

DISTRICT IV NABP ANNUAL MEETING

October 16-18, 2019

Embassy Suites by Hilton – Downtown Indianapolis, IN



MEDICATION ASSISTED THERAPY (MAT) FOR PHARMACISTS AND PHARMACY STUDENTS

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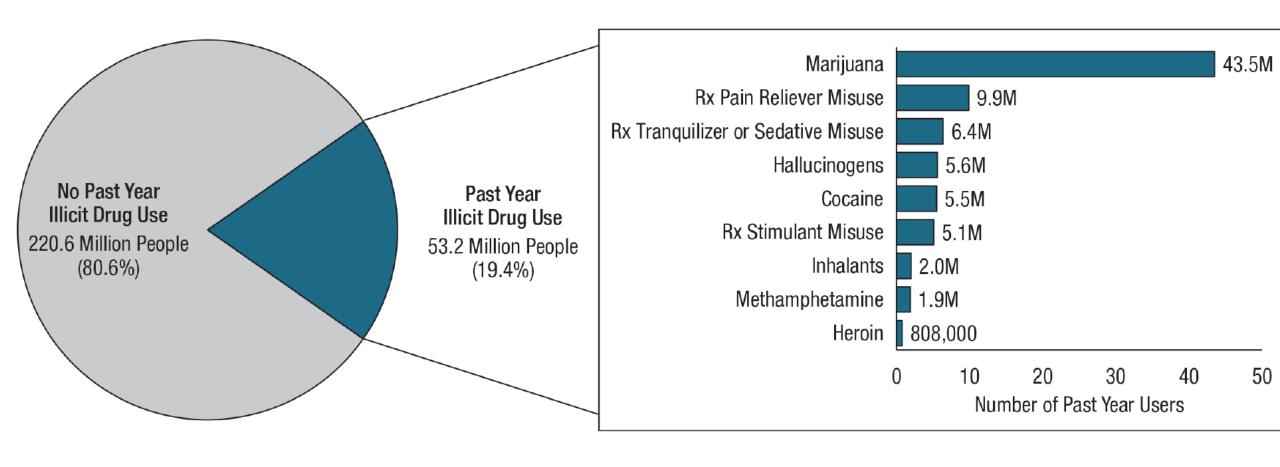


Learning Objectives

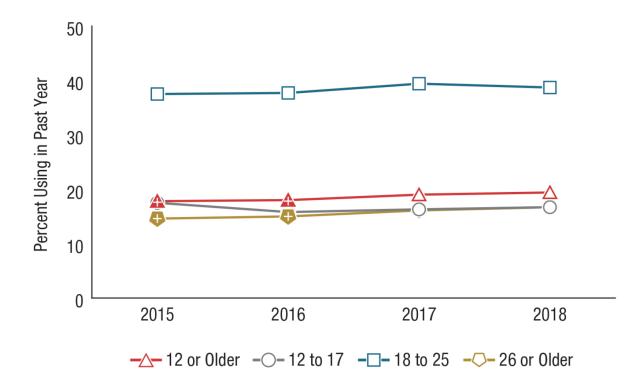
- Describe the current statistics and treatment needs for opioid use disorder
- Discuss the use of stigmatizing language and its impact on effective treatment
- Summarize MAT therapy for OUD and barriers to effective treatment





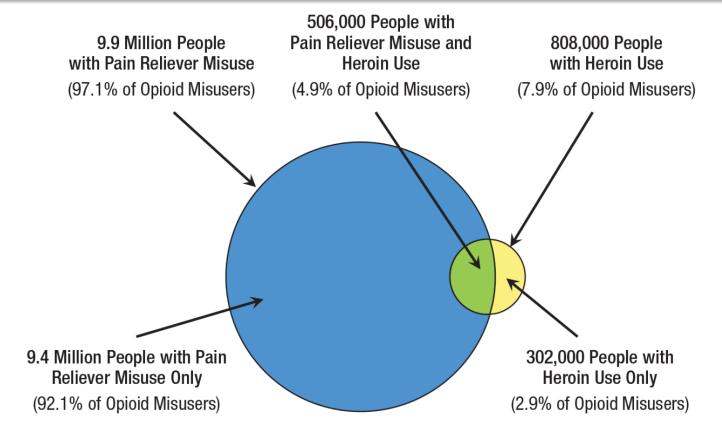


Past Year Illicit Drug Use Among People Aged 12 or Older: 2018



Age	2015	2016	2017	2018
12 or Older	17.8+	18.0+	19.0	19.4
12 to 17	17.5	15.8	16.3	16.7
18 to 25	37.5	37.7	39.4	38.7
26 or Older	14.6+	15.0+	16.1	16.7

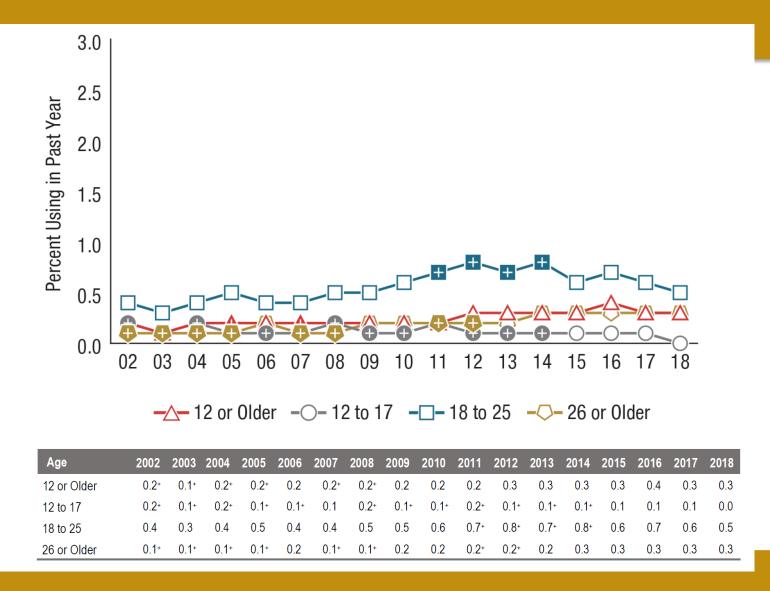
Past Year Illicit Drug Use Among People Aged 12 or Older: 2015 - 2018



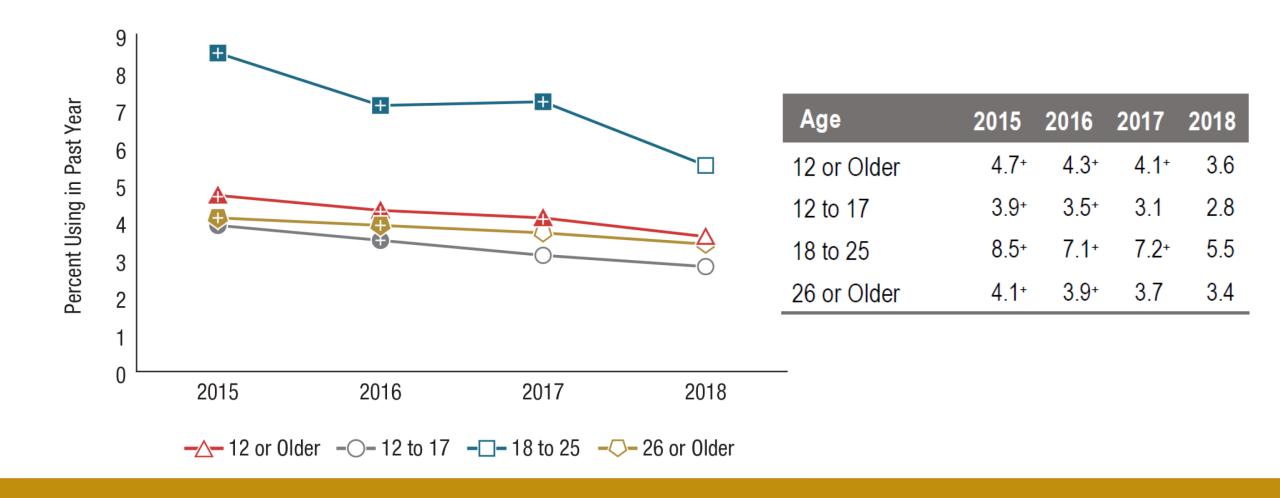
10.3 Million People Aged 12 or Older with Past Year Opioid Misuse

Past Year Opioid Misuse Among People Aged 12 or Older: 2018

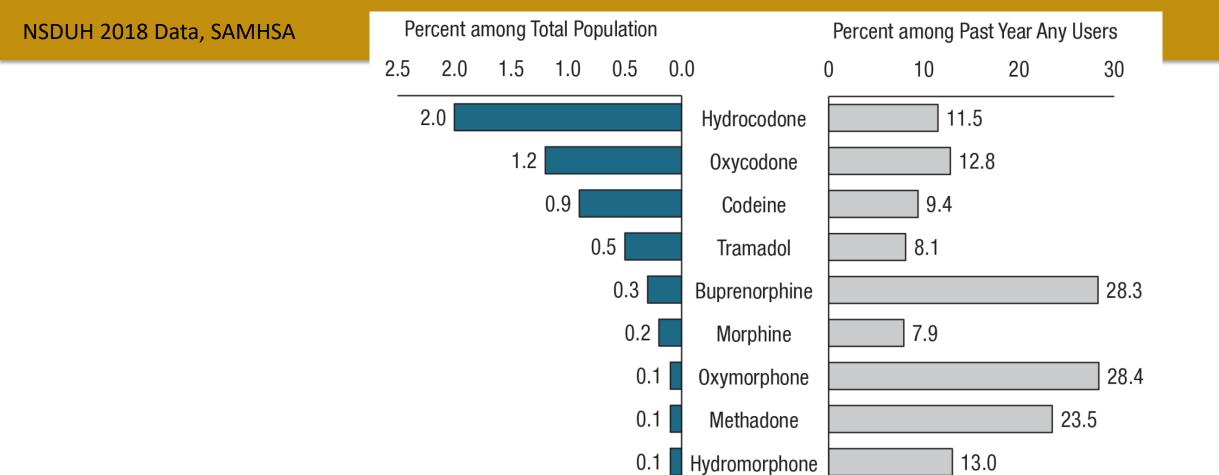
NSDUH 2018 Data, SAMHSA



Past Year Heroin Use Among People Ages 12 or Older: 2002 - 2018



Past Year Prescription Pain Reliever Misuse Among People Aged 12 or Older: 2015 - 2018



Past Year Prescription Pain Reliever Misuse Among People Aged 12 or Older by Selected Pain Reliever Subtype: 2018

0.1

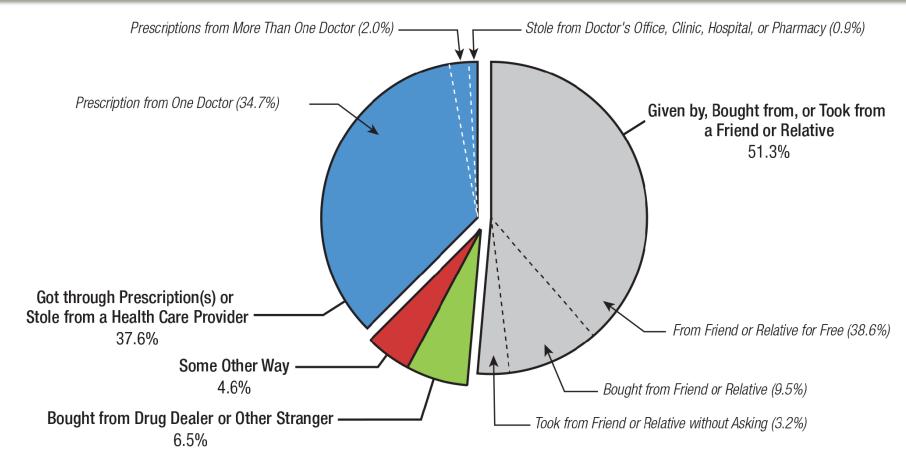
0.0

Fentanyl

Demerol

12.7

4.5



9.9 Million People Aged 12 or Older Who Misused Pain Relievers in the Past Year

Source Where Pain Relievers Were Obtained for Most Recent Misuse Among People Aged 12 or Older Who Misused Pain Relievers in the Past Year: 2018

Definition of Addiction - ASAM

"A primary, chronic disease of brain reward, motivation, memory, and related circuitry with a dysfunction in these circuits being reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors"





Overview of MAT Therapy

- Potential treatments for opioid use disorder (OUD) include withdrawal management in addition to psychosocial treatment OR psychosocial treatment combined with medication
- Withdrawal management alone can be a first step, but is not a primary treatment for OUD
- Withdrawal should only be considered as a part of a comprehensive and long-term plan that includes psychosocial treatment
- The choice of long-term treatment should be a decision made by both the clinician and the patient
- Is the patient open to medication treatment?
- What treatment setting does the patient prefer (inpatient vs outpatient, methadone clinic vs office-based)?
- Does the patient understand the role of medications in the treatment of opioid use disorder?
 - Maintenance treatment versus abstinence treatment
- What are the patient's past experiences with OUD treatment?





American Society of Addiction Medicine Treatment Guidelines



MAT – Place in Treatment/Evidence Base

- The use of medications combined with psychosocial treatment is superior to withdrawal management combined with psychosocial treatment, all medications are first-line treatment based upon patient need and circumstances
- Methadone maintenance is superior to withdrawal management alone, reduces opioid drug use, and lowers mortality
- Buprenorphine treatment is favored over no treatment decreases heroin use and improves treatment retention
- Naltrexone (oral and long-acting injection) is favored over placebo in the treatment of OUD





Treating Opioid Withdrawal

Symptoms of Opioid Withdrawal	Treatment of Individual Symptoms
Muscle Aches/Tension	Acetaminophen or non-steroidal inflammatory drug (ibuprofen/naproxen)
Agitation/Anxiety/Insomnia	Hydroxyzine/benzodiazepines
Abdominal Cramping/Nausea/Vomiting	Ondansetron
Diarrhea	Loperamide
Sweating/yawning/increased tearing/runny nose	Clonidine or Lofexidine

Short-term tapering doses of opioids or buprenorphine may be used in the withdrawal period. Buprenorphine should not be initiated until 12 - 18 hours after last use of a short-acting opioid (heroin or oxycodone) and 24 - 48 hours after last use of methadone

Lofexidine is FDA-approved for use in opioid withdrawal in the U.S.; clonidine is not FDA-approved, but has been used for several years as an off-label treatment





Methadone Overview

Methadone is a slow-acting opioid agonist that is superior to abstinence-based treatment

- Goals of methadone treatment include blocking the effects of other opioids, reducing craving, stopping or reducing the use of other opioids, promotion and facilitation of patient engagement in recovery
- Methadone for OUD is only available in certified opioid treatment programs; it may not be prescribed in an office-based setting for this use
- Methadone use may cause cardiac arrhythmias; prior to prescribing, evaluate patient history of structural heart disease, arrhythmia, or syncope and assess for other factors that could cause QTc prolongation (higher risk of arrhythmia)
- Methadone clinic treatment is covered by Indiana Medicaid





Federal Opioid Treatment Standards — Methadone Clinics

The Substance Abuse and Mental Health Services Administration (SAMHSA) is primarily responsible for certifying opioid treatment programs, including methadone clinics

- Person meets current criteria for an OUD with use for at least one year (time requirement waived for pregnant women), voluntarily choose treatment, sign informed consent
- Duration of retention in treatment is directly related to a successful outcome; no limits on duration of treatment or dosage level of medication.
- Medical and mental health, use of other substances, trauma should be evaluated.
- Counseling/psychotherapy is generally required.
- Testing for use of substances at least 8 random tests per year.
- Daily supervised dosing, "take-home" doses may be earned.





Buprenorphine Overview

Available in an office-based opioid treatment setting (OBOT)

- Goals of treatment are the same as for methadone
- Buprenorphine/naloxone is preferred for most patients; buprenorphine only is reserved for pregnant women
- Available in oral films and tablets; long-acting injection

- Drug Abuse Treatment Act (DATA) waiver is required to prescribe buprenorphine products
- May be given in an opioid treatment center where methadone is dosed; is available as office-based treatment





Requirements for Buprenorphine

Drug Abuse Treatment Act (DATA)

- Physicians can qualify for a waiver if they have addiction certification, boardcertification, OR complete 8 hours of training
- 30 patients in the 1st year, can apply to treat 100 patients for 1 year, then can increase to 275 patients
- Must be able to refer for counseling services
- Nurse practitioners and physician assistants can gain waiver after 24 hours of training and only up to 30 patients

Medicaid Prior Authorization

- Indiana Medicaid prefers the buprenorphine/ naloxone tablet formulation, can obtain the film under prior authorization
- Maximum dose = 24 mg daily without a prior authorization
- The Sublocade® long-acting subcutaneous injection is available after proving tolerability to oral buprenorphine/naloxone
- Indiana Medicaid prior authorizations suspended with audit of prescribers





Naltrexone Overview

Naltrexone is an opioid antagonist medication used to prevent relapse

- Will block the effects of all opioids, person should be detoxified from opioids and no longer physically dependent
- Naltrexone can precipitate severe withdrawal if the person is not appropriately detoxified or continues to have physical dependence
- Patients using naltrexone should carry a pocket or wallet card to let EMTs know in case of a need for pain management
- Persons receiving naltrexone who stop treatment and relapse are at an increased risk of overdose due to decreased tolerance
- Naltrexone is not required to be given in a specialized clinic (like methadone) and does not require a waiver to prescribe (like buprenorphine)





Comparison of Treatments — Individualized Patient Care

Patient factors are important in choosing MAT therapy

- Methadone clinics for daily dosing are often a long daily drive. Ensure the person has transportation and can make daily dosing without interfering with personal or work life
- Buprenorphine/naloxone requires a DATA 2000 waivered physician. There may not be enough physicians with a waiver in a community to support the need for treatment
- Naltrexone is an opioid antagonist. People have to be ready for this and not forced into this treatment; this leads to treatment failure and an increased risk of overdose
- Ensure awareness of patient insurance coverage Indiana Medicaid covers these medications, private insurance plans may have prior authorization processes; need to ensure continuity of care





Principles of Harm Reduction

"Users of Syringe Services Programs were 3x more likely to stop injecting drugs."

- Morbidity and Mortality Weekly Report **August 2nd, 2019**



What is Harm Reduction?

- Approach designed to reduce the harmful consequences associated with high risk activities.
- Do not try to "save" or "rescue".
- Support without judgement or assumption.
- Enables people to make informed choices.
- Encourages safer substance use.
- Participants return used needles to the program for safe disposal.
- Medical care is provided through wound care and access to immunizations.
- STD testing and treatment.





Stigma



People who struggle with opioid use disorder face a wide range of stigmas. A stigma is a mark of disgrace that sets a person or a group apart. When people are labeled primarily because of their opioid use disorder, they are being negatively stereotyped.

Language that includes biased and hurtful words can lead to discrimination and social exclusion. Stigma and discrimination are barriers to acknowledging the problem, seeking and accessing treatment and ultimately – to recovery.

Language is powerful – especially when talking about addictions.

Here are some examples of stigma reducing language that should be used.

Next Level Recovery: in.gov

Why does language matter?

Stigma remains the biggest barrier to addiction treatment faced by patients. The terminology used to describe addiction has contributed to the stigma. Many derogatory, stigmatizing terms were championed throughout the "War on Drugs" in an effort to dissuade people from misusing substances. Education took a backseat, mainly because little was known about the science of addiction. That has changed, and the language of addiction medicine should be changed to reflect today's greater understanding. By choosing language that is not stigmatizing, we can begin to dismantle the negative stereotype associated with addiction.

Next Level Recovery: in.gov

The National Alliance of Advocates for Buprenorphine Treatment

HELP REDUCE STIGMA

Language Matters

SAY THIS



NOT THIS

Person with opioid use disorder	Addict, user, druggie, junkie, abuser	
Disease	Drug habit	
Person living in recovery	Ex-addict	
Person arrested for a drug violation	Drug offender	
Substance dependent	Hooked	
Medication is a treatment tool	Medication is a crutch	
Had a setback	Relapsed	
Maintained recovery; substance-free	Stayed clean	
Negative drug screen	Clean	
Positive drug screen	Dirty drug screen	

Summary

- Past year illicit drug use has remained relatively stable.
- Past year opioid use for ages 18 25 has decreased.
- The source of misused opioids is most commonly a friend or relative.
- Use of opioid withdrawal treatment improves the chance of engagement in longer-term substance use disorder treatment.
- Methadone is only available as a maintenance treatment for OUD from a certified opioid treatment program.
- Buprenorphine is available as an office-based treatment, but can only be prescribed by a DATA-waivered provider.
- Discontinuation of naltrexone may carry a high risk of fatal overdose if the patient relapses due to a decrease in opioid tolerance.
- Stigma remains the biggest barrier to treatment words matter





THANKYOU



References

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THE OPIOID CRISIS:

FROM THE PAST TO AVOID REPEATING IT

JIM RYSER MA, LMHC, LCAC

DISCLOSURES

• Nothing to Disclose – except I had a true mullet at Farm Aid IV



OBJECTIVES

- Gain an understanding of the 12 steps as applied to Chronic Non Cancer Pain not just addiction
- Learn a "Focus on function" paradigm
- Help the patient be proactive and compliant in own care
- Promote Self Managed Care with accountability to others
- Learn how to avoid latrogenic Relapse
- Discuss MAT and use history to guide us

DISEASE - BEHAVIOR AND STIGMA

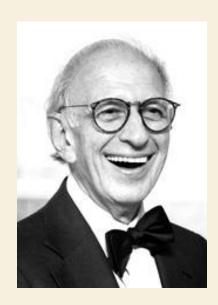
- STD's
- HIV
- Alcoholism treatment styles Antabuse was early "MAT" Cleveland VA study
- Opiate Addiction Naltrexone was hoped to be a cure in early '80's
- Heroin endocarditis and osteomyelitis issues denial of treatment?

PAIN OR SUFFERING?

 Nociception – associated with tissue damage

• Pain – unpleasant experience

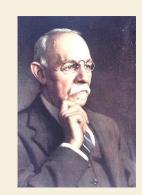
 Suffering – deterioration of the quality of life



LIFETIME PREVALENCE OF ADDICTION

• 12-15% of Americans





• 35% of people with chronic pain on opioids







SO, WHAT'S IT LIKE TO BE ADDICTED?

- Imagine your favorite food
 - Imagine someone telling you that you cannot have it ever again
 - Do you think that you would forget the taste, even after 50 years?
 - What would it be like the first time you have it again?

SIMILARITIES OF ILLNESS

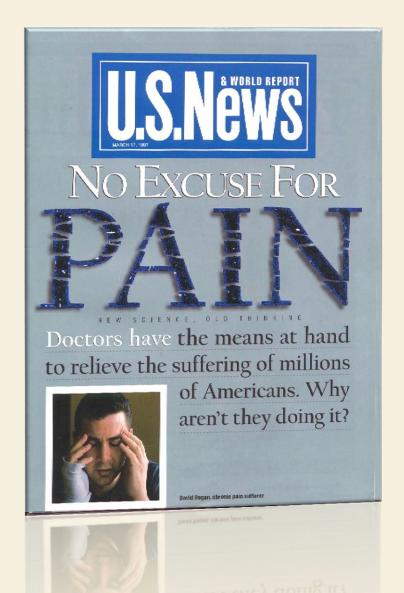
ADDICTION

- Continued use despite adverse or threatening consequences
- Isolation
- Loss of control
- Preoccupation with DOC
- Progression of disease process
- Tends to run in families

CHRONIC NON CANCER PAIN

- Continued behavior despite adverse or threatening consequences
- Isolation
- Loss of Control
- Preoccupation with pain
- Progression of disease process
- Also runs in families

SO - WHAT HAPPENED?



How we got here from pain treatment to the largest opiate addiction epidemic in the country...

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients¹ who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare inmedical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
Boston Collaborative Drug
Surveillance Program
Boston University Medical Center

1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D.

Waltham, MA 02154

5 sentence paragraph sent to **NEJM**

1980 letter to the editor

Cited as scientific evidence by over 600 scientific articles

N Engl J Med 2017; 376:2194-2195June 1, 2017DOI: 10.1056/NEJMc1700150

OPIOID RESEARCH VS USUAL PRACTICE

She blinded me with SCIENCE!



PHARMA AND OPIATES

- 24 BILLION dollars spent last year on marketing, that is more than was spent on RESEARCH!
- The opiate lobby is 8 times more manned than the NRA. This class of drugs includes suboxone and methadone.
- The chronic pain marketing template is repeating itself.

"SCIENCE" TODAY - TAKE IT WITH A GRAIN OF SALT...

- Medical journals have become big business
- Pharma is geared more toward making \$
- Data are often difficult to reproduce
- We don't see research that "fails"

Rigor Mortis – How Sloppy Science creates worthless cures, crushes hope, and wastes billions - 2017 by Richard Harris

RESEARCH

- Perfect patients
- ~ 6 months Rx
- Low-moderate doses
- No additional controlled substances
- Tightly controlled Rx by experts
- Same with MAT no rigorous studies on efficacy > six months

TYPICAL PRACTICE

- Perfect patients
- ~ 6 months Rx
- Low-moderate doses
- No additional controlled substances
- Tightly controlled Rx by experts
- Same with MAT no rigorous studies on efficacy > six months

CHRONIC OPIOID THERAPY

- Summary of existing data
 *At 18-24 months, 50% will have stopped opioids
- Loss of efficacy
- Adverse effects
 - *20% will have developed problems
 - *30% will have 30% pain reduction
 - *A few will have sustained, significant benefit but they typically can't be identified in advance

KNOWN ISSUES WITH LONG-TERM OPIOID USE

- Opiate induced hyperalgesia LT opioids CAUSE pain
- Contraindication with many drugs (benzos, soma)
- Tolerance
- Menstrual changes/Testosterone depletion
- Immunosuppression especially among HIV
- Sleep and respiration issues leading to polypharmacy

IN PRACTICE

- Patients at Highest Risk Receive the Most Drugs
 - 4,000,000 customers; Kaiser Permanente of Northern California & Group Health Cooperative of Seattle
- Substance use disorder pts
 - Higher dose regimens
 - More days supply
 - More likely to receive short- and long-acting Schedule II opioids
 - More likely to receive 180+ days of sedative-hypnotics
- Similar patterns were seen when comparing persons with an opioid use disorder to those without an opioid use disorder. (p<0.0001)

OXYCONTIN "SCIENTIFIC" MARKETING



MAT - MEDICATION ASSISTED THERAPY (OPIOIDS)

PAIN

- Thought to be safe
- No double blinded
 prospective studies on long term efficacy for opioids,
 most studies funded by
 Pharma
- Long term use profoundly affects body; sex hormones, depression, hyperalgesia, etc.

ADDICTION

- Thought to be safe
- No double blinded prospective studies on long term efficacy for suboxone, most studies funded by Pharma
- Long term use would be same as what we have seen for pain treatment

MAT - MEDICATION ASSISTED THERAPY (OPIOIDS/OPIOID AGONIST-ANTAGONIST)

- Suboxone reduces harm and patient morbidity but it is NOT treatment (acute pain management can be difficult)
 - So does heroin and clean needles; this alone is NOT treatment
- Methadone is cheaper, does not have safety profile (4000% increase in OD's over the past decade)
- Continuum of issues with long term opioid treatment Buprenorphone is most abused illicit drug in Finland
- Frank untruths promoted by the "experts" in MAT training

*Simojoki K, Alho H (2013) A Five-Year Follow-up of Buprenorphine Abuse Potential. J Alcoholism Drug Depend 1:111. doi:10.4172/2329-6488.1000111

MAT - MEDICATION ASSISTED THERAPY (NON-OPIOIDS)

- VIVITROL, oral naltrexone
 - Reduces cravings moderately in alcoholics
 - Also has antagonistic effect for opioids
 - Injectable and lasts one month
 - Difficult to treat acute pain, however (risks vs benefit) insert suggests use of IV Fentanyl with Narcan available

LATEST DATA FROM NIDA

- Recent NIDA study no difference between naltrexone and buprenorphine for maintaining sobriety
 - * 4 times less likely to start vivitrol due to detox difficulties
 - * Opioids can be safely used for detox Methodist had been doing this safely for 16 years with people with CNCP.
- Lee, J, Nunez, E, Novo, P, et al., Comparative effectiveness of extended-release naltrexone versus buprenorphine-naloxone for opioid relapse prevention (X:BOT): a multicentre, open-label, randomised controlled trial, *Lancet*, Published: 14 November 2017

THE FDA'S PART - DRUGS ALONE ARE NOT THE ANSWER

- 1995 FDA approves Oxycontin despite lack of evidence
- 2002 Suboxone approved for opiate maintenance
- 2014 FDA Approves Zohydro after being voted 11-2 against it.
- 2017 FDA Approves SUBLOCADE™ (Buprenorphine Extended-Release), the First and Only Once-Monthly Injectable Buprenorphine Formulation to Treat Moderate to Severe Opioid Use Disorder induction dose is 3 ½ times typical dose
 - The results of the studies found that patients who were treated with Sublocade had "more weeks without positive urine tests or self-reports of opioid use" than those who administered a placebo.
- 2018 FDA Story on the Today Show and 60 Minutes DEA Undermined by Corporate Lobbies

PHARMA MARKETING TO DISCOURAGE A PATIENT?

Dr. Edwin Salsitz, a well paid prescriber who teaches the use of buprenorphine for OBOT. He is well respected in ASAM, rife with COI.



https://youtu.be/WWqBgwREbrg

WE NEED COMPREHENSIVE TREATMENT AND COMPLIANCE MANAGEMENT

- We would not give a newly diagnosed diabetic needles and insulin and wish them luck
 - Education, diet, lifestyle change, practice and compliance
- We would not be given crutches without PT and education after a hip replacement
 - Education, diet, lifestyle change, practice, and compliance
 - Vinton County Ohio NPR Story
 - Reckitt Benckhiser fined I.4B for marketing tactics

BARRIERS TO LIFESTYLE CHANGE, AND LIFESTYLE CHANGE IS NEEDED

- We live in a "fix me now" mindset
- We tend to forget the longitudinal aspect of chronic illness
- ELOC vs ILOC in the patient population
- The real world of patient satisfaction
- It's good business to prescribe **I5B** in opiate sales in 2015

CONTRIBUTING ENVIRONMENTAL FACTORS FOR BOTH ILLNESSES

- Raw Nerves
- Anxiety
- Turmoil/Trauma
- Living with people with a defeatist attitude
- Living with people who wait on them because of their pain

CONTRIBUTING ENVIRONMENTAL FACTORS (CONTINUED)

- Living with someone who discourages physical exercise
- Living with someone who encourages obesity
- The use of drugs
- Physicians/Clinicians who prescribe just about anything
- Lack of spiritual support

ABSTINENCE BASED PAIN AND ADDICTIONS TREATMENT WITH 12 STEPS



- Groups are better than one-onone
 - Group Support/Compliance
 - Groups share triumphs and defeats
 - Need an action based and self managed philosophy
 - Groups stifle "terminal uniqueness"
 - We know opioids' long term effects

12 STEPS AND CHRONIC PAIN

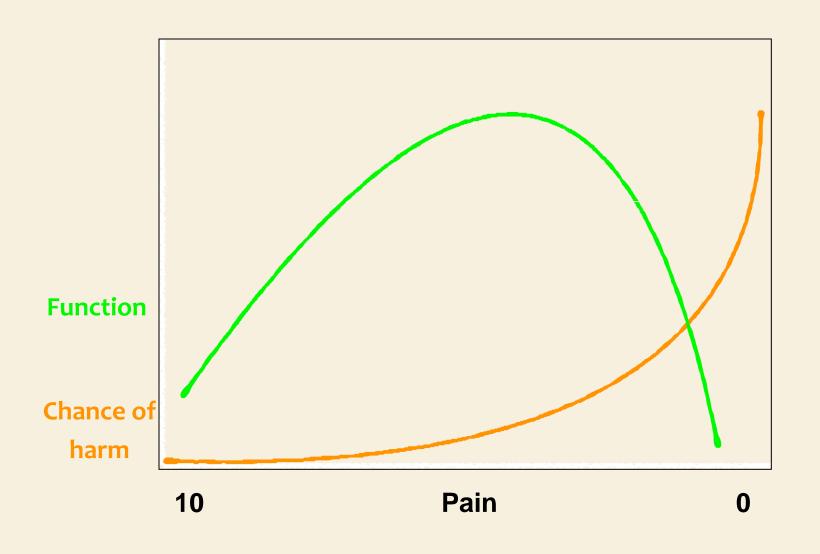
- Powerlessness over the pain perception page 58
- Dr. Shopping for a cure too much medicine? What's MY part? –
 page 62
- Learning a new lifestyle page 58
- Accountability Improves Compliance
- Exercise is STILL the best medicine



THERE IS NO MEDICINE THAT CAN MAKE UP FOR LACK OF EXERCISE...

Moses Maimonides

CHASING ZERO PAIN ETO Pain



OUR PART AS "CHEMICAL CODDLERS"

- We want to help
- Immediate "help" may exacerbate past problem
- Even conservatively, if there was a 5% chance of a person developing a fatal complication based on adding hydrocodone, would we still prescribe it?
- Opiate OD deaths have QUADRUPLED since 2001
- Shift of thought process for pain types acute, acute on chronic, EOL, CNCP, Palliative, Cancer
- Healthcare is in many ways set up to enable

OPIOID MISUSE SPECTRUM DIDIOI MISUSE SPECTRUM

opioid naive chronicpain addiction recreation diversion

Less interest

OPIOID THERAPY

More interest

IATROGENIC RELAPSE

- We should treat pain even in those with opiate addiction
- Opioids are best indicated for acute nociceptive pain
- Clinicians worry about whether they will cause addiction
- Rarely are we worried about relapse
- We should be

ADVANCED DIRECTIVES FOR THE PREVENTION OF IATROGENIC RELAPSE

-ADVANCE DIRECTIVES FOR ADDICTION IN REMISSION AND TO ENSURE CONTINUED RECOVERY

Patient Last Name		Patient First Name	Middle Initial
Birth Date		Medical Record Number	Date Prepared
A	In event of my inability to speak for myself, I am recovering from addiction to		
	() Alcohol () Opioids	() Benzodiazepines () Amp	ohetamine () Cocaine () Other
D	I would request if any mood altering medications are to be given that they are used sparingly		
В	and in amounts and formulations designed for my personal recovery to minimize iatrogenic relapse. Signed document allows for permission to use INSPECT at any time		
С	USE: Long acting () morphine () oxycodone () methadone () oxymorphone () other		
	USE: Short Acting () morphine ()oxycodone () hydrocodone () other		
D	Responsible Party for post procedural take home medications		
E	Scheduled () Every [] hours for [] days no longer than [] days		
F	Responsible prescribing clinician/Pharmacy (one of each only)		
G	Copy of current treatment agreement attached		
Н	Sponsor/Recovery Coach		

SO WHAT DO WE DO?

- Treat the pain
- Watch for observed intoxication and refer
- If on chronic opioids, these are considered baseline use additional short acting for BTP (IU Health order sets)
- Opioid Rotation
- Know your own reaction
- Other clinician challenges "WHAT AREYOU GONNA DO FOR ME?"

WHAT NOT TO DO

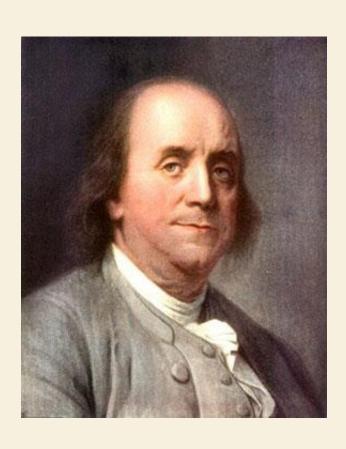
- Send them off with a 30 day supply and a letter of discharge THIS fuels the illicit trade
- Use short acting opioids for weaning
- Trust the addicted **or non addicted** patient to wean himself/herself
- Assume that ANY patient will disclose an addiction diagnosis

CONCLUSIONS

- Opioids are quite helpful for many patients with chronic non Cancer Pain as well as opiate addiction
- They are useless or harmful for many
- It is difficult to predict benefit/harm
- Harm to society is substantial, and increases with the use of higher doses

CONCLUSIONS

- Most societal harm likely occurs with people who never had a prescription
- With meticulous prescribing, those who benefit from opioids can get them safely, and those who do not benefit can be protected from them
- It is unclear the extent to which physicians can adequately protect society
- MAT with opioids have better outcome measurements; good for public health but may be dangerous for the individual long term (History)



NOTHING IS MORE FATAL TO HEALTH, THAN AN OVER CARE OF IT...

• Benjamin Franklin

THANK YOU...QUESTIONS?

