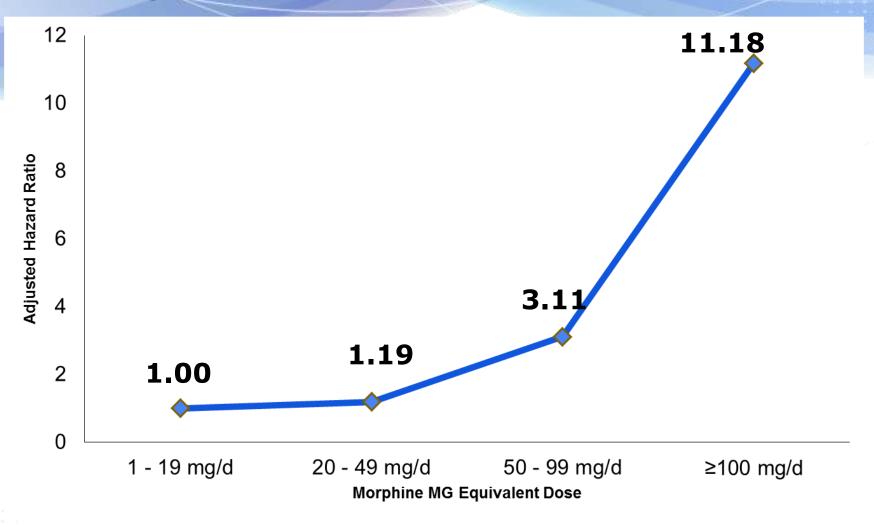
"Doing everything for everyone is neither tenable nor desirable. What is done should be inspired by *compassion* and <u>guided by science</u> and not merely reflect what the market will bear."

JAMA 1996; 269:3030

Risk Factors

Pharmacological Factors

High Opioid Dose and Overdose Risk



Dunn et al. Opioid prescriptions for chronic pain and overdose. Ann Int Med 2010;152:85-92

Risk of SUD/Abuse

OR (adjusted) when exposed to:

122 ≥120 MED/day

29 36-120 MED/day

15 1-36 MED/day

1 no opioid prescription

(considered non-exposed)

Note: The risk of abusing drugs and developing a SUD dramatically increases with increasing morphine equivalent dose (MED) per day

The Disease Process of Addiction

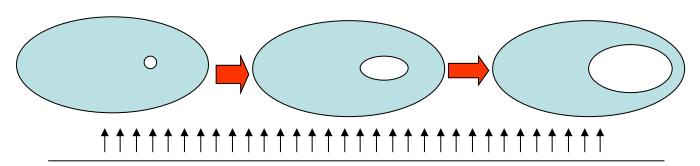
Substance
Use/Experimentation

Abuse

Dependence

Early Addiction (Substance Abuse)

Advanced Addiction (Substance Dependence)



REPEATED DRUG HITS

- Repertoire of adaptive behaviors: eating, sleeping, social, occupational, sexual behavior, etc.
- Drug seeking/drug taking

HOMETOWN CLINIC

John Doe, M.D. Family Practice 1234 Your Address YourCity, GA 98765 (987) 654-3210 Fax (987) 654-3211

Lic. #: A12345 DEA #: AA7654321 NPI #: 789456123

110922A12345 #00001

Fax (987) 654-3211

Miss. B. Havyor D08 4/06/86

321 Sobriety Lane Date 1/16/18 MF

R

Oxycodone/APAP 5 mg/325 mg

Sig.1-2 po each 6-8 hrs for 2 days,1 po each 6-10 hr for 2 days, 1 po each 8-12 hr as needed for 2 days, stop. (do not exceed 8/day) Disp.- twenty-four (24)

Heffil NR 1.2.3.4.5 Void After □ Spanish

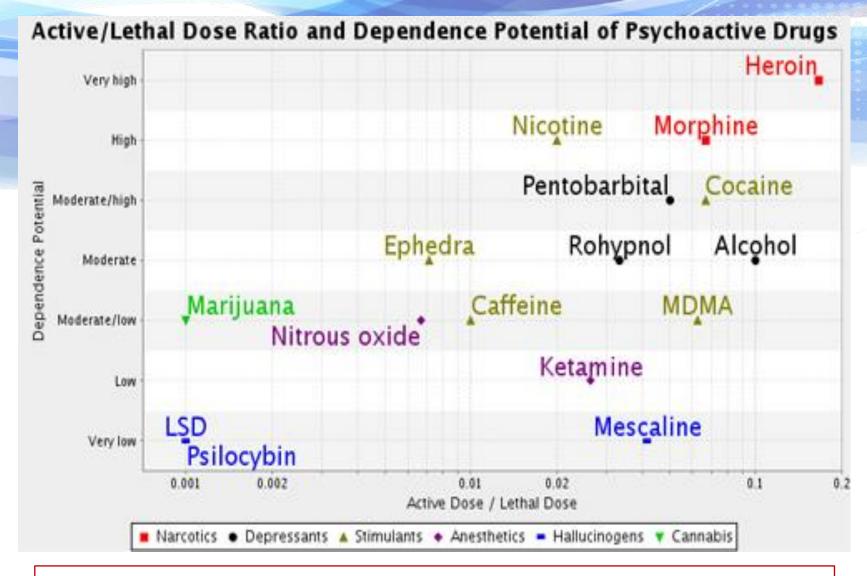
□ Do Not Substitute-Dispense As Written

P. G. Yuan MD

Signature



SEE BACK FOR LIST OF SECURITY FEATURES



Note: The **active dose / lethal dose** ratio is very high for cocaine, morphine and heroin. This indicates the danger of death from the abuse of these drugs is high if an abuser makes an error in the amount consumed

Table 3. Factors Associated with the Risk of Opioid Overdose or Addiction.

Factor	Risk			
Medication-related				
Daily dose >100 MME*	Overdose,8 addiction8			
Long-acting or extended-release formulation (e.g., methadone, fentanyl patch)	Overdose ^{14,41}			
Combination of opioids with benzodiazepines	Overdose ⁴²			
Long-term opioid use (>3 mo)† Overdose,43 ad				
Period shortly after initiation of long-acting or extended-release formulation (<2 wk)				
Patient-related				
Age >65 yr	Overdose ⁴⁶			
Sleep-disordered breathing‡ Overdose ⁴⁷				
Renal or hepatic impairment§	Overdose ⁴⁸			
Depression	Overdose, addiction ⁴⁹			
Substance-use disorder (including alcohol) Overdose,50 addiction				
History of overdose	Overdose ⁵¹			
Adolescence	Addiction ⁵²			

Predictors of Opioid Misuse

Multivariate Analysis:

Model*		Odds Ratio	p-value	
•	Age	0.95	0.027	
•	Drug or DUI Conviction	2.58	0.030	
•	History of Cocaine Abuse	4.30	0.001	
•	History of Ethanol Abuse	2.60	0.048	

Note: 62/169 met misuse criteria

Young, male, Etohism

BMC Health Services Research 2006, 6:46

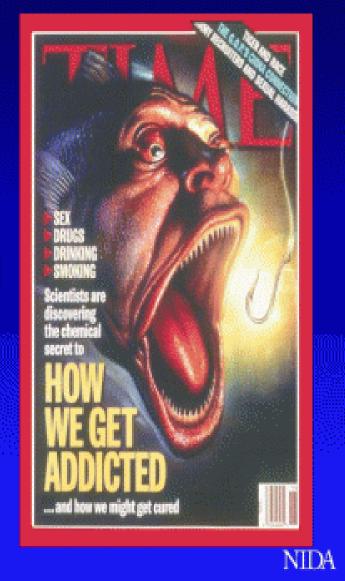
^{* % =} Positive urine cannabinoid and history of cocaine use were strongly correlated.

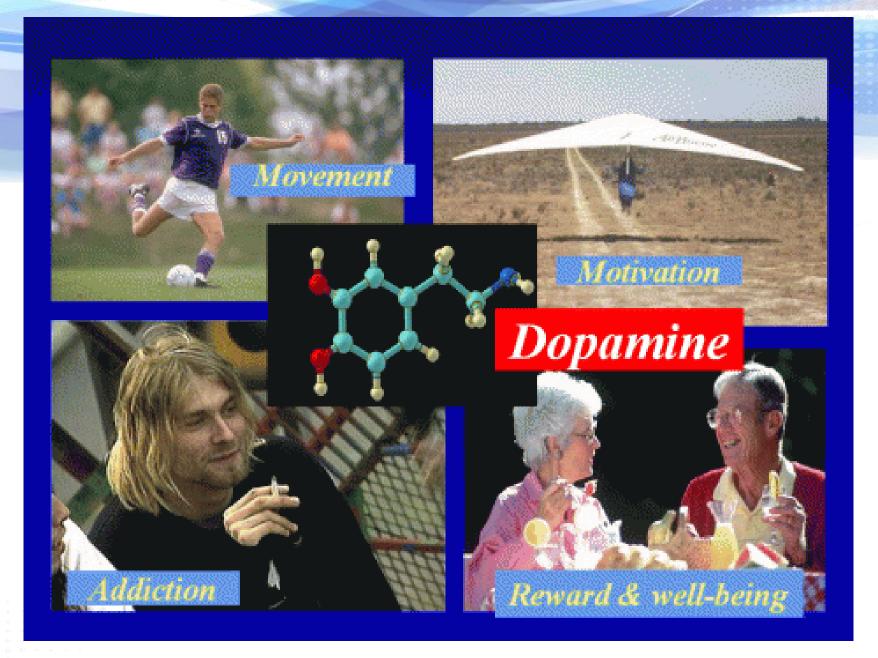
Risk Factors

Biological Factors

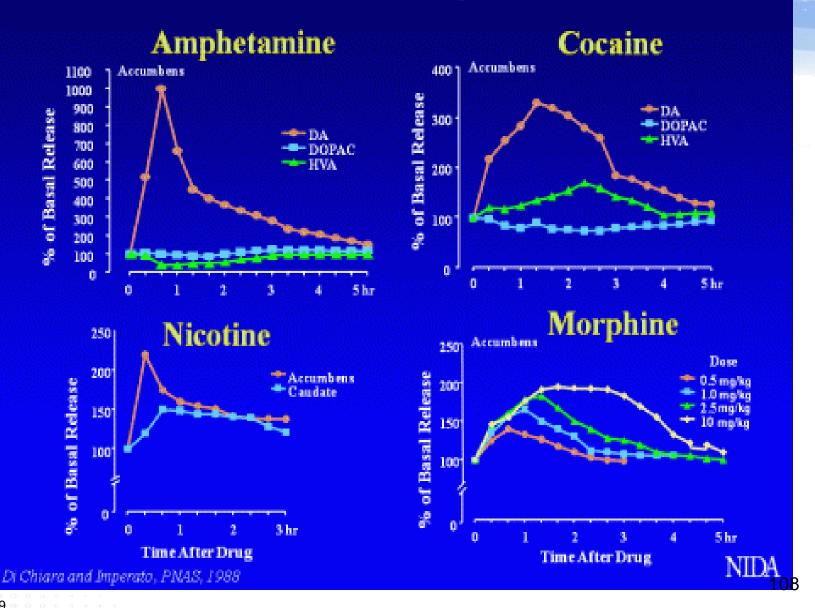
Why Do People Abuse Drugs?

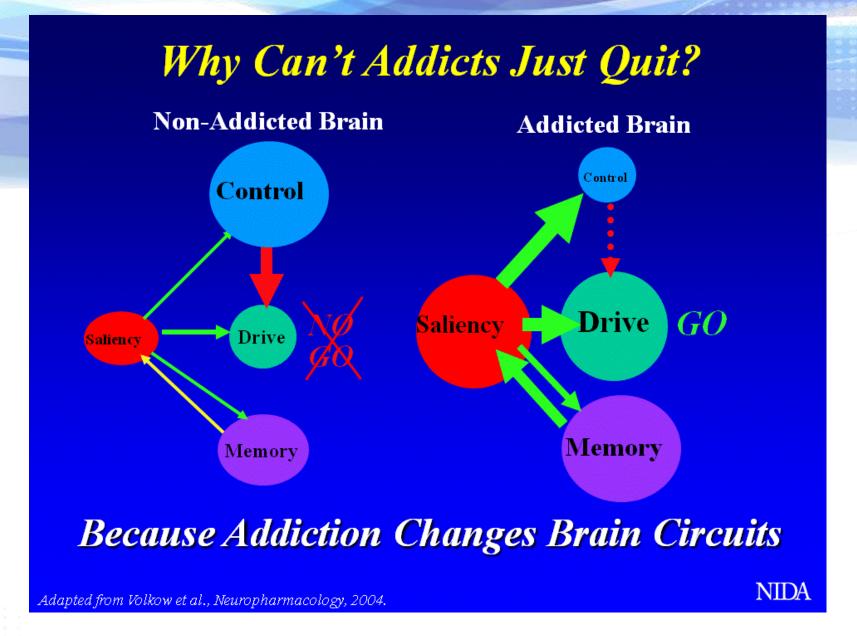
Drugs of Abuse
Engage *Motivation* and *Pleasure Pathways*of the Brain





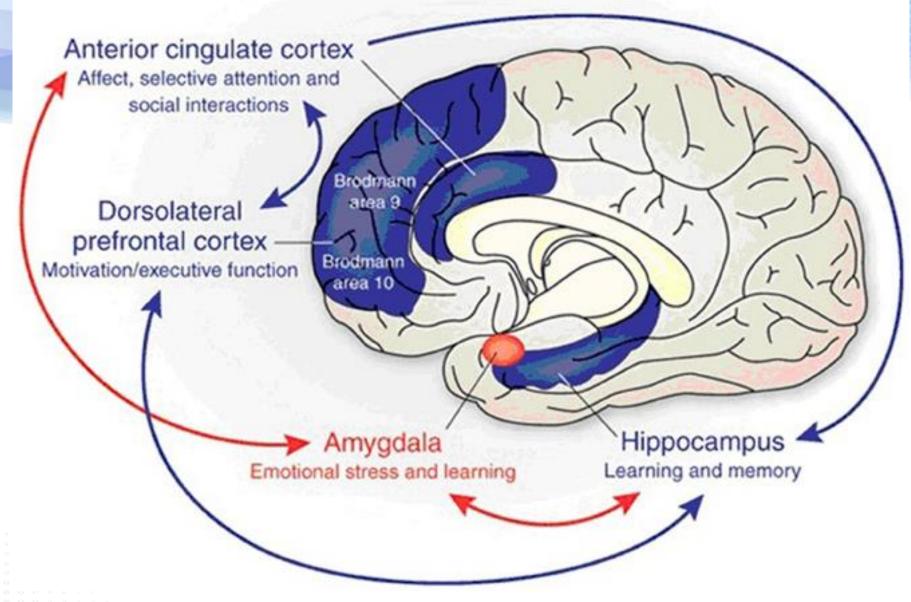
Effects of Drugs on Dopamine Release





Addiction and Changed Brain Circuits

The corticolimbic system

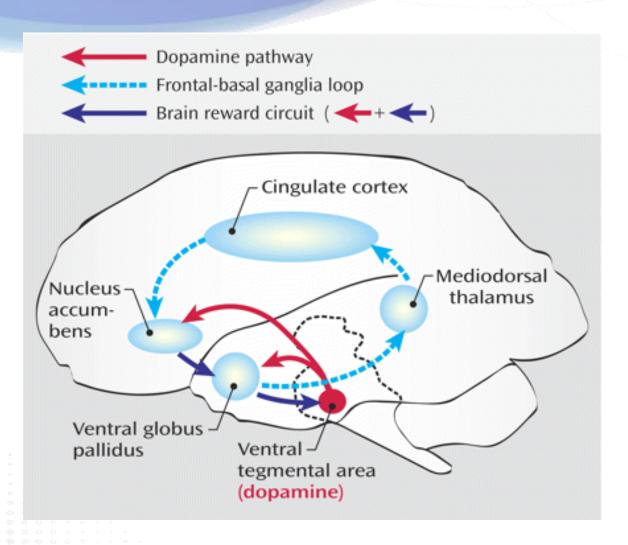


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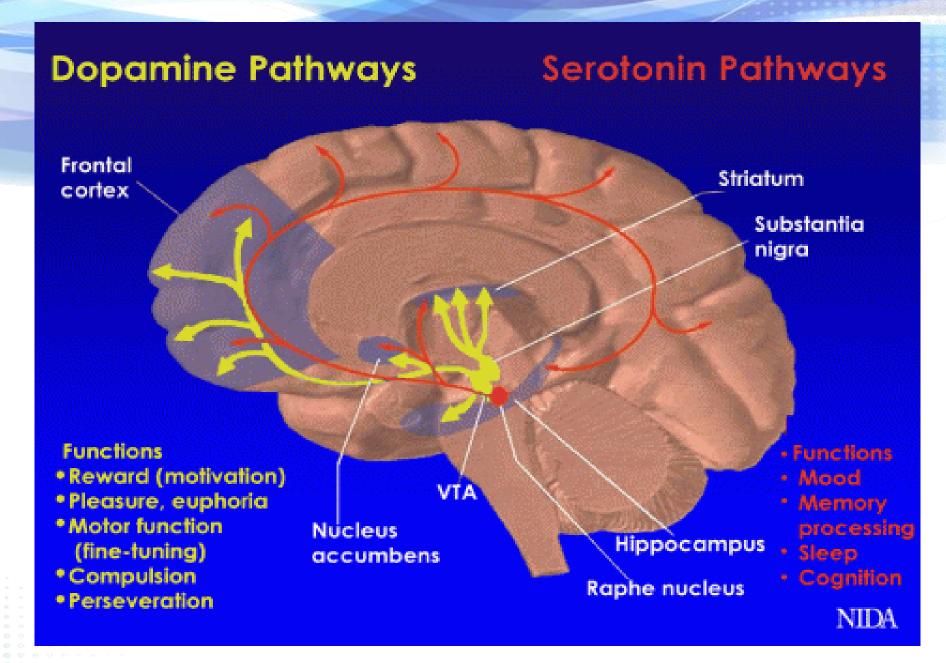
Plasticity: Hard Wired Addiction

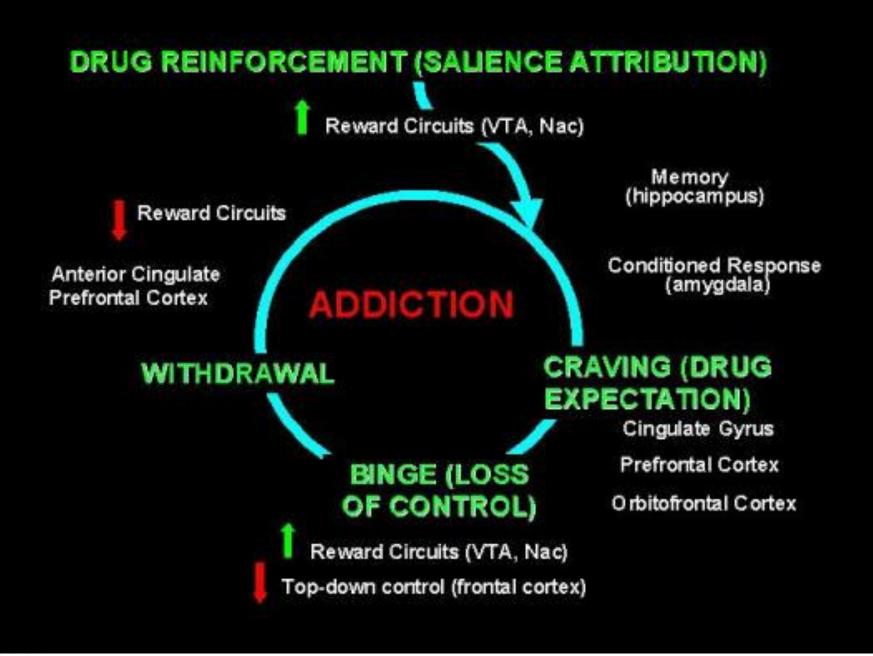
- Conditioning triggered by drug causes enhanced DA signaling when the addict experiences conditioned cues (seeking cues)
- This drives motivation to seek out and procure
- Activation of PFC and striatal regions
- Therefore, regional deficits induced by drug use link PFC/striatal to loss of control and compulsive drug intake when he/she is exposed to and or takes drug
- <u>Deficits reduce addicts' sensitivity to natural</u>
 <u>reinforcers</u> (harder to find pleasure/satisfaction)

Not a failure of morals or character



- Environment
- Genetic
- Mental illness
- Youth to 25
- > Neuroplastic
- > Chronic

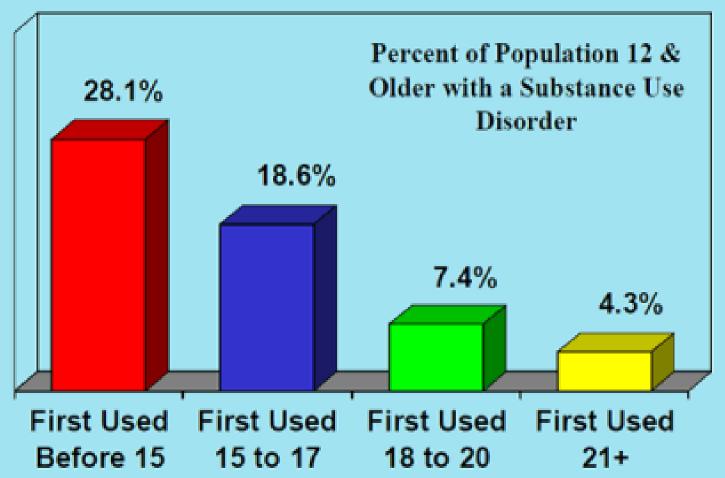




Risk Factors

SUD and Age

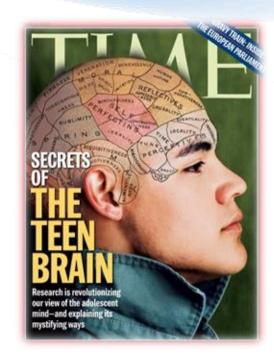
The Earlier Teens Use Any Substance, the Greater the Risk of Addiction



Source: CASA analysis of the National Household Survey on Drug Use and Health (NSDUH), 2009.

Adolescent Brain (<25 years old)

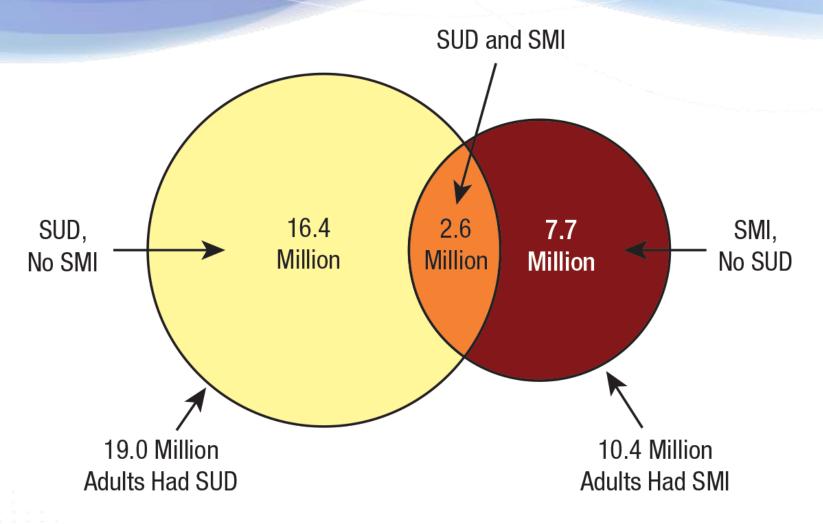
- 90% adults with substance abuse began smoking, drinking or using drugs < 18yo (tobacco, alcohol, and drugs)
 - Primed to take risks, immature decision making, judgment, impulse control
- Addictive substance use physically alter brain structure & function faster & more intensely than in adults
 - Interferes with brain development
 - Further impairing judgment
 - Significantly increase the risk of addiction



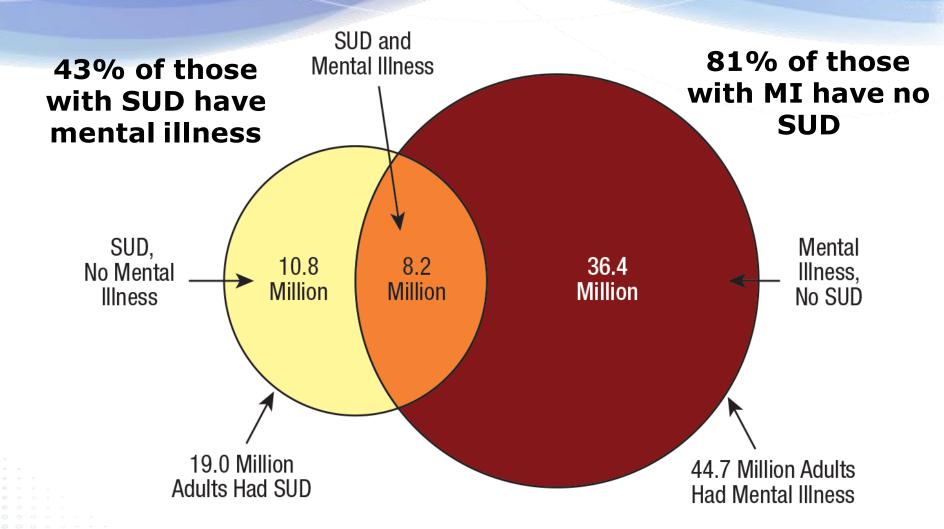
Risk Factors

SUD and Mental Illness

Overlap of SERIOUS Mental Illness (SMI) and SUD



Overlap of Mental Illness and SUD



2016 NSDUH

TABLE 2. Estimated Prevalence of Depression, Anxiety, and Substance Use Disorders in Commonly Occurring Chronic Pain Conditions

Variable	Prevalence (%)			
Depression				
Spinal pain (lumbar, thoracic, or neck) ²⁶⁻²⁹	2-56			
Neuropathic pain ³³⁻³⁶	4-12			
Fibromyalgia ¹⁷⁻²³	21-83			
Migraine headache ³⁷⁻⁴¹	17-28			
Temporomandibular joint disorder ^{24,25}	16-65			
Pelvic pain 42-46	19-22			
Abdominal pain ^{30 32}	9-54			
Arthritis ^{23,37,38,47-49}	3-39			
Anxiety				
Spinal pain (lumbar, thoracic, or neck) ^{26-29,38}	1-26			
Neuropathic pain ³⁴⁻³⁶	5-27			
Fibromyalgia 18-21,23	18-60			
Migraine headache ^{38,39,41}	2-45			
Temporomandibular joint disorder ⁵⁰⁻⁵²	15-65			
Pelvic pain 42,53	12-41			
Abdominal pain ^{30,32}	21-51			
Arthritis 23,37,38,48,49	I-35			
Substance use disorder				
Spinal pain (lumbar, thoracic, or neck) ²⁶⁻²⁹	4-14			
Neuropathic pain ⁵⁴⁻⁵⁶	1-9			
Fibromyalgia 19,20,23	1-25			
Migraine headache ⁴⁰	1-6			
Arthritis ^{23,49}	1-12			
Current and 12-mo prevalence rates grouped together.				

Risk Factors

- > Chronic Pain
- > Mental Illness
- > Substance Use Disorders (SUD)

COMPLICATED ASSOCIATIONS Cause and Effect ??



Simplistic, Failed and not Science Based

Responses by

- Health Care Providers
- Communities

Responses by

Health Care Providers

Difficult Starting Point

- Education Deficiency
- HCAHPS/Satisfaction Surveys
- Pain as 5th Vital Sign
- Predatory Sales and unscrupulous Pharma
- EBM (eminence based medicine)
 - Reflexive and Automated Opioidism
- Expectation-Reality Disequilibrium
- Majority people with SUDs do not feel a need to obtain treatment for the SUD.

Low Hanging Fruit?

 Prevalence of opioid abuse in chronic pain patients ranges between 20-24% across health-care settings.

Pain 2010, 150(2):332-339

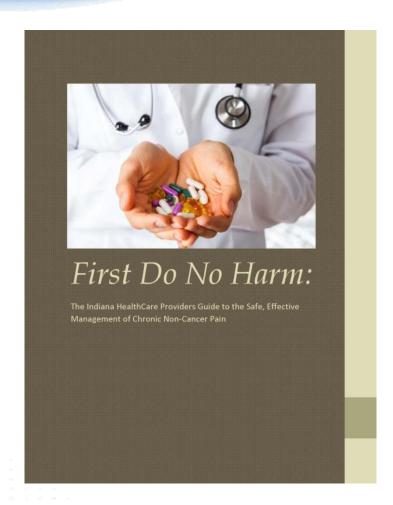
 Lifetime prevalence of DSM-V OUD those on chronic opioids: 9.7 % moderate & 3.5 % severe OUD

Substance Abuse and Rehabilitation 2015:683-91

P. MacKie's opinion for prevalence of OUD among patients on scheduled opioids for chronic pain: 8% - 18%

Healthcare Provider Toolbox:

www.bitterpill.in.gov

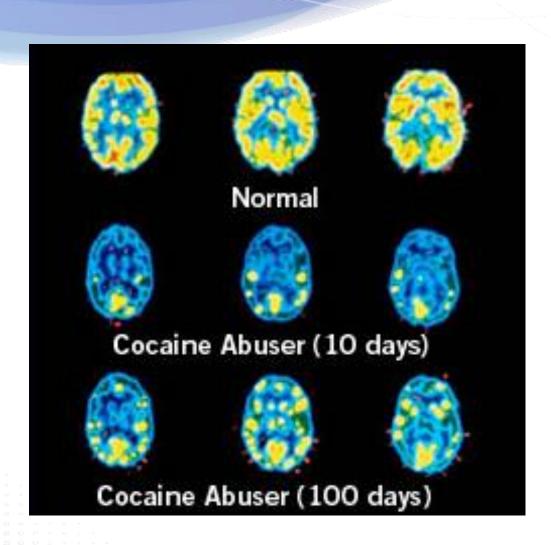


A comprehensive "Clinical Resource" to assist you in managing your patients with chronic pain

Integrative Addiction Care and Methadone

- 2005 Study with full complement of behavioral, psychological, medical and social support systems
- \$ 8-12 benefit for each \$1.0 spent on programs
 - 1. Less healthcare utilization
 - 2. Reduced spread of infectious illnesses
 - 3. Fewer overdoses
 - 4. Better employment
 - 5. Reduction in crime

Medicalize SUD



Chronic Brain Disease

Opioid Addiction Treatment Options

- Detoxification:
 - Medication-assisted
 - Abstinence-based
- Medication Assisted Treatment (MAT):
 - Methadone
 - Buprenorphine-w/o naloxone
 - Naltrexone
- Abstinence-based therapy:
 - Long-term residential
 - Intensive outpatient
 - Behavioral therapies , (NA)

Medically Assisted Therapy (MAT)

Naltrexone (Vivitrol)

- Antagonist blocks all effects of opioids
- Oral and injectable forms (long-lived)
- Must be totally detoxed prior to use
- Effective for opioid and alcohol addiction treatment
- Can "override" blockade with high doses of opioids
- Risk of overdose, hepatotoxicity, injection reactions
- Works best in highly motivated individuals parole, probation, early release

MAT (cont.)

Buprenorphine (Subutex/Suboxone)

- Partial agonist
- Suboxone has antagonist,
 - * naloxone
- Decreased risk of overdose/abuse
- Office-based treatment
- Sublingual dosing
- Physicians DEA training/certification
- Limitations on number of people an individual physician can treat
- Covered by Medicaid

Characteristics of Medications for Opioid-Addiction Treatment.			
Characteristic	Methadone	Buprenorphine	Naltrexone
Brand names	Dolophine, Methadose	Subutex, Suboxone, Zubsolv	Depade, ReVia, Vivitrol
Class	Agonist (fully activates opioid receptors)	Partial agonist (activates opioid recep- tors but produces a diminished re- sponse even with full occupancy)	Antagonist (blocks the opioid receptors and interferes with the rewarding and analgesic effects of opioids)
Use and effects	Taken once per day orally to reduce opioid cravings and withdrawal symptoms	Taken orally or sublingually (usually once a day) to relieve opioid cravings and withdrawal symptoms	Taken orally or by injection to diminish the reinforcing effects of opioids (potentially extinguishing the asso- ciation between conditioned stimuli and opioid use)
Advantages	High strength and efficacy as long as oral dosing (which slows brain uptake and reduces euphoria) is adhered to; excellent option for patients who have no response to other medications	Eligible to be prescribed by certified physicians, which eliminates the need to visit specialized treatment clinics and thus widens availability	Not addictive or sedating and does not result in physical dependence; a re- cently approved depot injection for- mulation, Vivitrol, eliminates need for daily dosing
Disadvantages	Mostly available through approved outpatient treatment programs, which patients must visit daily	Subutex has measurable abuse liability; Suboxone diminishes this risk by in- cluding naloxone, an antagonist that induces withdrawal if the drug is injected	Poor patient compliance (but Vivitrol should improve compliance); initi- ation requires attaining prolonged (e.g., 7-day) abstinence, during which withdrawal, relapse, and early dropout may occur

Access to MATs Saves Lives

A study of heroin-overdose deaths in Baltimore between 1995 and 2009 found an association between the increasing availability of methadone and buprenorphine and reduction in mortality with a 50% decrease in fatal overdoses

Am J Public Health 2013; 103:917-22

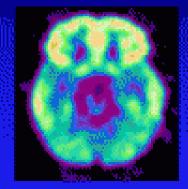
Outcomes far better with MAT

<u>Outcomes</u>	No MAT	Methadone
Retention	154/1000	684/1000
Morphine +urine	701/1000	463/1000
Criminal Activity	118/1000	46/1000
Mortality	17/1000	8/1000

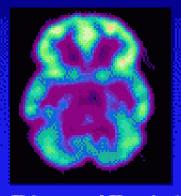
Addiction is Like Other Diseases...

- It is preventable
- It is treatable
- It changes biology
- If untreated, it can last a lifetime

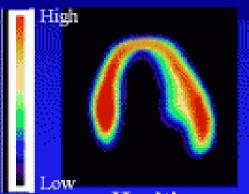
Decreased Brain Metabolism in Drug Abuser Decreased Heart Metabolism in Heart Disease Patient



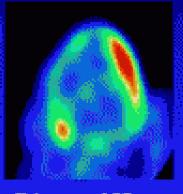
Healthy Brain



Diseased Brain/ Cocaine Abuser



Healthy Heart



Diseased Heart

Research supported by NIDA addresses all of these components of addiction.

NIDA

Summary

- OUD and SUD are common
- Risk Factors include-Genetics, chaotic environment, exposure, youth and mental illness
- Providers can be judicious with opioids and still provide adequate analgesia
- OUD is present in 5-22 % of those receiving opioids chronically for pain

Summary (cont.)

- Ask and or use survey tools to help identify those with OUD and use open non-judgmental language
- Knowing current or past OUD may help reduce risk of iatrogenic relapse
- MAT saves lives, MAT great investment

Responses by

Communities

- > Legislatures
- > Dental Boards
- > Organizations

eSB 226: 7 Day *Emergency* Rules

- July 1, 2017
- Exclusions For Emergency Rule
 - MAT, cancer, palliative/hospice
- Adult 1st time Rx by the prescriber
- All persons < 18 yrs.
- Professional judgement out
- Partial Refill Request

eSB 226: 7 Day Emergency Rules

- 1) If the prescription is for an adult who is being prescribed an opioid for the first time by the prescriber, the initial prescription may not exceed a seven (7) day supply.
- 2) If the prescription is for a child who is less than eighteen (18) years of age, the prescription may not exceed a seven (7) day supply
- Partial Refill Request
- Professional judgement out & document

eSB 226: 7 Day *Emergency* Rules

- Partial Refill Request
 - Guardian/legal representative of or the Patient
 - 30 days and then forfeit remainder
 - E.g. may elect to fill 12 of 24 tablet Rx and determine if more is required before 30 days
- Professional judgement out & <u>document</u>
 - If > 7 days of opioids are to be given, there must be language in the medical record justifying the professional judgement of longer duration Rx

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Medical Licensing Board Rules Pain's 10 Commandments

- Thou shall diagnosis with appropriate care, get old records
- Thou shall do psychological assessment
- Risk Stratification Tool
- Thou shall provide informed consent and prognosis with Treatment Agreement and <u>functional</u> goals
 - Exit strategy/protocol, ETOH and NAS

Medical Licensing Board Rules Pain's 10 Commandments (cont.)

- Thou may use <u>trial</u> of opioid therapy and modalities
 - safe storage of medication
- Thou shall use a Pain Assessment Tool
- Thou shall see the patient at 4 months or sooner
- Thou must employ drug monitoring & PDMP(pill counts)
- Thou may not have paucity of documentation
- When > 60 MED- formal re-evaluation and education

Exemptions

Patients that are <u>exempt</u> from monitoring under these rules include those who are:

- Terminally ill
- Involved with a palliative care service
- Managed in a hospice program
- Residents of a registered nursing home

Late to the Dance

- Eskenazi Health 2011
- American Academy of Neurology 2014
- National Safety Council 2014
- Most Legislatures by 2015
- Centers for Disease Control Guidelines 2016
- IU's Grand Challenge 2017 and \$50,000,000
- American Dental Association 2018
 - Supports Mandates on Opioid Prescribing and Continuing Education

ADA Policy States:

- The ADA supports mandatory continuing education in prescribing opioids & other controlled substances
- The ADA supports statutory limits on opioid dosage and duration of no more than seven days for the treatment of acute pain, consistent with the CDC evidence-based guidelines
- The ADA supports dentists registering with & utilizing prescription drug monitoring programs to promote the appropriate use of opioids and deter misuse and abuse

Considerations when Managing Pain

- Alternative interventions
- Risk stratification
- > Assess for SUD/OUD

Before and during treatment

- Assessment of mental status
- > Informed consent
- Periodic visits
- > 7-day rule
- > Aaron's rule availability of Naloxone

Never start that which you will not stop Exit Strategy at Onset



"It sort of makes you stop and think, doesn't it"

Alternative Interventions



"It sort of makes you stop and think, doesn't it"

Non-Pharmacologic Interventions

- Education
- Ice/Heat
- Exercise
 - Aerobic, ROM
 - strength
- Yoga, Tai Chi
- PT/OT
- Nutrition
- Manual
 - Massage
 - Chiropractic

- Acupuncture
- CBT, mindfulness, hypnosis
- Relaxation Response
- Tobacco cessation, weight loss
- Counseling
- Interventional pain modalities
- Education

Non-Opioid Medications

MSK/Inflammatory pain

- Acetaminophen
- NSAIDS
- Topical anesthetics (lidocaine)
- Anti-inflammatory cream
- Steroid injections
- Muscle relaxants
- Whole food plant-based nutrition

Restore Sleep

- Melatonin
- TCA's
- Trazadone
- Doxepin
- Aroma therapy

Neuropathic pain

- TCA's (SOR-A)
- Topical anesthetics
- Linoleic acid
- Neuropathic creams
- SNRI's (SOR-A)
- Anticonvulsants

Visceral pain

- NSAIDS/acetaminophen
- Antispasmodics

Table 1. Efficacy data from high-quality studies for analgesic agents available in the United States in order of effectiveness (most to least) according to NNTB*. 22,24

DRUG OR DRUG COMBINATION, DOSE	NNTB	95% CONFIDENCE INTERVAL	AT LEAST 50% MAXIMUM PAIN RELIEF OVER 4-6 HOURS, %		XIMUM PAIN TIME TO REMEDICATION	
			Active	Placebo	Active	Placebo
Ibuprofen Plus Acetaminophen, 400 Milligrams/1,000 mg	1.5	1.4 to 1.7	72	6	8.3	1.7
Ibuprofen Plus Acetaminophen, 200 mg/500 mg	1.6	1.5 to 1.8	69	6	7.6	1.7
Acetaminophen Plus Oxycodone, 1,000 mg/10 mg	1.8	1.6 to 2.2	68	13	9.8	1.5
Diclofenac (Potassium), 100 mg	1.9	1.7 to 2.3	65	13	6.3	2.0
Ketoprofen, 25 mg	2.0	1.8 to 2.3	62	12	46 [†]	79 [†]
Diclofenac (Potassium), 50 mg	2.1	1.9 to 2.5	64	17	4.5	1.7
Diflunisal, 1,000 mg	2.1	1.8 to 2.6	62	15	10.9	3.2
Ibuprofen (Fast-Acting), 200 mg	2.1	1.9 to 2.4	57	10	43 [†]	78 [†]
Ibuprofen (Fast-Acting), 400 mg	2.1	1.9 to 2.3	65	18	32 [†]	82 [†]
Ibuprofen Plus Caffeine, 100 mg/200 mg	2.1	1.9 to 3.1	59	10	26 [‡]	60 [‡]
Ketoprofen, 100 mg	2.1	1.7 to 2.6	66	18	43 [†]	85 [†]

2.2

Acetaminophen Plus Codeine. 800-1.000 mg/60 mg

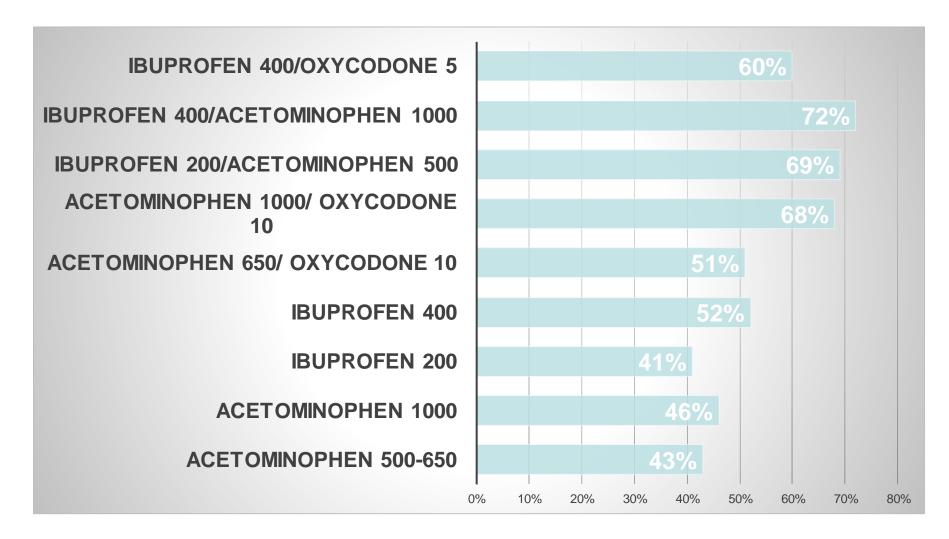
1.8 to 2.9

53

5.0

2.3

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



Oral Analgesics for Postoperative Pain

Analgesic(s)	Dose (mg)	NNT vs Placebo ≥ 50% maximum pain relief over 4-6 hours
SINGLE AGENTS:		
Ibuprofen	600	2.7
Naproxen	500	2.7
Celecoxib	400	2.6
Acetaminophen (APAP)	1000	3.6
Oxycodone	15	4.6
Codeine	60	12.0
Gabapentin	250	11.0
COMBINATIONS:		
Ibuprofen + APAP	400+1000	1.5
Ibuprofen + oxycodone	400+5	2.3
APAP + oxycodone	325+5	5.4
APAP + codeine	300+30	6.9

~50,000 participants

~460 high-quality studies (mostly dental extractions)

Perform your own evaluation

- Take a thorough history
- Perform a targeted physical exam
- Establish a working diagnosis
- Do appropriate tests
- Obtain & review records of past care

FORM 3.2 Brief Pain Invento	ory		What tre			mec	licati	ons a	re you	ı rece	iving
Date//	Time:		for your	pain	£.	90000					
Name:	First Middle Initial										_
Throughout our lives, most of from time to time (such as n sprains, and toothaches). Hat other than these everyday kit 1. Yes 2. No	ninor headaches, ve you had pain		In the Pa treatmenthe one releif you 10 20	nts or perce ou hav	med ntage	that	ns pr most	rovide t shov	ed? P vs hov so 9	lease	circle ch 0%
2) On the diagram shade in the	areas where you feel	relie	ef								elief
pain. Put an X on the area to		1/6	Circle the the past A. Gene	24 h	ours,	pain					
			1 2	3	4	5	6	7	8	9	30000
ight \ \ \ \ \ Left	fi Right		es not rfere							interf	
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you can imagine

Risk Stratification More Than Classic Aberrancy

- Physical
- Family history
- Social/Domestic
- Mental Health
- PDMP
- Rx Combinations
- Stable housing?
- Toxicology data
- Releases from Providers
 - "fired"

- Age <45, esp. < 25
- Tobacco use
- Chaos/ Life Trauma Hx
- Legal history
 - Web inquiries EZ
 - DOC-site
- Abuse (sexual) history
 - Esp. when young
- Repeated traumas
 - Non-sports related

Especially Important

- Assess Risk for substance abuse/harm
- Assess Mental health status

Assessment for OUD

Screenings for prior or current opioid use <u>before treatment</u>

Substance Abuse Assessment – Survey Tools

Ask patients about any past or current history of **substance abuse** (alcohol, Rx meds, or illicits) prior to initiating treatment for chronic pain with opioids

- ORT Opioid Risk Tool
- SOAPP Screener/Opioid Assessment for Patients in Pain (starting opioids)
- COMM Common Opioid Misuse Measure (pts already using opioids)



These survey tools will be available at: www.bitterpill.in.gov

Any truth is better than indefinite doubt



Prescription Drug Monitoring Check INSPECT It's the Law

Assessment of mental health status

Screenings for mental illness before treatment

Table 3. Factors Associated with the Risk of Opioid Overdose or Addiction.						
Factor						
Medication-related						
Daily dose >100 MME*	Overdose,8 addiction8					
Long-acting or extended-release formulation (e.g., methadone, fentanyl patch)	Overdose ^{14,41}					
Combination of opioids with benzodiazepines	Overdose ⁴²					
Long-term opioid use (>3 mo)†	Overdose,43 addiction44					
Period shortly after initiation of long-acting or extended-release formulation (<2 wk)	Overdose ⁴⁵					
Patient-related						
Age >65 yr	Overdose ⁴⁶					
Sleep-disordered breathing:	Overdose ⁴⁷					
Renal or hepatic impairment∫	Overdose ⁴⁸					
Depression	Overdose, addiction ⁴⁹					
Substance-use disorder (including alcohol)	Overdose,50 addiction49					
History of overdose	Overdose ⁵¹					
Adolescence	Addiction ⁵²					

Pain and Mental Illness

41 million with mental illness, (2011, National Survey)

- 1. Magnifies medical/somatic symptoms
- 2. Elevation of Cost
- 3. Diminishes treatment success
- 4. Treat it yesterday and augment if needed.

Depression can interfere with the management of pain and requires treatment for adequate pain outcomes

Condition	Prevalence Chronic Pain Patients
Depression	33% - 54% ^{22,23}
Anxiety Disorders	16.5% - 50% 22,24
Personality Disorders	31% - 81% 25,26
PTSD	49% veterans ²⁷ ; 2% civilians ²⁴
Substance Use Disorders	15% - 28% ^{22,25}
PTSD, posttraumatic stress disorder.	

Gen Hosp Psychiatry. 2012;34(1):46-52

Curr Psychiatry Rep. 2006;8(5):371-376

J Clin Psychol Med Settings. 2011;18:145-154f
SCOPE of Pain Boston University

16% with mental illness get 51% of opioid

J Am Board Fam Med 2017; 30:407-417

Mental Health Assessment – Survey Tools

Chronic pain may be caused, influenced or modulated by ...

- Depression (PHQ-2, PHQ-9)
- Post Traumatic Stress Disorder
- Anxiety/Panic Disorder (GAD-7)



Note: Treat any underlying psychiatric diagnosis first or, at least, concurrently

Informed Consent when prescribing opioid medications



- Discuss the risks and benefits of opioid treatment
- Provide clear explanation to help patients understand key elements of treatment plan
- Counsel women of childbearing age about the potential for fetal opioid dependence and neonatal abstinence syndrome (NAS)

Informed Decision

Possible Benefits

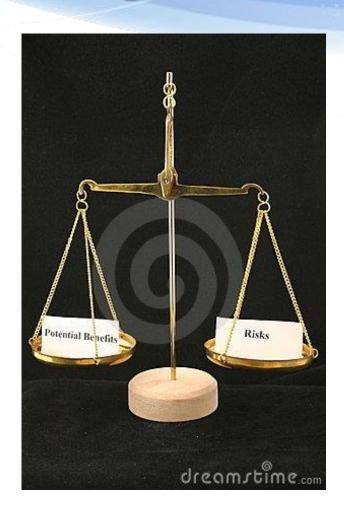
- Less pain
 - Rarely > 30-50%
 - Chronic pain
 - Only 4 mo.
- Function/QOL
- Getting on Disability

Possible Adverse Rxns

- Disordered sleep
- Gastroparesis
- Hypogonadism
- Osteoporosis/fractures
- Myocardial infarction
- Neonatal Abstinence Syndrome
- OD and death
- Opioid Induced hyperalgesia
- Opioid use Disorder

Review and Sign a Treatment Agreement

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



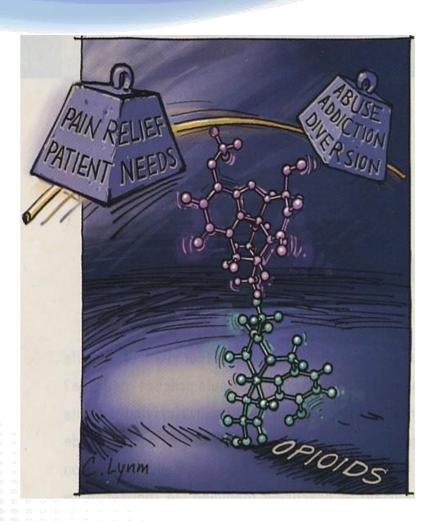
Periodic Scheduled Visits

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



AFFECT • ACTIVITIES (FUNCTION) • ANALGESIA • ADVERSE EFFECTS • ABERRANT

Reassessment is required when MME ≥ 60



- 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

Opioid Use Disorder and the 7 day Rule

Limits on prescribing opioid medications

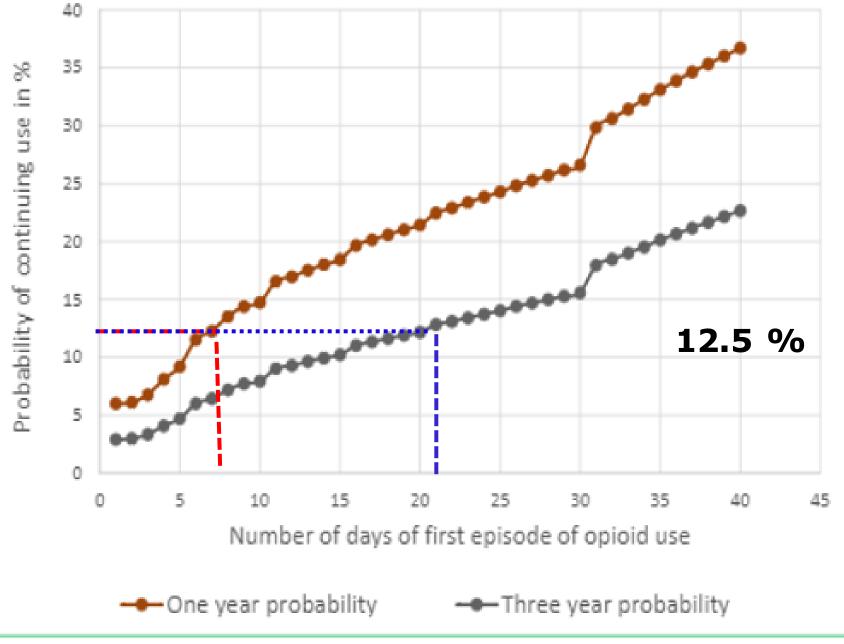
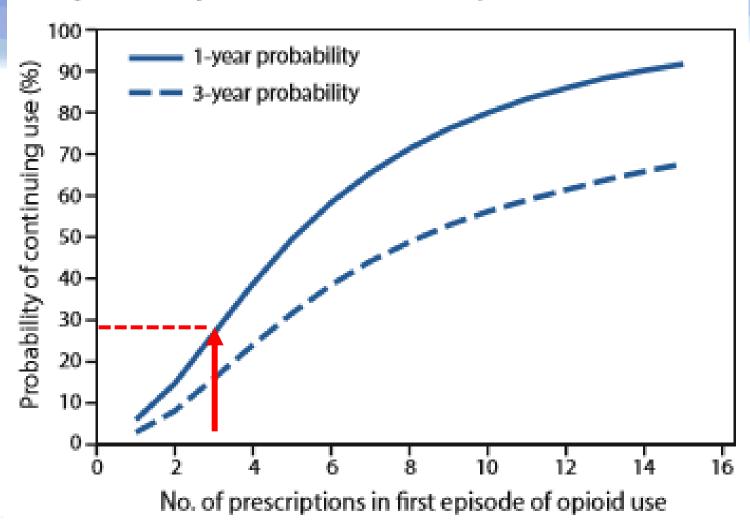


FIGURE 2. One- and 3-year probabilities of continued opioid use among opioid-naïve patients, by number of prescriptions* in the first episode of opioid use — United States, 2006–2015



Indiana Laws

- 2014 Chronic Opioid Prescribing LawSim
- 2017 7 Day Prescribing Law
- 2018 CME requirement- 2 hrs each 2 years

CME must address opioid prescribing

and opioid abuse

2018 - INSPECT requirement

2021 – E-Scribe

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

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

Electronic CS Perscriptions

- January 1, 2021, all Indiana prescriptions for controlled substances must be transmitted electronically to the pharmacy. Paper prescriptions for controlled substances will no longer be allowed. In response to this new state regulation, IDA's IDEA Board vetted two companies that provide this service. IDEA is pleased to announce that <u>DrFirst</u> has been selected as the IDA preferred vendor for electronic prescriptions.
- Temporary Waiver from E-Prescribing
 Requirement can be obtained

Points to Note

- If an opioid naïve person is given a 7 day Rx for opioids there is a 12.5 % chance of this person being on opioids @12 months
- A 21 day Rx is associated with 12.5 % risk of being on opioids at 3 years
- Similarly, the more Rxs one receives, the more likely opioid use will continue to 12 months or even 36 months

General Surgery in Vermont – Opioid Pills

- N 127 of 330 total patients
- Pill = 5 mg oxycodone
- Phone survey
- Based on patient recall

TABLE 2. Opioid Pills Taken

Operation	Partial Mastectomy	Partial Mastectomy With Sentinel Node Biopsy	Laparoscopic Cholecystectomy	Laparoscopic Inguinal Hernia Repair	Open Inguinal Hernia Repair
Surveys completed	20	21	48	20	18
Pills prescribed	415	490	1450	650	540
Pills taken	61 (14.7%)	126 (25.7%)	474 (32.7%)	189 (14.7%)	168 (31.1%)
Pills remaining	354 (85.3%)	364 (74.3%)	976 (67.3%)	461 (85.3%)	372 (69.9%)

1.9% obtained a refill

General Surgery in Vermont – Opioid Pills

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	3	6	10	9	9.3
		Average num	ber of pil	ls used	

Defining Optimal Length of Opioid Pain Medication – Prescription After Common Surgical Procedures

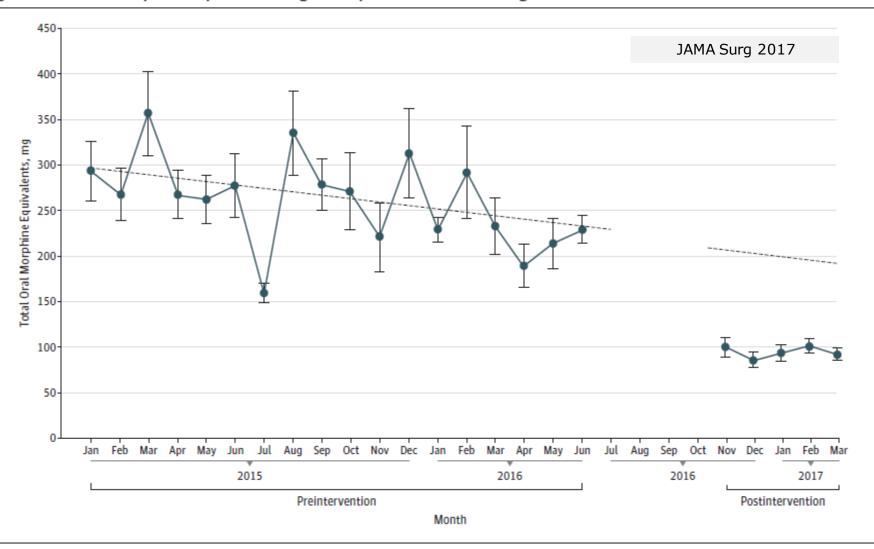
- Cohort study of 215,140
- Median observed prescription lengths were
 - 4 days for general surgery procedures
 - 4 days for women's health procedures
 - 6 days for musculoskeletal procedures.
- Rx lengths associated with lowest refill rates
 - 9 days for general surgery
 - 13 days for women's health,
 - 15 days for musculoskeletal procedures.

Post-op Prescription Guidelines – Elective Laparoscopic Cholecysectomy

- University of Michigan
- November 2016 to March 2017
- Median opioid <u>prescribed</u> 250 to 75 mg
- Median opioid <u>used</u> from 30 to 20 mg (P = .04), with no change in Pain Score
- 2.5% Pts requested refills vs. 4.1% in the preguideline
- APAP/NSAID use from 21 to 49 % (little home change)

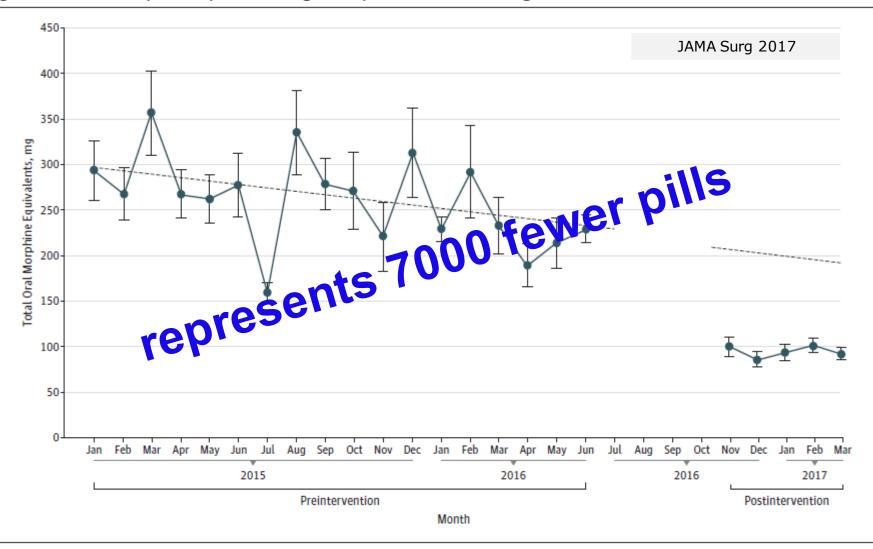
Reduction in opioid prescribing through evidence-based prescribing guidelines

Figure. Reduction in Postoperative Opioid Prescribing After Implementation of Prescribing 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.

Figure. Reduction in Postoperative Opioid Prescribing After Implementation of Prescribing 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.

Post-Operative Opioid Prescribing Recommendations UPDATED 2019

Procedure	Oxycodone* 5mg tablets
Laparoscopic Cholecystectomy	10
Open Cholecystectomy	15
Appendectomy – Lap or Open	10
Hernia Repair – Major or Minor	10
Colectomy – Lap or Open	15
lleostomy/Colostomy Creation, Re-siting, or Closure	15
Open Small Bowel Resection or Enterolysis	20
Thyroidectomy	5
Sleeve Gastrectomy	10
Prostatectomy	10
Laparoscopic Anti-reflux (Nissen)	10
Laparoscopic Donor Nephrectomy	10
Cardiac Surgery via Median Sternotomy	15

Procedure	Oxycodone* 5mg tablets
Hysterectomy – Vaginal, Lap/Robotic, or Abdominal	15
Cesarean Section	15
Breast Biopsy or Lumpectomy	5
Lumpectomy + Sentinel Lymph Node Biopsy	5
Sentinel Lymph Node Biopsy Only	5
Wide Local Excision ± Sentinel Lymph Node Biopsy	20
Simple Mastectomy ± Sentinel Lymph Node Biopsy	20
Modified Radical Mastectomy or Axillary Lymph Node Dissection	30
Carotid Endarterectomy	10
Total Hip Arthroplasty	30
Total Knee Arthroplasty	50
Dental	0



^{*}The recommendations remain the same if prescribing hydrocodone 5mg

Points to Note

- Post-op pain can be managed with much less opioids than used in the past
- Gynecologic, General and Orthopedic post-op care can all use less opioids
- Patients/guardians can request partial fills on Rxs and obtain the balance before 30 days
- Over 7 days of opioids for new patients and for those under 18 requires appropriate documentation in the medical record

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 SR and Benzo

- Greater pain, pain interference with life, and lower feelings of self-efficacy with respect to their pain
- Being prescribed "higher risk" (>200 MED)
- Antidepressant and/or antipsychotic medications
- Substance use (including more illicit and injection drug use, alcohol use disorder, and daily nicotine use)
- Greater mental health comorbidity and Health Costs

What about Methadone?

- A complex medication with a long half-life, highly variable pharmacologic properties and many drug-drug interactions
- It represented about3% of opioid prescribing
- It was responsible for about 30% of opioid-related deaths

Be very cautious when co=prescribing



Assessment for OUD

Screenings for opioid use during treatment

Three Objectives:

Any truth is better than indefinite doubt

Prescription Drug Monitoring
INSPECT

Drug Monitoring

Urine

Blood

Saliva

Pill Counting

Early and late

Providers hands-off



Prescription Drug Monitoring Program

- Use PDMP regularly for new and established patients to detect unsafe patterns of medication acquisition.
- PDMP is free and easy to use;
 www.in.gov/inspect
- PDMP query @ initiation
- Min. is 4 times per year for those with Patient-Provider Agreements



Thank you Pharmacists!

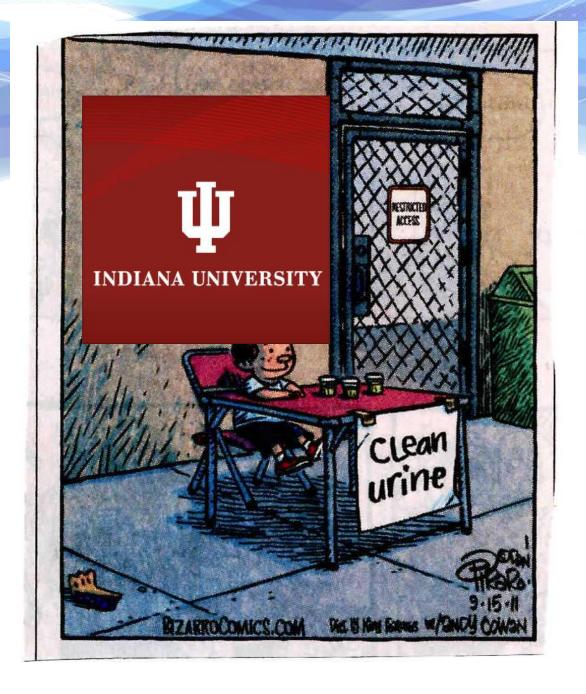
Urine Drug Monitoring

UDM has evolved to become a standard of care when prescribing opioids

- Detecting illicit substances
- Monitoring patient adherence to prescribed medications
- UDM at initiation of an opioid trial & at least annually (starting 12/2014)
- Interpretation is critical

"You're in trouble" or Urine Trouble





Aaron's Law

- Named after Aaron Sims, a young Hoosier who lost his battle with heroin addiction in 2013
- April 2015: Aaron's Law was signed by Indiana Governor Mike Pence
- Allows anyone to get naloxone and make it legal for anyone to administer the drug
- Allows a pharmacist to dispense naloxone to an individual <u>without a prescription</u>

Some Improvement

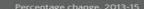
Recent changes in the approach to pain management and the reduction on reliance on opioid medications is having an effect

Indiana

Large drop in opioid prescriptions from 2013 to 2015

Opioid Painkiller Prescriptions

State initiatives and increased awareness of the opioid epidemic have spurred physicians to take a more cautious approach to prescribing opioid painkillers. The national rate of opioid prescribing dropped 10 percent between 2013 and 2015, falling in every state but South Dakota.





Some Improvement

However, still have many challenges, including ...

People with SUDs may not seek treatment

- Pain as 5th Vital Sign
- HCAHPS/Satisfaction Surveys



- Reflexive and Automated Opioidism
- Ignorance = Educational Opportunity
- The majority of people with SUDs do not feel a need to obtain treatment for the SUD and or can't easily access

Our prime purpose in this life is to help others. If you can't help them, at least don't hurt them. HHDL

- Opioids are helpful in short term
- Opioid use poses risks with acute or chronic use
- Safe and disciplined approach must be employed
- Rx opioid troubles are decreasing
- Polymodal approaches should be used
- Opioid Use Disorder needs to be understood and those with it compassionately and safely helped

Lessons Learned

- The U.S. and Indiana are in the midst of an <u>opioid epidemic</u>. A large and increasing portion of the population that are using opioids inappropriately and have an <u>opioid use disorder (OUD)</u>
- The <u>patients you treat</u> may be using opioids, either through prescriptions or illicitly
- You can check whether your patients have received prescription medications through pharmacies by using <u>INSPECT</u>
- It is important to obtain an accurate <u>history of medication and drug</u>
 <u>use</u> by you patients, as this may influence how you prescribe pain
 medications
- Patients with a <u>OUD complicate the legitimate management of</u> <u>orofacial pain</u> in these patients

Lessons Learned (cont.)

- Individuals who are misusing opioid medications may also have a
 <u>mental illness</u> that needs to be recognized and managed in order to
 appropriately and effectively manage their pain
- There are <u>guidelines</u> that have been published (online) by recognized authorities in opioid abuse and pain management that provide specific information about pain management for both <u>acute pain</u> and <u>chronic</u> <u>pain</u>
- Please refer to these guidelines for the latest information on pain management and the role of prescription medications, especially in context to the current opioid epidemic