



# Managing Pain Safely Forum II

Partnership HealthPlan of California

January 15, 2016

# OBJECTIVES

- To understand the neuroscience of prolonged opioid use
- To understand the similarities and differences with addiction
- To understand approaches to working with patients affected by chronic pain
- To participate in interactive breakout sessions

# LOGISTICS

- Folders
  - Agenda
  - Presenter Biographies
  - PHC Contact List
  - Evaluation
  - PHC Website
  - NoRxAbuse Flyer
  - MPS County Webinar Flyer
- CME Logistics
- Q&A Process



# HOUSEKEEPING

- Restroom Locations
- Electronic Devices
- WIFI Name: Red Lion Guest
- WIFI Code: Harley
- Presentation Materials Online

<http://www.partnershiphp.org/Providers/HealthServices/Pages/MPSUpcomingEvents.aspx>





# GROUND RULES

- Begin and end on time
- Be open-minded – respect all ideas and opinions
- Use technology sparingly and place on silent
  - If you must take a call, please step out of the room
- Be engaged – participate
- **Have fun!!!**

# Conflict of Interest

- All presenters have signed a conflict of interest form and have declared that there is no conflict of interest and nothing to disclose for this presentation.

LET'S GET STARTED

Let's get started . . .



LET'S GET STARTED

ENJOY THE  
FORUM!



# Managing Pain Safely: Progress on Reducing Opioid Overuse in the PHC Service Area

Robert Moore, MD, MPH  
Medical Director,  
Partnership HealthPlan of  
California

January 15, 2016

# Managing Pain Safely – 2016 Update

Accomplishments

Progress towards goal

How we will achieve goal



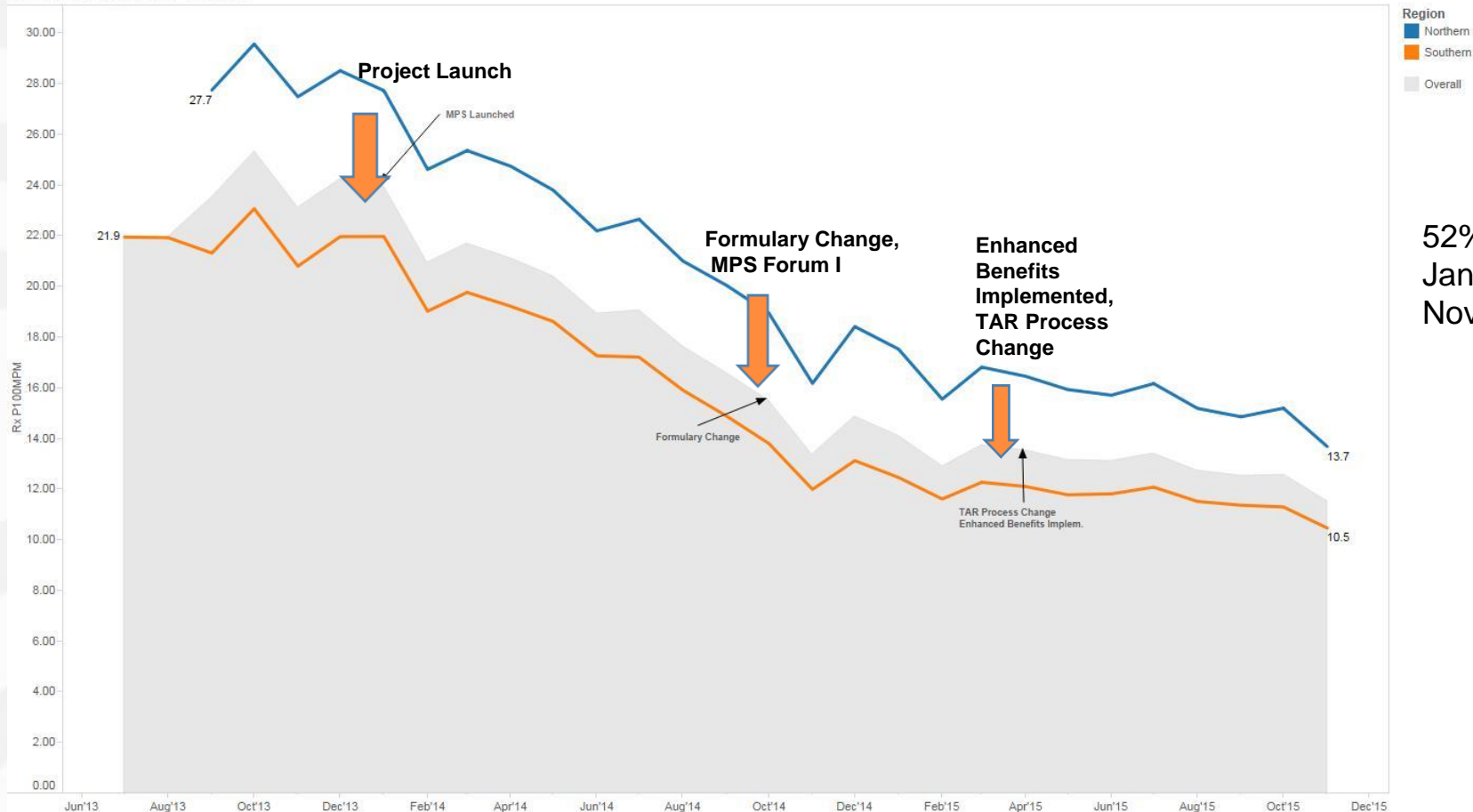


## Accomplishments:

Review of PHC Opioid  
Prescription Data

# MPS Data – Total Prescriptions

Opioid Prescriptions P100MPM

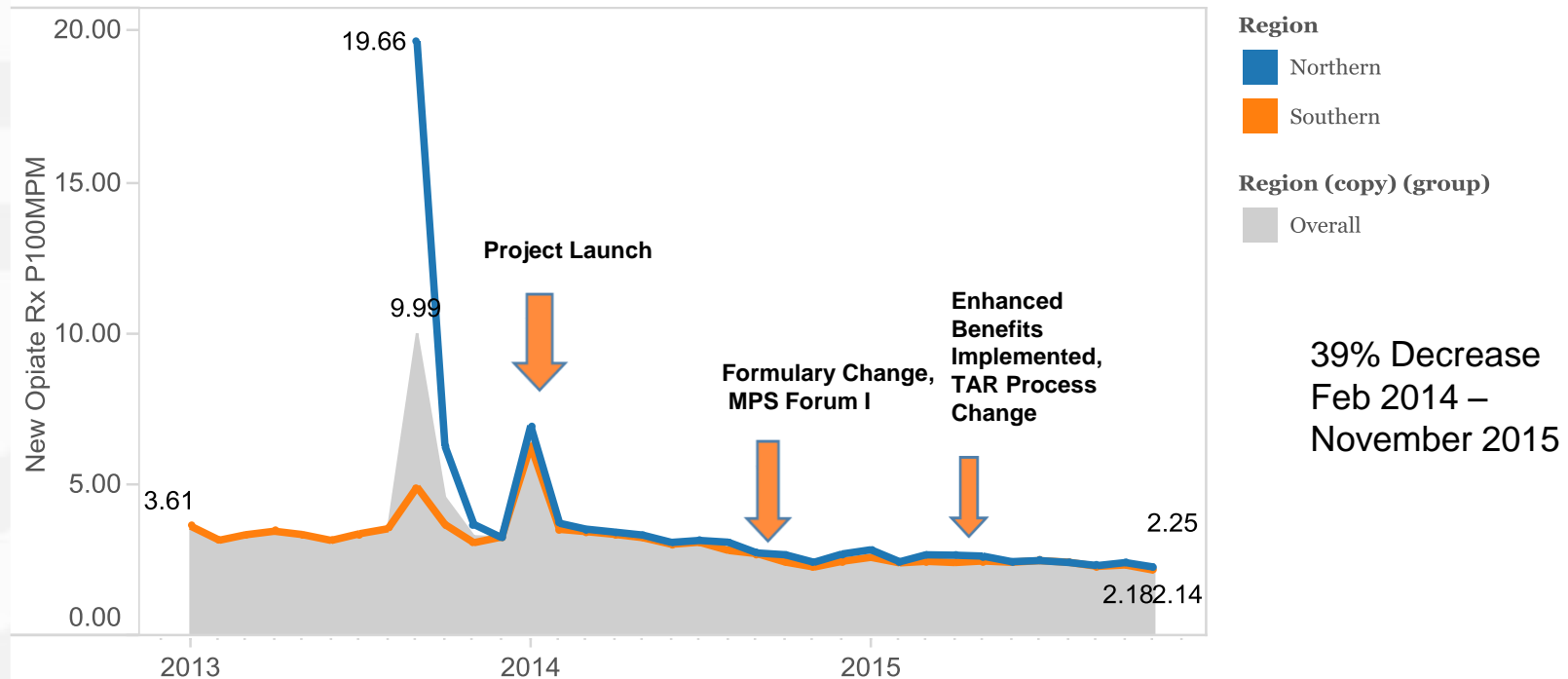


52% Decrease  
Jan 2014 –  
November 2015



# MPS Data – Initial Prescriptions

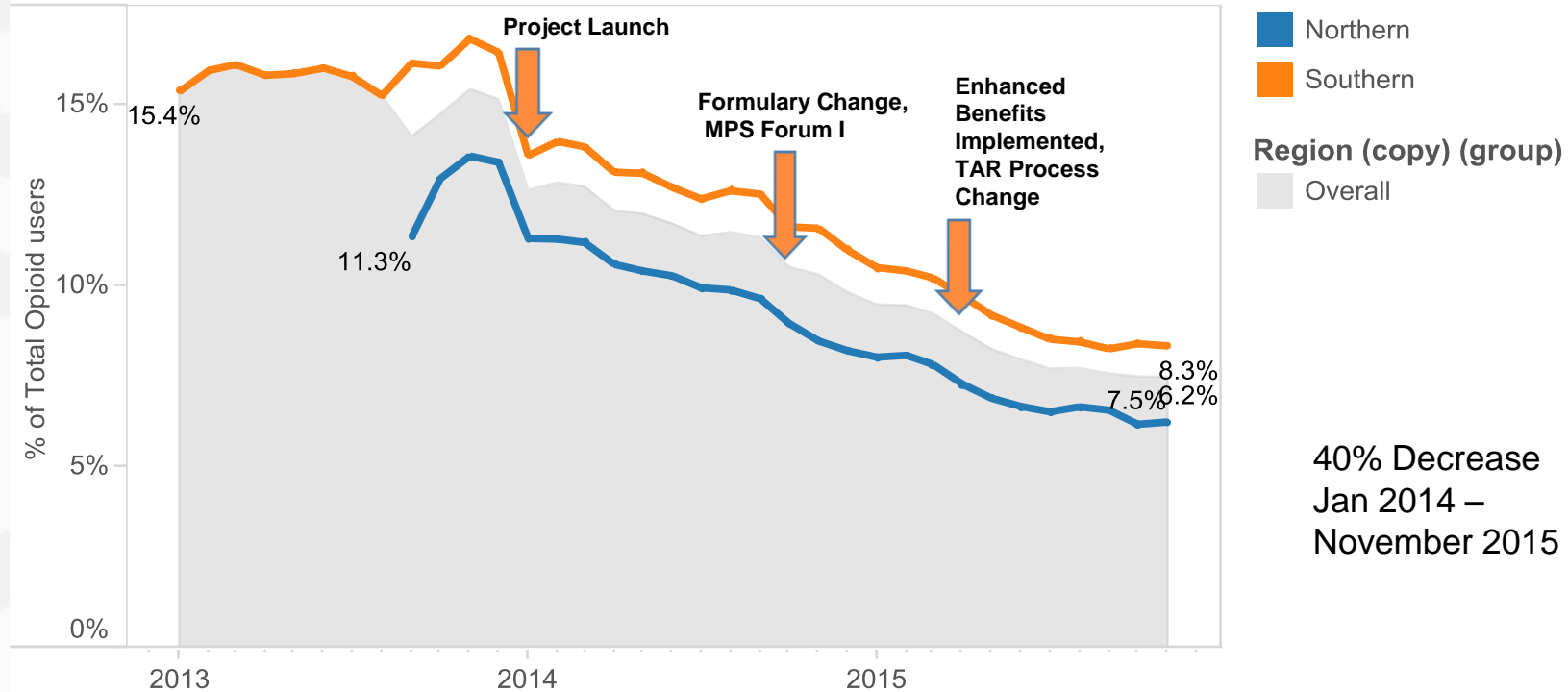
## Initial Opiate Fills P100MPM



The trends of Initial Rx P100MPM and Initial Rx P100MPM for fill\_dt Month. The marks are labeled by Initial Rx P100MPM. For pane Initial Rx P100MPM: Color shows details about Region (copy) (group). For pane Initial Rx P100MPM (2): Color shows details about Region. The data is filtered on Initial and Date Filter. The Initial filter keeps Y. The Date Filter

# MPS Data – Unsafe Dose

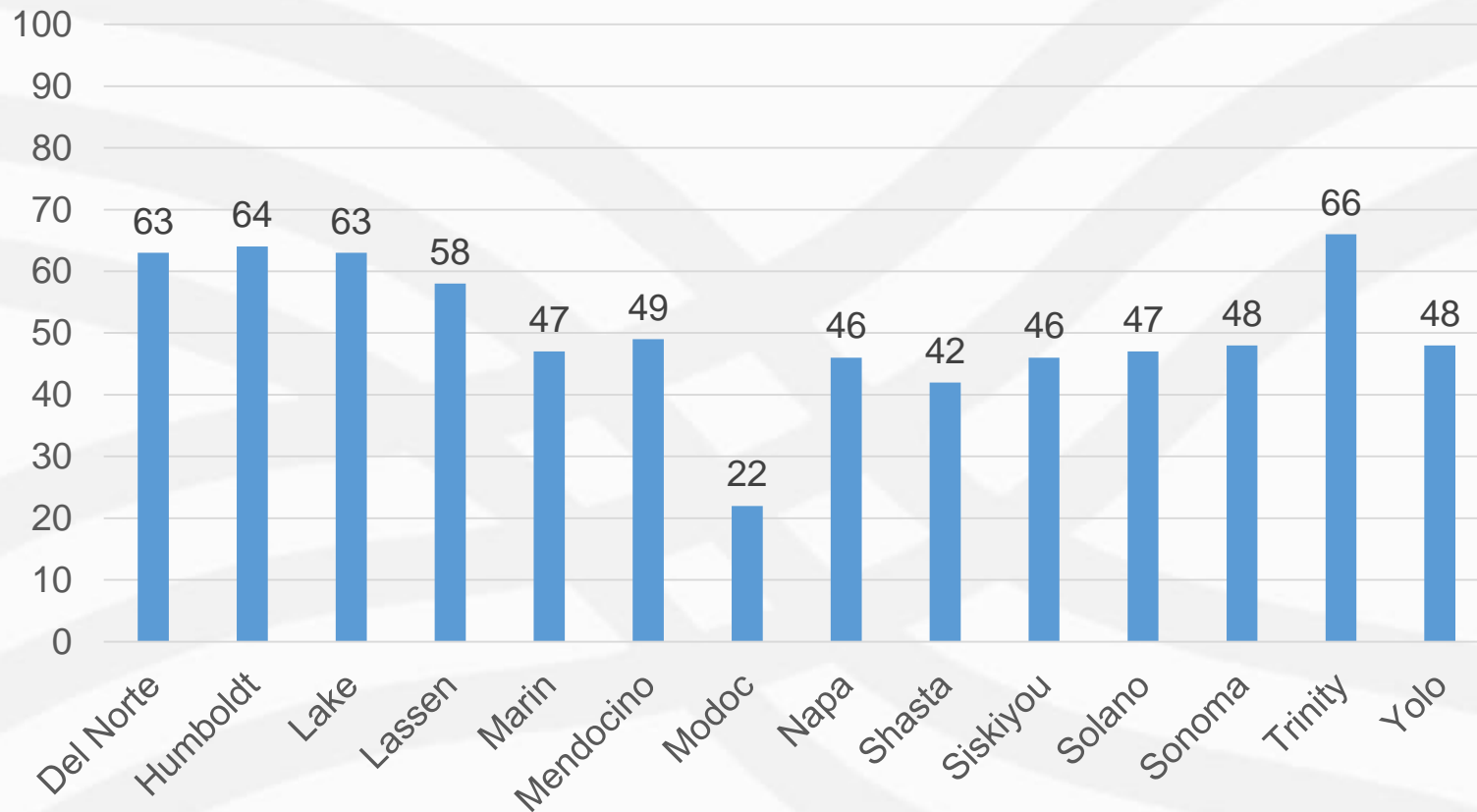
## % Opioid Users on Unsafe Dose (>120 MED)



The trends of % of Total Opioid users and % of Total Opioid users for Latest Fill Month broken down by User type. For pane % of Total Opioid users (2): Color shows details about Region. For pane % of Total Opioid users: Color shows details about Region (copy) (group). The data is filtered on Date Filter and Latest Fill. The Date Filter filter keeps True.

# Percent Decrease of Unsafe Dose

% Decrease Unsafe Dose  
December 2013-November 2015





**Accomplishments:**

Health Plan Activities

# MPS Workgroups

**MPS Technical Support**

Data Management

Pharmacy

Provider Network

Care Coordination/Utilization Management/ Member Services

Legislative Policy/Regulation/Communication

Community Support

**MPS Steering Committee**

# Interventions

Education

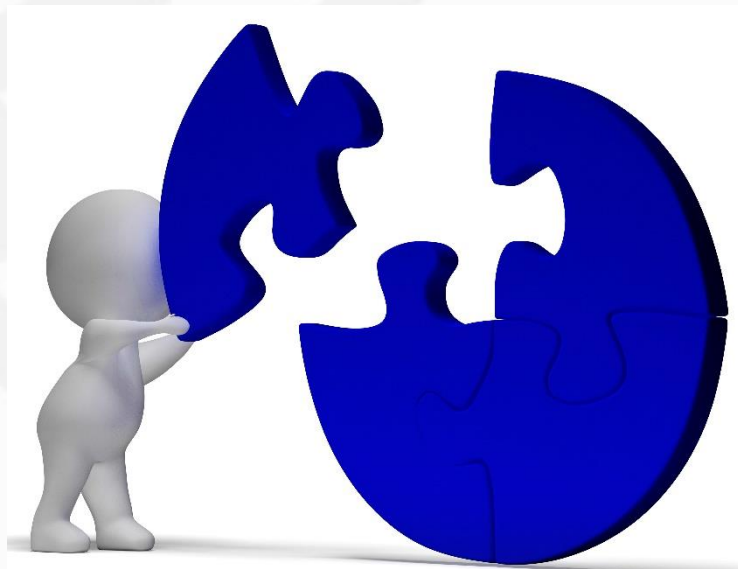
Health plan pharmacy prior authorization changes

Additional options for treating pain

Community activation

Aligned incentives

Additional resources

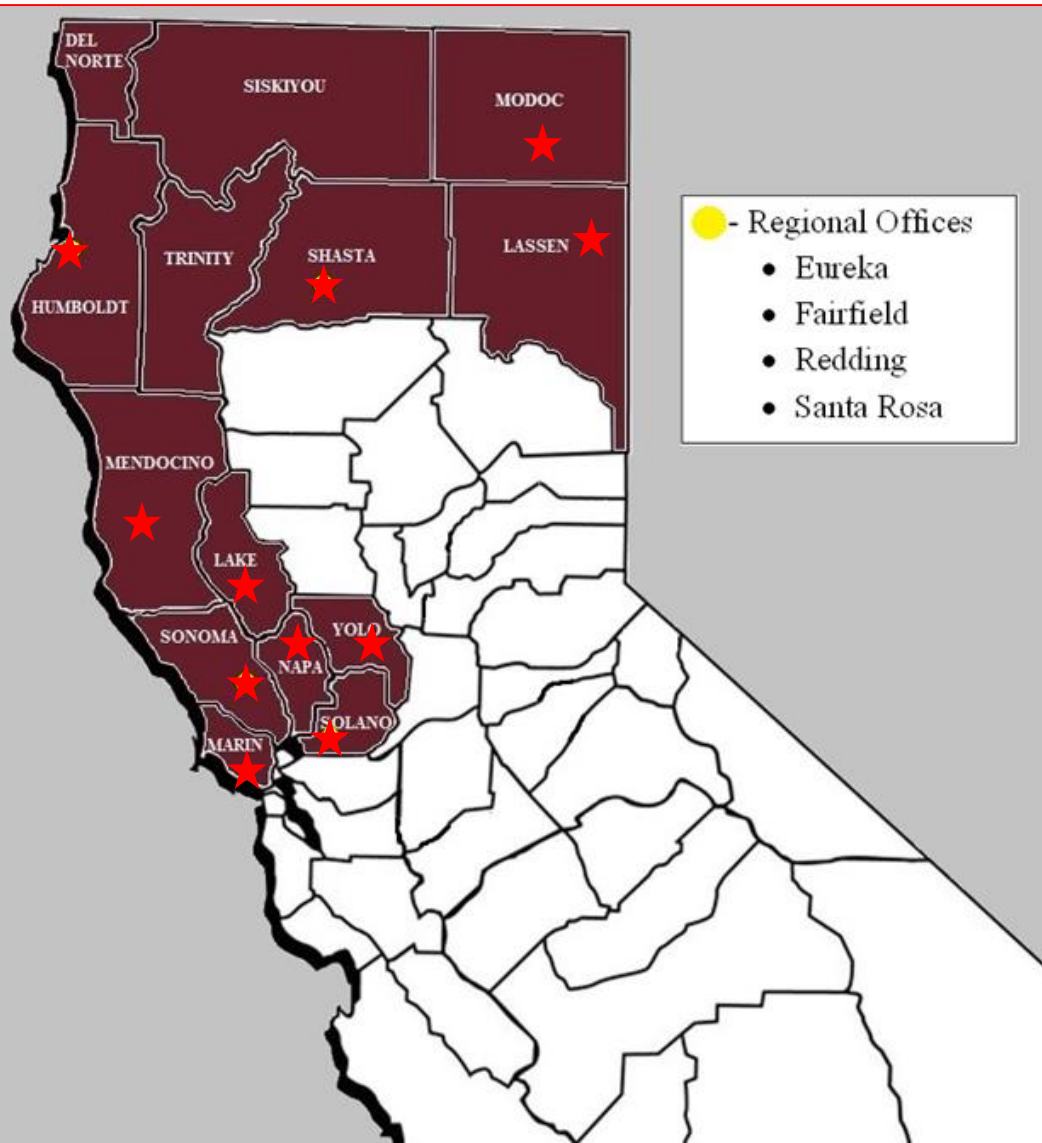





**Accomplishments:**

Community Coalitions

# PHC Counties Participating in CHCF Regional Opioid Safety Coalition Grant Program



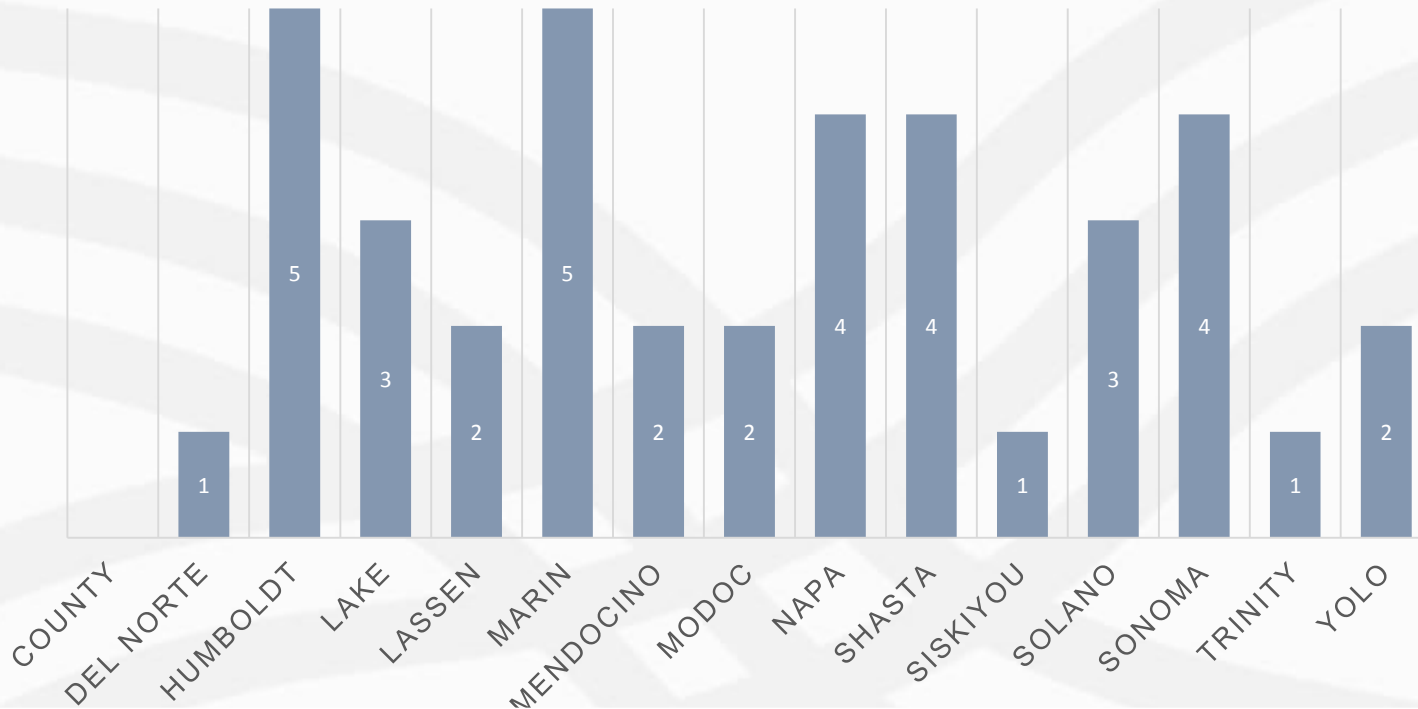
10 PHC Counties are participating in CHCF's Regional Opioid Safety Coalition Grant Program

 CHCF Opioid Safety Coalition County



# Community Coalition Status

PHC COUNTY COALITION STATUS



## Key

1	Little or No Effort (Yet)
2	Initial Meetings, Beginning of Framework Formation
3	Framework Formation, Action Teams Initiating
4	Strong Effort- Framework Implemented, Regular Meetings, Active Action Teams, Working towards Milestones
5	Robust Effort- Active Action Teams, Accomplishing Milestones, Measurable Results



**Accomplishments:**

Primary Care Providers

# Interventions

Opioid Oversight Committees

Setting up Health Center-wide policies

Tapering

Integrated Behavioral Health

Talking to patients, one by one.





Progress Towards Goal

# Managing Pain Safely – Aim Statement

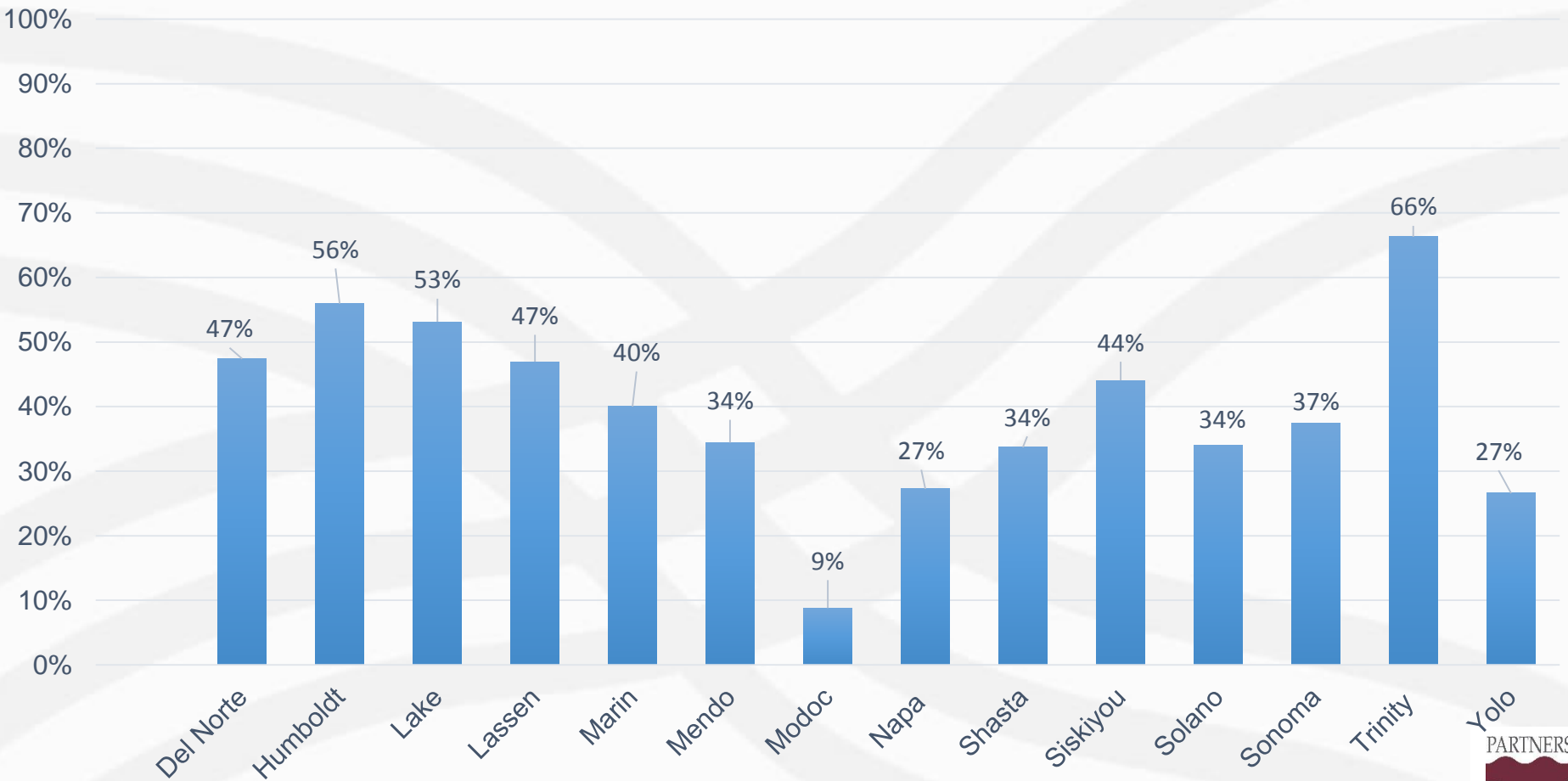
By December 31, 2016, we will improve the health of PHC members by ensuring that prescribed opioids are for appropriate indications, at safe doses, and in conjunction with other treatment modalities as measured by a:

- Decrease in total number of initial prescriptions by 75%
- Decrease in total number of prescription escalations by 90%
- Decrease in total number of patients on high-dose opioids\* by 75%

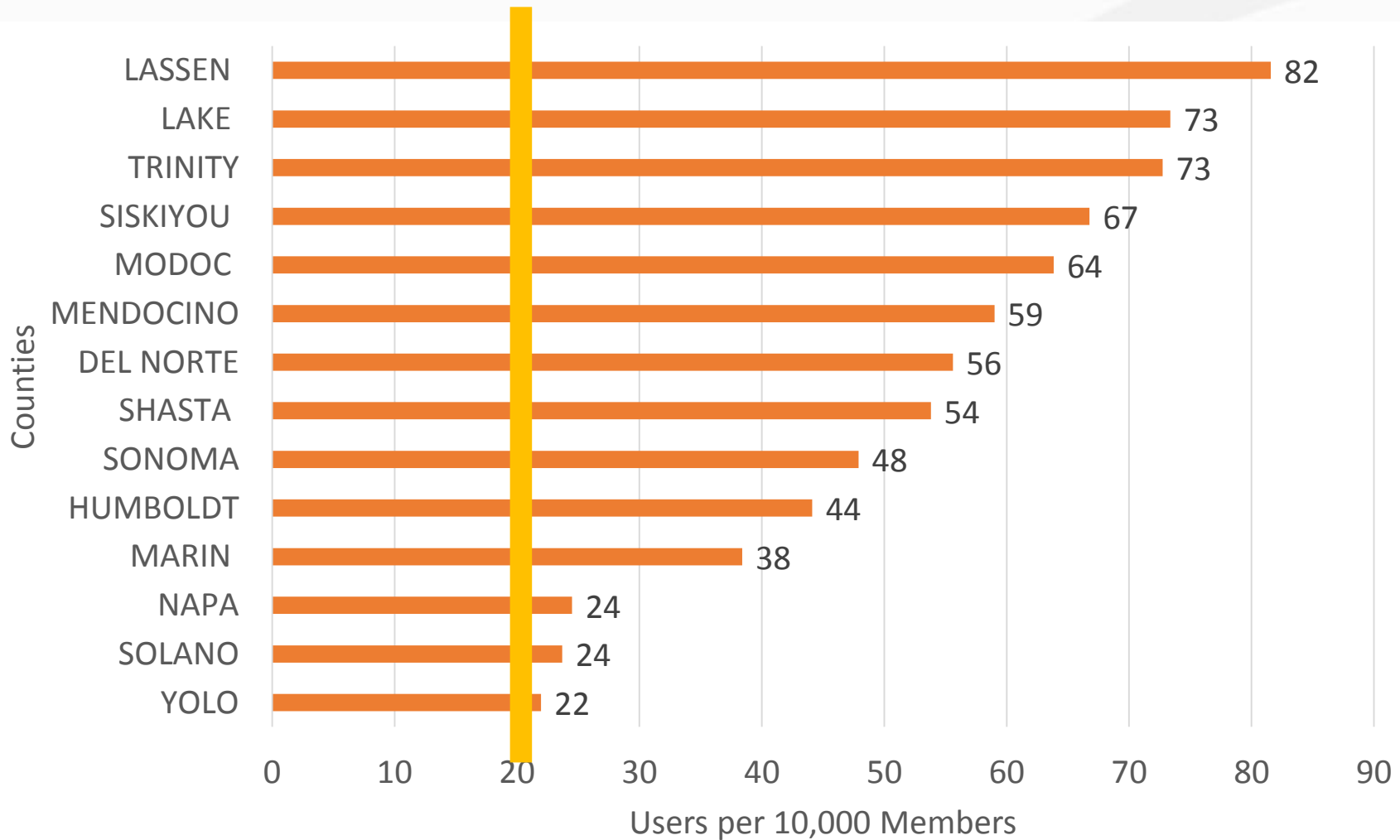
\*Defined as greater than 120 mg. MED

# Percent Decrease of Unsafe Dose

% Decrease Unsafe Dose January 2014-October 2015



# Rate of High Opioid Users: End of 2015





# Achieving Our Goal: I

Health Plan Activities for  
2016



# Looking Ahead in 2016: Health Plan Activities

Provision of tele-consult services for complex patients on high-dose opioids

Education and coordination around addiction screening and treatment

Partner with CHCF for continued support in developing and sustaining local efforts targeted at reducing improper use of opioids

Planning process for creating integrated clinics for high utilizers

Pharmacy academic detailing

MPS provider level data sharing

Tapering guide/ toolkit

Naloxone Pilot



## Achieving Our Goal: II

State Wide Activities

# Looking Ahead in 2016: State Wide Activities

Support for Community Coalitions

Planning for Integrated Approach to Patients on  
High Doses of Chronic Opioids

CDC Guidelines

CURES 2.0



## Achieving Our Goal: III

Prescriber Activities

# Looking Ahead in 2016: Prescriber Activities

- Sign up for tele-consult services for complex patients on high-dose opioids
- Make local opioid oversight committees more robust
- Participate in regional coalitions
- Give feedback on draft plan for integrating chronic pain treatment with Medication Assisted Therapy
- Ask your PHC Regional Medical Director to meet with you and/or your clinicians to review their individual PHC opioid data and to review MPS
- Tapering guide/ toolkit
- Distribute Naloxone and educate patients/families on how to use it.

# Thank You!!!

Robert Moore, MD, MPH, Medical Director,  
Partnership HealthPlan of California





Cory Waller, Medical Director Center for  
Integrated Medicine

*Spectrum Health Medical Group*





# **An Overview Of Substance Use Disorders Partnership Health Plan**

Sharone Abramowitz M.D.

Psychiatrist & Addiction Medicine Board Certified

Behavioral & Addiction Medicine Director, Primary Care Medicine  
Residency, Highland Hospital, Alameda Health System

Executive Council, Calif Society of Addiction Medicine

Motivational Interviewing Network of Trainers

Integrative Psychiatry Private Practice, Oakland & San Francisco

**[www.Abramowitz-Psychiatry.com](http://www.Abramowitz-Psychiatry.com)**

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- Epidemiology
- Brain & Addiction
- DSM V
- Opiates
- Marijuana
- Alcohol
- Screening & Counseling

# What we will cover ...

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## Pair off

### Speakers

- Think of an impactful interaction you've had with one of your addiction pts (positive or negative)
  - Emotional impact, what did you learn?, what you need to learn?
- Speak for 90 seconds

### Listeners

- Listen without speaking
- Your face will show natural responsiveness
- After time is called, you have 60 seconds to summarize in your own words the story you just heard.

### Reverse

# Summarizing

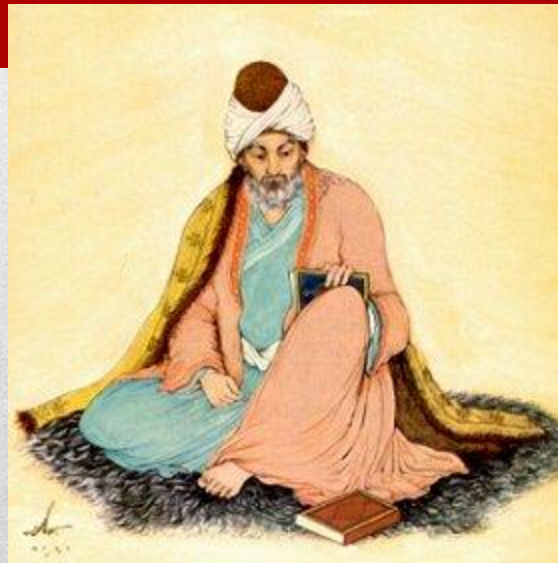
## Empathy Exercise

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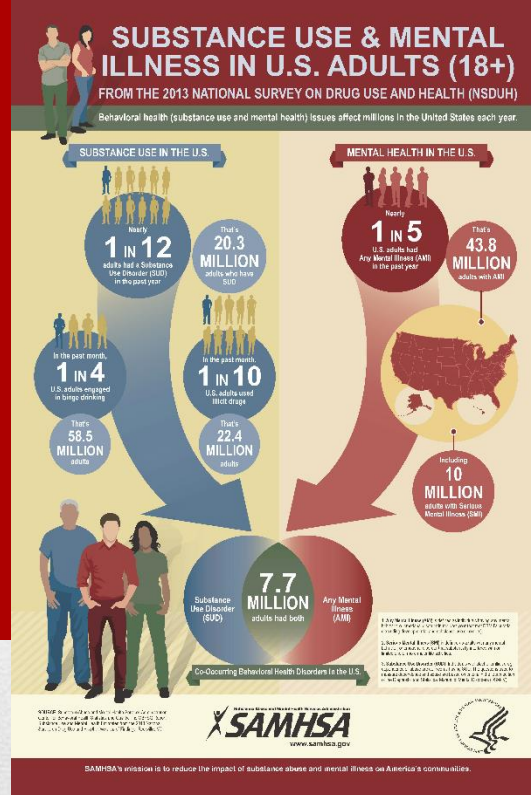
***“The wound is the place  
where  
the light enters you.”***



**Rumi**

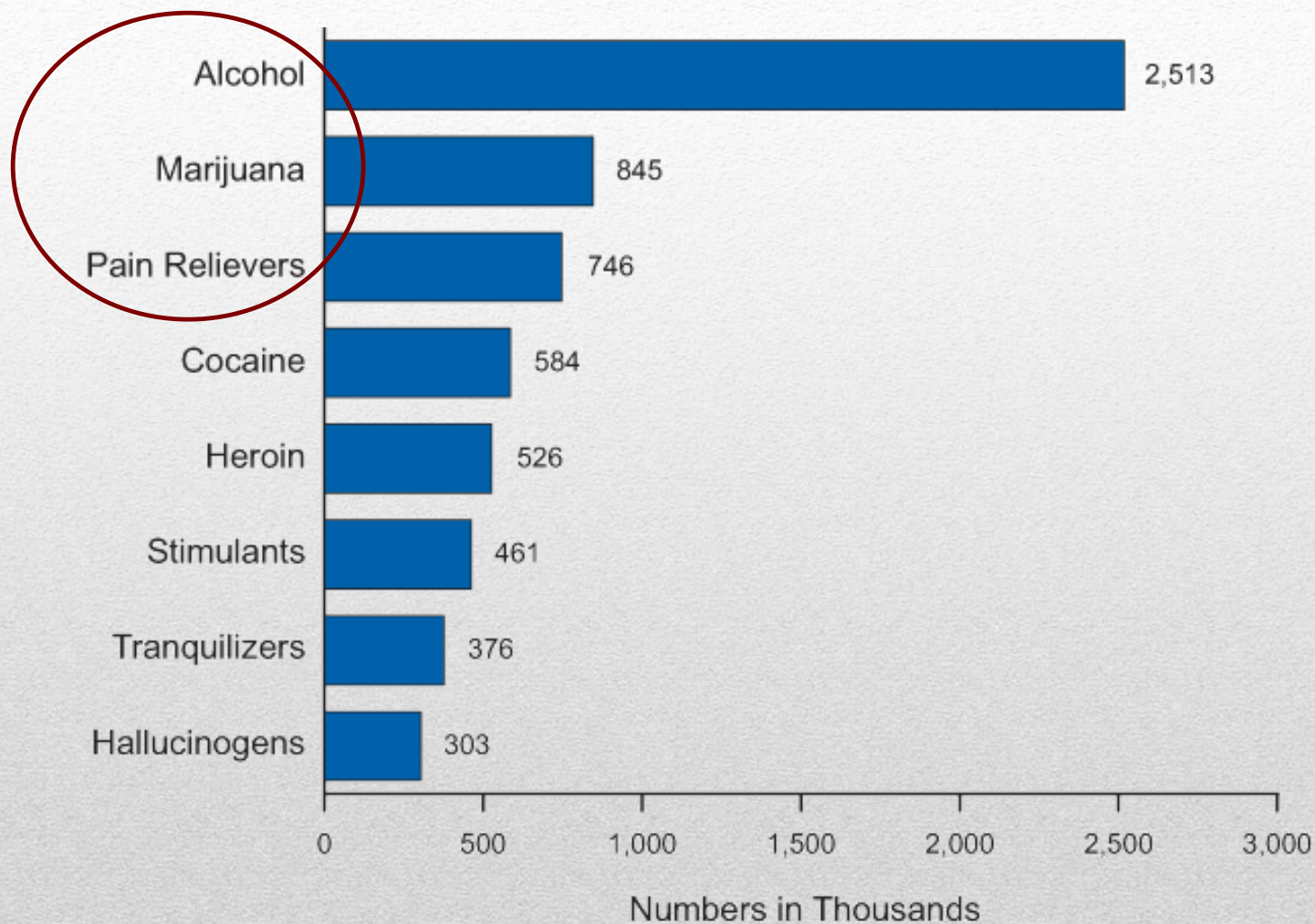
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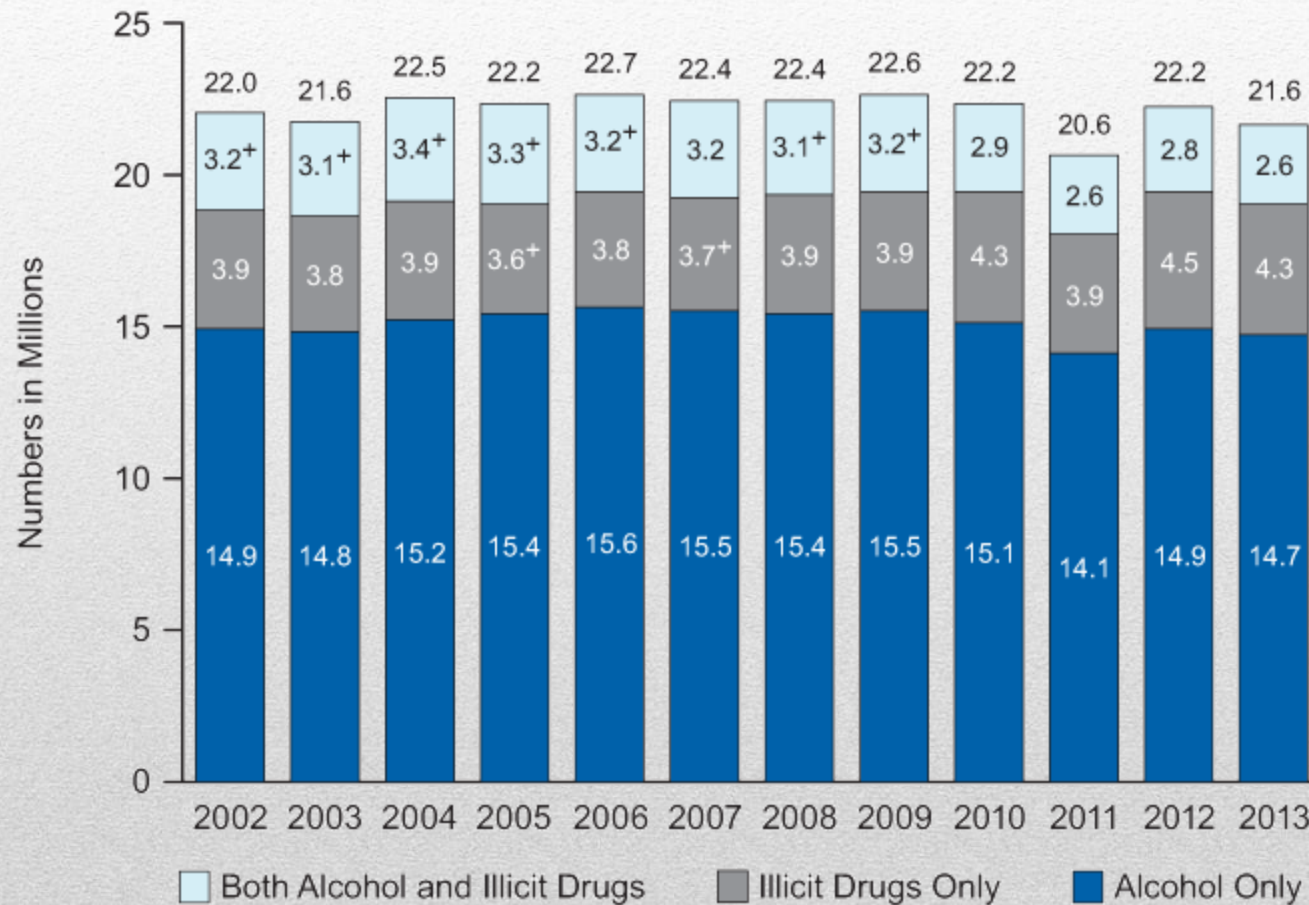
# EPIDEMIOLOGY

## Substances for Which Most Recent Treatment Was Received in the Past Year among Persons Aged 12 or Older: 2013

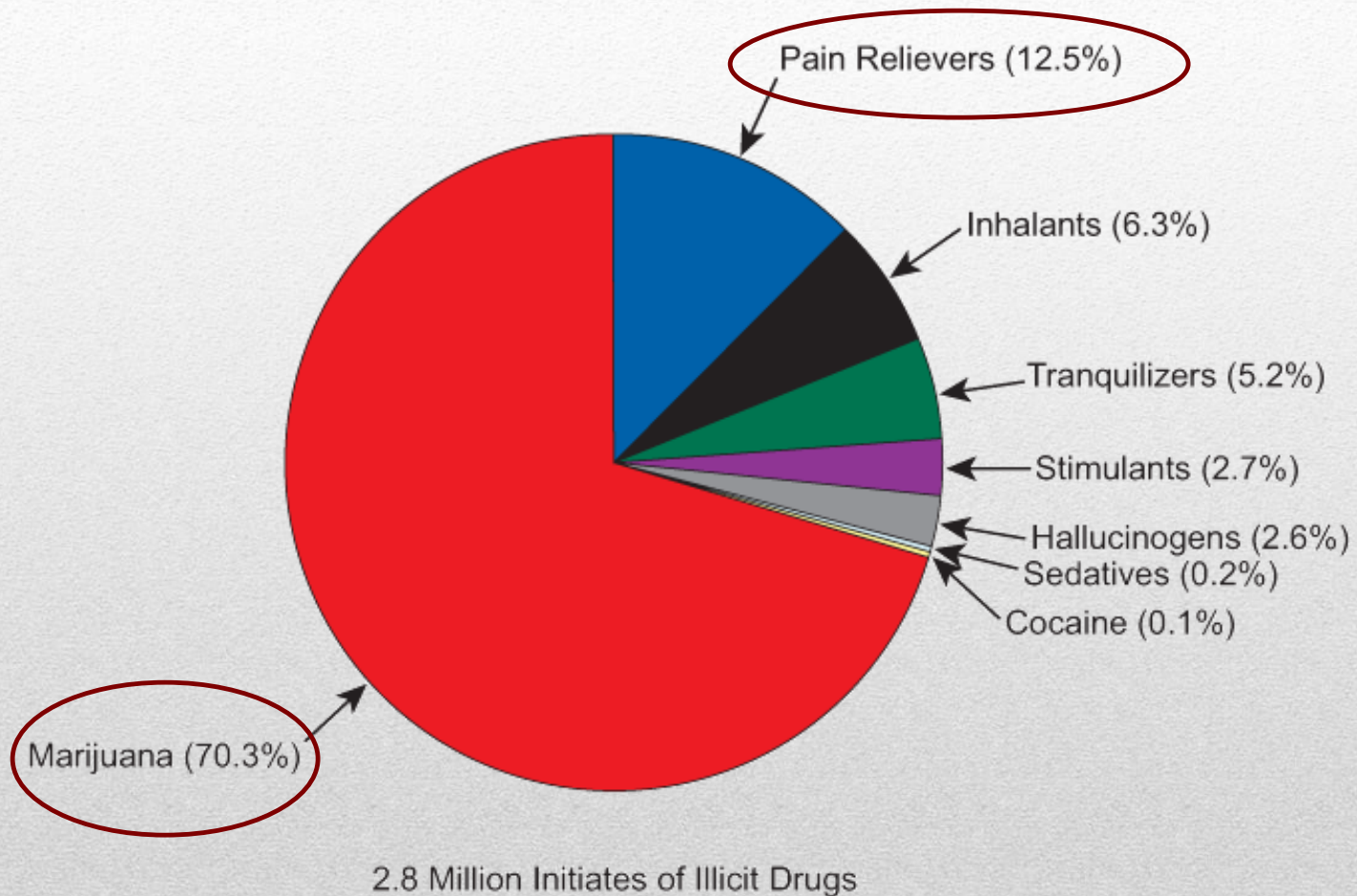




## Substance Dependence or Abuse in the Past Year among Persons Aged 12 or Older: 2002-2013

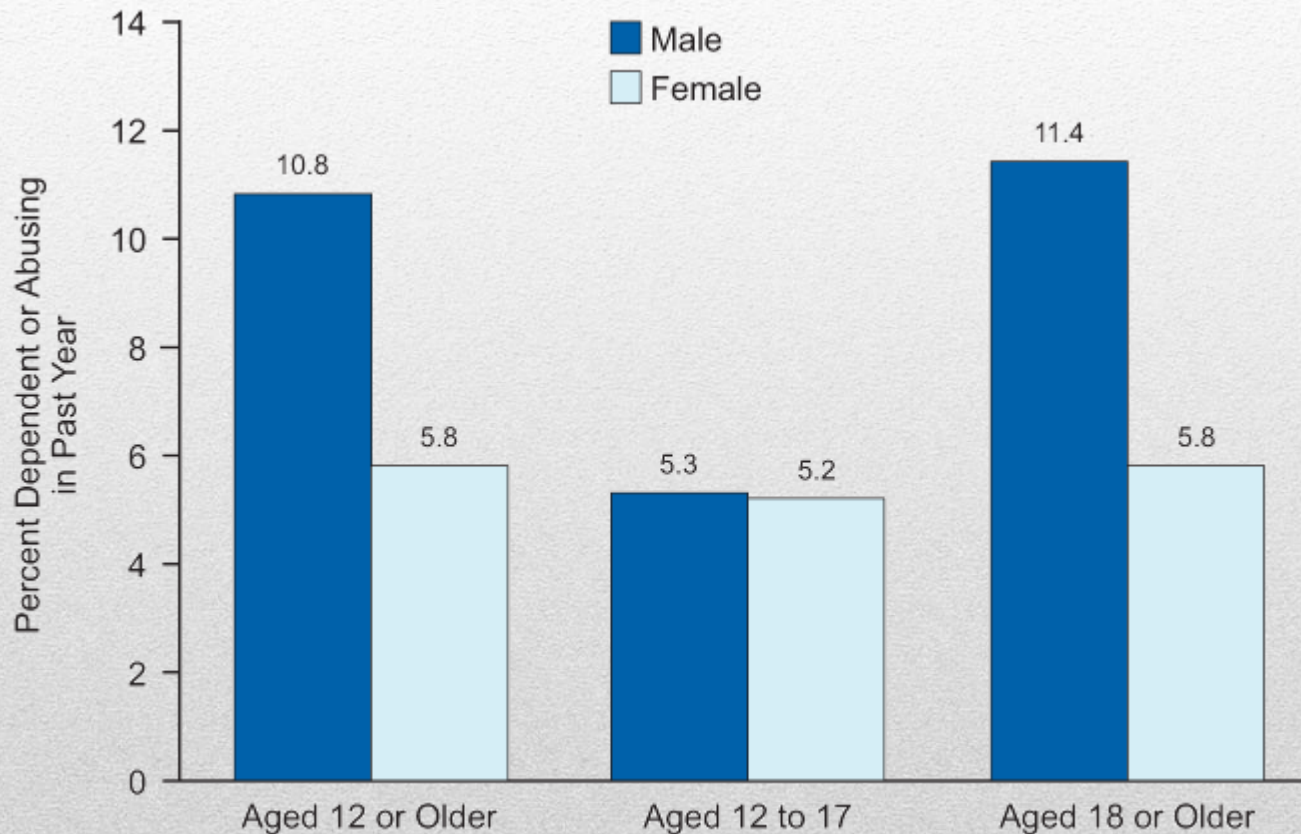


## First Specific Drug Associated with Initiation of Illicit Drug Use among Past Year Illicit Drug Initiates Aged 12 or Older: 2013

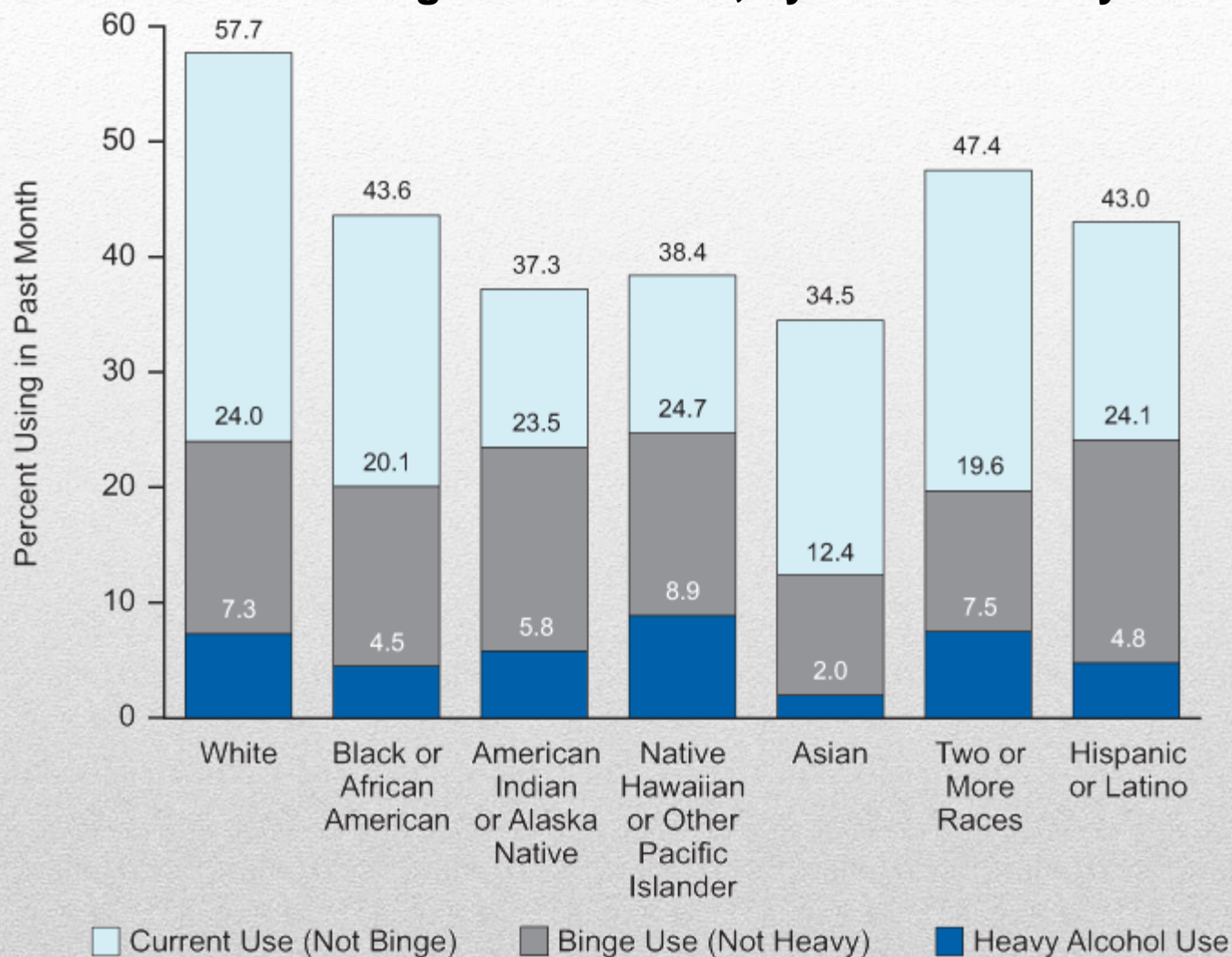




## Substance Dependence or Abuse in the Past Year, by Age and Gender: 2013

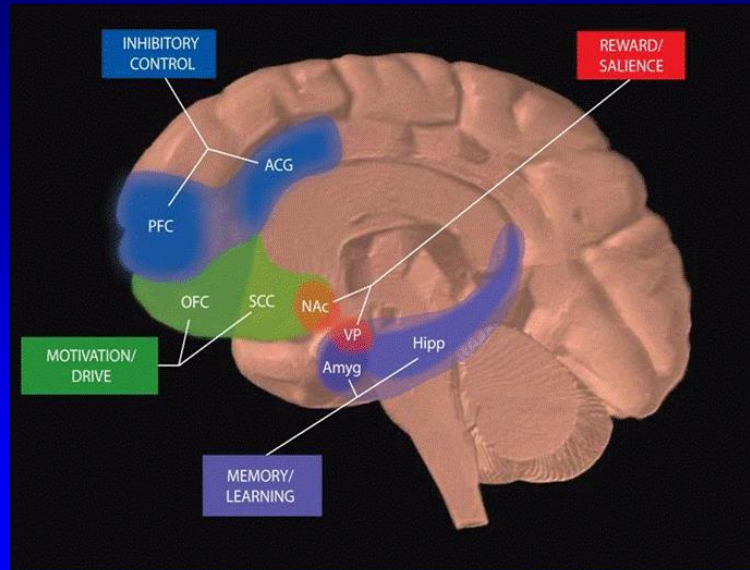


## Current, Binge, and Heavy Alcohol Use among Persons Aged 12 or Older, by Race/Ethnicity: 2013





## *Circuits Involved In Drug Abuse and Addiction*



**All of these brain regions must be considered in developing strategies to effectively treat addiction**

NIDA

# THE BRAIN & ADDICTION

## SUDs as a Chronic Brain-Based Disease

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# Epigenetics & SUDs

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# Adverse Childhood Events (ACE)

**CDC & Kaiser San Diego Study**

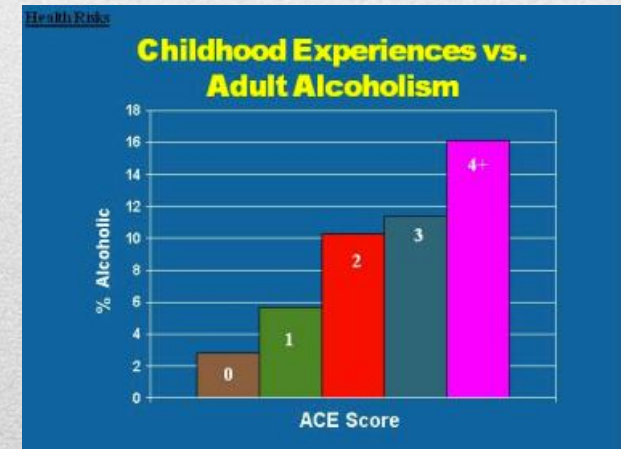
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<http://www.cdc.gov/violenceprevention/acestudy/>

## 4 or more categories of ACEs, compared to those w/ none:

- 4-12-fold risks for alcoholism, drug abuse, depression, and suicide attempt
- 2- 4-fold increase in smoking, poor self-rated health
- 1.4- 1.6-fold increase in physical inactivity and severe obesity
- **# of ACEs showed a graded relationship to the presence of adult diseases including:** ischemic heart disease, cancer, chronic lung disease, skeletal fractures, and liver disease.

Am J Preventive Med 1998



Useful to ask all pts:

“Have you ever been harmed physically, sexually, emotionally as a child or an adult?”

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Drug and stress innate immune gene induction  
creates the neurobiology of addiction

Disrupts frontal cortical  
behavioral control  
mechanisms.

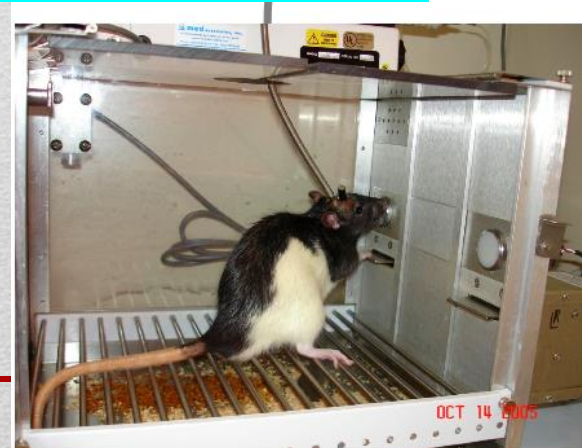
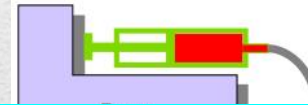
Increases limbic  
negative affect,  
craving and anxiety.

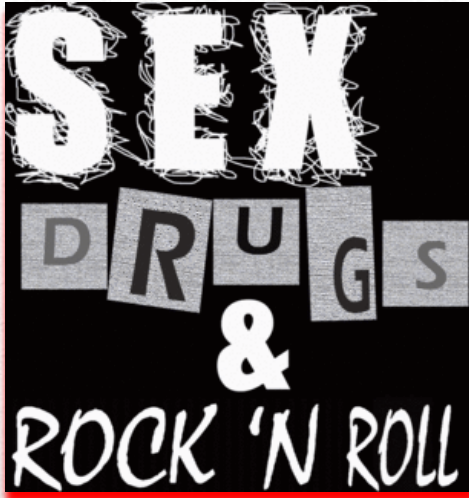
Frontal Cortex  
Goal setting  
Motivation  
Planning  
Impulse Inhibition

Amygdala  
Hippocampus  
Anxiety, Urgency  
Negative Affect  
Craving  
Impulsiveness

Adapted from Crews and Boettger

We admitted we were powerless over drugs –  
that our lives had become unmanageable.





## Dopamine

Sex, food, drugs, social connections  
VTA (mesolimbic)

Pleasure, reward, socializing

Addiction \*

Psychosis \*

Pain processing  
PNS & CNS pain system

Chronic pain \*

Movement  
Substantia Niagra

Parkinson's disease

Executive Function  
PFC

ADHD \*

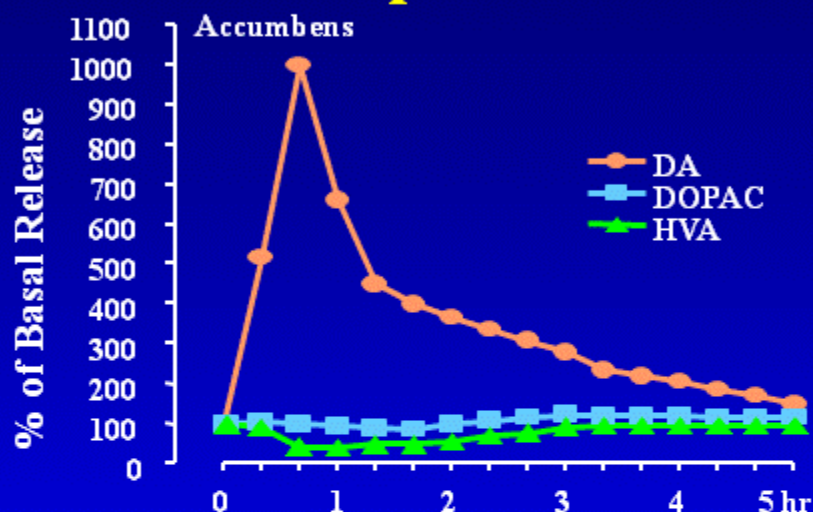
Inhibits PRL  
hypothalamus

Stop lactating

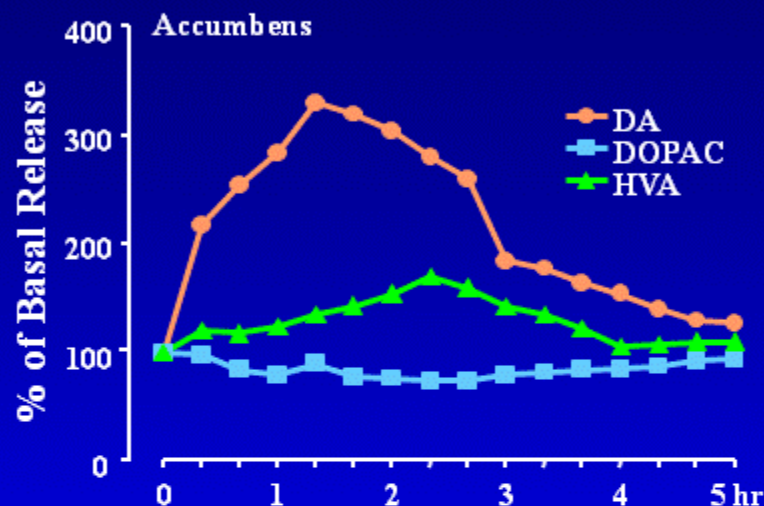


# Effects of Drugs on Dopamine Release

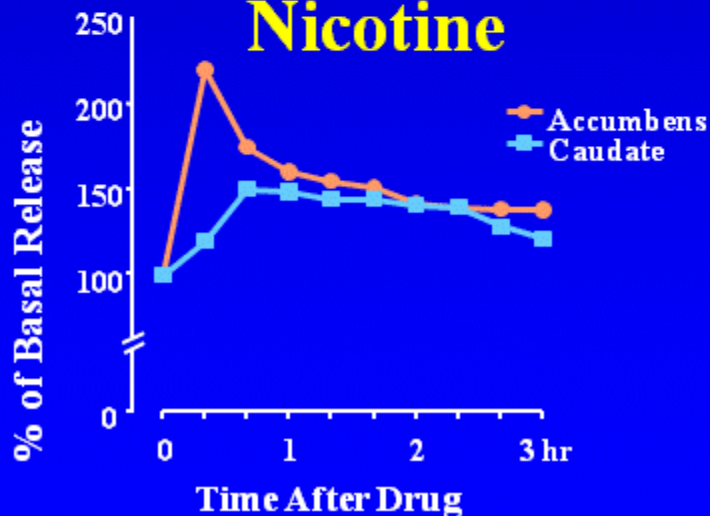
## Amphetamine



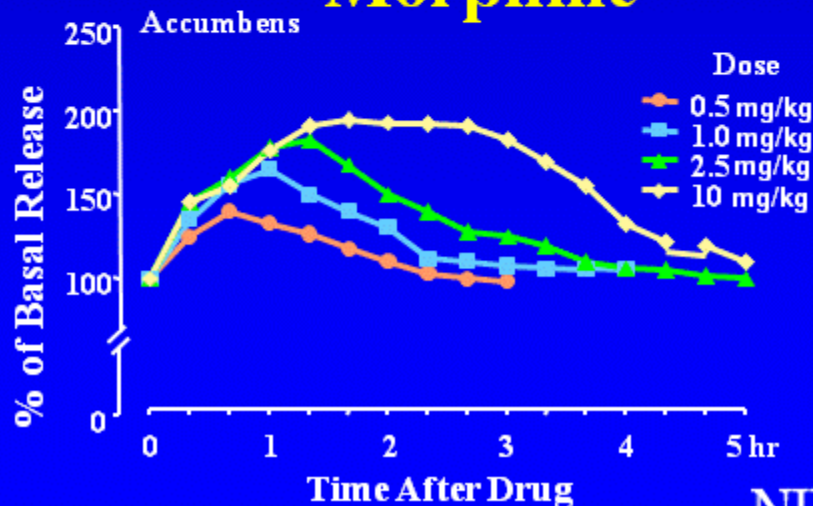
## Cocaine



## Nicotine



## Morphine



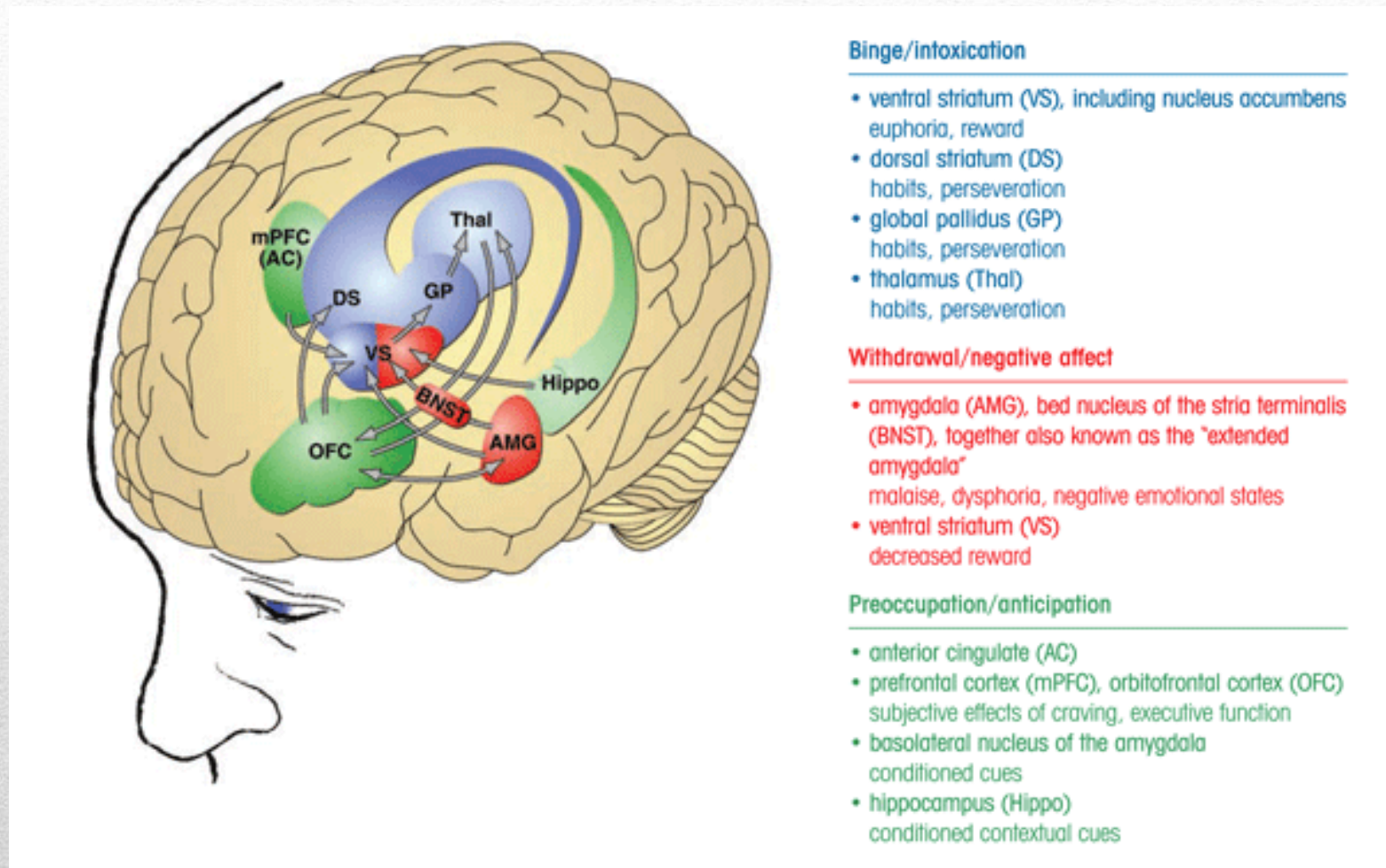
Dr. Nora Volkow on Addiction: A  
Disease of Free Will, July 2015  
[www.youtube.com/watch?  
v=X1AEvkWxbLE](http://www.youtube.com/watch?v=X1AEvkWxbLE)



Dr. Nora Volkow  
NIDA Director

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## 3 Stages of the Addiction Cycle

G. Koob, The Potential of Neuroscience to Inform Treatment, NIAAA





The image shows the front cover of the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5). The cover is dark blue with white text. At the top, it says "DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS" in a serif font. Below that, in a smaller font, it says "FIFTH EDITION". The title "DSM-5" is prominently displayed in a large, bold, sans-serif font. Below the title is a large, empty white rectangular box. At the bottom of the cover, it says "AMERICAN PSYCHIATRIC ASSOCIATION" in a small, sans-serif font. The cover is set against a white background, which is itself centered within a larger red rectangular frame.

DIAGNOSTIC AND STATISTICAL  
MANUAL OF  
MENTAL DISORDERS  
FIFTH EDITION

DSM-5

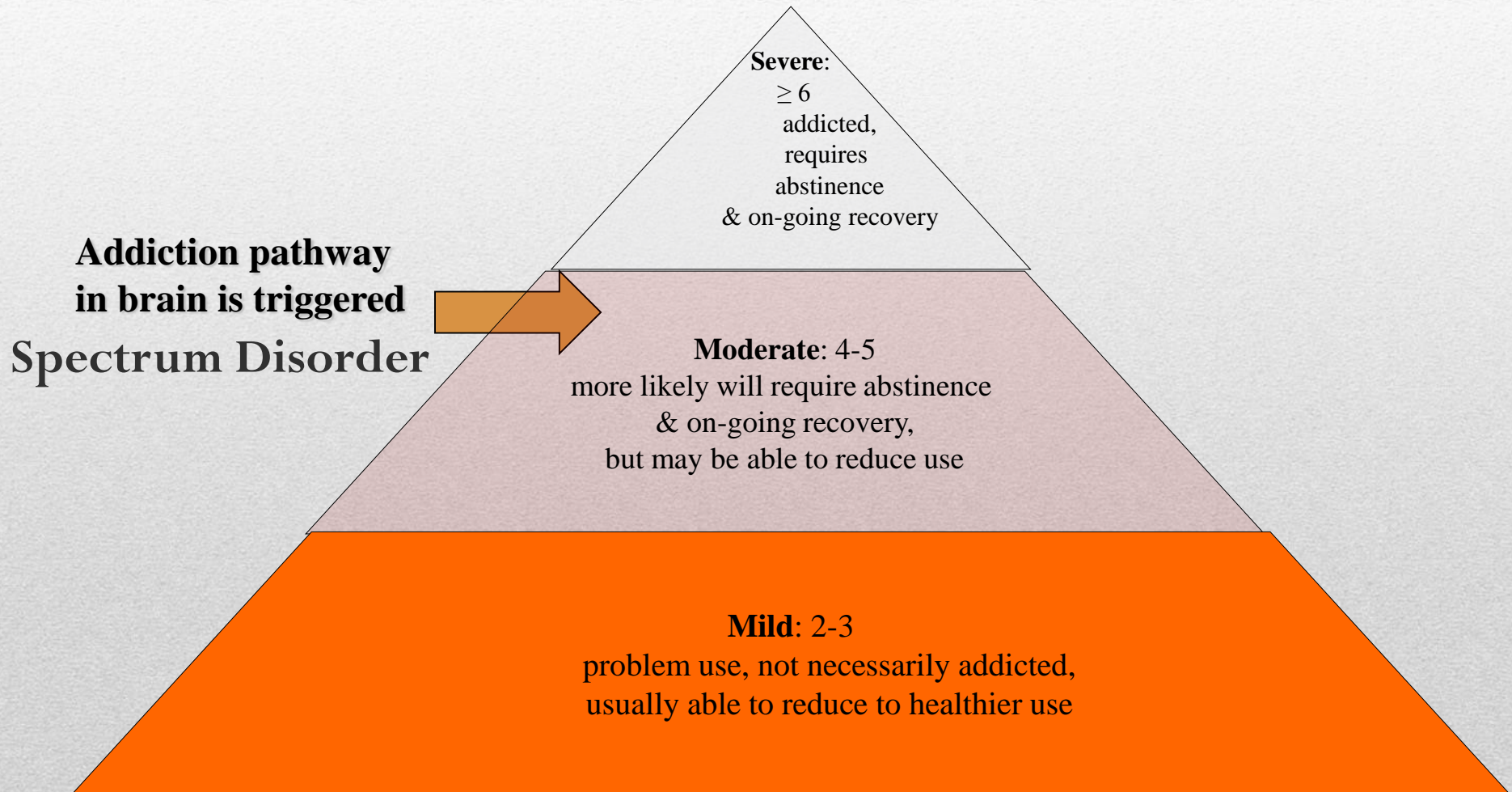
AMERICAN PSYCHIATRIC ASSOCIATION

# DSM 5 CRITERIA

## Alcohol Use Disorder

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# DSM 5: Alcohol/Drug Use Disorder





Impaired Control  
(1-4)

Social  
Impairment  
(5-7)

Risky Use  
(8-9)

Pharmacological  
Criteria  
(10-11)

11 dsm 5 criteria

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# DSM 5: Alcohol Use Disorder Criteria

Within a 12-month period:

- Took more than intended
  - Unsuccessful efforts to cut down
  - Lots of time spent obtaining, using, or recovering
  - Craving
  - Failures to fulfill obligations at work, school, home
  - Use despite social or interpersonal problems
  - Giving up activities because of opioids
  - Use when physically hazardous
  - Use despite negative psych or physical impact
  - Tolerance (not a criteria for opioids)
  - Withdrawal (not a criteria for opioids)
- MILD: 2-3
  - MODERATE: 4-5
  - SEVERE: 6 or more
-



# What are the 4 C's of Addiction?

- Loss of **C**ontrol
  - **C**ompulsive use
  - **C**ontinued use despite harm
  - **C**raving
-

- In the last year:
  - Have you ever drunk or used drugs, including prescription drugs, more than you meant to?
  - Have you felt you wanted or needed to cut down on your drinking or drug use, including prescription drugs?
  - 1 pos answer: 80% sensitivity/specificity
    - Brown, et al. J Am Board Fam Pract 2001.

## Two Item Conjoint Screen: TICS

used in *Screening Brief Intervention & Referral to Treatment (SBIRT)*

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**Single Question Screen**  
(National Institute on Alcohol Abuse and Alcoholism, Variations Exist)

*Question:* How many times in the past year have you had X or more drinks in a day? (X is 5 for men, 4 for women.)

*Scoring:* One or more is considered a positive screen for alcohol misuse.

Score	Sensitivity (95% CI)	Specificity (95% CI)	+LR	−LR
≥1	82% (73%–89%)	79% (73%–84%)	3.9	0.2

**AUDIT-C**

Question	Points				
	0	1	2	3	4
1. How often do you have a drink containing alcohol?	Never	Monthly or less	2–4 times a month	2–3 times a week	4 or more times a week
2. How many drinks containing alcohol do you have on a typical day when you are drinking?	1 or 2	3 or 4	5 or 6	7–9	10 or more
3. How often do you have 6 or more drinks on one occasion?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily

*Scoring:* Points from the 3 questions are summed for a total 0 to 12. A positive screen for alcohol misuse is usually considered ≥4 for men and ≥3 for women but may be adjusted for increased sensitivity or specificity. If patients answer *never* for the first question, scores of 0 can be entered for questions 2 and 3.

Score	Sensitivity	Specificity	+LR (95% CI)	−LR (95% CI)
Men ≥4	0.86	0.89	7.8 (5.5–11.1)	0.16 (0.1–0.2)
Women ≥3	0.73	0.91	7.9 (6.2–10)	0.29 (0.2–0.4)

The full AUDIT questions can be found at the World Health Organization. AUDIT, the alcohol use disorders identification test: guidelines for use in primary care. 2nd ed. Geneva, Switzerland: World Health Organization, Department of Mental Health and Substance Dependence; 2001.

***The DAST-10 survey: These questions refer to the past 12 months. One point is awarded for each “Yes” answer.***

1. Have you used drugs other than those required for medical reasons?	Yes / No
2. Do you abuse more than one drug at a time?	Yes / No
3. Are you unable to stop using drugs when you want to?	Yes / No
4. Have you ever had blackouts or flashbacks as a result of drug use?	Yes / No
5. Do you ever feel bad or guilty about your drug use?	Yes / No
6. Does your spouse (or parents) ever complain about your involvement with drugs?	Yes / No
7. Have you neglected your family because of your use of drugs?	Yes / No
8. Have you engaged in illegal activities in order to obtain drugs?	Yes / No
9. Have you ever experienced withdrawal symptoms (felt sick) when you stopped taking drugs?	Yes / No
10. Have you ever had medical problems as a result of your drug use (e.g., memory loss, hepatitis, convulsions, bleeding)?	Yes / No



## Treatment Effectiveness Assessment (TEA)

The TEA asks you to express the extent of changes for the better from your involvement in the program to this point (or how things are if it's your first TEA or baseline) in four areas: substance use, health, lifestyle, and community. For each area, think about how things have become better and circle the results on the scale below: the more you have improved, the higher the number – from 1 (not better at all) to 10 (very much better). In each area write down the one or two changes most important to you in the Remarks section. Feel free to use the back of this page to add details, explain remarks, and make comments.

**Substance use:** How much better are you with drug and alcohol use? Consider the frequency and amount of use, money spent on drugs, amount of drug craving, time spent being loaded, being sick, in trouble and in other drug-using activities, etc.

None or not much			Better				Much better		
1	2	3	4	5	6	7	8	9	10

Remarks:

**Health:** Has your health improved? In what way and how much? Think about your physical and mental health: Are you eating and sleeping properly, exercising, taking care of health problems or dental problems, feeling better about yourself, etc?

None or not much			Better				Much better		
1	2	3	4	5	6	7	8	9	10

Remarks:

**Lifestyle:** How much better are you in taking care of personal responsibilities? Think about your living conditions, family situation, employment, relationships: Are you paying your bills? Following through with your personal or professional commitments?

None or not much			Better				Much better		
1	2	3	4	5	6	7	8	9	10

Remarks:

**Community:** Are you a better member of the community? Think about things like obeying laws and meeting your responsibilities to society: Do your actions have positive or negative impacts on other people?

No or not much			Better				Much better		
1	2	3	4	5	6	7	8	9	10

Remarks:

# Brief Addiction Monitor

# THE UNITED STATES

We account for:



OF THE GLOBAL  
POPULATION

&



OF THE GLOBAL PRESCRIPTION  
OPIATE CONSUMPTION

## PRESCRIPTION OPIATE SUD

**#3 most abused substance in the U.S.**

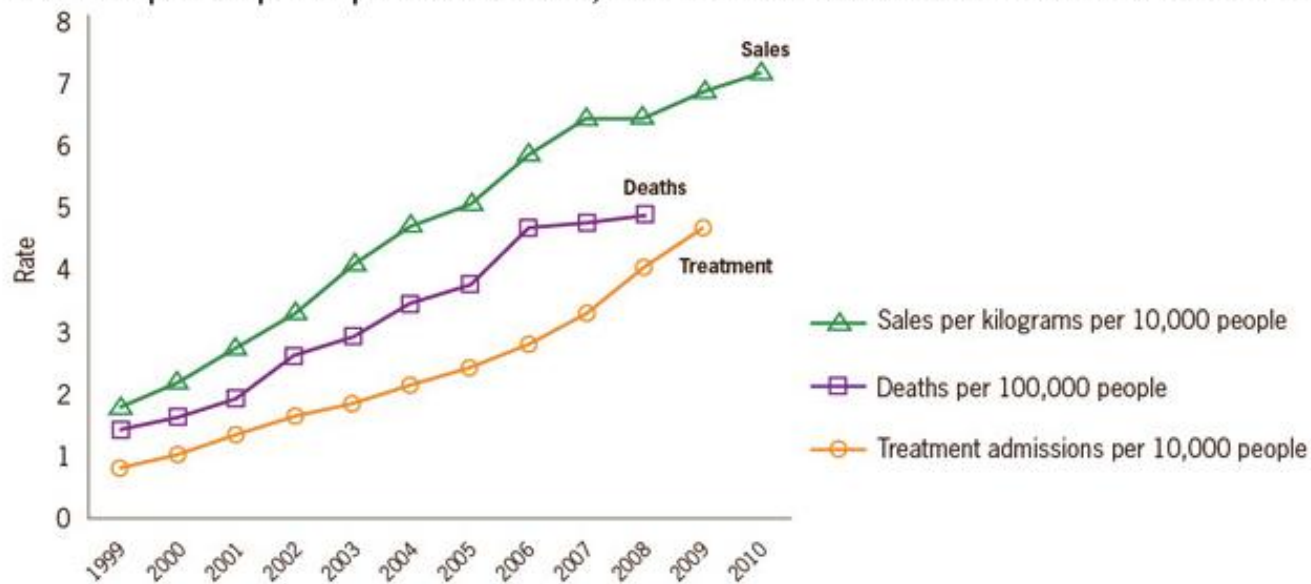
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## 1 Month

Enough prescription painkillers were prescribed in 2010 to medicate every American adult around-the-clock for a month.

Rates of prescription painkiller sales, deaths and substance abuse treatment admissions (1999-2010)



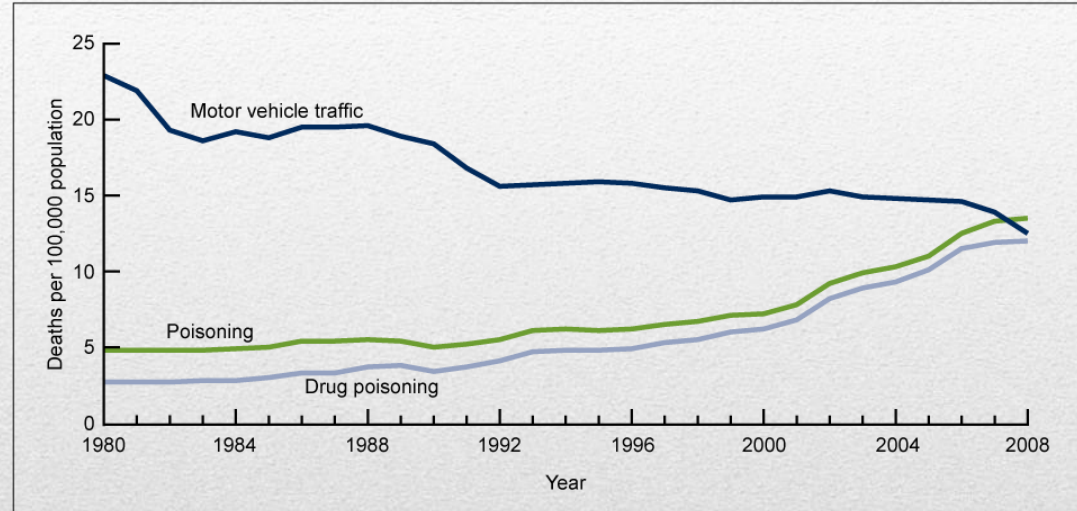
SOURCES: National Vital Statistics System, 1999-2008; Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA), 1999-2010; Treatment Episode Data Set, 1999-2009



Drug overdose was the leading cause of injury & death in 2012 for 25-64 yo. Drug overdose caused more deaths than motor vehicle traffic crashes.

Centers for Disease Control and Prevention. Web-based Injury Statistics Query and Reporting System (WISQARS) [online]. (2014) Available from URL: <http://www.cdc.gov/injury/wisqars/fatal.html>.

Figure 1. Motor vehicle traffic, poisoning, and drug poisoning death rates: United States, 1980–2008

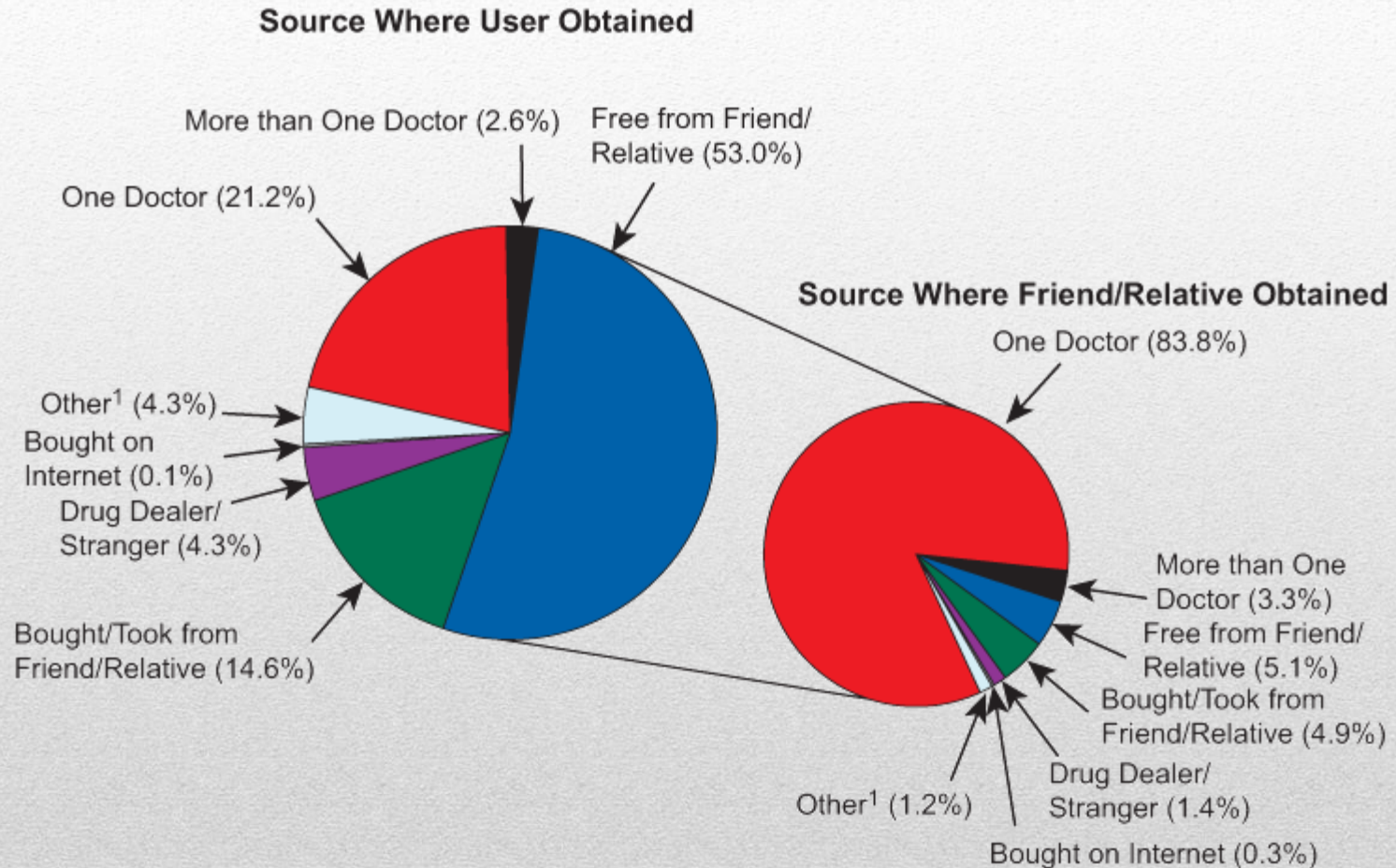


NOTE: In 1999, the *International Classification of Diseases, Tenth Revision (ICD-10)* replaced the previous revision of the ICD (ICD-9). This resulted in approximately 5% fewer deaths being classified as motor-vehicle traffic-related deaths and 2% more deaths being classified as poisoning-related deaths. Therefore, death rates for 1998 and earlier are not directly comparable with those computed after 1998. Access data table for Figure 1 at [http://www.cdc.gov/nchs/data/databriefs/db81\\_tables.pdf#1](http://www.cdc.gov/nchs/data/databriefs/db81_tables.pdf#1).

SOURCE: CDC/NCHS, National Vital Statistics System.



## Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older: 2012-2013



She gets her hair  
from her mom.

Her eyes from her dad.

And her drugs  
from her grandma's  
medicine cabinet.

70% of children who abuse prescription drugs get  
them from family or friends. Prevent your children from  
abusing your own medication by securing your meds in  
places your child cannot access.

**BE AWARE. DON'T SHARE.**

For more information, go to [www.lockyourmeds.org](http://www.lockyourmeds.org).



**Tell pts w/ abusable  
prescription meds  
to lock them up!**



35% of primary care pts have chronic  
non-cancer pain (CNCP)

opioids are the most  
commonly prescribed treatment

Morasco J Pain 2011 March, Fleming J Pain 2007 July

Are opioids the optimal  
treatment for CNCP ?

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- Weak evidence that pts w/ CNCP who continued on opioids long-term (> 6 months) experienced significant pain relief
  - But not clear if function or quality of life was improved
- Some evidence short-term efficacy (for both pain and function) of opioids to treat CLBP compared to placebo
- No placb-RCTs supporting the effectiveness and safety of long-term opioid therapy for treatment of CLBP

**NO**

Cochrane Reviews 2010 & 2013

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Addiction:  
Substance Use Disorder

Prescription Drug Misuse

Aberrant Medication-Taking Behaviors  
A spectrum of patient behaviors  
that *may* reflect misuse

Total Chronic Pain Population

Chronic opioid therapy (COT)  
may worsen pain experience:

- 1. Tolerance
- 2. Intermittent withdrawal
- 3. Hyperalgesia



Sweating: Over Past 1/2 Hour not Accounted for by Room Temperature or Patient Activity		
0 = no report of chills or flushing	• 3 = beads of sweat on brow or face	
1 = subjective report of chills or flushing	• 4 = sweat streaming off face	
2 = flushed or observable moistness on face		
Restlessness Observation During Assessment		
0 = able to sit still	• 3 = frequent shifting or extraneous movements of legs/arms	
1 = reports difficulty sitting still, but is able to do so	• 5 = Unable to sit still for more than a few seconds	
Pupil Size		
0 = pupils pinned or normal size for room light	• 2 = pupils moderately dilated	
1 = pupils possibly larger than normal for room light	• 5 = pupils so dilated that only the rim of the iris is visible	
Bone or Joint Aches if Patient was Having Pain Previously, only the Additional Component Attributed to Opiate Withdrawal is Scored		
0 = not present	• 2 = patient reports severe diffuse aching of joints/muscles	
1 = mild diffuse discomfort	• 4 = patient is rubbing joints or muscles and is unable to sit still because of discomfort	
Runny Nose or Tearing Not Accounted for by Cold Symptoms or Allergies		
0 = not present	• 2 = nose running or tearing	
1 = nasal stuffiness or unusually moist eyes	• 4 = nose constantly running or tears streaming down cheeks	
GI Upset: Over Last 1/2 Hour		
0 = no GI symptoms	• 3 = vomiting or diarrhea	
1 = stomach cramps	• 5 = multiple episodes of diarrhea or vomiting	
2 = nausea or loose stool		

COWS Clinical Opioid  
withdrawal scale



- Normal for opiates, benzodiazepines, barbituates, others
- Reduction in response to a given dose after repeated administration
- Brain neuroadapts to incoming drugs to maintain homeostasis
- Results in need for increasing doses to maintain equipotent analgesic effects
  - Koob, Le Moal Annu Rev Psychol 2008

## **Tolerance and Withdrawal (W/D)**

---

- Tolerance may paradoxically activate a pro-nociceptive mechanism that counteracts opioid analgesia
  - Pain scores reported higher in COT pts than in matched pts without opioid treatment
  - Pain sensitivity is increased in opioid SUDs and with methadone maintenance treatment
    - Mao J, Psych Annals, 2006, Curr Pain Headach Rep. 2006, Am J of Psych, 2006

## Hyperalgesia:

## Opioids May Worsen Pain

---



# Other Opioid Side Effects

- Acetaminophen toxicity with combo
  - Nausea and constipation
  - Psychomotor compromise w/ increase risk of falls
  - Methadone QT prolongation
  - Increased sleep disturbances
  - Mood impairment
  - Decreased testosterone, estrogen, cortisol, others
  - Hyposexuality
  - Immuno-compromise due to NK cell impairment, etc.
  - Drug interactions: ex. inhibit opioid metabolism
    - Pain Physician 2008
-

# Opioid Risk Tool (ORT): method to risk-stratify and deliver appropriate care

		Mark Each Box That Applies	Score if Female	Score if male
1. Family History of Substance Abuse	<input type="checkbox"/> Alcohol <input type="checkbox"/> Illegal Drugs <input type="checkbox"/> Prescription Drugs		1 2 4	3 3 4
2. Personal History of Substance Abuse	<input type="checkbox"/> Alcohol <input type="checkbox"/> Illegal Drugs <input type="checkbox"/> Prescription Drugs		3 4 5	3 4 5
3. Age (Mark Box if 16-45 years)			1	1
4. History of Preadolescence Sexual Abuse			3	0
5. Psychological Disease	<input type="checkbox"/> Attention-Deficit/Hyperactivity Disorder; <input type="checkbox"/> Obsessive Compulsive Disorder; <input type="checkbox"/> Bipolar Disorder; <input type="checkbox"/> Schizophrenia <input type="checkbox"/> Depression		2 1	2 1

Total Score \_\_\_\_\_ Risk Category \_\_\_\_\_

**Low Risk 0-3: 6% chance of developing problematic behaviors**

**Moderate Risk 4-7: 28% chance ...**

**High Risk >7: >90% chance ...**

Webster & Webster, Pain Med. 2005.



**Low Risk:** follow up every 3 months, managed by PCP, routine CURES, urine drug screen, annual review of pain agreement

**Medium Risk:** Past history of SUD, but not actively addicted; PCP with consultant or review committee support, monthly visits, more frequent monitoring including pill counts

**High Risk:** Patient actively addicted/abusing; unstable major psychiatric disorder; should be in narcotic treatment program, or managed by PCP with buprenorphine and behavioral health treatment

- Adapted from Gourlay, et al 2005, 2009

# **Approach to monitoring depends on risk level**

---

## **What are the risk factors for prescription opioid induced SUD?**

- a. Personal hx of substance abuse**
  - b. Hx of sexual abuse**
  - c. Age less than 45**
  - d. Hx of psychiatric illness**
  - e. All of the above**
-



**Compared to CNCP pts without SUDs, CNCP pts with SUDs are:**

- a. Less likely to be treated with opioids**
- b. More likely to be treated with opioids**
- c. More likely to have restricted early refills**
- d. A & C**
- e. B & C**

**40.3% vs 26.2%**

---

## Behaviors May or May Not Be consistent with SUD?

R/o opioid misuse due to opioid adaptation or pain under treatment

- Express desperation over current sx's
    - Aggressively asks providers to provide more opiates
    - Repeated requests for early refills
    - Doctor shopping
  - Uses more meds than prescribed
    - Hoards meds
    - Taken someone else's meds
  - Use MJ, smokes cigs, drinks to help with pain
  - Resistant to integrated pain care
  - Some adverse consequences related to use (family, work, health)
  - Ever used opioids to treat other symptoms: rule out other psychiatric diagnoses
-



## Loss of control of use and much adverse consequences related to use

- Frequent “lost prescriptions”
- Shows no concern about opioid side-effects or interest in integrative care approaches
- Preoccupation with obtaining prescription opioids for other than analgesia
  - R/o self-tx for untreated dual diagnosis
- Seen multiple providers w/o disclosure
  - Check CURES Physician Drug Monitoring Program (PDMP)
- Injecting oral medication
  - Check for skin signs
- Associated with illegal activities
  - Prescription theft and forgery
  - Stole drugs from other
  - Illegal buying
  - Prostitution to get drugs or money to buy drugs
  - Theft to get money to buy drugs

- Fishman, Responsible Opioid Prescribing, Federation of State Medical Boards, Miotto, et al. Psychiatr Clin N Am 35 (2012)

## Behaviors Highly consistent with SUD

---



- Opiate Replacement Therapy (ORT)
  - Suboxone
  - Methadone
- Help families and pts to understand this
  - Compare to thyroid replacement therapy
- Why?
  - Likely chronic endogenous opioid deficiency
    - Need chronic opioid receptor occupation (other opiates don't do this)
  - Acute WD can be managed
  - PAWS drives relapse

# Best Evidence-Based Treatment for Opioid SUD

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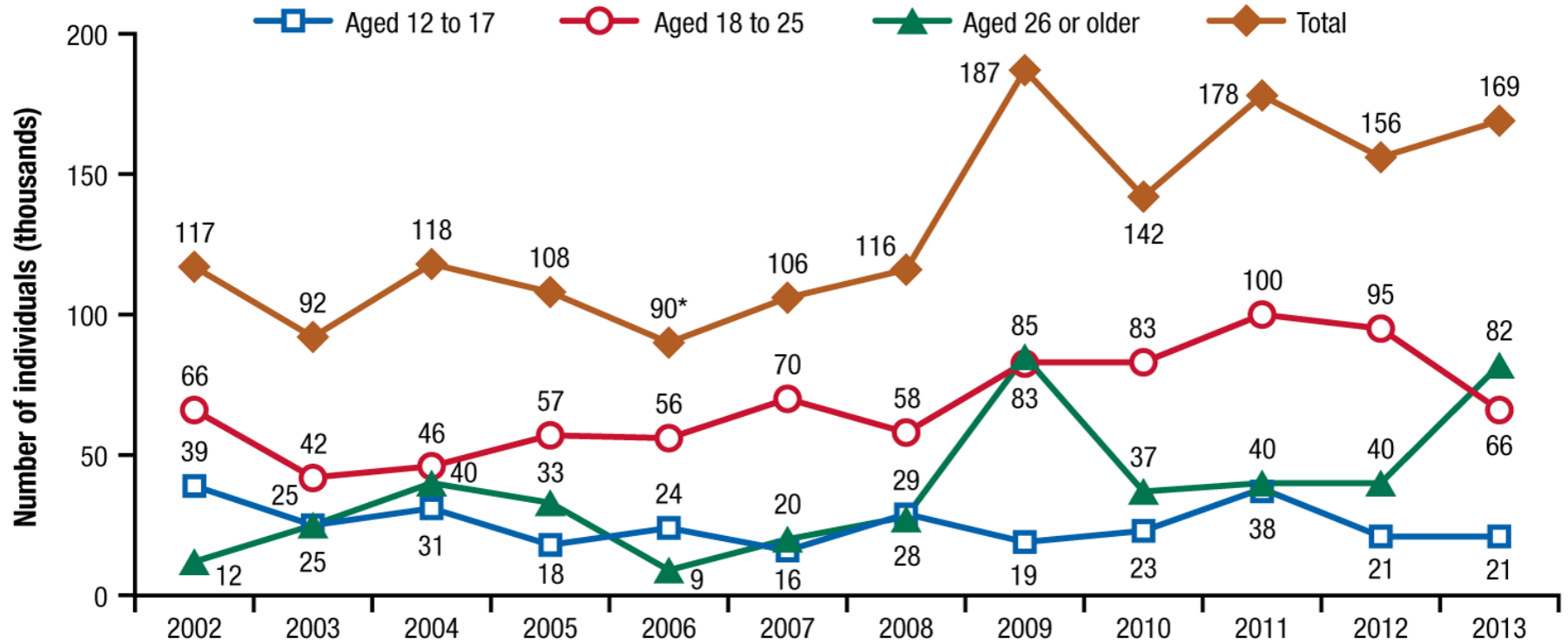
- Anxiety/Depression
- Sleep disturbances
- Fatigue
- Dysphoria/Irritability
- Decreased ability to focus on a task
- Deficits in executive control
- **Can mimic:**
  - **Mood disorder**
  - **Sleep disorder**
  - **ADHD**

Post Acute WD Syndrome (PAWS):  
Opioids

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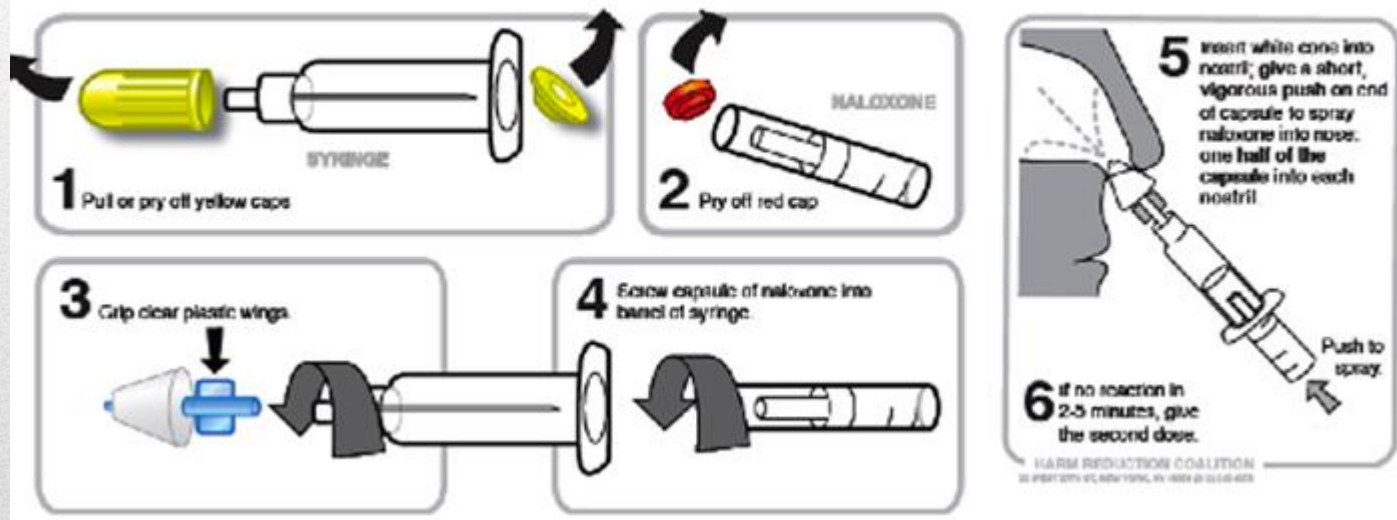


## Past year initiation of heroin among individuals aged 12 or older, by age group: 2002 to 2013

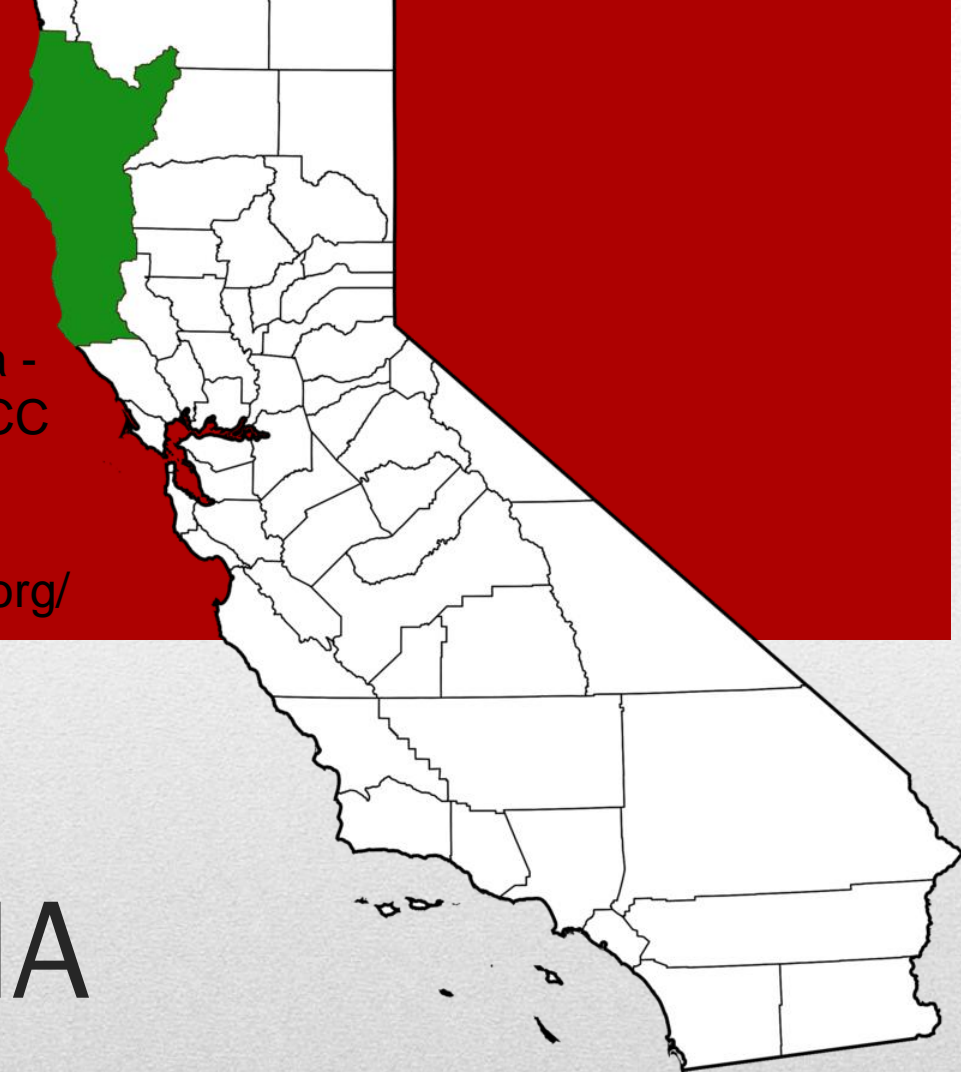




## HOW TO GIVE NASAL SPRAY NARCAN



# Naloxone Saves Lives



"Emerald Triangle" by O'Dea -  
Own work. Licensed under CC  
BY-SA 3.0 via Wikimedia  
Commons -  
[https://commons.wikimedia.org/  
wiki/](https://commons.wikimedia.org/wiki/)

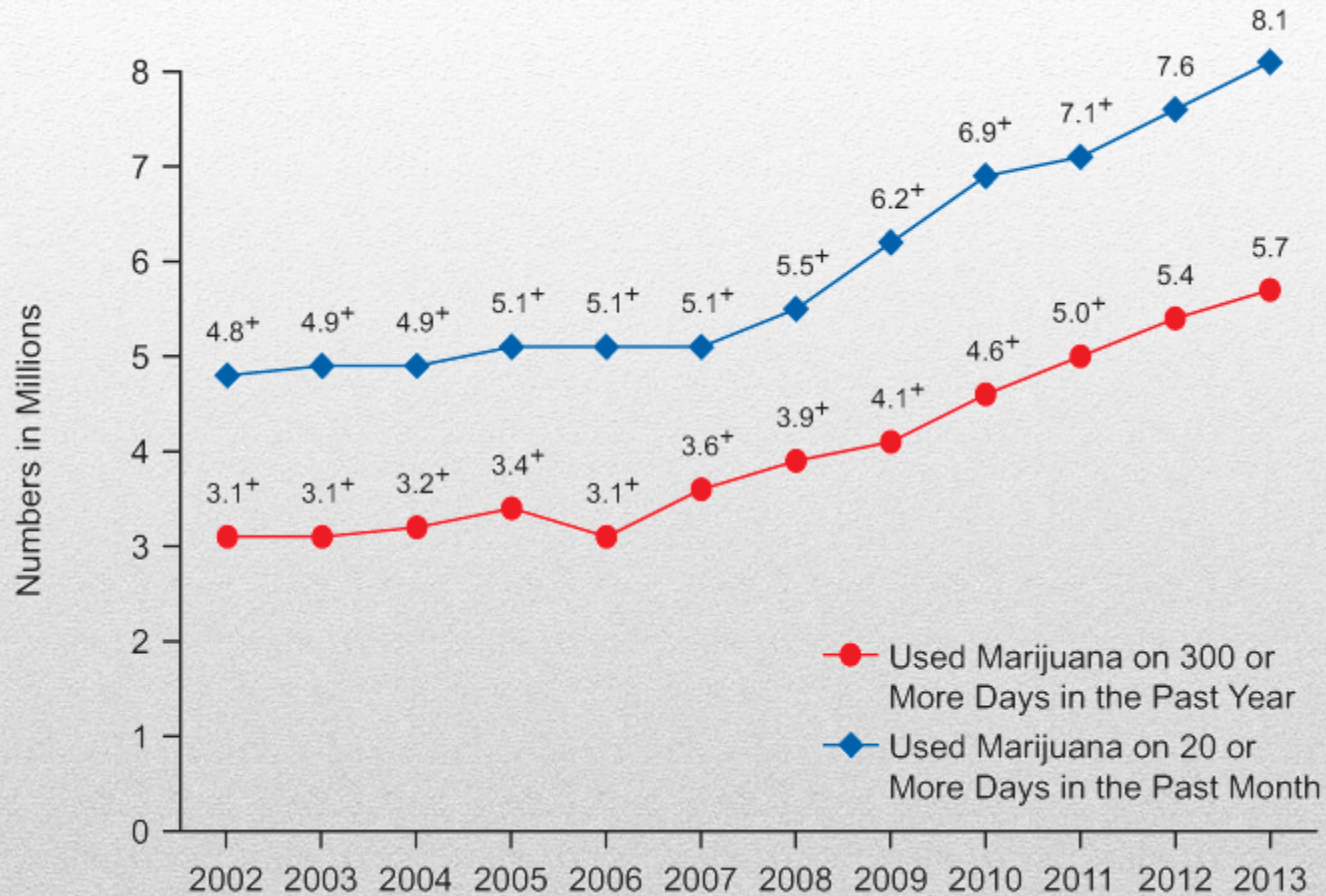
# MARIJUANA

**#2 most abused substance in the U.S.**

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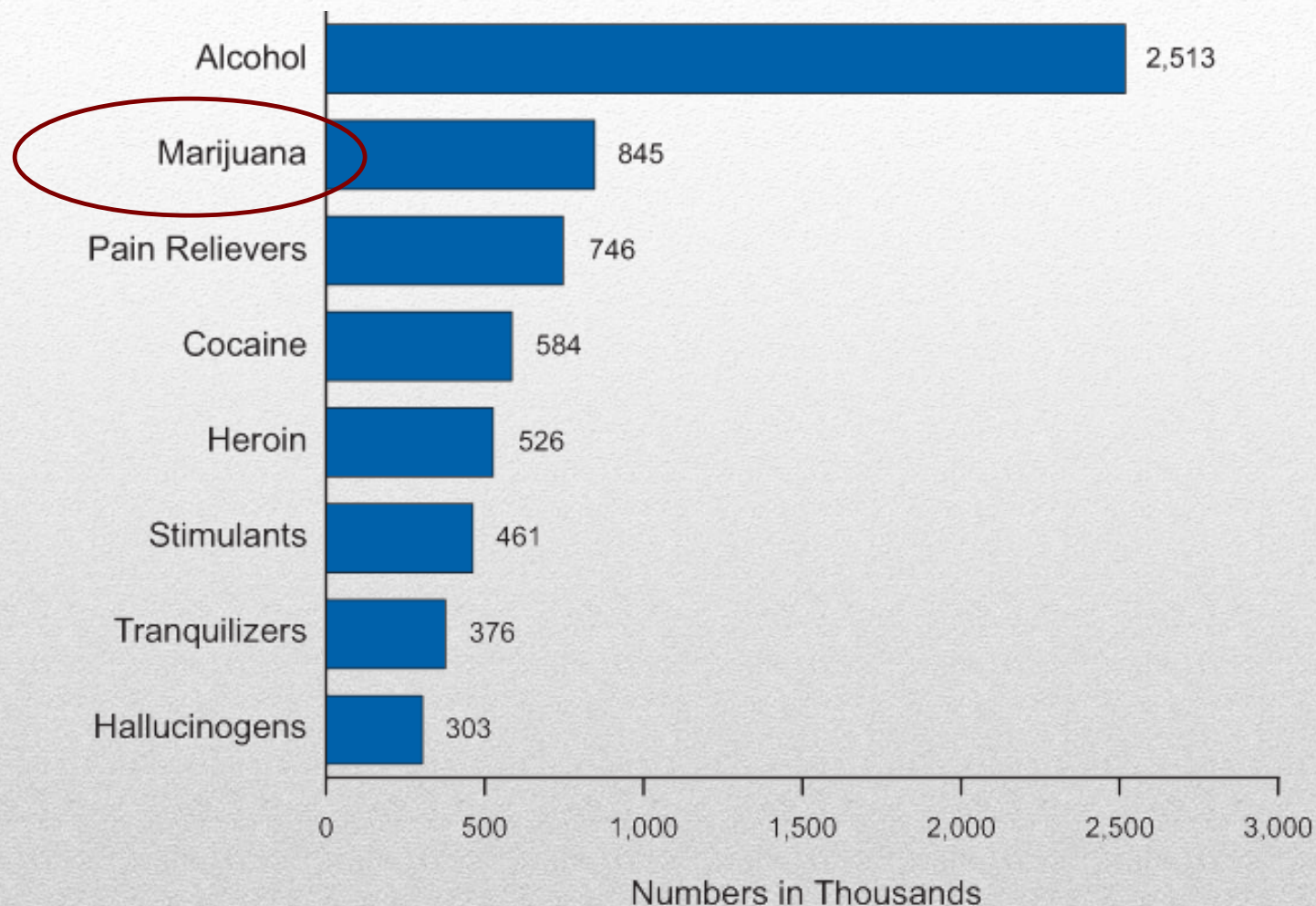


## Daily or Almost Daily Marijuana Use in the Past Year and Past Month among Persons Aged 12 or Older: 2002-2013





## Substances for Which Most Recent Treatment Was Received in the Past Year among Persons Aged 12 or Older: 2013



## Endocannabinoids

neuromodulators scattered throughout the brain and spinal cord

**CB1:** in brain & spinal cord

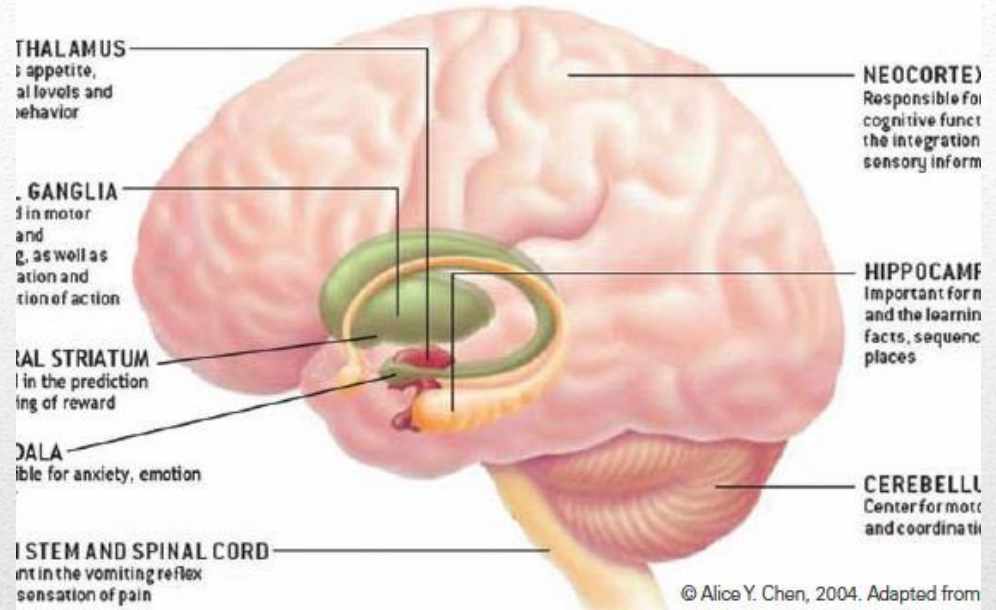
**CB2:** in immune system

## Intoxication Symptoms:

Euphoria, psychosis, impaired memory & cognition, reduced locomotor function, increased appetite, antiemetic, antispasmodic, sleep-promoting, anti-anxiety, pain-relieving

Koppel, et al, Neurology 2014

## Marijuana's Effects on the Brain



When marijuana is smoked, its active ingredient, THC, travels throughout the body, including the brain, to produce its effects. It attaches to sites called cannabinoid receptors on nerve cells in the brain, affecting the way those cells function. These receptors are abundant in parts of the brain that regulate movement, coordination, learning and memory, as well as functions such as judgment, and pleasure.

NIDA website

# Why we like 'weed' & not hay?



- MJ contains > 60 pharmacologically active cannabinoids
  - Primary cannabinoids in MJ
    - THC (tetrahydrocannabinol)
      - Euphoria
      - Psychosis
    - Cannabidiol
      - Not psychoactive
      - Possible anti-anxiety & anti-psychotic
  - THC:Cannabidiol ratio engineered to achieve desired effects
    - Pertwee, Br J Pharmacology 2006
    - Hill, JAMA 2015



# Weed is Not Oregano

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# Neurotoxic Effect of MJ on Youth

- Dunedin prospective study: n=1037. Neuropsych testing done at 13 yo (before cannabis initiation) and again at age 38 yo (after persistent cannabis use, at least 4d/wk).
    - 8 point drop in IQ, even if quit in adulthood
    - Persistent use was associated with neuropsych decline broadly across domains of functioning, even after controlling for years of education
    - Persistent use interfered with everyday cognitive functioning
    - Among adolescent former persistent users, impairment was still evident after cessation of use for 1 y or more
    - Suggest a neurotoxic effect of cannabis on the adolescent brain and highlight the importance of prevention and policy efforts targeting adolescents
      - Meier et al, Proc Natl Acad Sci U S A. 2012
-

- CUDIT-R

- Scores of  $\geq 13$  identify DSM-5 moderate and severe CUD
- $\geq 13$  demonstrated significantly greater psychological distress and poorer physical and mental health functioning
  - NIDA: Screening for DSM-5 cannabis dependence using the Cannabis Use Identification Test–Revised
  - CUDIT-R: Adamson et al. Drug and Alcohol Dependence 2010

# Cannabis Use Disorder Identification Test

---



**Have you used any cannabis over the past six months? YES / NO**

**If YES**, please answer the following questions about your cannabis use. Circle the response that is most correct for you in relation to your cannabis use *over the past six months*

1. How often do you use cannabis?
 

Never	Monthly or less	2-4 times a month	2-3 times a week	4 or more times a week
0	1	2	3	4
2. How many hours were you "stoned" on a typical day when you had been using cannabis?
 

Less than 1	1 or 2	3 or 4	5 or 6	7 or more
0	1	2	3	4
3. How often during the past 6 months did you find that you were not able to stop using cannabis once you had started?
 

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
0	1	2	3	4
4. How often during the past 6 months did you fail to do what was normally expected from you because of using cannabis?
 

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
0	1	2	3	4
5. How often in the past 6 months have you devoted a great deal of your time to getting, using, or recovering from cannabis?
 

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
0	1	2	3	4
6. How often in the past 6 months have you had a problem with your memory or concentration after using cannabis?
 

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
0	1	2	3	4
7. How often do you use cannabis in situations that could be physically hazardous, such as driving, operating machinery, or caring for children:
 

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
0	1	2	3	4
8. Have you ever thought about cutting down, or stopping, your use of cannabis?
 

Never	Yes, but not in the past 6 months	Yes, during the past 6 months
0	2	4

*This scale is in the public domain and is free to use with appropriate citation:*



## Mood:

- Irritability
- Anxious or worried
- Depressed
- Restless
- Insomnia and fatigue
- Low appetite or losing weight

## Physical Symptoms:

- Stomach pain
- Sweatiness
- Shakiness
- Fever
- Chills
- Headache

- NIDA

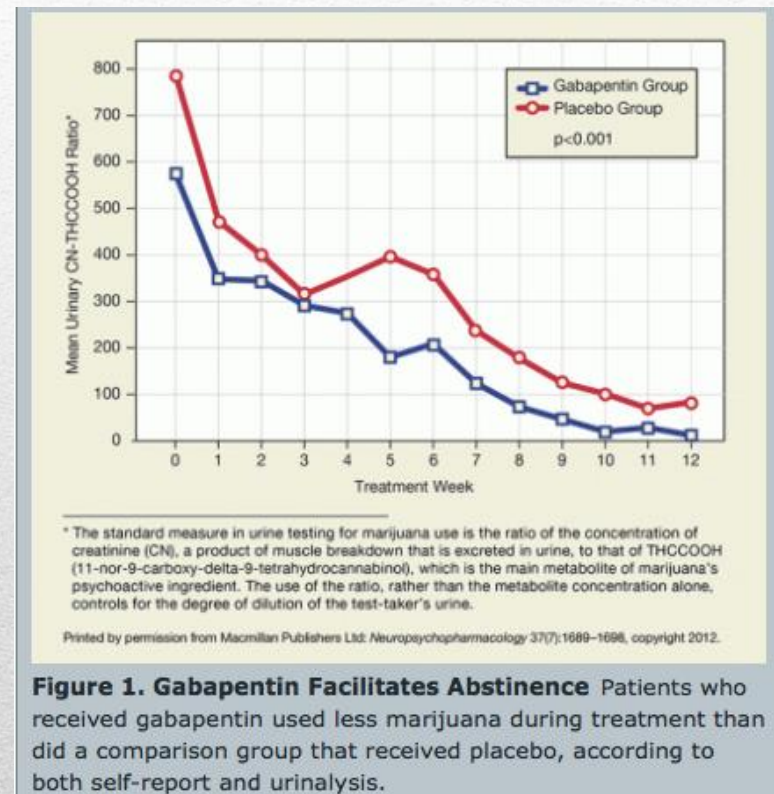
# Marijuana Withdrawal Symptoms

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# Gabapentin Treatment for CUD

Treated with gabapentin in a pilot RCT DBP x 12 wks, tapered up to 300/300/600:

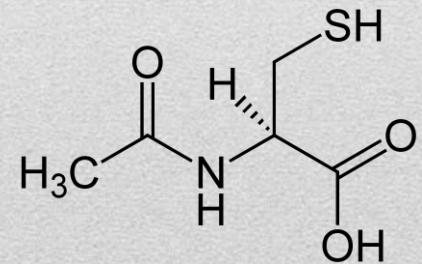
- Reduced use more
- Reported fewer symptoms of drug withdrawal
- Showed sig greater improvement in overall performance on tests of executive function
  - Mason et al. Neuropsychopharm 2012





OTC supplement *N*-acetylcysteine works via glutamate modulation in the nucleus accumbens

- RCT DBP x 8 wks CUD adolescents (ages 15-21 years; N=116) received NAC (1200 mg bid)
  - Included contingency rewards & brief counseling
- Participants receiving NAC had more than twice the odds, compared with those receiving placebo, of having negative urine cannabinoid test results during treatment
- NAC was well tolerated, with minimal adverse events



## NAC Treatment for CUD

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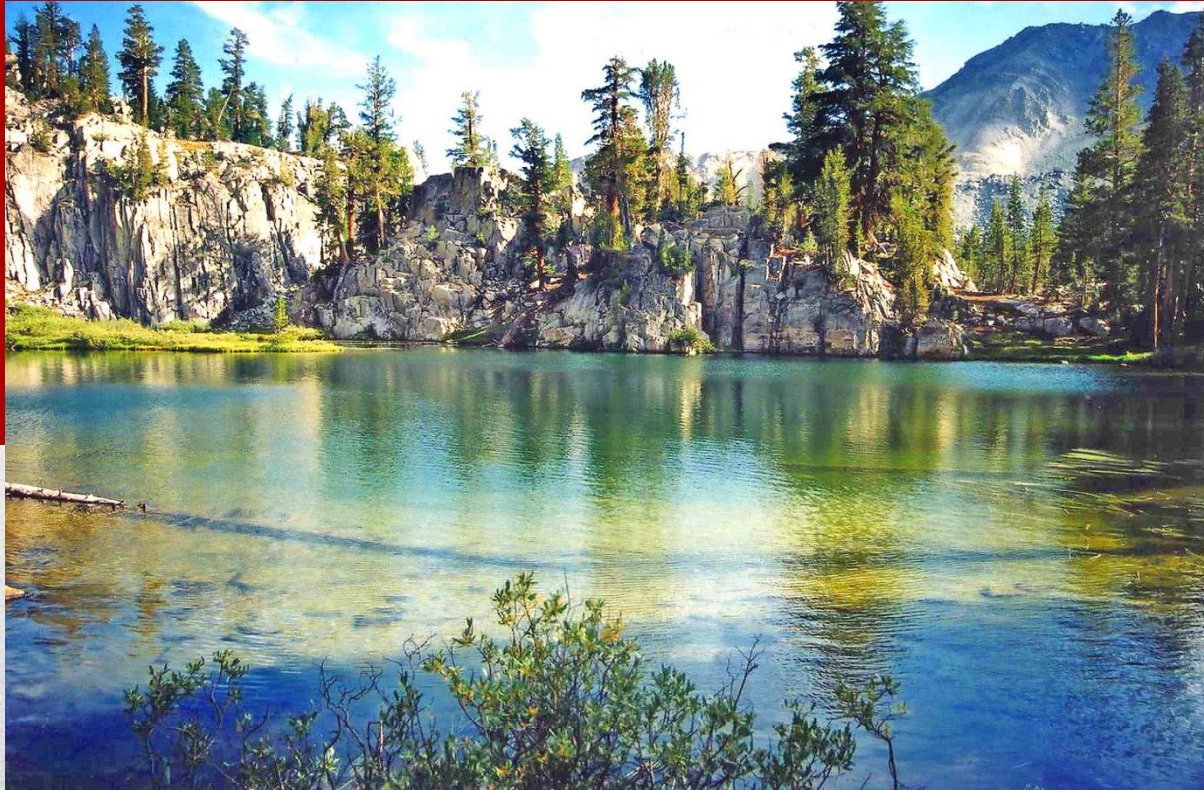


- References:
  - Hill, JAMA 2015
  - American Academy of Neurology, Neurology 2014
- FDA approved:
  - Dronabinol & nabilone
    - N/V due to cancer chemotherapy
    - Appetite stimulation in wasting illness
  - Best RCT evidence for:
    - MS spasticity
    - Chronic pain
    - Neuropathic pain

# MJ Medical Uses ?







**BREAK**  
15 minutes

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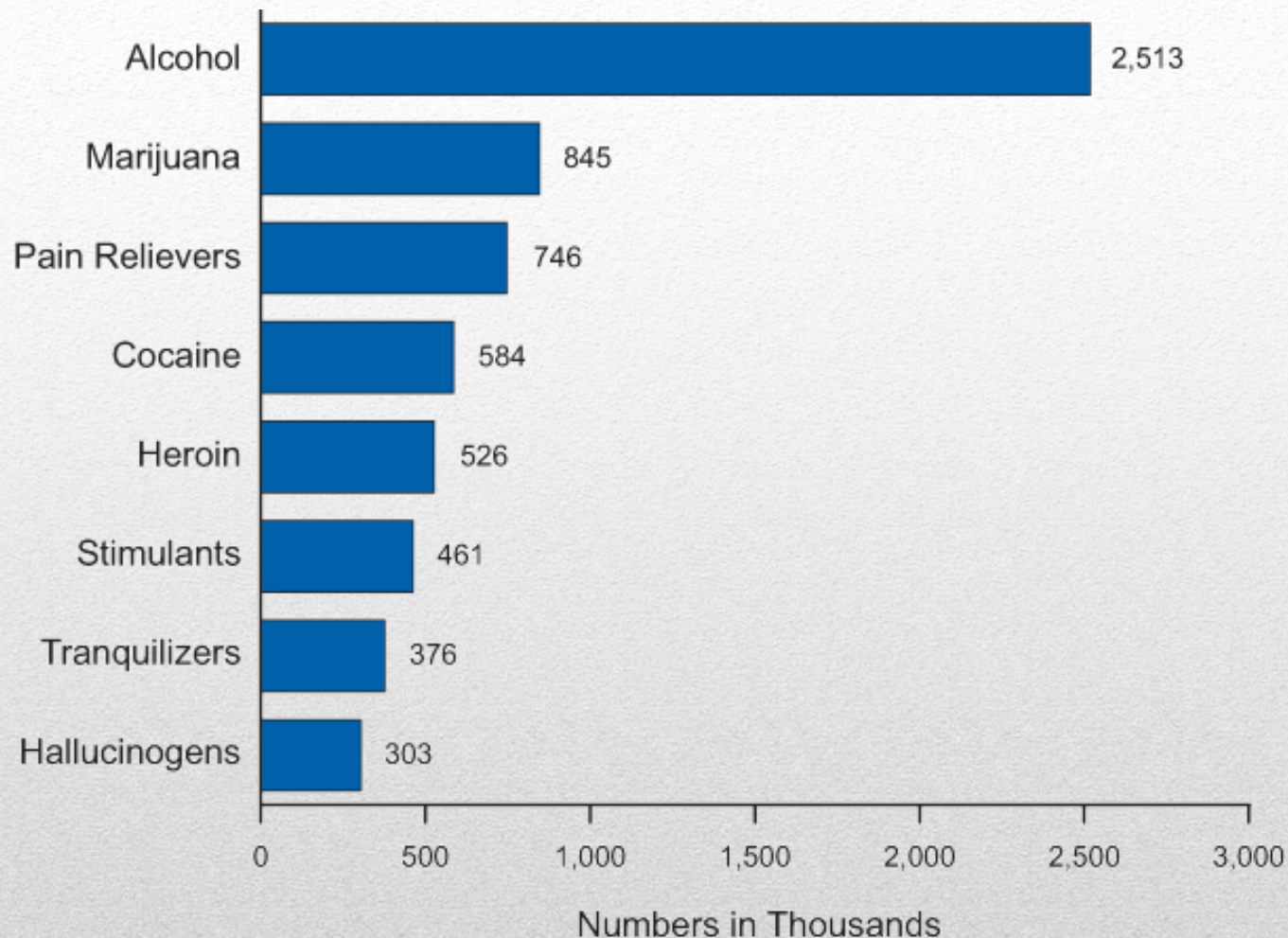


# ALCOHOL

**#1 most abused substance in the U.S.**

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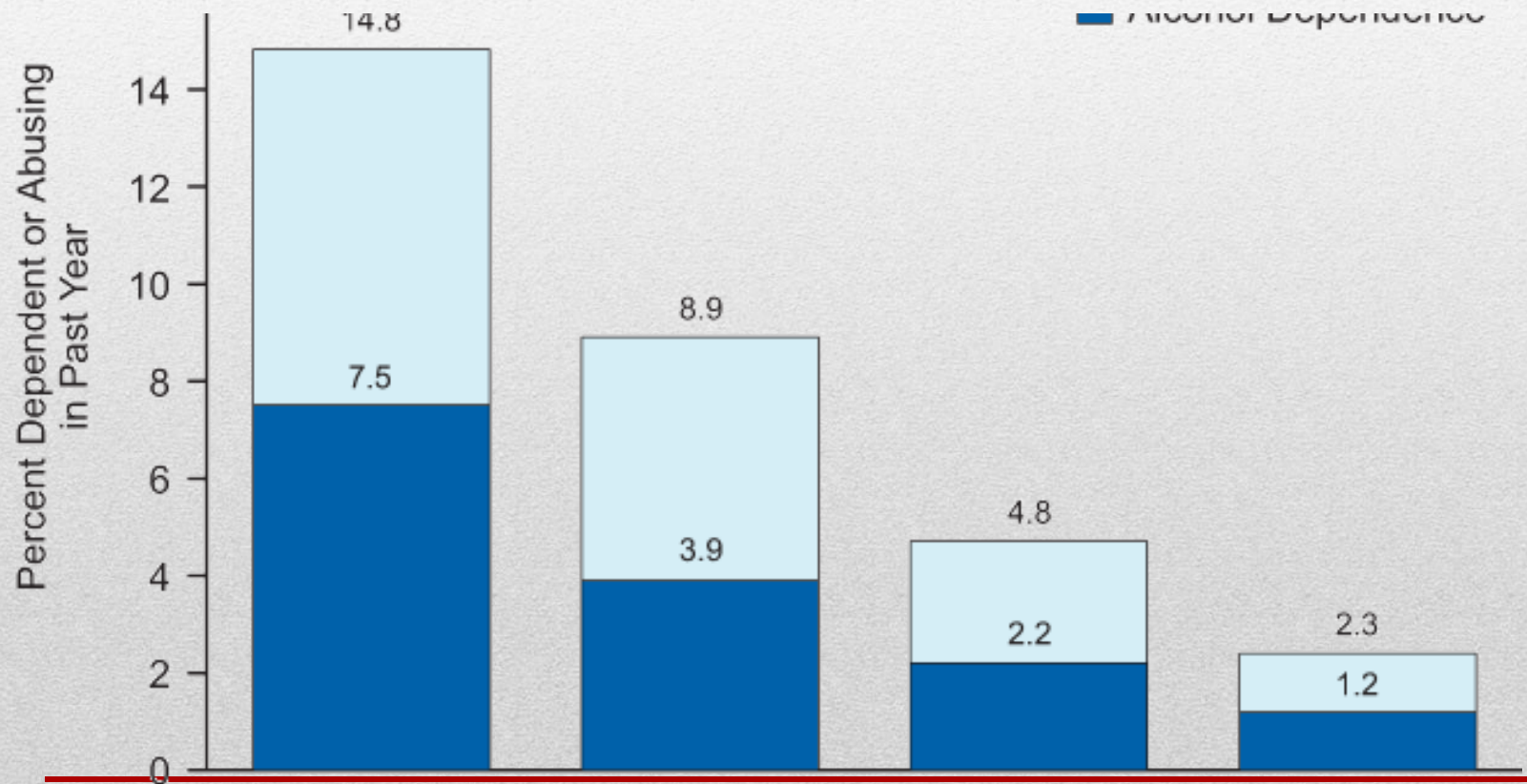


**Substances for Which Most Recent Treatment Was Received in the Past Year: 2013**

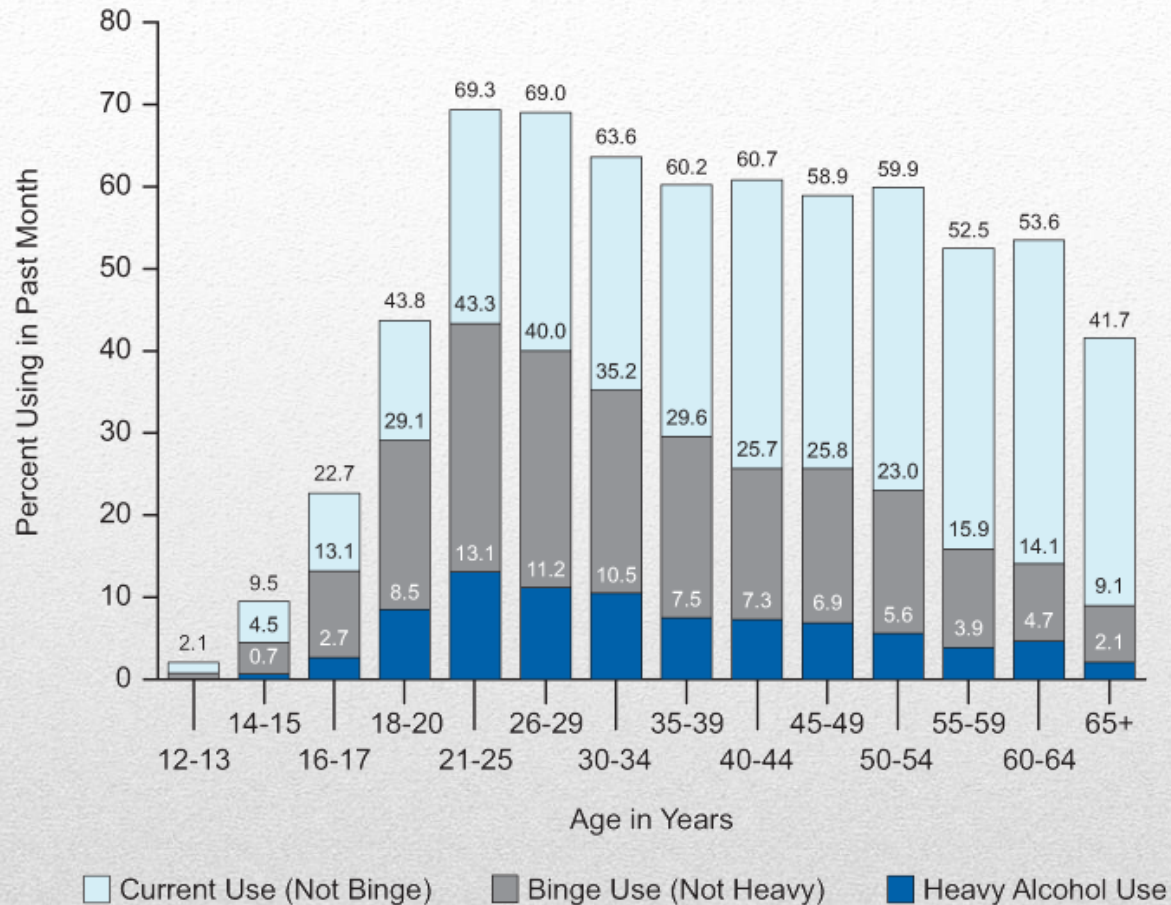
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# Alcohol Dependence or Abuse in the Past Year among Adults Aged 21 or Older, by Age at First Use of Alcohol: 2013

NSDUH 2013, SAMHSA







## Current, Binge, and Heavy Alcohol Use: 2013

---



# ETOH & Brain Reward Circuits

- Dopamine system
    - Indirectly increases DA in mesocorticolimbic system
      - Positively reinforces & rewards ETOH's effects
      - Makes ETOH addictive
  - Opioid system
    - Indirectly activates the opioid system
      - Reinforces the effects of mu-receptors
      - Creates a 'buzz' high
  - GABA system
    - Increases GABA + inhibits glutamate: inhibitory system
      - Decreases anxiety, increases sedation
-

# ETOH Biomarkers

## R/O Denial

- Elevated MCV + GGT: 95% sensitive for abuse
    - GGT elevated 24 hrs to 2 wks after heavy ETOH use
      - Nml = 0-45 females, 0-53 males
    - Returns to nml within 2-6 wks of abstinence
    - Detects binge drinking
  - AST:ALT ratio  $>2:1$  = 90% chance of ALD
  - Elevated GGT + AST:ALT  $>2:1$  = 95% sensitive for abuse
-





Alcohol Screening, Brief Intervention,  
and Referral to Treatment

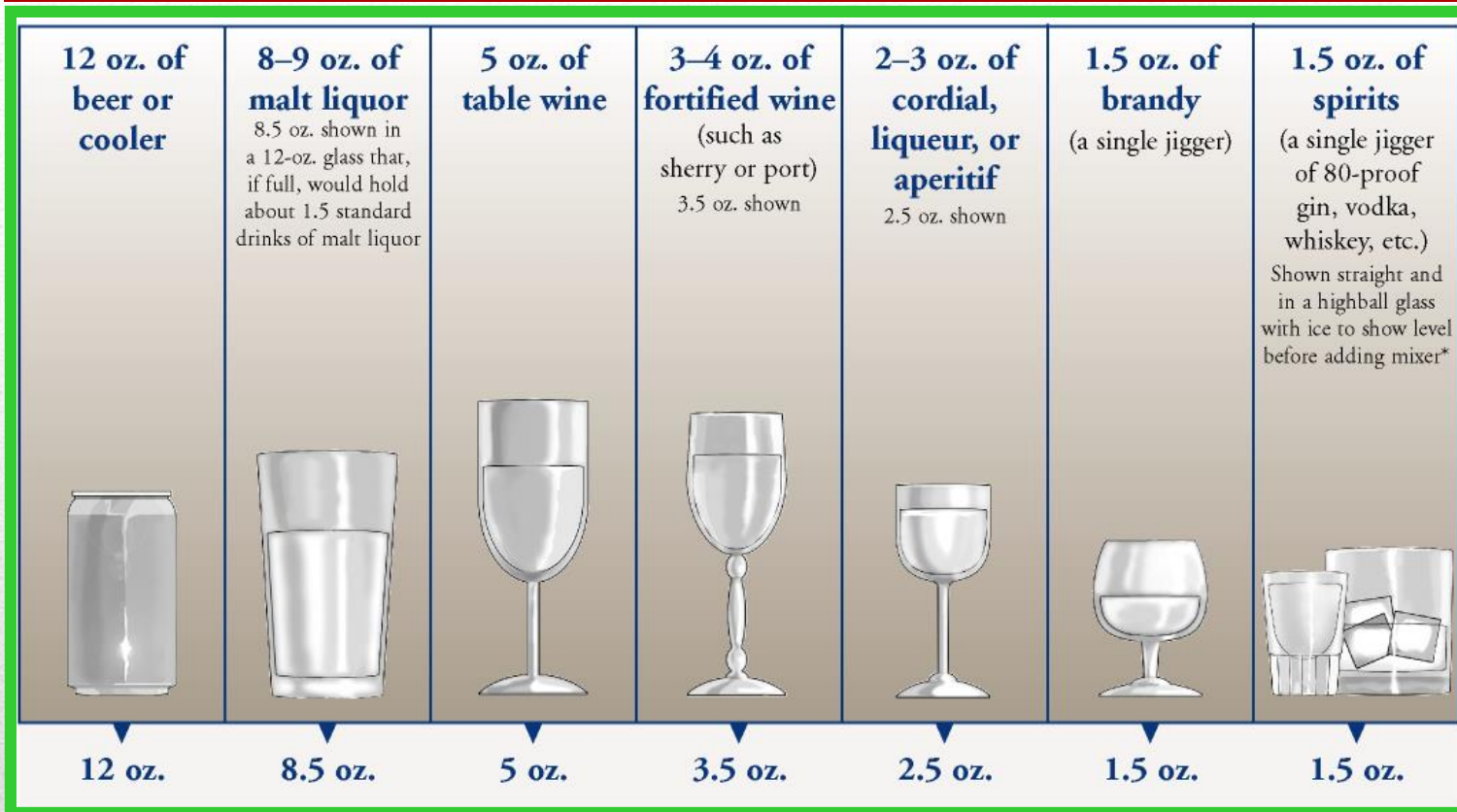
# SBIRT Screening

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# SBIRT Treatment Outcomes

- At risk drinkers
    - Identified
    - Given education and Brief MI
    - Reduce drinking by 25% over following year
  - Dependent drinkers (similar across studies & treatment modalities)
    - 1/3 remission x 1 yr
      - Abstinence or non-abstinence remission
    - 1/3 will show substantial improvement, but have some heavy drinking episodes
    - 1/3 will show no effect
    - Relapse occurs in most over ensuing 5-10 yrs
-



## What's a Standard Drink?

In the U.S., a standard drink is any drink that contains about 14 grams of pure alcohol

---



I KNEW I COULD  
CUT DOWN TO  
ONE DRINK A DAY!





**For healthy men up to age 65—**

- no more than 4 drinks in a day AND
- no more than 14 drinks in a week

**For healthy women**

**(and healthy men over age 65)—**

- no more than 3 drinks in a day AND
- no more than 7 drinks in a week

# **Maximum ‘Healthy’ Drinking Limits**

---

- “How many times in the past year have you had X or more drinks in a day?”
  - X is 5 for men and 4 for women, and a response of  $>1$  is considered positive
    - 81.8% sensitive and 79.3% specific for the detection of unhealthy alcohol use
    - 87.9% sensitive and 66.8% specific for the detection of a current AUD
      - Smith, et al. J Gen Intern Med. 2009 July; 24(7): 783–788.

## **1-Item Saitz question (recommended by the NIAAA)**

---



# Alcohol Medication Treatment

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- Ask about past WD sx's
- Use a CIWA-Ar ([www.pcbehavioralhealth.com](http://www.pcbehavioralhealth.com))
  - 0-8 No medication is necessary
  - 9-14 Medication is optional
  - A score of 15 or over requires meds
    - Consider hospitalization

# Outpatient Alcohol Withdrawal

---

Patient: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

Pulse or heart rate, taken for one minute: \_\_\_\_\_ Blood pressure: \_\_\_\_/\_\_\_\_

**Nausea and vomiting.** Ask "Do you feel sick to your stomach? Have you vomited?"

Observation:

- 0—No nausea and no vomiting
- 1—Mild nausea with no vomiting
- 2—
- 3—
- 4—Intermittent nausea with dry heaves
- 5—
- 6—
- 7—Constant nausea, frequent dry heaves, and vomiting

**Tremor.** Ask patient to extend arms and spread fingers apart.

Observation:

- 0—No tremor
- 1—Tremor not visible but can be felt, fingertip to fingertip
- 2—
- 3—
- 4—Moderate tremor with arms extended
- 5—
- 6—
- 7—Severe tremor, even with arms not extended

**Paroxysmal sweats**

Observation:

- 0—No sweat visible
- 1—Barely perceptible sweating; palms moist
- 2—
- 3—
- 4—Beads of sweat obvious on forehead
- 5—
- 6—
- 7—Drenching sweats

**Anxiety.** Ask "Do you feel nervous?"

Observation:

- 0—No anxiety (at ease)
- 1—Mildly anxious
- 2—
- 3—
- 4—Moderately anxious or guarded, so anxiety is inferred
- 5—
- 6—
- 7—Equivalent to acute panic states as occur in severe delirium or acute schizophrenic reactions

**Agitation**

Observation:

- 0—Normal activity
- 1—Somewhat more than normal activity
- 2—
- 3—
- 4—Moderately fidgety and restless
- 5—
- 6—
- 7—Paces back and forth during most of the interview or constantly thrashes about

**Tactile disturbances.** Ask "Do you have you any itching, pins-and-needles sensations, burning, or numbness, or do you feel like bugs are crawling on or under your skin?"

Observation:

- 0—None
- 1—Very mild itching, pins-and-needles sensation, burning, or numbness
- 2—Mild itching, pins-and-needles sensation, burning, or numbness
- 3—Moderate itching, pins-and-needles sensation, burning, or numbness
- 4—Moderately severe hallucinations
- 5—Severe hallucinations
- 6—Extremely severe hallucinations
- 7—Continuous hallucinations

**Auditory disturbances.** Ask "Are you more aware of sounds around you? Are they harsh? Do they frighten you? Are you hearing anything that is disturbing to you? Are you hearing things you know are not there?"

Observation:

- 0—Not present
- 1—Very mild harshness or ability to frighten
- 2—Mild harshness or ability to frighten
- 3—Moderate harshness or ability to frighten
- 4—Moderately severe hallucinations
- 5—Severe hallucinations
- 6—Extremely severe hallucinations
- 7—Continuous hallucinations

**Visual disturbances.** Ask "Does the light appear to be too bright? Is its color different? Does it hurt your eyes? Are you seeing anything that is disturbing to you? Are you seeing things you know are not there?"

Observation:

- 0—Not present
- 1—Very mild sensitivity
- 2—Mild sensitivity
- 3—Moderate sensitivity
- 4—Moderately severe hallucinations
- 5—Severe hallucinations
- 6—Extremely severe hallucinations
- 7—Continuous hallucinations

**Headache, fullness in head.** Ask "Does your head feel different? Does it feel like there is a band around your head?"

Do not rate for dizziness or lightheadness; otherwise, rate severity.

- 0—Not present
- 1—Very mild
- 2—Mild
- 3—Moderate
- 4—Moderately severe
- 5—Severe
- 6—Very severe
- 7—Extremely severe

**Orientation and clouding of sensorium.** Ask "What day is this? Where are you? Who am I?"

Observation:

- 0—Orientated and can do serial additions
- 1—Cannot do serial additions or is uncertain about date
- 2—Date disorientation by no more than two calendar days
- 3—Date disorientation by more than two calendar days
- 4—Disorientated for place and/or person

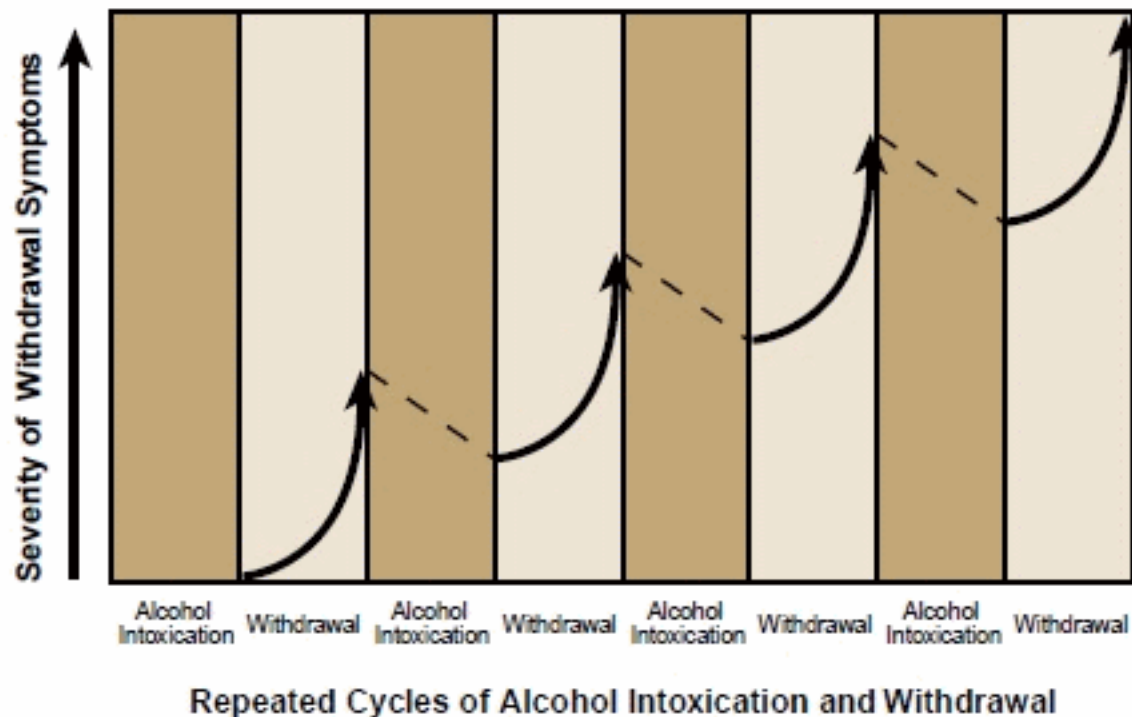
Total score: \_\_\_\_\_ (maximum = 67)

Rater's initials \_\_\_\_\_

### Timing of Alcohol Withdrawal Syndromes

Syndrome	Clinical findings	Onset after last drink
Minor withdrawal	Tremulousness, mild anxiety, headache, diaphoresis, palpitations, anorexia, GI upset	6 to 36 hours
Seizures	Generalized, tonic-clonic seizures, status epilepticus (rare)	6 to 48 hours
Alcoholic hallucinosis	Visual (occasionally auditory or tactile) hallucinations	12 to 48 hours
Delirium tremens	Delirium, tachycardia, hypertension, agitation, fever, diaphoresis	48 to 96 hours





**Figure 1** Graphic representation of the kindling concept during alcohol withdrawal. The term "kindling" refers to the phenomenon that people undergoing repeated cycles of intoxication followed by abstinence and withdrawal will experience increasingly severe withdrawal symptoms with each successive cycle.

## **Double-Blind Trial of Gabapentin vs Lorazepam in the Tx of Alcohol Withdrawal**

**Methods:** 100 individuals seeking opt tx of alcohol withdrawal randomized to double-blind treatment with 2 doses of gabapentin (900 mg tapering to 600 mg or 1200 tapering to 800 mg) or lorazepam (6 mg tapering to 4 mg) for 4 days.

**Results:** CIWA-Ar scores decreased over time in all groups; **high-dose gabapentin was statistically superior but clinically similar to lorazepam.**

During treatment, lorazepam- treated participants had higher probabilities of drinking on the first day of dose decrease (day 2) and the second day off medication (day 6) compared to gabapentin-treated participants. Post-treatment, gabapentin-treated had less probability of drinking during the follow-up post-treatment period ( $p = 0.2$  for 900 mg and  $p = 0.3$  for 1200 mg) compared to the lorazepam-treated participants ( $p = 0.55$ ). **The gabapentin groups also had less craving, anxiety, and sedation compared to lorazepam.**

**Conclusions:** Gabapentin was well tolerated and effectively diminished the symptoms of alcohol withdrawal in our population especially at the higher target dose (1200 mg) used in this study. Gabapentin reduced the probability of drinking during alcohol withdrawal and in the immediate postwithdrawal week compared to lorazepam.

---



# The COMBINE Study

## **largest alcohol treatment to date**

- **RCT: 2001- 2004, 1383 recently alcohol-abstinent volunteers (median age, 44 years) with primary alcohol dependence.**
  - **Interventions: 8 groups received management with 16 weeks of naltrexone (100 mg/d) or acamprosate (3 g/d), both, and/or both placebos, with or without a combined behavioral intervention (CBI). A ninth group received CBI only (no pills). Patients were also evaluated for up to 1 year after treatment.**
  - **Main Outcome Measures: Percent days abstinent from alcohol and time to first heavy drinking day.**
    - *JAMA. 2006;295*
-



- All 9 groups had a substantial reduction in days of drinking
- The patient groups who demonstrated the best drinking outcomes after 16 weeks received:
  - Naltrexone with medical management (MM) counseling alone (no specialty CBI)
  - Or received specialty CBI with placebo pills and MM counseling
  - No advantage found for adding acamprosate either to MM or CBI
- This acamprosate result is puzzling, given the many European studies that have reported an acamprosate effect (over placebo) for maintaining abstinence from alcohol.

## Results of the COMBINE Study

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# Naltrexone

- Mechanism: opioid antagonist
    - Blocks ETOH's euphoric effect
    - Limits heavy drinking relapse
    - Limits craving
  - Clinical use
    - Check LFTs
      - May give if mildly elevated
      - Consistent effect is to overall lower LFTs
    - Start after acute ETOH withdrawal
    - Best to start when beginning psychosocial treatment
    - 25 mg and increase after 7d to 50 mg
      - Initial transient S/E's: nausea, HA, dizziness, weakness
-



# Acamprosate

- Mechanism: GABA agonist and NMDA modulator
    - Not metabolized by liver
    - May help maintain abstinence, reduces heavy drinking
      - Prevents relapse, reduced drinking in those who do
    - US COMBINE Study no advantage over placebo
    - European meta-analyses conclusions
      - Modest effect over placebo
      - Effects increased as tx duration increased (3-12 months)
  - Clinical use
    - Check RFTs before use in elderly or renal disease
    - Start after acute ETOH withdrawal
    - Best to start when beginning psychosocial treatment
    - 1998 mg/day (2- 333 mg tabs TID)
      - S/Es: transient diarrhea, bloating, pruritis
-



# Disulfiram (Antabuse)

- Mechanism: Inhibits aldehyde dehydrogenase
    - DER: ingesting ETOH increases acetaldehyde
      - Flushing, palpitations, decreased BP
      - N/V, SOB, dizziness, blurred vision, confusion
      - Severe: hypotension, tachy/bradycardia, death
        - >500 mg + >2oz ETOH
        - Reported to occur rarely w/ smaller doses + 1 drink
  - For those highly committed to sobriety
    - Take 250 mg, carry ID
    - Avoid OTC & foods with ETOH
    - Wait 2 wks after d/c for ETOH exposure
  - Side-effects: Hepatotoxicity: monitor LFTs closely. Optic neuritis: watch for visual changes. Peripheral neuropathy
-

- Gabapentin
  - 300-600 bid to tid prn
- Topiramate
  - GABAergic anticonvulsant
  - May improve depressive, anxiety, PTSD and obsessive-compulsive drinking symptoms
  - Positive dbprc study, may get away with 75 mg qhs (taper up slowly)
    - Topiramate for treating alcohol dependence. *JAMA*; 2007;298(14):1641–1651.
    - Treatment of alcohol dependence with low-dose topiramate: an open-label controlled study. *BMC psychiatry*. 2011;11(1):41.
- SSRIs
  - Especially effective if also meet MDD criteria
  - Start with citalopram, taper up to 20 mg
  - Study showed when trazadone stopped for early recovery insomnia, worsened relapse

## Others ... (not FDA approved)

---





# Counseling Approaches

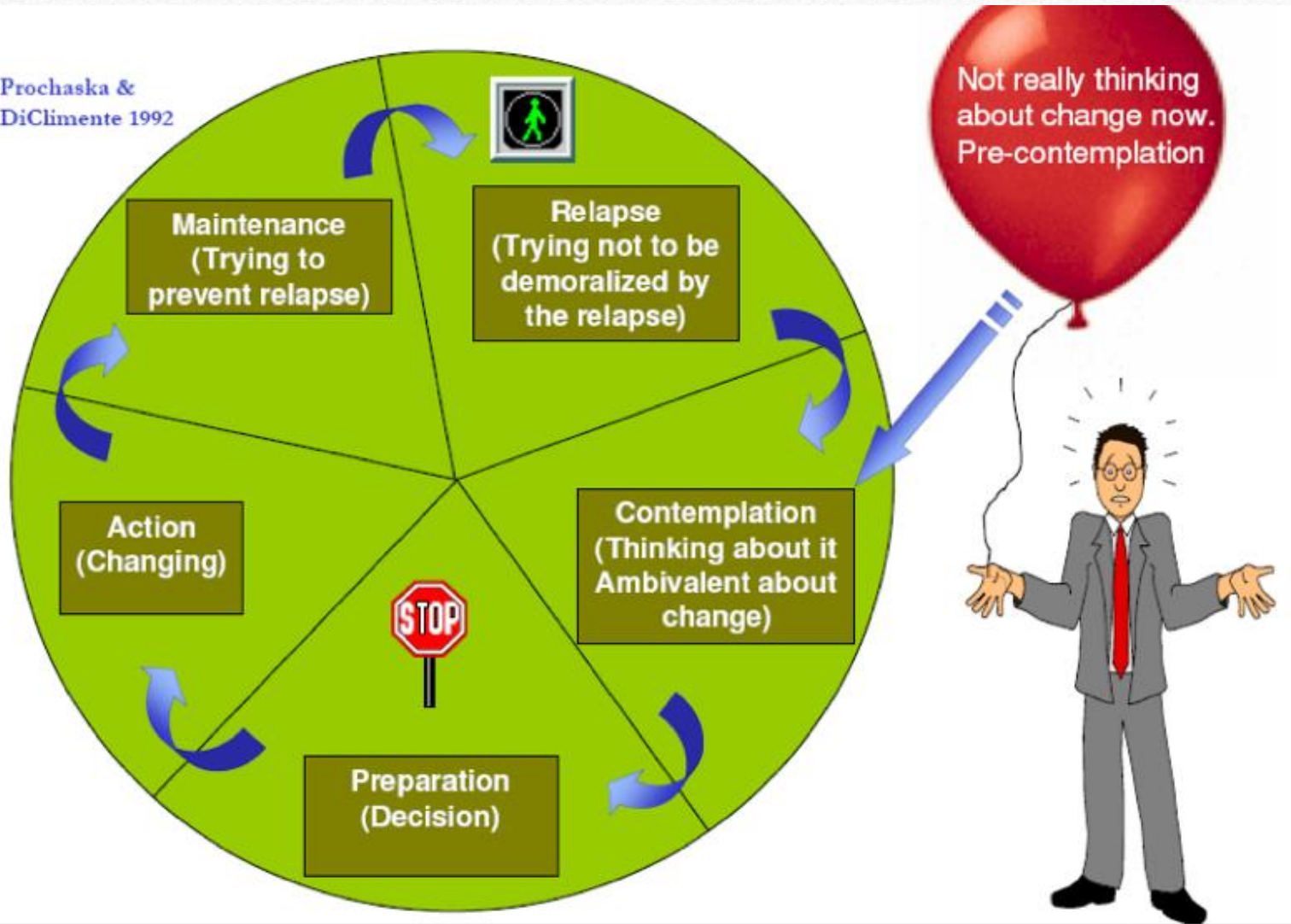
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# Assess Stage Of Change

## “Where are you at with your drinking?”

Prochaska &  
DiClemente 1992

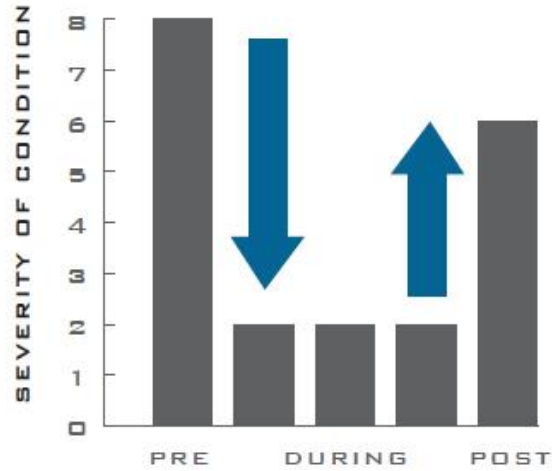


## WHY IS ADDICTION TREATMENT EVALUATED DIFFERENTLY?

BOTH REQUIRE ONGOING CARE

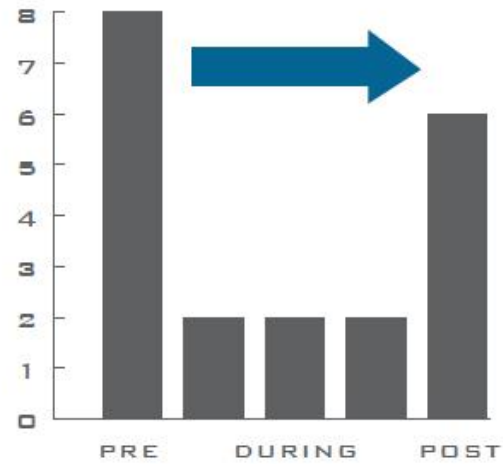
YES!!!

*Hypertension Treatment*



NO???

*Addiction Treatment*

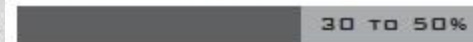


STAGE OF TREATMENT

NIDA: Principles of Drug Addiction Treatment:  
A Research-Based Guide (Third Edition)

*Percentage of Patients Who Relapse*

TYPE 1 DIABETES



DRUG ADDICTION



HYPERTENSION



ASTHMA





## ***Brief MI Strategy***

# **Pros & Cons**

***SBIRT screened positive:***

**Pros first:** “What works for you about...?”

- Repeat using a reflective statement

**Cons second:** “What’s less useful for you about...?”

- Repeat using a reflective statement
- Brings out change talk

**Anything else?**

- End with a summarizing statement
  - May move pt away from denial
-



# ***Brief MI Strategy***

## **Ask-Tell-Ask**

Collaborative way to provide medical feedback and education:

- *Ask*: How much do you know about...
  - *Tell*: Would you mind if I tell you some further info? Or, What happens to some people is that...?
  - *Ask*: How does that fit with your own sense of things? What is your reaction to this information? Where does this leave you?
-

- CBT
  - ETOH, MJ, Cocaine, Meth, Nicotine
- Contingency management/motivational incentives
  - ETOH, stimulants, opioids, MJ, nicotine
- 12-step facilitation
  - ETOH, stimul, opiates
- Family Behavioral Therapy
- MI
  - ETOH, MJ, nicotine
- Matrix Model
  - Stimulants
  - Learn about issues critical to addiction/relapse, direction & support from a therapist, and become familiar with self-help programs. monitored through urine testing.

# Evidence Based Treatments

NIDA

---



- 6 criterion required for establishing causation: (1) magnitude of effect; (2) dose response effect; (3) consistent effect; (4) temporally accurate effects; (5) specific effects; (6) plausibility.
- Evidence for criteria 1, 2, 3, 4 and 6 is very strong
  - Rates of abstinence are about twice as high among those who attend AA (criteria 1, magnitude)
  - Higher levels of attendance are related to higher rates of abstinence (criteria 2, dose response);
  - Prior AA attendance is predictive of subsequent abstinence (criteria 4, temporal)
  - Mechanisms of action predicted by theories of behavior change are present in AA (criteria 6, plausibility)

## Alcoholics Anonymous Effectiveness: Faith Meets Science

Kaskutas, J Addict Dis 2009

---



# Positive AUD/SUD

and pt is at preparation stage of change ...

“Others have found these 3 alternatives helpful, which would work best for you?”

- 12-step alone
  - 12-step plus intensive outpatient treatment
  - 12-step plus residential treatment
  - Other programs in your community
-

# 12 Step Preparation



- What are your concerns?
  - Can someone go with you to a first meeting?
    - You don't have to talk. Just watch.
  - Try a few meetings to find one where you feel socially comfortable
    - Home meeting
    - Action plan to commit to go to one meeting
  - Keep eye out for a “temporary” sponsor
  - Look at it like rehab after a knee replacement
    - Not easy, hard work, but necessary to walk again
-

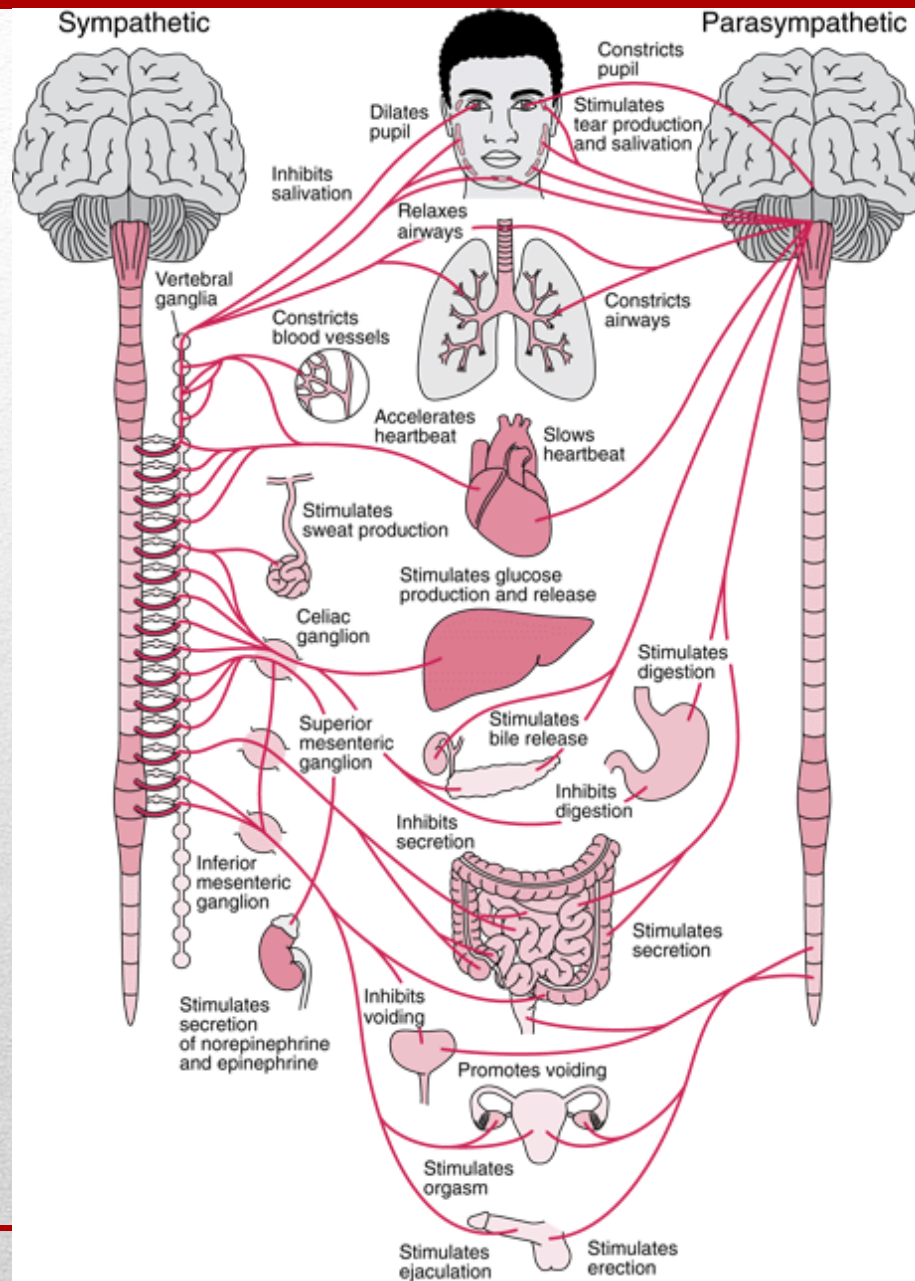


# AUD Integrative Approaches

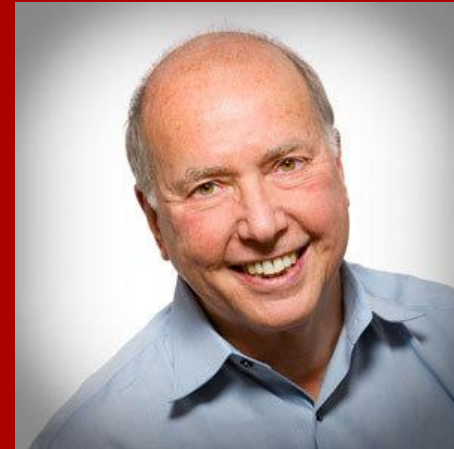
[www.pcbehavioralhealth.com](http://www.pcbehavioralhealth.com)

- Smart Recovery and Life Ring
  - Other 12-Step
    - Adult Children of Alcoholics , Alanon & Alateen
  - Mindfulness-based
    - Refuge Recovery
    - Meditation Centers
  - Auricular acupuncture for cravings
  - Exercise
  - Sleep hygiene
  - Nutrition and supplements
    - B complex & thiamine
    - Vitamin D
    - Fish Oil: 2000 mg EPA
    - Magnesium
    - MVI
    - NAC
-





Thanks to James Gordon MD  
Center for Mind-Body Medicine  
(he credits Stephen Levine for idea)



# SOFT BELLY BREATHING EXERCISE (A BACK POCKET RELAXATION TOOL)

---





# QUESTIONS

15 minutes

---





Lunch

12:00-12:45pm



## Diversion Breakout Session

# Preventing Prescription Drug Diversion

Managing Pain Safely Forum  
January 15, 2016  
Matt Willis, MD MPH



# What is drug diversion?

**Drug diversion:** The transfer of any prescribed controlled substance from the individual for whom it was prescribed to another person.

# Your Experiences

- Have you ever stopped prescribing?
- What were some of the warning signs to make you stop prescribing?
  - What type of diversion were you suspicious of?
- What would have helped you navigate this encounter?

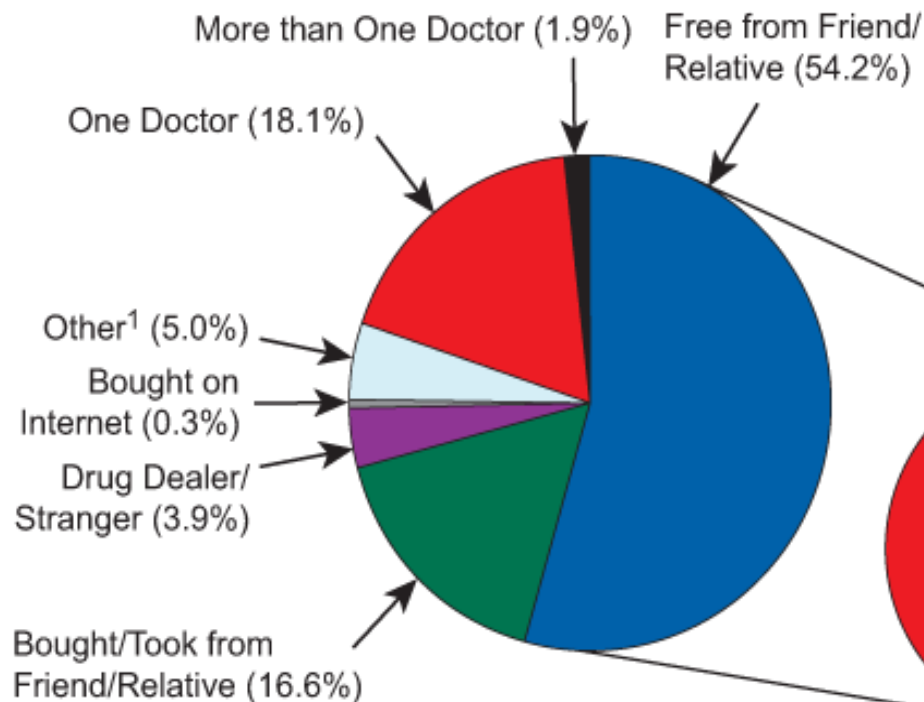
# How are drugs diverted?

- All stages in the “life of the pill” are controlled under law
  - Manufacture, transport, storage, prescription, dispensing, use, disposal
  - All persons with access are specially entrusted
- Diversion can occur at any stage
- Sold, stolen, traded, given away

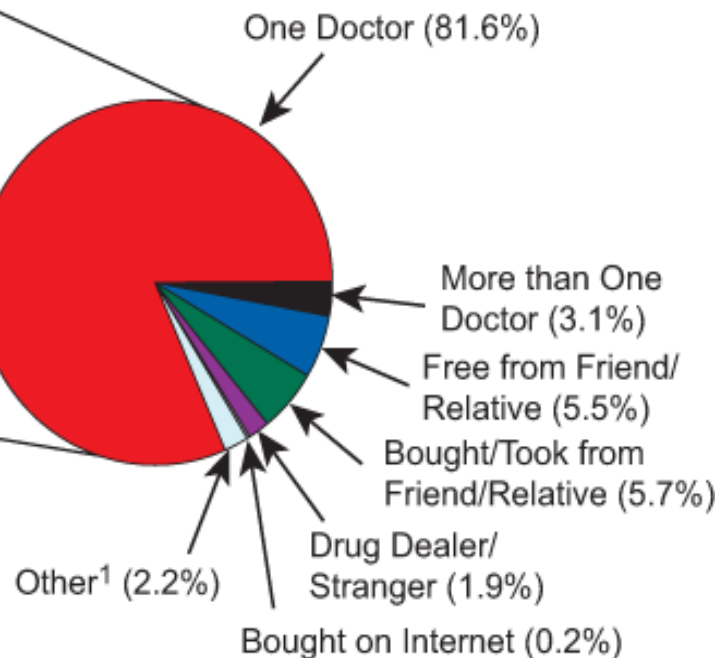


# SOURCES FOR NONMEDICAL USE OF PAIN RELIEVERS

**Source Where User Obtained**



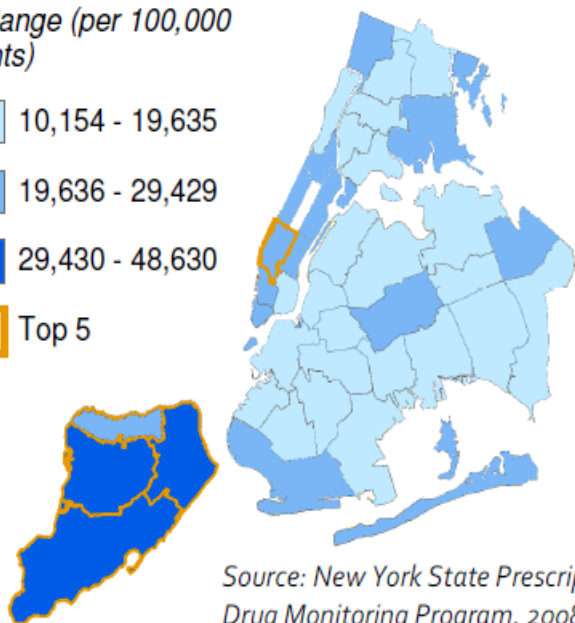
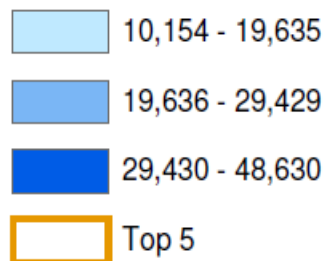
**Source Where Friend/Relative Obtained**



# Neighborhoods with Highest Rates of Opioid Prescriptions Also Have the Highest Rates of Overdose Deaths

## Rates of hydrocodone and/or oxycodone prescriptions filled by NYC neighborhood<sup>5</sup>

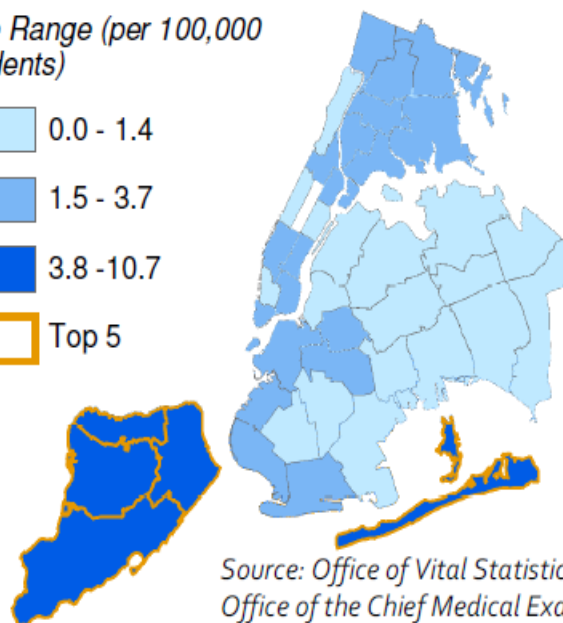
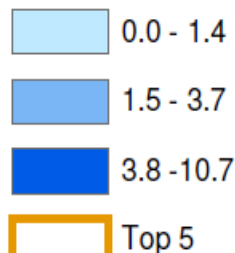
Rate Range (per 100,000 residents)



Source: New York State Prescription Drug Monitoring Program, 2008-2009

## Rates of unintentional opioid analgesic poisoning (overdose) deaths by NYC neighborhood<sup>4</sup>

Rate Range (per 100,000 residents)



Source: Office of Vital Statistics & Office of the Chief Medical Examiner, 2008-2009

**Definitions:** The United Hospital Fund (UHF) classifies NYC into 42 neighborhoods, comprised of contiguous zip codes. Income is defined by the percent of households below 200% of the federal poverty level (Census 2000) and separated into three groups: low-income (43%-70%), medium-income (30%-43%) and high-income (13%-30%). To ensure rate stability, two years of prescription and death data were combined for neighborhood analyses.

Q: What is the approximate street value of an 8 ounce bottle of Promethazine with codeine?

A: +/- \$300

Q: What are some names for cocktails made with promethazine w/ codeine?

A: Purple drank, purple sizzurp





Q: What is a Xanny Bar?

A: Xanax (Alprazolam) 2mg



Q: What is the most popular strength of Oxycodone on the street?

A: 30mg tabs



Q: What is the approximate street value for Oxycodone?

A: \$1 per mg

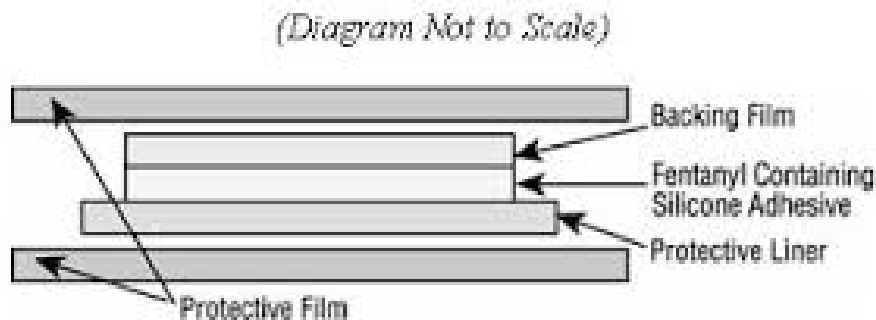
A quick math exercise—

Oxycodone 30mg x \$1/mg x 180 tablets =  
**\$5400**



Q: How are people abusing the Fentanyl patch

A: They are scraping the patch, drawing it up, and injecting it



# How to Prevent Diversion

# Established Guidelines

PHP and CDC Opioid prescribing guidelines include:

- PDMP (CURES)
- Toxicology screens
- Medication agreements
- Safe storage
- Safe disposal

New CDC Opioid Prescribing Guidelines

**Improving the Way Opioids are Prescribed  
for Safer Chronic Pain Treatment**



## The problem:

Existing guidelines vary in recommendations, and primary care providers say they receive insufficient training in prescribing opioid pain relievers. It is important that patients receive appropriate pain treatment, and that the benefits and risks of treatment options are carefully considered.



**259 million**

In 2012, health care providers wrote 259 million prescriptions for opioid pain relievers – enough for every American adult to have a bottle of pills <sup>1</sup>



**300% increase**

Prescription opioid sales in the United States have increased by 300% since 1999<sup>2</sup>, but there has not been an overall change in the amount of pain Americans report<sup>3,4</sup>.



**2 million**

Almost 2 million Americans, age 12 or older, either abused or were dependent on opioid pain relievers in 2013.<sup>5</sup>



**16 thousand**

In 2013, more than 16,000 people died in the United States from overdose related to opioid pain relievers, four times the number in 1999.<sup>6</sup>

## Improving practice:

Improving the way opioids are prescribed through clinical practice guidelines can ensure patients have access to safer, more effective chronic pain treatment while reducing the number of people who misuse, abuse, or overdose from these powerful drugs.



# Marin County Prescribers Survey, 2015

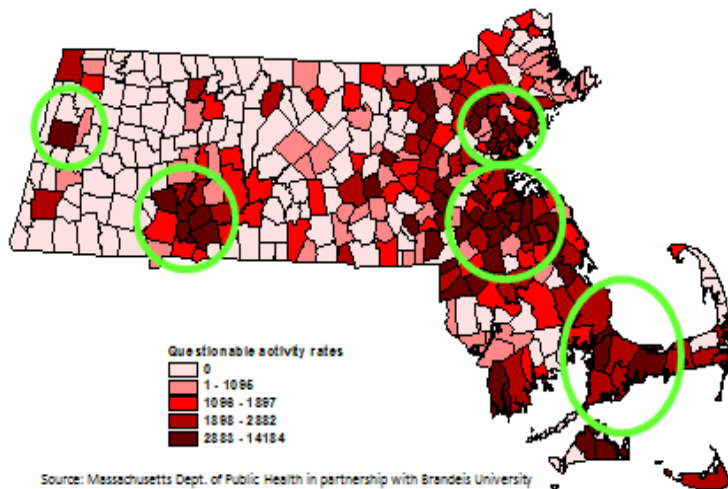
- Providers who self-report as operating under opioid prescribing guidelines were:
  - **8** times more likely to perform urine drug screening
  - **12** times more likely to use a medication agreement
  - **17** times more likely to utilize CURES

# An Argument for Using CURES When Prescribing

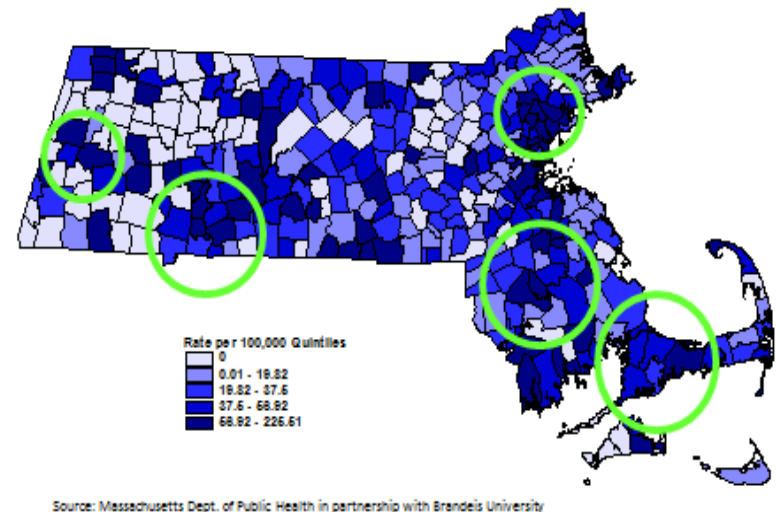
“Shopping” as a portion of all prescriptions

Opioid Overdoses

2005 Prescriptions Associated with Questionable Activity  
(Rates per 100,000 Prescriptions) by Pharmacy Town



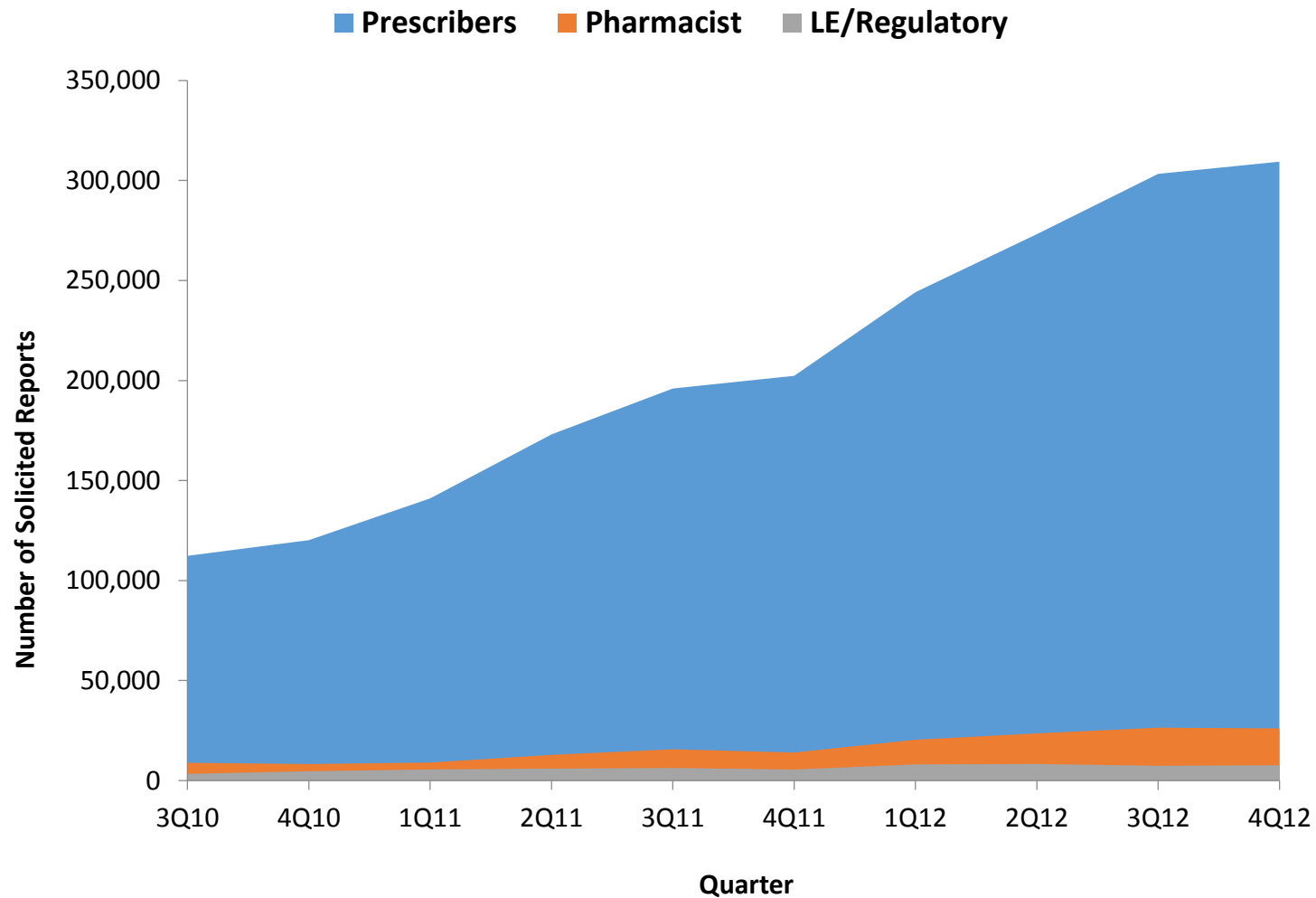
2005 Opioid-related Overdoses  
Rate per 100,000 by Town



Slide provided courtesy of Peter Kreiner, PMP Center of Excellence at Brandeis. Doctor shopping= 4+ prescribers and 4+ pharmacies for CS in six months.

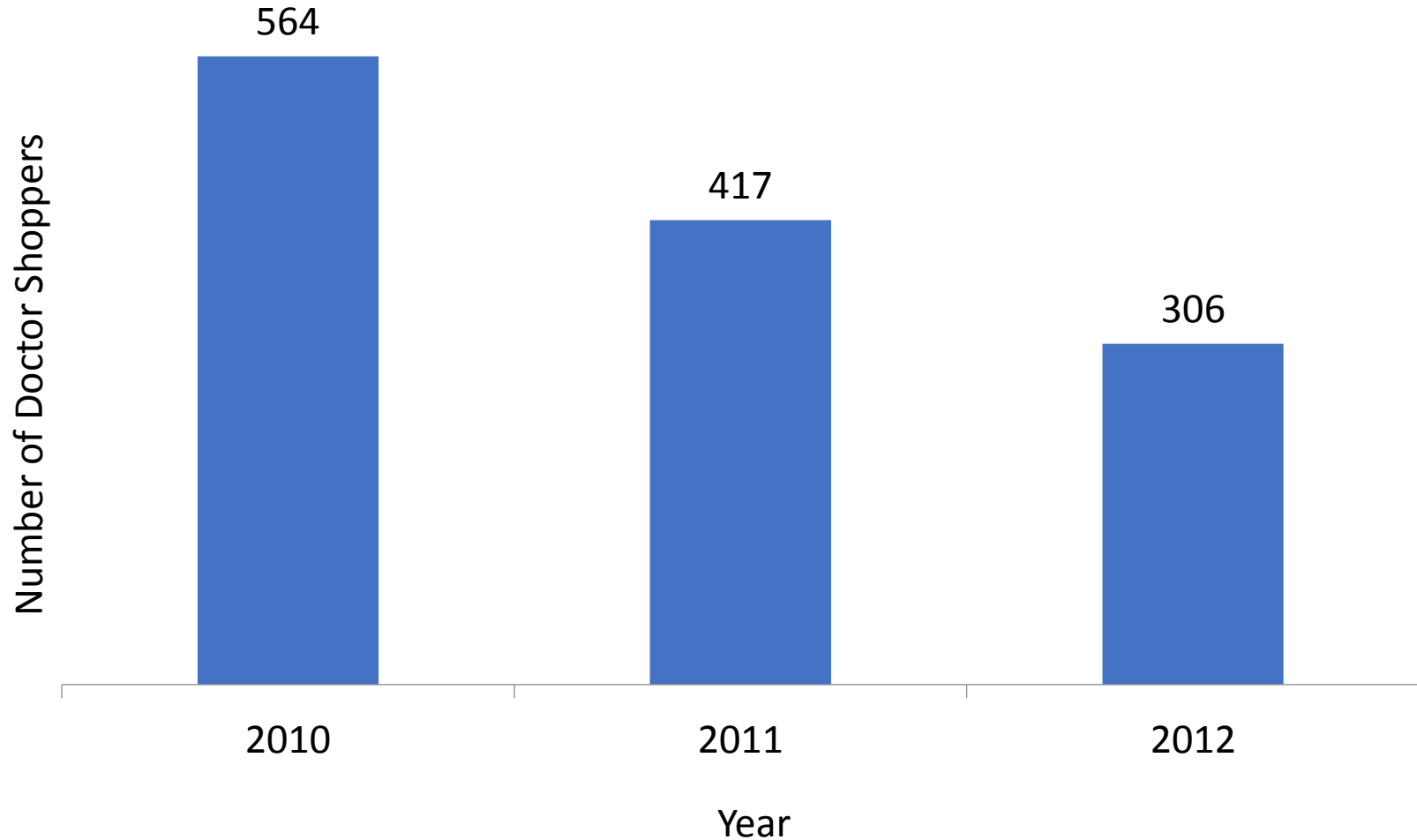
# CHANGES CAN BE MADE:

## SOLICITED PDMP REPORTS, OKLAHOMA, 2010-2012





# CHANGES CAN BE MADE: AS PDMP USAGE INCREASED, DOCTOR SHOPPING DECREASED IN OKLAHOMA



# CURES 2.0 User Features

- Delegation Authority
  - Multiple designees can run report
- Peer-to-Peer Communication
  - Messaging between prescribers and with pharmacists
- Patient Safety Alerts/Messaging



# CURES 2.0 Patient Safety Alerts

- Prescriber's Rx Recipients being Prescribed More than 100 MME/Day
- Prescriber's Rx Recipients being Prescribed More than 40 mg Methadone /Day
- Prescriber's Rx Recipients Who Have Obtained Prescriptions from 6 or More Prescribers, or 6 or More Pharmacies During Last 12 Months





## Patient Safety Alerts

- Prescriber's Rx Recipients Who Are Currently Prescribed Opioids More Than 90 Consecutive Days
- Prescriber's Rx Recipients Who Are Currently Prescribed Both Benzodiazepines and Opioids

# CURES ACCESS IS MANDATORY

On Sept. 27, 2013, Senate Bill 809 passed requiring prescribers and pharmacists to *apply* for CURES access.

H&S Code section 11165.1 (a)(1)(A)(i)

A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances...shall, before **July 1, 2016**, or upon receipt of a federal DEA registration, whichever occurs later, submit an application to obtain approval to access CURES.

H&S Code section 11165.1 (a)(1)(A)(ii)

A pharmacist shall, before **July 1, 2016**, or upon licensure, whichever occurs later, submit an application to obtain approval to access CURES.

Use of the PDMP by prescribers and dispensers for prescription abuse prevention/intervention is *voluntarily*.

# Law Enforcement: Example of Marin County DA Communication



OFFICE OF THE DISTRICT ATTORNEY  
MARIN COUNTY, CALIFORNIA

*Prevention \* Prosecution \* Protection*

*Edward S. Berberian*  
District Attorney

*Barry G. Borden*  
CHIEF DEPUTY DISTRICT  
ATTORNEY

*Robert R. Guidi*  
CHIEF INSPECTOR

*Peggy M. Toth*  
CHIEF, FINANCE  
AND ADMINISTRATION

[Date]

\*  
\*  
\*

Re: Defendant's name; Marin County Superior Court Case No. \*A

Dear Physician's Name:

It has come to our attention that \* is currently, or was recently a patient of yours.

On \*, 2014, a criminal complaint was filed against \*, alleging violations of Section \* of the \* Code, occurring on \*. A copy of the Complaint is attached hereto for your reference.

This information is being provided as the result of a partnership between the Marin County District Attorney's Office, Marin Health & Human Services, and Partnership HealthPlan of California. The goal of this partnership is to share information with physicians regarding unlawful prescription drug diversion and misuse, enabling physicians to make informed treatment decisions.

Please do not hesitate to contact our office if you have any questions.

Very truly yours,

EDWARD S. BERBERIAN  
DISTRICT ATTORNEY

\*

Deputy District Attorney

“The goal of this partnership is to share information regarding diversion... enabling physicians to make informed treatment decisions.”



# Death Diary: 49 year old female “Compliant”

12 Rx – 1 Psychiatrist – 1 Pharmacy

September	Clonazepam 1mg #45 , 45
October	Clonazepam 1mg - #30, 45, 90
November	Clonazepam 1mg - #90
December	Clonazepam 1 mg - #15,90
January	Clonazepam 1 mg - #120
February	Clonazepam - #120
March	Clonazepam - #30, 120

Autopsy: Oxycodone

# Death Diary: 59 year old male “Holy Trinity”

75 Rx – 1 Psychiatrist – 3 Primary Care – 1 Pain

September	Hydrocodone, Soma Hydromorphone, Ambien
October	Clonazepam, Soma, Hydromorphone, Ambien, Hydrocodone, Soma, Clonazepam
November	Hydromorphone, Hydrocodone, Soma, Clonazepam, Hydromorphone
December	Hydrocodone, Hydrocodone, Soma, Clonazepam, Hydromorphone, Ambien
January	Hydrocodone, Soma, Clonazepam, Hydromorphone 4 mg, Ambien
.....	
August	Hydrocodone, Soma, Clonazepam, Morphine 60 mg , Ambien

Autopsy: Morphine, Ambien, Sertraline, Hydroxyzine

# Death Diary: 56 Year Old Female

## “Start on methadone, End on Methadone”

23 Scripts  
10 Providers

February, March

No Meds

April

ER#1: Hydrocodone #10

Dr. R: Codeine#40, Lorazepam #42

May

Dr. P: Hydrocodone #15, Lorazepam #20

June

ER#2: Hydrocodone #20, Lorazepam #20

August

ER#3: Oxycodone #20, Lorazepam #21

ER#4: Oxycodone #21, Lorazepam #20

September

ER#5: Oxycodone #20, Lorazepam #6

Dr. L: Methadone #120

October

Dr. L: Methadone #120

ER #6: Hydrocodone #15

Dr. W: Lorazepam #8

November

ER #3: Oxycodone #5, Lorazepam #4

Dr. L: Methadone #120

December

Dr. L: Methadone #120

January

ER #7: Lorazepam #4

February 1, 2013

Dr. L: Methadone #30

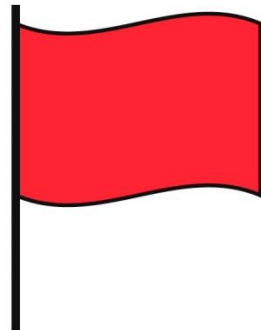
Death: February 7, 2013

Methadone, Clonazepam, Phenytoin, Carbamazepine, Gabapentin



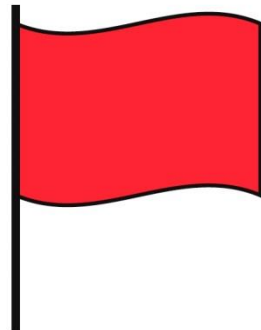
# Flags

- Combinations or “cocktails” of frequently abused controlled substances
- New clients with limited documentation and specific regimen requests
- Multiple prescribers in CURES
- Discrepancy between self report and CURES findings
- Discrepancy between self report and UDS
- Travel long distance to visit
- Strong preference for specific medication or brand



# Flags

- Reluctance to allow examination or to provide urine for UDS
- Discussion of analgesic dominant issue of visit
- UDS +ve for illicit drugs or –ve for prescribed drugs
- Lack of interest in self management strategies
- Failure to attend appointments e.g. physiotherapy
- Hostile / aggressive (sudden change if not satisfied)
- Refusal to sign treatment agreement



*Thank You*





## Behavioral Health for Chronic Pain Patients Breakout Session

# Chronic Pain: Skills for Patients and Practitioners

*Presented by:*  
**Pat Dwyer, Ph.D.**  
**Psychologist**  
Kaiser Permanente  
Chronic Pain Program  
[pat.j.dwyer@kp.org](mailto:pat.j.dwyer@kp.org)  
(707) 651-4451

# What NOT to Say!

## WARNING!!!

[www.chronic-illness.org](http://www.chronic-illness.org)

Things **NOT** to say to someone with a disabling chronic illness:

- ...but you don't look sick
- ...everybody gets tired
- ...you're just having a bad day
- ...it must be nice not having to go to work
- ...I wish I had time to take a nap
- ...if you'd get out more
- ...you're just getting older
- ...if you'd get more exercise
- ...it can't be that bad
- ...it's all in your head
- ...you're just depressed
- ...there are people worse off than you
- ...you'll just have to tough it out
- ...you just need a more positive attitude
- ...this, too, shall pass

(I wouldn't wish what I have on anyone, but unless you get it, you just don't get it.)



# **At Our First Contact We Want Our Patients To Know**

- **Goals functional improvement, not zero pain along with keeping our patients safe**
- **You have real pain and it's as bad as you say**
- **Meds aren't enough**
- **Skills and Pills will help more**
- **Use movement and exercise for improvement**
- **Stage of Change-we'll be working on what's hardest to change**

Like an iceberg PAIN is more  
than what we see



# Assessment

- Mood evaluation and assessment for risk for harm to self or others
- Risk Factors and Protective Factors
- I put in every note--Patient does not appear to present an imminent risk for suicide



# Risk Factors

Passive thoughts would be better off dead

Insomnia vs Global Insomnia

Impulsivity

Psychic anxiety/agitation

Severe Hopelessness

Severe Anhedonia

Medication Overdose, recent or remote

ED visits for suicidal ideation

Recent suicide attempt or serious gesture

Specific plan, intent and means

Intoxication

Mood congruent delusions of doom

Severe Ruminations

Guns -who is holding them, safety locks,

bullets

# Protective Factors

Hopeful

Seeking help

Seeking better pain control

Problem solving

Social support

Future goals

Religious

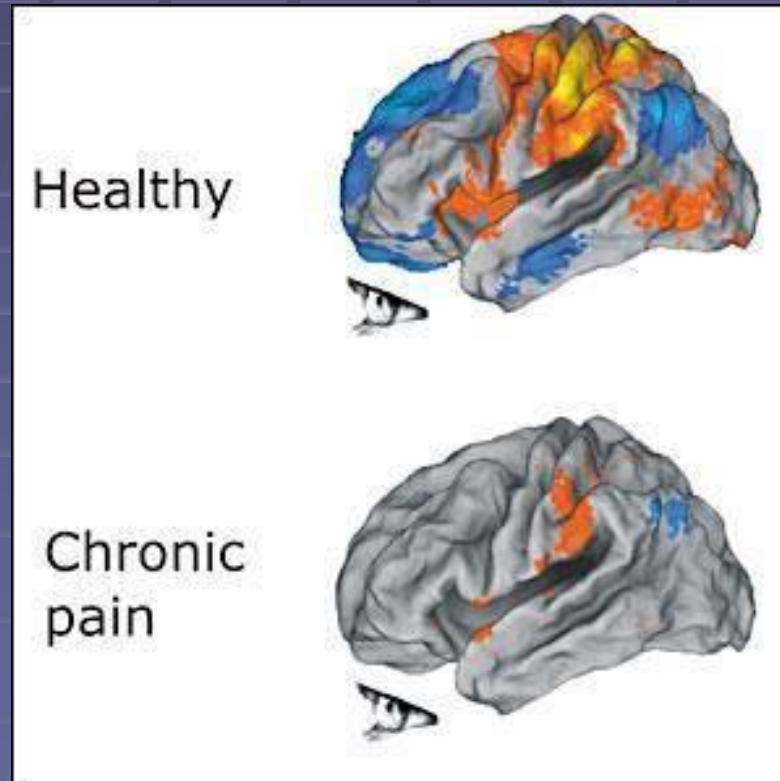
Children or grandchildren

Family member holds meds

Patient is followed in PSY

Aware of PSY crisis resources  
including going to the ED and dialing  
911 if needed

# The Brains of a Healthy vs Chronic Pain Person



Northwestern University fMRI scan



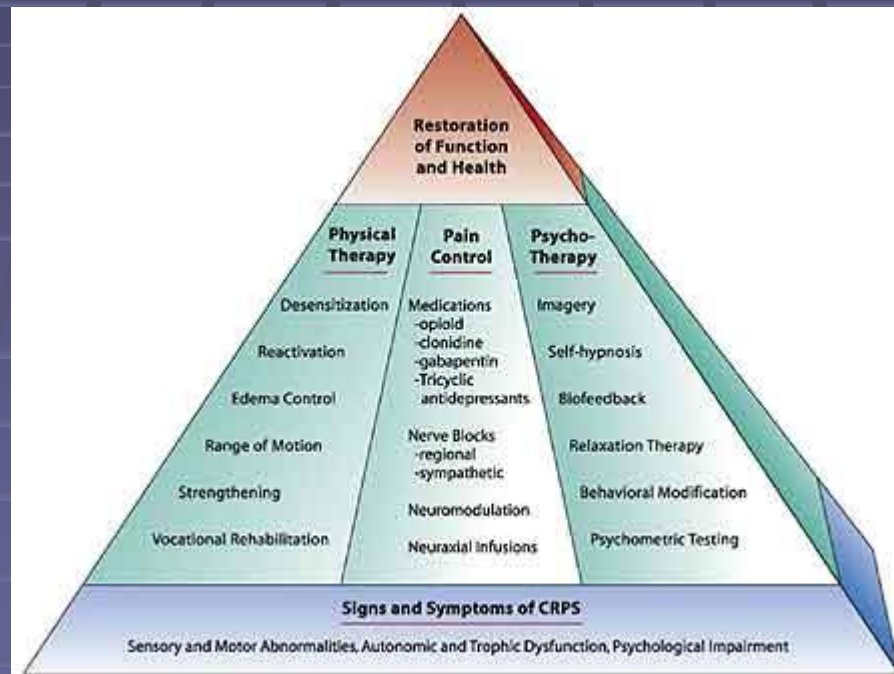
# At Evaluation

- Try to give the patient something to leave with, some hope
- Ask about their occupation use that with your skills metaphors
- Reinforce their resilience
- Ask them about something that is positive
- See if they notice their mind/body response and the shift in their comfort level and reduction in their pain level
- Sign release to coordinate care

# Ways to help our patients manage



# Complexity of Improved Function





# **Pain Pathways and the Mind-Body Connections**

- **Gate Control Theory (1965, 1982) and Melzak (2001) the matrix**
- **Biopsychosocial Factors that Open or Close the Gate**
- **Mind-Body Connections**
- **Using Mindfulness techniques**
- **Psychoneuroimmunology (PNI)**

# Melzak & Wall (1965, 1982)

## Factors that Open and Close the Gate

### Close

Successful Surgery  
Medications  
Good Diet  
Movement  
Pacing (activity/rest)  
Positive outlook  
Hopefulness  
Managing the pain  
Pleasant events

### Open

Surgery/broken bones  
Drug and ETOH overuse  
Poor Diet/Nicotine  
Deconditioning  
Worry about Hurt vs Harm  
Negative outlook  
Hopelessness  
Focusing on the pain  
Depression/Anger

# Pain Management Tools

- Goal Setting
- Behavior Change - *Premack Principle*
- Predicting “*The good the bad and the ugly*”
- Automatic Thought Records
- Pleasant Events for mood improvement “*Left brain shift*”
- Pacing activity/rest cycle vs “*Just do it*”
- Relaxation- “*small, medium and large*”
- Communication *use the cell phone and say NO*
- Sleep- *try a fan, turn the clock, nap*



# **The Mind-Body Connection**

- **The brain is not a passive recipient of pain signals**
- **Thoughts and feelings can “rewire” the brain and increase experience of pain**

# Relaxation Practice Time at the Beach Small, Medium, Large



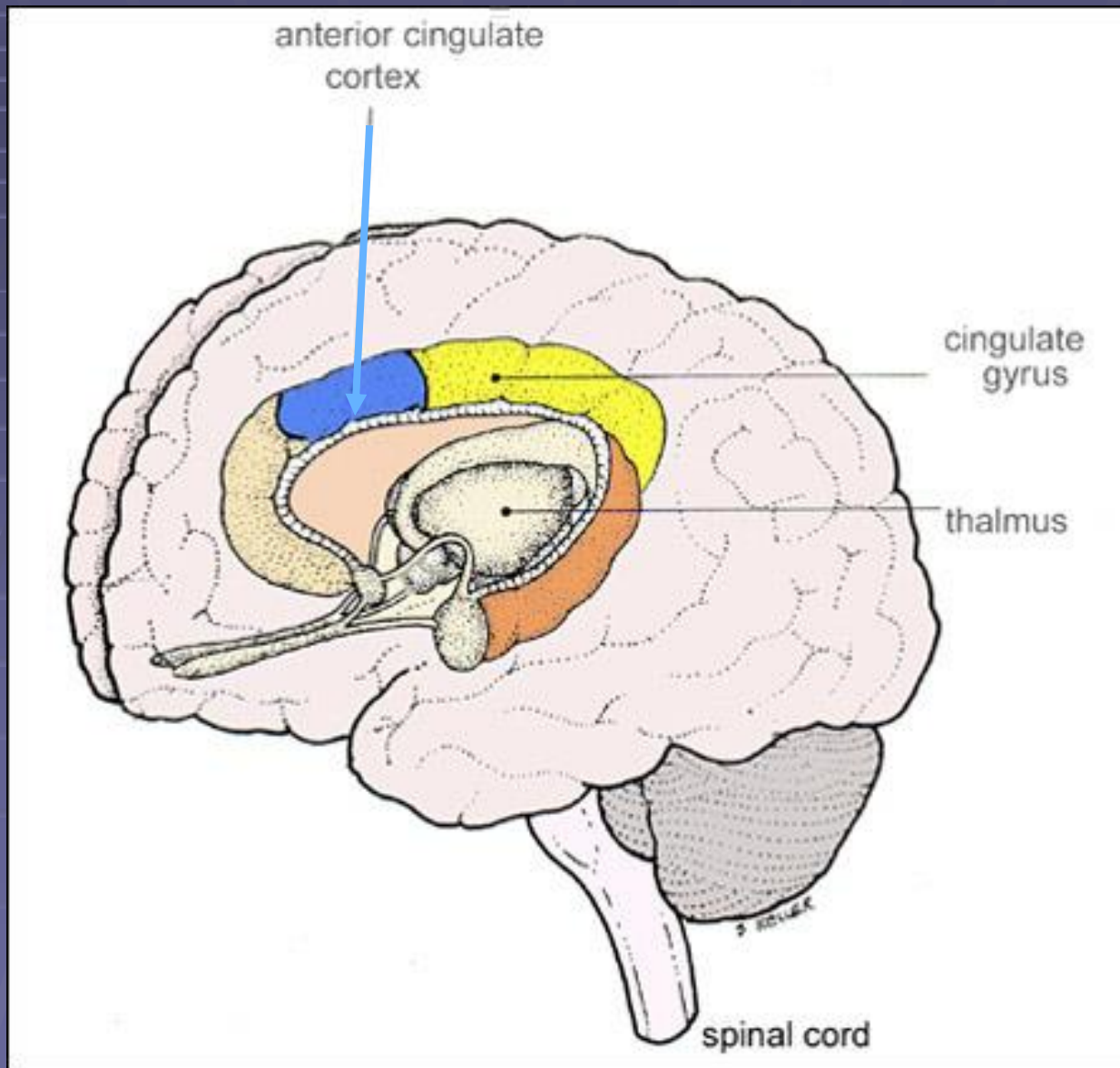
# Changing the Brain

- Patients can gain control over specific brain regions with training
- Rostral Anterior Cingulate Cortex (rACC) leads to control over pain perception even severe, chronic pain

deCharms, R. Christopher et al. (2005) Proc. Natl. Acad Sci. USA 102, 18626-18631.



# Anterior Cingulate Cortex



Hod Carrier  
Cologne, Germany 1929  
August Sanders Photographer



Learning to let go  
of what we don't need

# Cortical Re-Organization

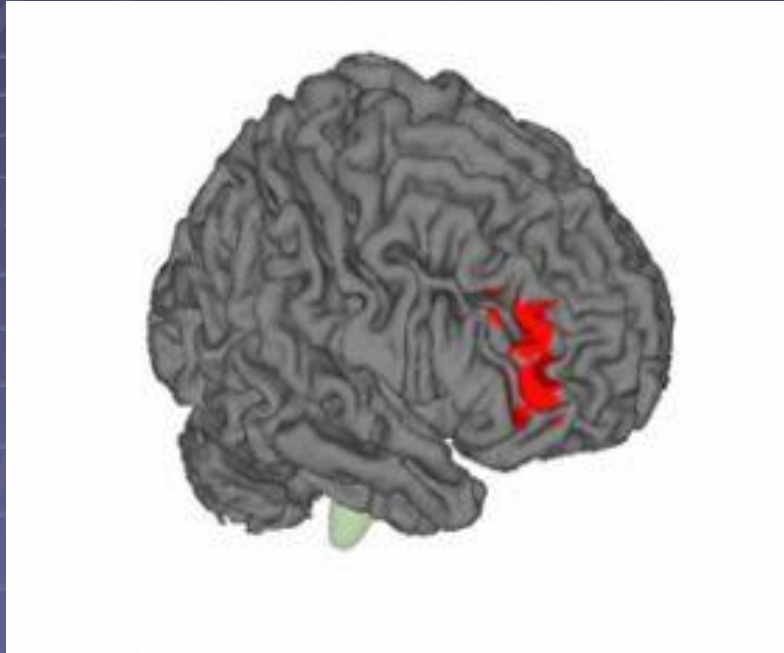
- Cortical plasticity related to chronic pain can be modified by behavioral interventions that provide feedback to the brain areas that were altered by somatosensory pain memories

Flor, H. Appl Psychophysiol Biofeedback 2002 Sep, 27(3) 215-27.

Flor, H. Jour Rehab Med 2003. May 41, (Suppl) 66-72



# Where Placebo Effect Works in the Brain



- Using PET scans found that when treated with placebo the brain released more opioids to relieve pain

The research team of Tor Wager, Columbia University

# Pain and Positive Expectation

- Positive expectations (i.e. decreased pain) produce a reduction in perceived pain by 28.4% and compares to a dose of morphine with an expected 25% reduction in pain
- Data provide a neural mechanism that can modulate pain by positive expectations and has implications for use of CT skills

Koyama, T. McHaffie, J.G., Laurienti, P.J., Coghill, R.C.. Proc Natl Acad Sci USA. 2005; 102:12950-12955.

# **Humor and Psychological Well-Being**

**Relationships between sense  
of humor and reports of  
physical well-being are  
supported in the literature.**



# At Termination

- ✓ Document treatment is ended
- ✓ Ways to continue to use skills
- ✓ Patient can return in the future

You too must have something  
that makes you smile





## Buprenorphine Induction Breakout Session





# Buprenorphine MAT

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Director, Center for Integrative Medicine

Medical Staff Chief, Division of Pain Management

# Objectives

- How to Choose the right patients
- Special needs for pregnant patients
- Workflow
- Documentation
- Long Term Planning
- Regulatory Requirements

# Who is appropriate for buprenorphine?

Positive DSM 5 with a score of 2 or greater

Positive DAST (6 or greater) for opioids

Per the SAMHSA guidelines, a patient should have a 1 year history of opioid use disorder prior to use of methadone. (however, many caveats)

No guidance on Buprenorphine



# Before the first dose

Informed consent should be obtained

Physical exam

Toxicological evaluation

# Dose Equivalents

## Buprenorphine/naloxone

Suboxone (SL-film)	Zubsolv (ODT)	Bunavail (B-Film)
2 mg / 0.5 mg	1.4 mg / 0.36 mg	---
4 mg / 1 mg	2.9 mg / 0.71 mg	2.1 mg / 0.3 mg
8 mg / 2 mg	5.7 mg / 1.4 mg	4.2 mg / 0.7 mg
12 mg / 3 mg	8.6 mg / 2.1 mg	6.3 mg / 1 mg
----	11.4 mg / 2.9 mg	----

# First dose when flipping from full agonist opioids

In general the patient should either be completely negative for opioids in the urine or in mild to moderate withdrawal based on the clinical opioid withdrawal scale (COWS)

Patients who are negative for opioids can be given up to 8 mg

Patients who are positive for opioids, but in moderate withdrawal should receive 2-4 mg.

If the withdrawal worsens then can give up to 24 mg to abate withdrawal



# Partial agonist/agonist-antagonist

Nubaine:

- Nalbuphine belongs to the agonist-antagonist group. This exerts its analgesic actions by agonistic activity at opioid kappa (“κ”) receptors. It possess opioid mu (“μ”) receptor antagonistic activity leading to less abuse potential (and unwanted withdrawal).

Stadol:

- Butorphanol exhibits partial agonist and antagonist activity at the μ opioid receptor, as well as competitive antagonist activity and partial agonist activity at the κ opioid receptor.

Buprenorphine:

- Buprenorphine is considered a partial μ-opioid agonist displaying high affinity for and slow dissociation from the μ-opioid receptor.

# Antagonist



Narcan:

Naloxone



Vivitrol:

Naltrexone

# Typical opioid “flip”



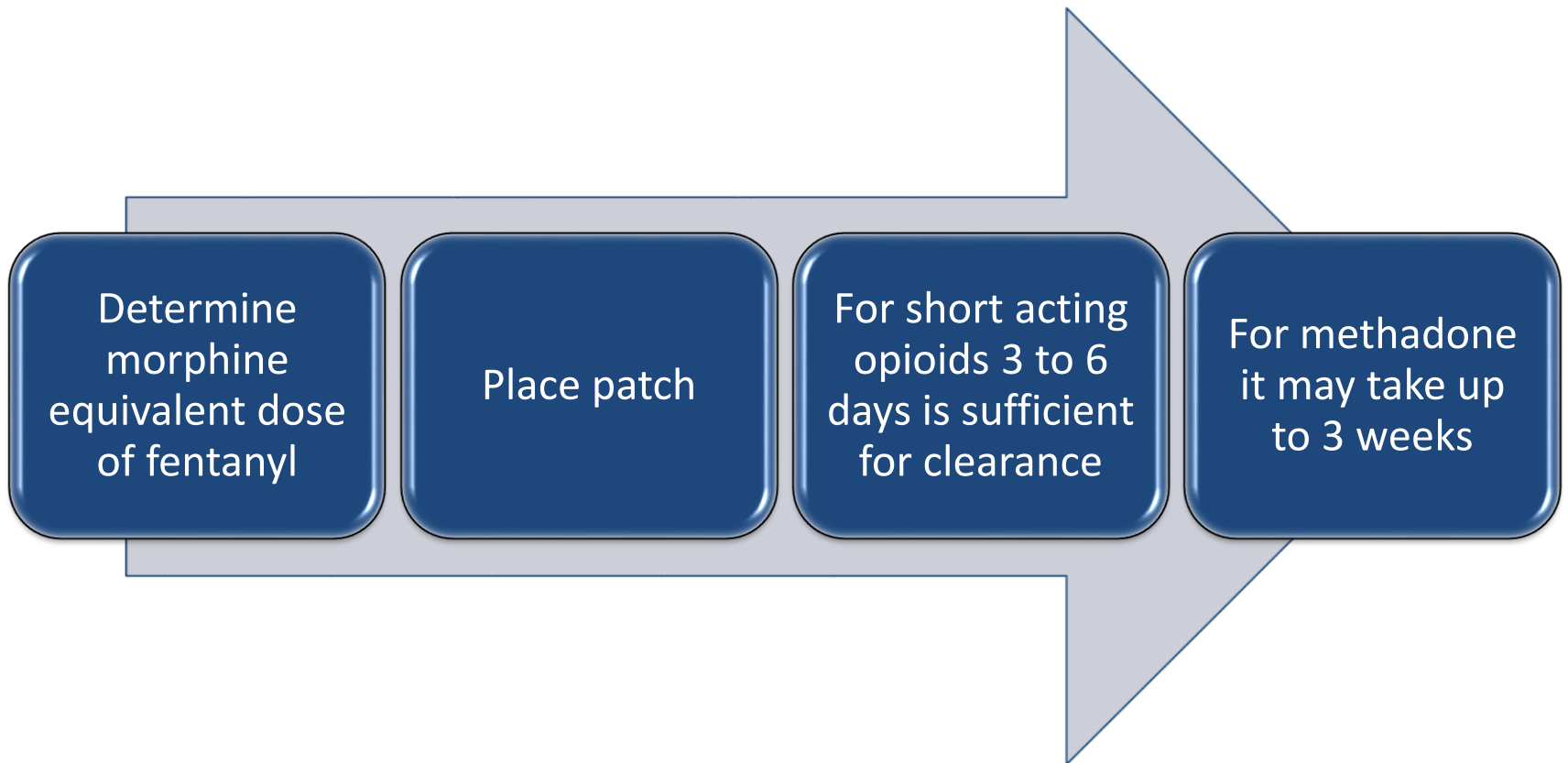


# Other types of induction

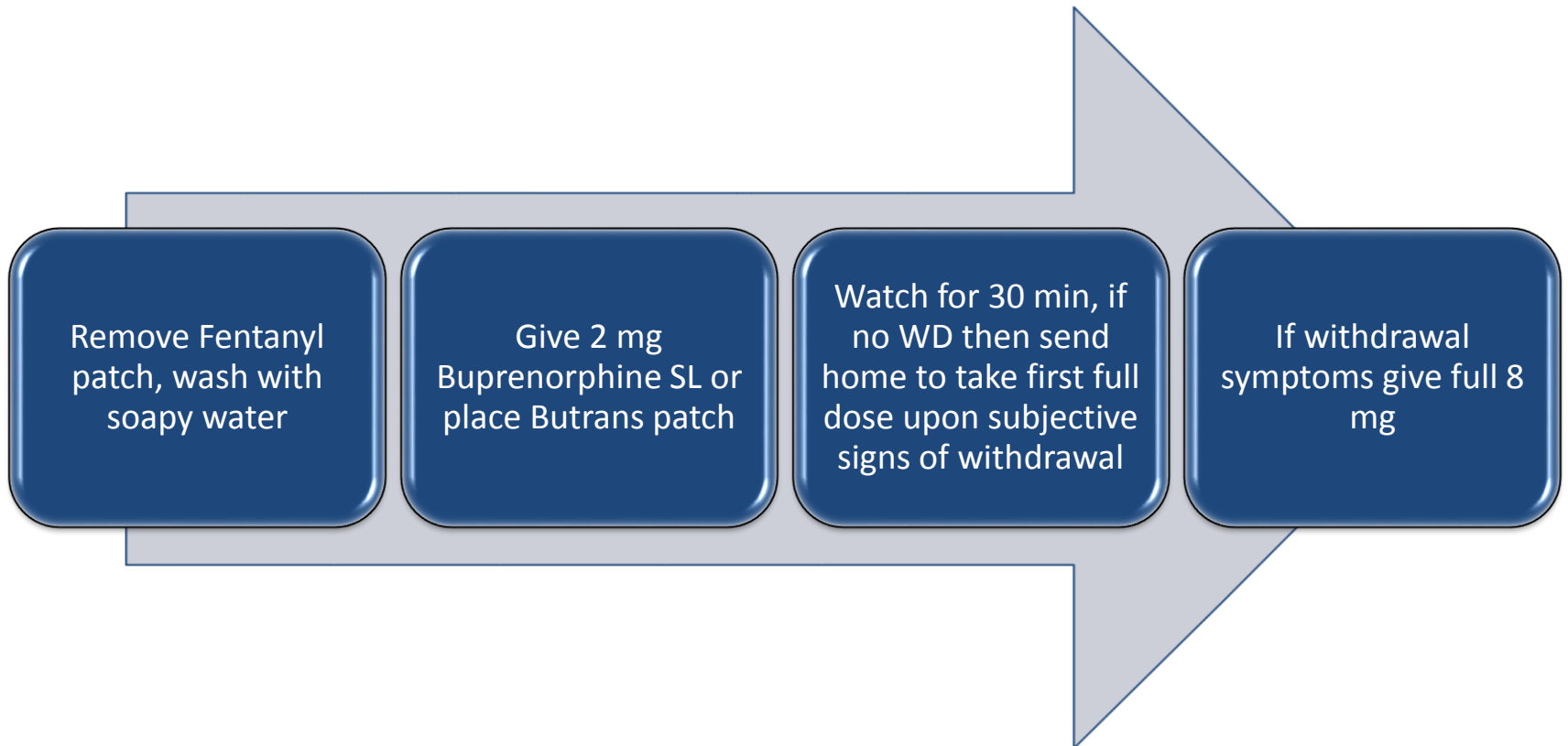
**Butrans-** Place transdermal buprenorphine patch on skin. It takes 36 hours to peak. After 36-48 hours remove the patch and give 1<sup>st</sup> SL buprenorphine dose of 4-8 mg

**Fentanyl Bridge-** For patients on opioids place morphine equivalent patch on skin. Have patient return in 72 hours. Give 2 mg of buprenorphine, remove the patch and have patient take next SL dose of Bup when they start to experience withdrawal

# Fentanyl Bridge



# Induction





# Fentanyl Bridge Data

Of the 54 inductions attempted for short acting opioids all completed, however patients with greater than 90 mg of methadone have had mixed results

We now use it as a “standard” option along with Butrans

Works great for patients in the hospital

- Can discharge on fentanyl and start Buprenorphine on first out patient visit

We now use it for pregnant patients as well

# Risks

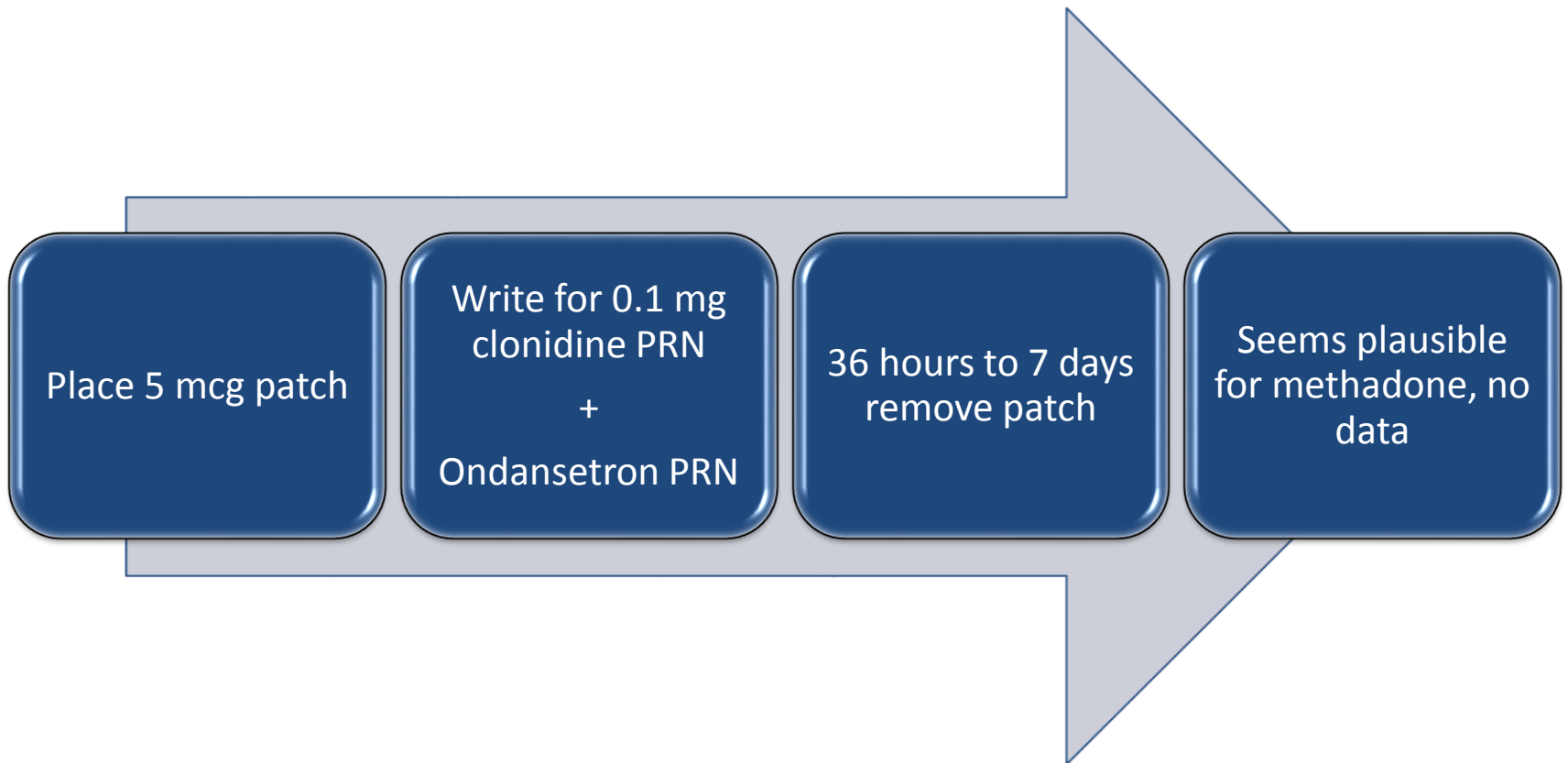
Not considered  
standard of care

- Patients should be apprized of the risks, benefits and alternatives
- Close monitoring is required

Fentanyl has  
abuse potential

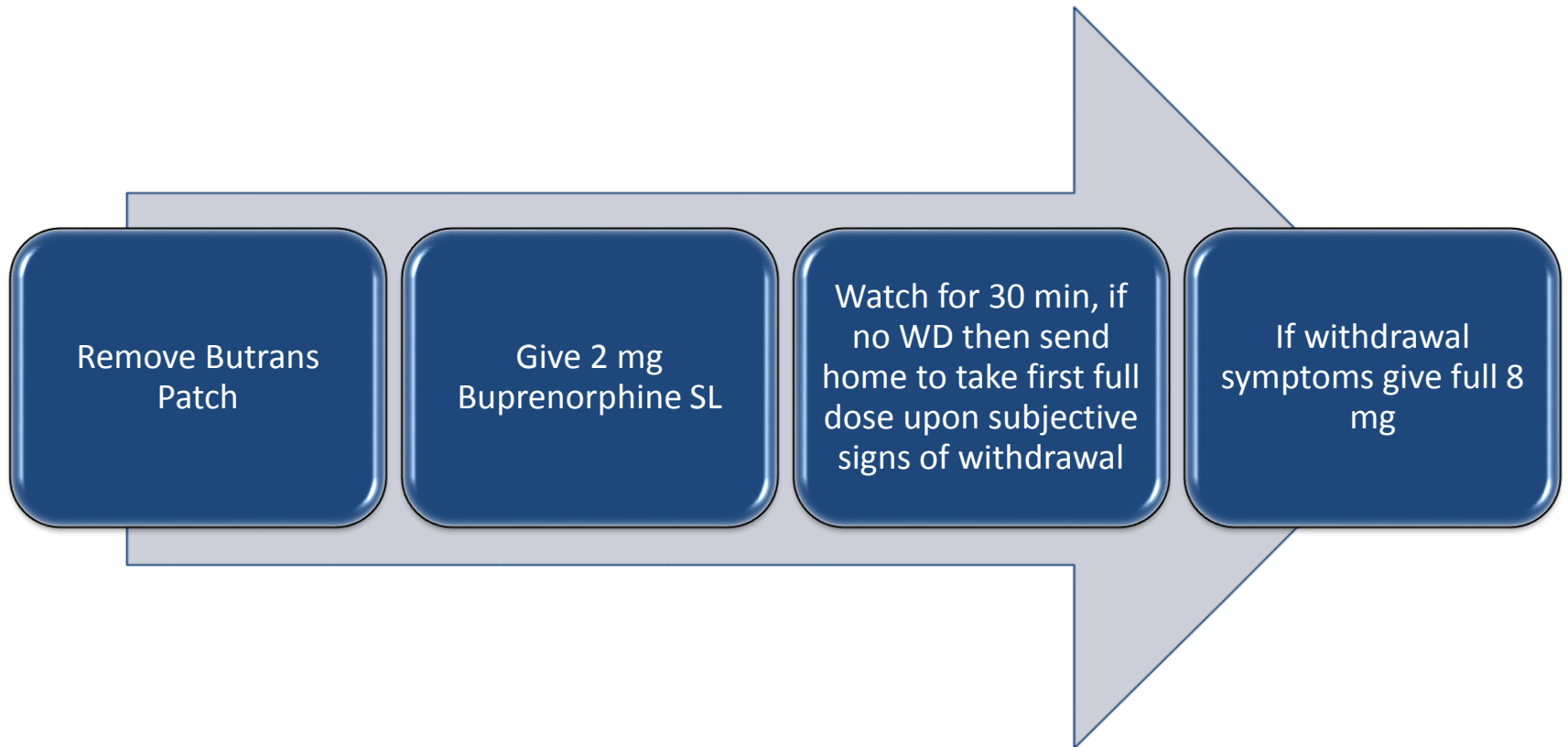
- If patients previous drug of choice then not a great med
- If patient is an injector then use Mylan brand patch
- If patient is an oral abuser then the liquid brands are preferred
- Write for 1-2 patches at a time

# Butrans Bridge





# Induction



# Data

Kornfeld et al, Transdermal Buprenorphine, Opioid Rotation to Sublingual Buprenorphine, and Avoidance of Precipitated Withdrawal: A Review of the Literature and Demonstration in Three Chronic Pain Patients Treated with Butrans

We have used on 16 patients with same positive results.

We now use it for pregnant patients as well

# Pregnant Patients

Main risk is unabated withdrawal leading to preterm labor and/or precipitous delivery

Higher in 1<sup>st</sup> and 3<sup>rd</sup> trimester

Probably overstated risk if monitored appropriately.

Same pre-eval requirements as non-pregnant patients

# Pregnant Patients

For first few, OK to do in OB triage or in collaboration with OB and/or fetal monitoring.

My first 5 were inpatient and no anomalies were found to justify the need for inpatient monitoring

Induction should always be done in person and watched for 1 hour after 1<sup>st</sup> dose



# MOTHER Study

Addiction. 2012 Nov;107 Suppl 1:28-35. doi: 10.1111/j.1360-0443.2012.04036.x.

- Maternal Opioid Treatment: Human Experimental Research (MOTHER)--approach, issues and lessons learned.
- Jones HE1, Fischer G, Heil SH, Kaltenbach K, Martin PR, Coyle MG, Selby P, Stine SM, O'Grady KE, Arria AM.

The Maternal Opioid Treatment: Human Experimental Research (MOTHER) project, an eight-site randomized, double-blind, double-dummy, flexible-dosing, parallel-group clinical trial is described. This study is the most current--and single most comprehensive--research effort to investigate the safety and efficacy of maternal and prenatal exposure to methadone and buprenorphine.

At least seven important lessons have been learned from the MOTHER study: (i) an interdisciplinary focus improves the design and methods of a randomized clinical trial; (ii) multiple sites in a clinical trial present continuing challenges to the investigative team due to variations in recruitment, patient populations and hospital practices that, in turn, differentially impact recruitment rates, treatment compliance and attrition; (iii) study design and protocols must be flexible in order to meet the unforeseen demands of both research and clinical management; (iv) staff turnover needs to be addressed with a proactive focus on both hiring and training; (v) the implementation of a protocol for the treatment of a particular disorder may identify important ancillary clinical issues worthy of investigation; (vi) timely tracking of data in a multi-site trial is both demanding and unforgiving; and (vii) complex multi-site trials pose unanticipated challenges that complicate the choice of statistical methods, thereby placing added demands on investigators to effectively communicate their results

# Birth Plan

**Patient example: 23 y/o on 8mg of buprenorphine-naloxone 2 times per day (BID)**

## **Spontaneous vaginal delivery:**

- Decrease Buprenorphine to 8 mg daily
- May use epidural but would use fentanyl as opioid
- Add Ketorolac 15-30mg IV every 6-8 hours or Ibuprofen 800mg every 8 hours
- After 36 hours return to 8mg of Buprenorphine-naloxone BID
- Discharge on same dose with no further opioid prescriptions

## **C-section Delivery:**

- Decrease buprenorphine to 8mg daily
- Spinal analgesia using fentanyl as the opioid
- Add Ketorolac 15-30mg IV every 6-8 hours or Ibuprofen 800mg every 8 hours
- If still painful would use Patient Controlled Analgesia (PCA) at 150 mcg/4 hours with no basal rate for 36-48 hours
- May add 1 gram of IV acetaminophen Q 6 hours
- Increase buprenorphine-naloxone to 8 mg 3 times per day and call provider to obtain insight and provide appropriate care transition

# Early Monitoring

Patient should be monitored closely for diversion, and ingestion of other sedatives such as Alcohol and/or Benzo's

Generally patient should be seen weekly for 6 weeks, bi-weekly for 8 weeks and the monthly there after.

This is only if the urine toxicology is positive for buprenorphine and negative for other illicit substances. If they are negative for bup or positive for other substances then they should continue weekly until stable

# Long Term Planning

Need 18 months to 2 years for neuronal Stabilization

Patient centered wean

Early High intensity BH with long term recovery program (groups etc)

Hope is for long term abstinence (70-80%)



# Work Flow in Primary Care



# Patient Documentation

## HPI

- Drug use from age of 12 to current
- DSM 5 Criteria met
- DAST Criteria met
- Co-Occurring evaluation
- PE
  - Focused on Mental Status
  - Sequela of drug abuse (injection marks, superficial skin infections, Murmurs)

# Documentation

## Labs

- Hep C, HIV, STDs, CMP, CBC, UDS

## Diagnosis

- Use DSM 5 Designation

## Plan

- Include medication dose and frequency
- Include BH referral and basic plan (i.e. CBT, DBT, 12 step, Contingency Management)
- Other drug use and plan of action (Benzo, MJ, etc.)

# Office based Documentation

Keep an active list of all current patients  
(seen within the last 30 days)

Keep a list of all past patients and why  
they are no longer patients

Call your regional DEA agent and ask for a  
preemptive visit and evaluation.



# Regulatory Requirements

DATA  
2000

- Must have X license
- 30 patients year 1
- Can apply for 100 patients year 2

# FAQ's

- With a DATA 2000 waiver, can I *prescribe* approved buprenorphine products for opioid addiction in more than one practice location? Can I *dispense* approved buprenorphine products from more than one location?
  - Physicians with DATA 2000 waivers may prescribe approved buprenorphine products for opioid addiction in any appropriate practice setting in which they are otherwise credentialed to practice (e.g., office, hospital). However, they may store and dispense approved buprenorphine products (or any other controlled substances) only at the practice address(es) that they have registered with the DEA. Only one DATA-waiver unique identification number will be issued for each DATA-waived physician, no matter how many practice locations or DEA registrations a physician may have.

# FAQ's

- I've heard this new model for the treatment of opioid addiction referred to as "office-based opioid therapy." Does that mean that physicians with DATA 2000 waivers can use approved buprenorphine products to treat opioid addiction only in the office-based setting?
  - **No.** Treatment of opioid addiction under the authority of a DATA 2000 waiver is not confined to the office-based setting. Physicians with DATA 2000 waivers may treat opioid addiction with approved buprenorphine products in any practice settings in which they are otherwise credentialed to practice and in which such treatment would be medically appropriate (e.g., office, community hospital, health department).

# FAQ's

- Can physicians and other authorized hospital staff administer buprenorphine to a patient who is addicted to opioids but who is admitted to a hospital for a condition other than opioid addiction?
  - Neither the Controlled Substances Act (as amended by the Drug Addiction Treatment Act of 2000) nor DEA implementing regulations (21 CFR 1306.07(c)) impose any limitations on a physician or other authorized hospital staff to maintain or detoxify a person with an opioid treatment drug like buprenorphine as an incidental adjunct to medical or surgical conditions other than opioid addiction.
  - Thus, a patient with opioid addiction who is admitted to a hospital for a primary medical problem other than opioid addiction, e.g., myocardial infarction, may be administered opioid agonist medications (e.g., methadone, buprenorphine) to prevent opioid withdrawal that would complicate the primary medical problem. A DATA 2000 waiver is not required for practitioners in order to administer or dispense buprenorphine (or methadone) in this circumstance. It is good practice for the admitting physician to consult with the patient's addiction treatment provider, when possible, to obtain treatment history



- May physicians in residency training programs obtain DATA waivers?
  - The DATA legislation does not specify that a physician in a residency training program who otherwise meets the qualifications for a DATA waiver is ineligible to apply for and obtain a waiver. Therefore, SAMHSA has granted DATA waivers to physicians in residency training who have unrestricted licenses and the appropriate DEA registration. Individual States may have laws with more restrictive rules regarding who may prescribe or dispense Schedule III narcotic drugs for detoxification or maintenance treatment.

# FAQ's

- **Are there specific Federal record keeping requirements for office-based opioid therapy?**
  - DEA record keeping requirements for office-based opioid therapy go beyond the Schedule III record keeping requirements. According to DEA: Practitioners must keep records (including an inventory that accounts for amounts received and amounts dispensed) for all controlled substances dispensed, including approved buprenorphine products (21 PART 1304.03[b]). In some cases, patients return to the prescribing physician with their filled approved buprenorphine products prescriptions so that the practitioner can monitor the induction process. While it is acceptable for the patient to return to the practitioner with their filled prescription supplies, practitioners shall not store and dispense controlled substances that are the result of filled patient prescriptions.

# References

- Kranzler, Ciraulo and Zindel, Clinical Manual of Addiction Psychopharmacology (2<sup>nd</sup> addition) American Psychiatric Publishing. 2014
- The ASAM National Practice Guideline For the Use of Medications in the Treatment of Addiction Involving Opioid Use. 2015
- The State of Michigan MAT Treatment Guidelines For Opioid Use Disorder, R. Corey Waller. 2014

# Question 1

- Which of the following is correct?
  - A. You can safely start buprenorphine while a patient is still taking a full agonist
  - B. The first dose can be up to 24 mg if patient is in withdrawal
  - C. Patients must be completely free of other opioids
  - D. Patients should be given a 30 day prescription on day 1

Answer:     B





## Closing and Evaluation

# Summary of Day

- Integrated Clinics to treat substance use disorder
- The neuroscience behind SUD
- Screening for SUD
- Behavioral health techniques when working with chronic pain patients/ patients with SUD
- Red flags and warning signs for diversion
- Medication assisted treatment

# Looking Ahead in 2016: Health Plan Activities

Provision of tele-consult services for complex patients on high-dose opioids

Education and coordination around addiction screening and treatment

Partner with CHCF for continued support in developing and sustaining local efforts targeted at reducing improper use of opioids

Planning process for creating integrated clinics for high utilizers

Pharmacy academic detailing

MPS provider level data sharing

Tapering guide/ toolkit

Naloxone Pilot

# Looking Ahead in 2016: Prescriber Activities

- Sign up for tele-consult services for complex patients on high-dose opioids
- Make local opioid oversight committees more robust
- Participate in regional coalitions
- Give feedback on draft plan for integrating chronic pain treatment with Medication Assisted Therapy
- Ask your PHC Regional Medical Director to meet with you and/or your clinicians to review their individual PHC opioid data and to review MPS
- Tapering guide/ toolkit
- Distribute Naloxone and educate patients/families on how to use it.



# MPS Data Sharing Webinars

## MANAGING PAIN SAFELY DATA SHARING WEBINARS



This February, we will be hosting four county-focused webinars highlighting the data collected through our Managing Pain Safely program. The webinar will include a discussion of aggregate county-level data for specific measures and include a real-life example of provider-level data (all provider identifiable information will be omitted). This will be an opportunity for PHC providers to view the data collected, ask questions, and learn how to request additional data.



Visit the MPS webpage to register for one of the following webinars.

### Northern Region

**February 9:** Humboldt and Del Norte Counties

**February 10:** Shasta, Siskiyou, Trinity, Modoc, and Lassen Counties

### Southern Region

**February 11:** Mendocino, Lake, Sonoma, and Marin Counties

**February 22:** Yolo, Napa, and Solano Counties

### Contact Us

- For additional information for Northern Region webinars contact:  
Marya Choudhry at (530) 999-6903 or [mchoudhry@partnershiphp.org](mailto:mchoudhry@partnershiphp.org)
- For additional information for Southern Region webinars contact:  
Danielle Niculescu at (707) 420-7617 or [DNiculescu@partnershiphp.org](mailto:DNiculescu@partnershiphp.org)



# Thank You!

