

Medication Assisted Treatment: Right for you, Right for your Recovery?

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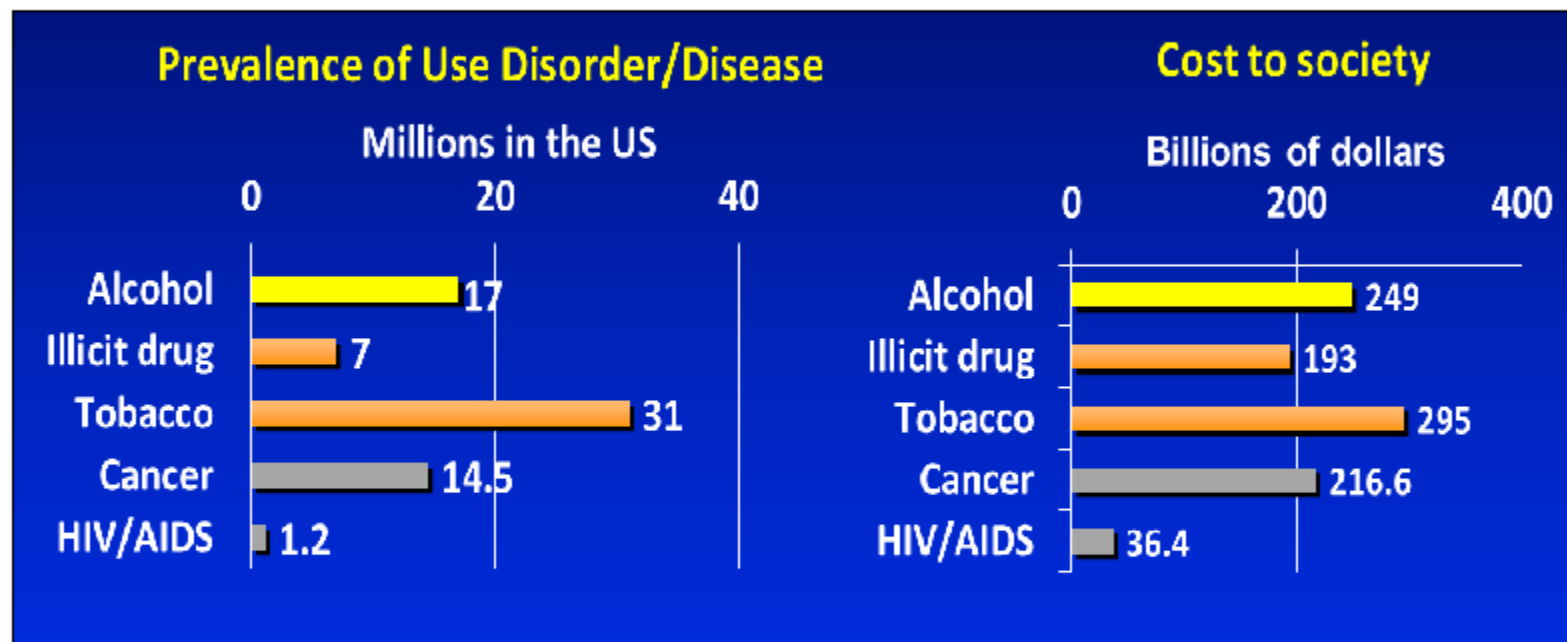
Historically

- Treatment options were limited with little long term follow up.
 - Typical Inpatient Detox and rehab in a “28 day” program
 - Comfort medications or agonist taper; typically with methadone
 - 12 step programs for follow up after rehab (AA/NA)
 - Federally regulated methadone clinics in communities.
 - effective but controversial

Objectives

- Identify the medications used in medication assisted treatment.
- Understand the role of medication assisted treatment in recovery.
- Have a better understanding of how to present MAT to your patients or refer them for treatment/MAT.

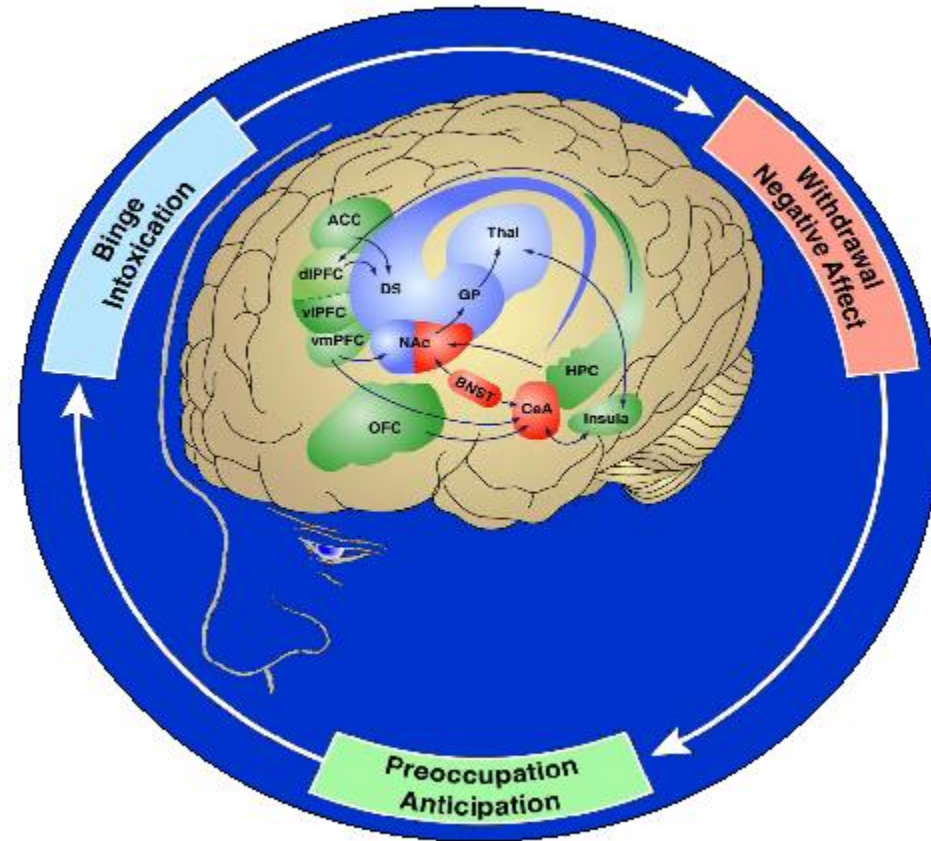
Cost and Scope of Addiction Related Problems



Sources: Prevalence – NSDUH (2014), NCI (2014), CDC (2012); Cost – CDC (2015), National Drug Intelligence Center - National Drug Threat Assessment (2011), 2014 Surgeon General's Report, NHLBI (2012), Hutchinson et. al. 2006.



Neurobiological Circuitry Implicated in Addiction

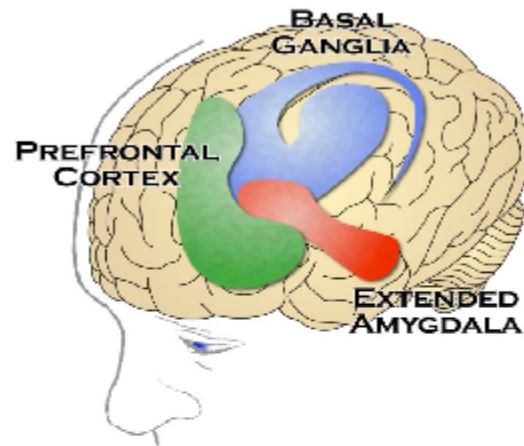


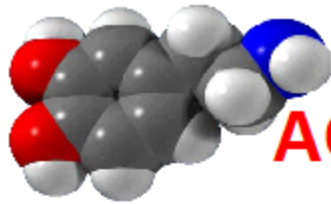
From: Koob GF, Volkow ND. *Neuropsychopharmacol Rev*, 2010, 35:217-238; George O, Koob GF. *Proc Natl Acad Sci USA*, 2013, 110:4165-4166.



Primary Brain Regions Involved in SUDs

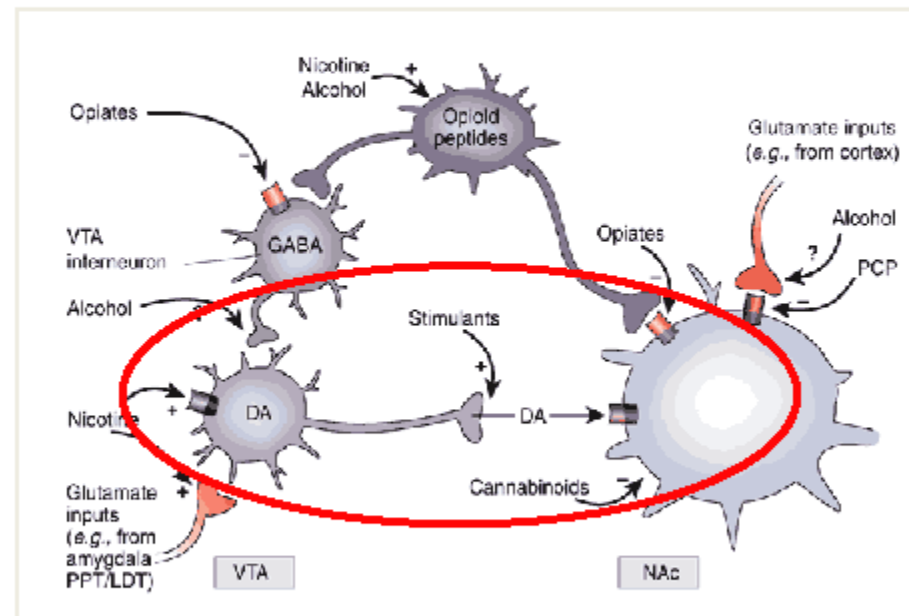
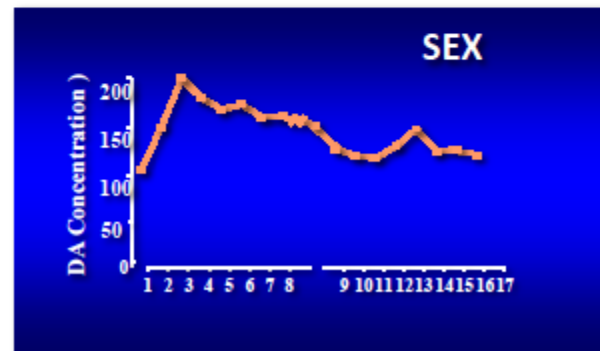
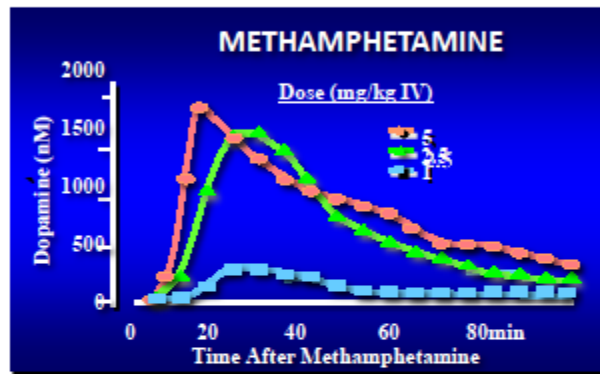
- **Basal ganglia:** controls the rewarding, or pleasurable, effects of substance use (**nucleus accumbens**); responsible for the formation of habitual substance taking (**striatum**)
- **Extended amygdala:** involved in stress and the feelings of unease, anxiety, and irritability that accompany withdrawal
- **Prefrontal cortex:** involved in executive function—the ability to organize thoughts and activities, prioritize task, and make decisions—including exerting control over substance use





Drugs and Natural Rewards

ACTIVATE Dopamine in Reward Regions



Nestler, Nature Neurosci, 2005.



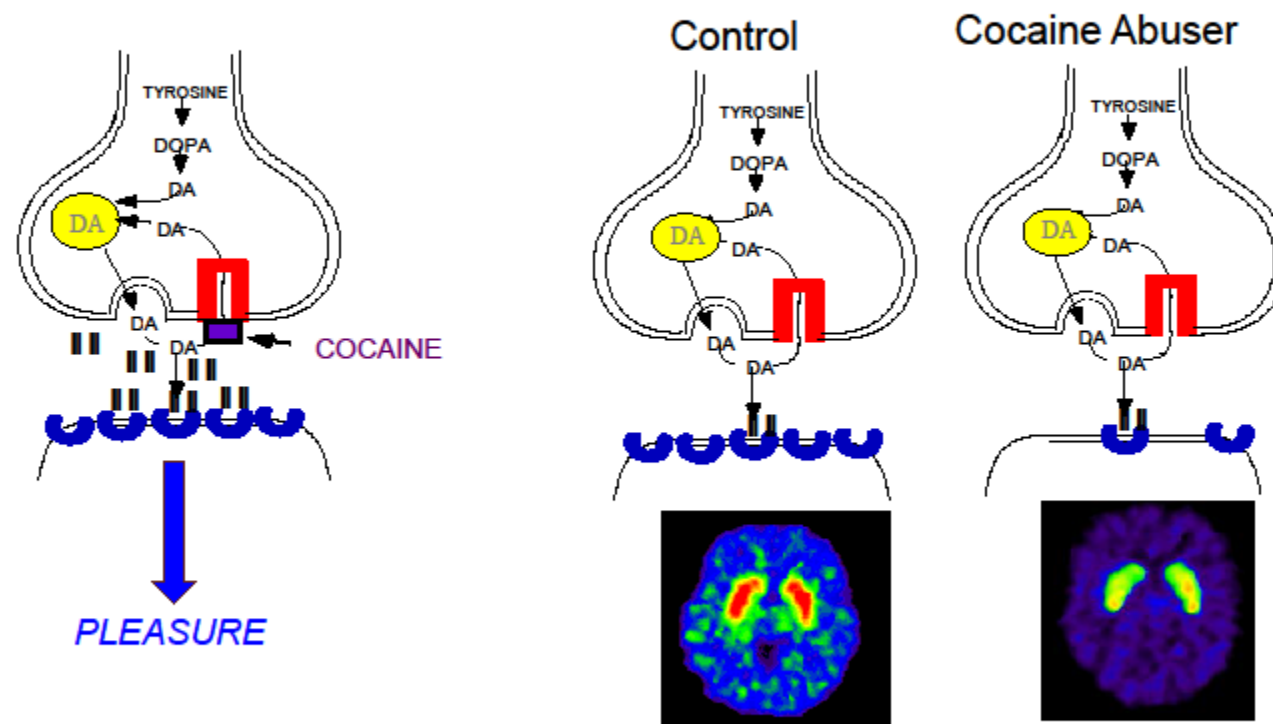
Key Findings

- Addiction is a **chronic, relapsing brain disorder** with potential for recurrence and recovery
- Addiction involves a **three-stage cycle** that becomes more severe with continued substance use:
 - binge/intoxication stage
 - withdrawal/negative affect stage
 - preoccupation/anticipation stage
- The cycle is associated with **dramatic and persistent changes in three principal brain regions**:
 - basal ganglia
 - extended amygdala
 - prefrontal cortex

Key Findings

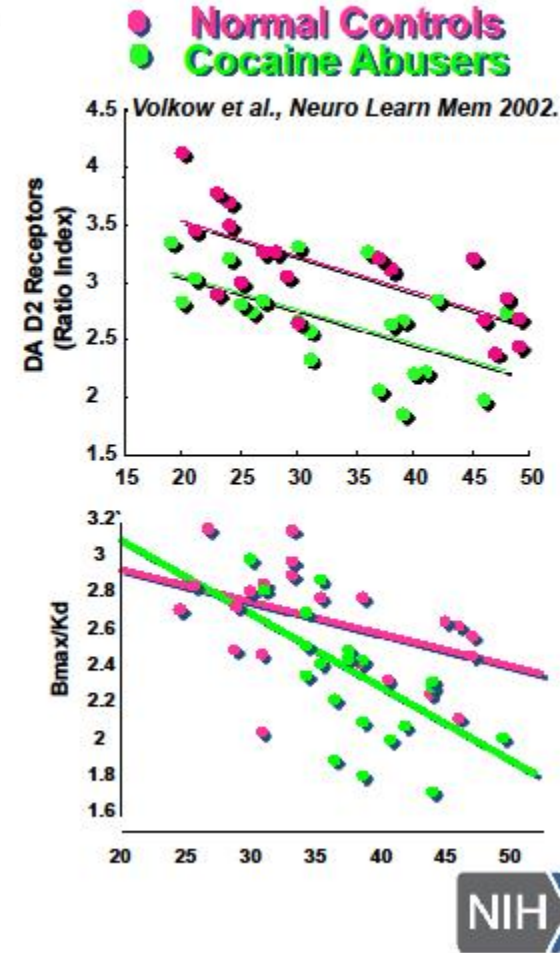
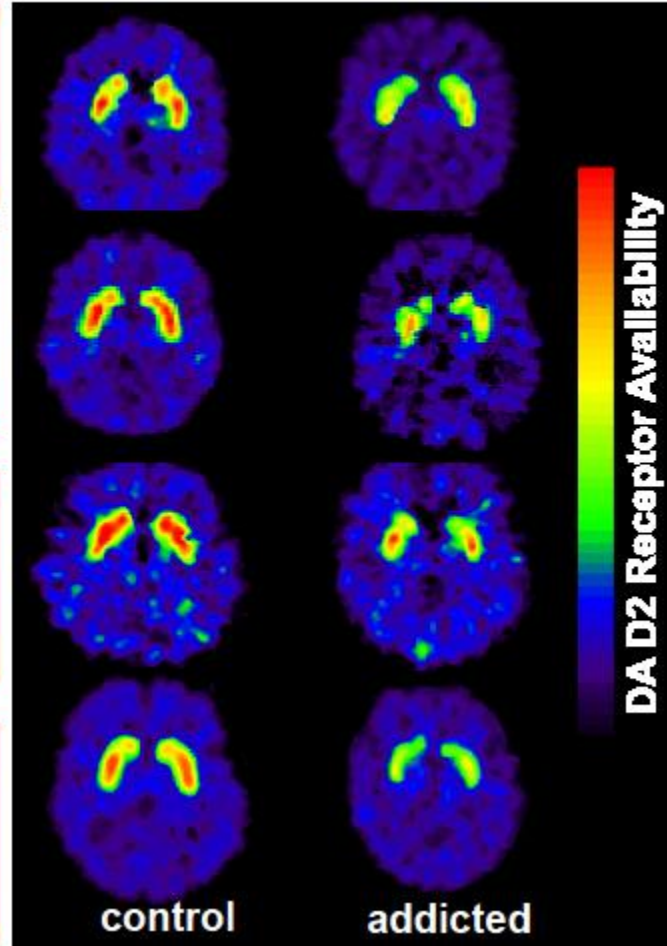
- Disruptions in these brain regions:
 - enable substance-associated cues to trigger substance seeking (i.e., they increase incentive salience)
 - reduce sensitivity of brain reward systems and heighten activation of brain stress systems
 - reduce functioning of brain executive control systems, which are involved decision-making and regulating actions, emotions, and impulses
- Brain changes persist long after substance use stops; it is not known how much these changes may be reversed or how long it takes
- Adolescence is a critical “at-risk period” for substance use and addiction
- All addictive drugs have especially harmful effects on the adolescent brain, which is still undergoing significant development

Repeated Drug Use **Changes the Brain** *Weakens the Brain Dopamine System*

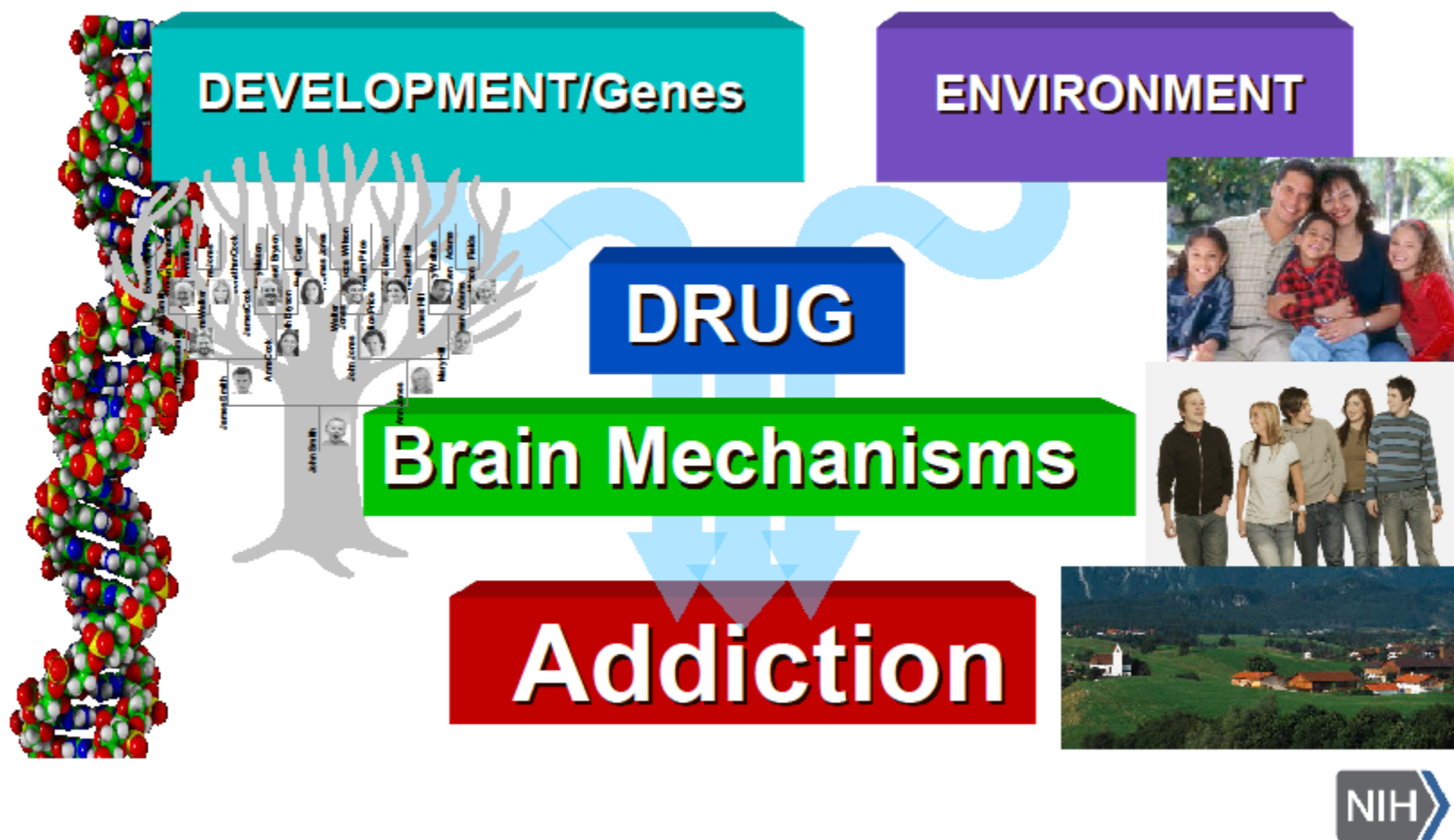


**REPEATED USE OF COCAINE OR OTHER DRUGS
REDUCES LEVELS OF DOPAMINE D2 RECEPTORS**

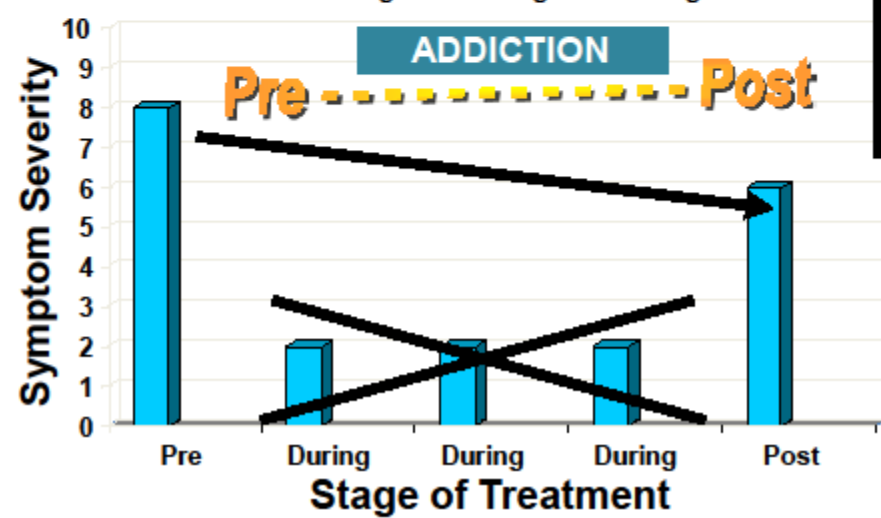
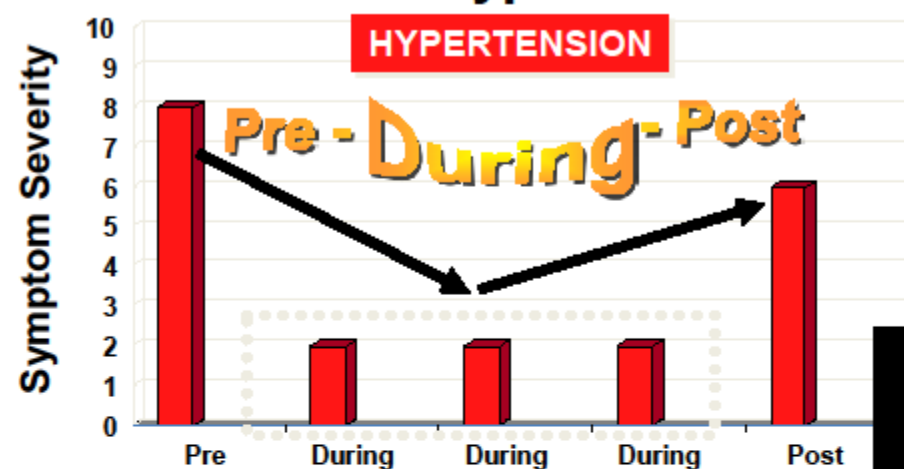
Dopamine D2 Receptors are Lower in Addiction



Addiction Involves *Multiple Factors*



Evaluation of A Hypothetical Treatment

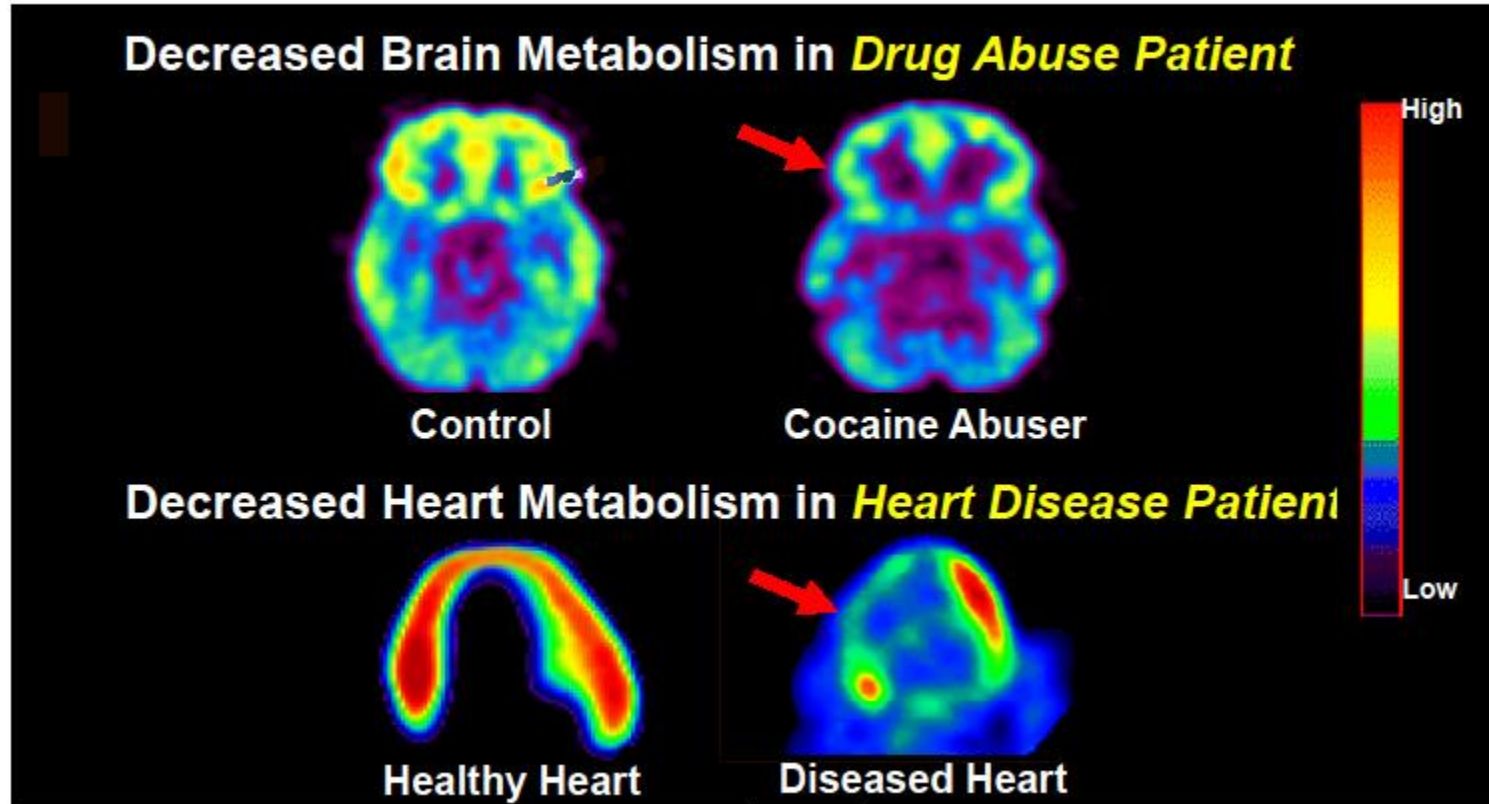


*Just Like Hypertension,
Addiction Is A
Chronic Disease That
Requires Continued Care*

Source: McLellan, AT, *Addiction* 97, 249-252, 2002.

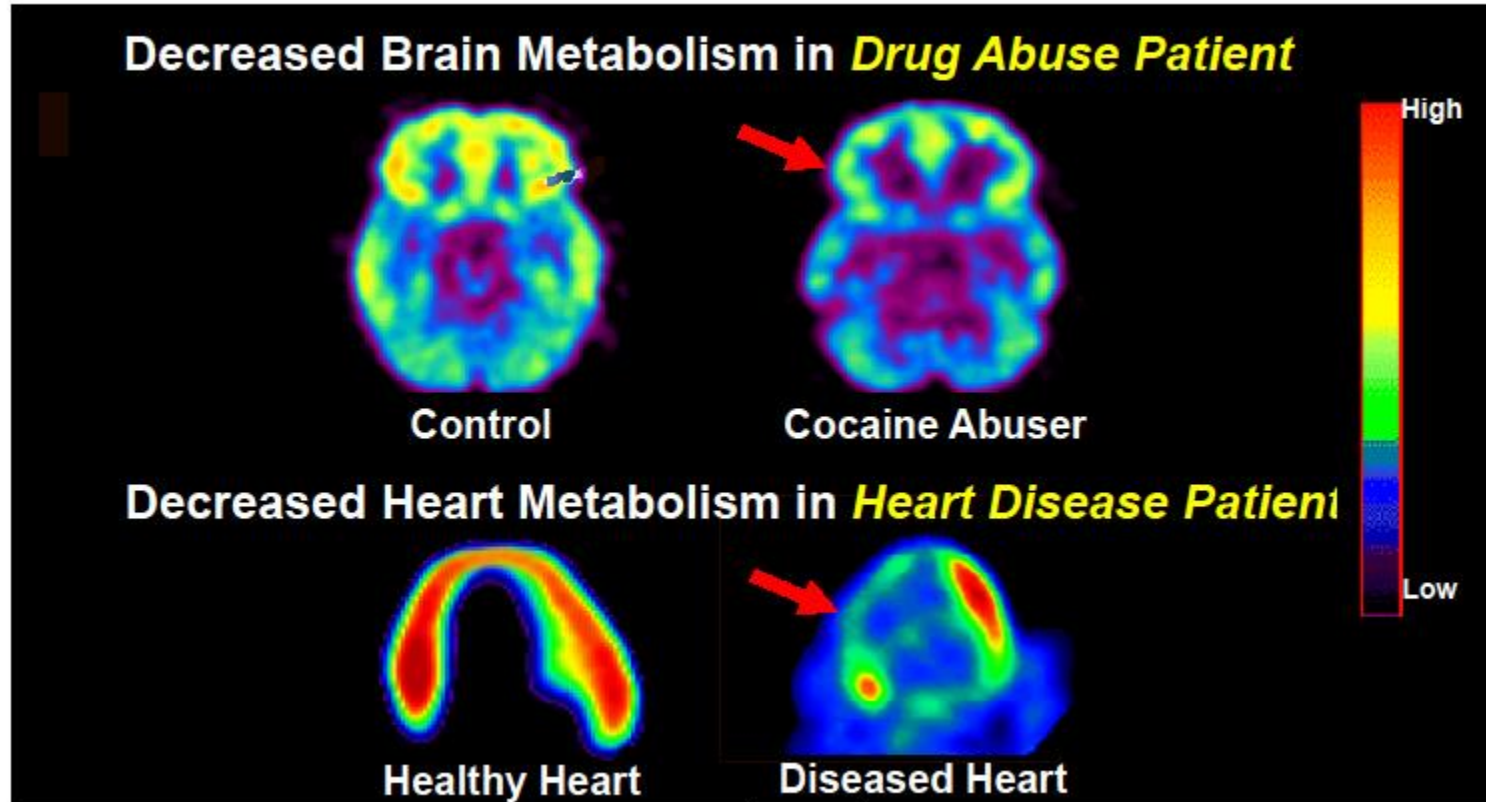


ADDICTION IS A DISEASE OF THE BRAIN
as other diseases it affects the tissue function



Sources: From the laboratories of Drs. N. Volkow and H. Schelbert

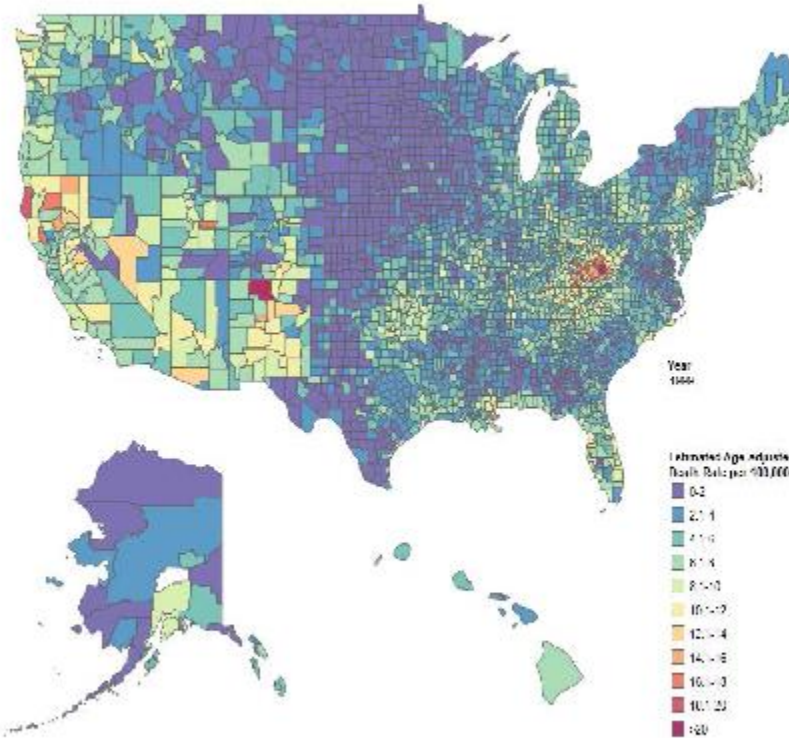
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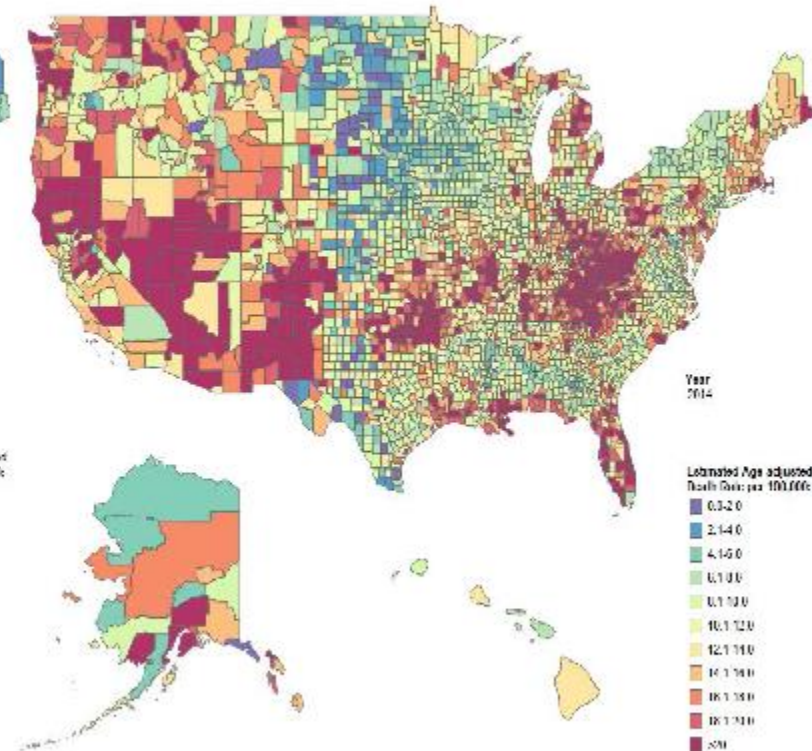
Sources: From the laboratories of Drs. N. Volkow and H. Schelbert

Overdose Death Rates

1999



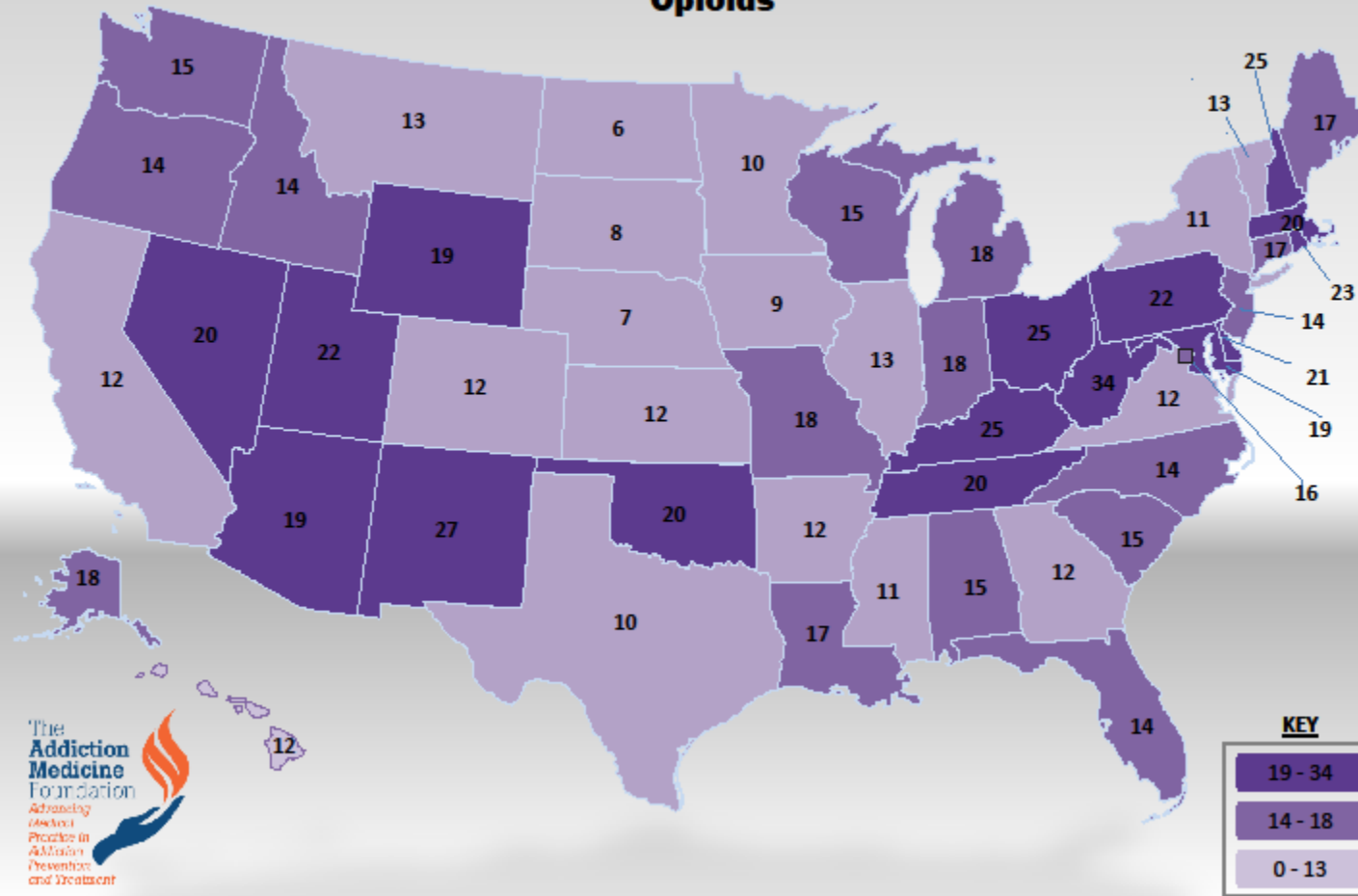
2014



Designed by L. Rossen, B. Bastian & Y. Chong. SOURCE: CDC/NCHS, National Vital Statistics System.



Death Rate per 100,000 Residents **Opioids**



President Barack Obama

**National Prescription Drug
Abuse and Heroin Summit**

Atlanta Georgia -- March 29, 2016

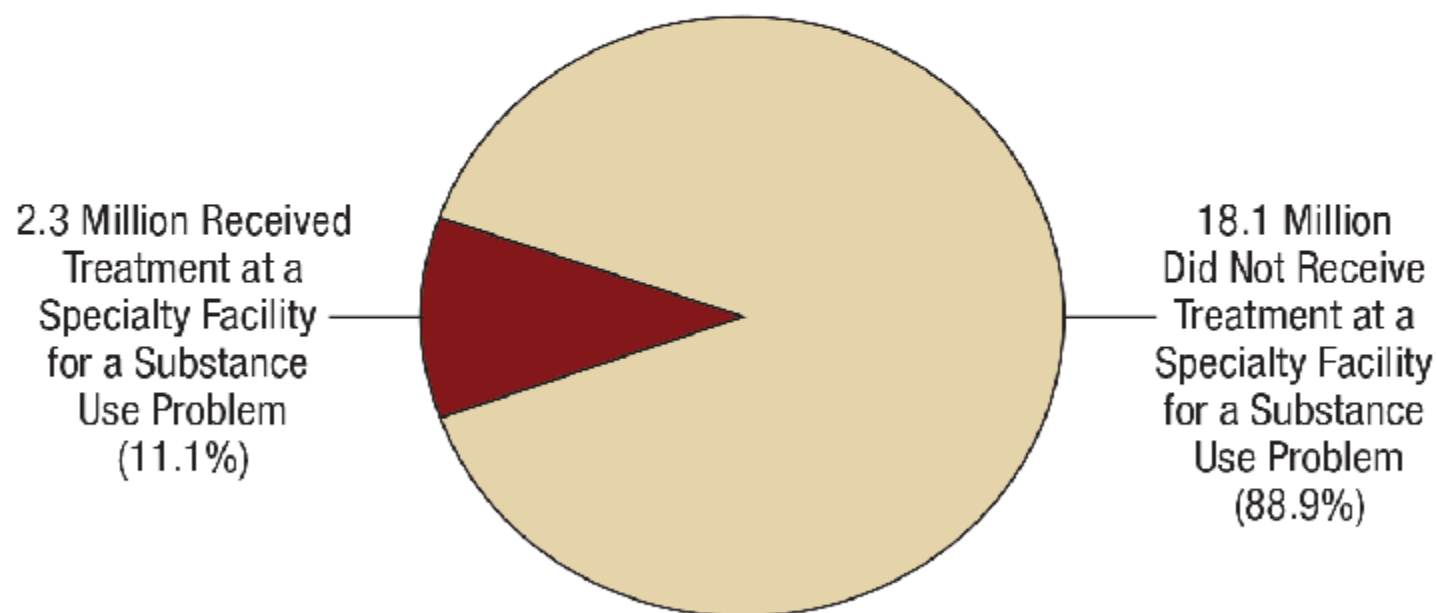


***“.....we need to recognize that addiction is a disease.
If we treat addiction like a crime then we're doing
something that'sineffective.***

***.... taking parity seriously so that mental health issues
and addiction issues are treated as a disease in the
same way that if somebody came in with a serious
medical illness that it's treated”***



Receipt of Specialty Treatment in Past Year Adults 18 or Older Who Needed Substance Use Treatment in the Past Year: 2015 NSDUH



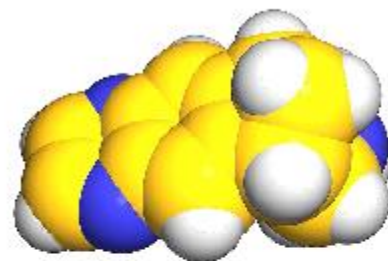
20.4 Million Adults Needed Substance Use Treatment



Medical Treatment for Addictions

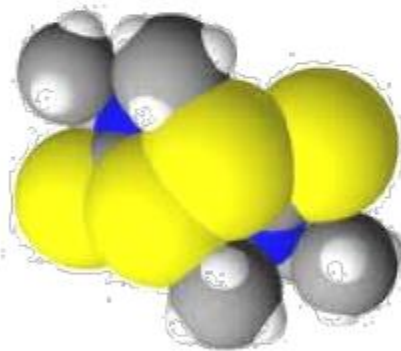
For Nicotine Addiction

- Nicotine Replacement Therapies (NRT)
- Bupropion
- Varenicline



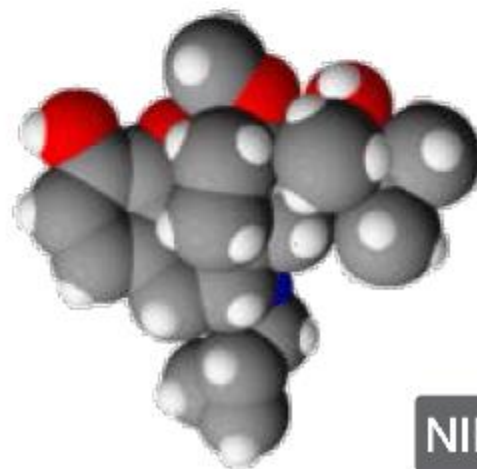
For Alcoholism

- Disulfiram
- Naltrexone
- Acamprosate
- Naltrexone ER



Opioid Addiction

- Methadone
- Naltrexone ER
- Buprenorphine



Regulation and Standard Setting

Protecting public health, privacy, and patients' rights by supporting regulation and standard setting



DEPARTMENT OF HEALTH AND
HUMAN SERVICES

42 CFR Part 8

RIN 0930-AA22

Medication Assisted Treatment for
Opioid Use Disorders

AGENCY: Substance Abuse and Mental
Health Services Administration (SAMHSA),
HHS.

ACTION: Proposed rule.

SUMMARY: The Secretary of the
Department of Health and Human Services
(the Secretary) (HHS) proposes a rule to
increase the highest patient limit for
qualified physicians to treat opioid use
disorder under section 303(g)(2) of the
Controlled Substances

Medication Assisted Treatment (MAT)

MAT is treatment for opioid addiction that includes the use of medication along with counseling and other support. The most common medications used in MAT are :

1. Methadone
2. Buprenorphine
3. Naltrexone

Medication Assisted Treatment

- What medications can be used for treatment of Opioid Use Disorders in the United States??
- DATA 2000
- Methadone by prescription (pain only) DEA CII
- Naltrexone by prescription

Partial Agonist /Antagonist Medications

Buprenorphine (Suboxone)

- DATA 2000
- DEA X number
- Limited prescribers by design
 - Waived Physician (??)
 - Limits 30,100, 275 (recent)
 - Is a CIII substance and further regulated some states.

Naltrexone (Vivitrol)

- Initially approved for Alcohol dependence then Opioid Dependence
- NOT a controlled Substance
- No limited prescribers
- No additional training

Medication-Assisted Treatment for Opioid Addiction



Facts for Families and Friends



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Treatment
www.samhsa.gov

ADDICTION

WHAT'S TRUE AND WHAT'S NOT

Addiction is a disease. It cannot be cured, but it can be treated with medication, counseling, and support from family and friends. Addiction is NOT a sign of weakness. It is NOT TRUE that all anybody needs to kick addiction is to "be strong."

The goal of medication-assisted treatment is to recover from addiction. It does NOT replace one addictive drug with another. It provides a safe, controlled level of medication to overcome the use of a problem opioid.

A substance abuse treatment provider must obtain informed consent (agreement in writing) before sharing information about patients.

There are two exceptions to this privacy rule: (1) if it appears that patients may harm themselves or others and (2) if patients have been ordered into treatment by the courts. To learn more about privacy rights, talk to a substance abuse treatment provider.

Recovery is possible. But it takes work. After treatment is finished, everything is NOT automatically fine again. Recovery takes commitment every day, through treatment and beyond.

MEDICATION GUIDE

VIVITROL® (viv-i-trol)

(naltrexone for extended-release injectable suspension)

Read this Medication Guide before you start receiving VIVITROL injections and each time you receive an injection. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about VIVITROL?

VIVITROL can cause serious side effects, including:

1. Risk of opioid overdose.

You can accidentally overdose in two ways.

- VIVITROL blocks the effects of opioids, such as heroin or opioid pain medicines. **Do not** take large amounts of opioids, including opioid-containing medicines, such as heroin or prescription pain pills, to try to overcome the opioid-blocking effects of VIVITROL. This can lead to serious injury, coma, or death.
- After you receive a dose of VIVITROL, its blocking effect slowly decreases and completely goes away over time. If you have used opioid street drugs or opioid-containing medicines in the past, using opioids in amounts that you used before treatment with VIVITROL can lead to overdose and death. You may also be more sensitive to the effects of **lower** amounts of opioids:
 - after you have gone through detoxification
 - when your next VIVITROL dose is due
 - if you miss a dose of VIVITROL
 - after you stop VIVITROL treatment

It is important that you tell your family and the people closest to you of this increased sensitivity to opioids and the risk of overdose.

You or someone close to you should get emergency medical help right away if you:

- have trouble breathing
- become very drowsy with slowed breathing
- have slow, shallow breathing (little chest movement with breathing)
- feel faint, very dizzy, confused, or have unusual symptoms

2. Severe reactions at the site of the injection (injection site reactions).

Some people on VIVITROL have had severe injection site reactions, including tissue death (necrosis). Some of these injection site reactions have required surgery. Call your healthcare provider right away if you notice any of the following at any of your injection sites:

- intense pain
- the area feels hard
- large area of swelling
- lumps
- blisters
- an open wound
- a dark scab

Tell your healthcare provider about any reaction at an injection site that concerns you, gets worse over time, or does not get better by two weeks after the injection.

3. Sudden opioid withdrawal.

Anyone who receives a VIVITROL injection must not use any type of opioid (must be opioid-free) including street drugs, prescription pain medicines, cough, cold, or diarrhea medicines that contain opioids, or opioid dependence treatments, buprenorphine or methadone, **for at least 7 to 14 days** before starting VIVITROL. Using opioids in the 7 to 14 days before you start receiving VIVITROL may cause you to suddenly have symptoms of opioid withdrawal when you get the VIVITROL injection. **Sudden opioid withdrawal can be severe, and you may need to go to the hospital.**

You must be opioid-free before receiving VIVITROL unless your healthcare provider decides that you don't need to go through detox first. Instead, your doctor may decide to give your VIVITROL injection in a medical facility that can treat you for sudden opioid withdrawal.

4. Liver damage or hepatitis. Naltrexone, the active ingredient in VIVITROL, can cause liver damage or hepatitis.

Tell your healthcare provider if you have any of the following symptoms of liver problems during treatment with VIVITROL:

- stomach area pain lasting more than a few days
- dark urine
- yellowing of the whites of your eyes
- tiredness

Your healthcare provider may need to stop treating you with VIVITROL if you get signs or symptoms of a serious liver problem.

What is VIVITROL?

VIVITROL is a prescription injectable medicine used to:

- treat alcohol dependence. You should stop drinking before starting VIVITROL.
 - prevent relapse to opioid dependence, **after** opioid detoxification.
- This means that if you take opioids or opioid-containing medicines, you must stop taking them before you start receiving VIVITROL. See **"What is the most important information I should know about VIVITROL?"**

To be effective, treatment with VIVITROL must be used with other alcohol or drug recovery programs such as counseling. VIVITROL may not work for everyone.

It is not known if VIVITROL is safe and effective in children.

Who should not receive VIVITROL?

Do not receive VIVITROL if you:

- are using or have a physical dependence on opioid-containing medicines or opioid street drugs. See **"What is the most important information I should know about VIVITROL?"**
- To see whether you have a physical dependence on opioid-containing medicines or opioid street drugs, your healthcare provider may give you a small injection of a medicine called naloxone. This is called a naloxone challenge test. **If you get symptoms of opioid withdrawal after the naloxone challenge test, do not start treatment with VIVITROL at that time.** Your healthcare provider may repeat the test after you have stopped using opioids to see whether it is safe to start VIVITROL.
- are having opioid withdrawal symptoms. Opioid withdrawal symptoms may happen when you have been taking opioid-containing medicines or opioid street drugs regularly and then stop.

Symptoms of opioid withdrawal may include: anxiety, sleeplessness, yawning, fever, sweating, teary eyes, runny nose, goose bumps, shakiness, hot or cold flushes, muscle aches, muscle twitches, restlessness, nausea and vomiting, diarrhea, or stomach cramps. See **"What is the most important information I should know about VIVITROL?"** Tell your healthcare provider if you have any of these symptoms before taking VIVITROL.

- are allergic to naltrexone or any of the ingredients in VIVITROL or the liquid used to mix VIVITROL (diluent). See the end of this Medication Guide for a **complete list of ingredients** in VIVITROL and the diluent.

What should I tell my healthcare provider before receiving VIVITROL?

Before you receive VIVITROL, tell your healthcare provider if you:

- have liver problems
- use or abuse street (illegal) drugs
- have hemophilia or other bleeding problems
- have kidney problems
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if VIVITROL will harm your unborn baby.
- are breastfeeding. It is not known if VIVITROL passes into your milk, and if it can harm your baby. Naltrexone, the active ingredient in VIVITROL, is the same active ingredient in tablets taken by mouth that contain naltrexone. Naltrexone from tablets passes into breast milk. Talk to your doctor about whether you will breastfeed or take VIVITROL. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you take any opioid-containing medicines for pain, cough or colds, or diarrhea. See **“What is the most important information I should know about VIVITROL?”**

If you are being treated for alcohol dependence but also use or are addicted to opioid-containing medicines or opioid street drugs, it is important that you tell your healthcare provider before starting VIVITROL to avoid having sudden opioid withdrawal symptoms when you start VIVITROL treatment.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How will I receive VIVITROL?

- VIVITROL is injected by a healthcare provider, about 1 time each month.
- VIVITROL is given as an injection into a muscle in your buttocks using a special needle that comes with VIVITROL.
- After VIVITROL is injected, it lasts for a month and it cannot be removed from the body.
- If you miss your appointment for your VIVITROL injection, schedule another appointment as soon as possible. See **“What is the most important information I should know about VIVITROL?”**
- Whenever you need medical treatment, be sure to tell the treating healthcare provider that you are receiving VIVITROL injections and mention when you got your last dose. This is important because VIVITROL can also block the effects of opioid-containing medicines that might be prescribed for you for pain, cough or colds, or diarrhea.
- Carry written information with you at all times to alert healthcare providers that you are taking VIVITROL, so that they can treat you properly in an emergency. Ask your healthcare provider how you can get a wallet card to carry with you.

What should I avoid while receiving VIVITROL?

Do not drive a car, operate machinery, or do other dangerous activities until you know how VIVITROL affects you. VIVITROL may make you feel dizzy and sleepy. See **“What are the possible side effects of VIVITROL?”**

What are the possible side effects of VIVITROL?

VIVITROL can cause serious side effects, including:

- See **“What is the most important information I should know about VIVITROL?”**
- **Depressed mood.** Sometimes this leads to suicide, or suicidal thoughts, and suicidal behavior. Tell your family members and people closest to you that you are taking VIVITROL. You, a family member, or the people closest to you should call your healthcare provider right away if you become depressed or have any of the following symptoms of depression, especially if they are new, worse, or worry you:
 - You feel sad or have crying spells.
 - You are no longer interested in seeing your friends or doing things you used to enjoy.
 - You are sleeping a lot more or a lot less than usual.
 - You feel hopeless or helpless.
 - You are more irritable, angry, or aggressive than usual.
 - You are more or less hungry than usual or notice a big change in your body weight.
 - You have trouble paying attention.
 - You feel tired or sleepy all the time.
 - You have thoughts about hurting yourself or ending your life.

- **Pneumonia.** Some people receiving VIVITROL treatment have had a certain type of pneumonia that is caused by an allergic reaction. If this happens to you, you may need to be treated in the hospital. Tell your healthcare provider right away if you have any of these symptoms during treatment with VIVITROL:
 - shortness of breath or wheezing
 - coughing that does not go away

- **Serious allergic reactions.** Serious allergic reactions can happen during or soon after an injection of VIVITROL. Tell your healthcare provider or get medical help right away if you have any of these symptoms of a serious allergic reaction:
 - skin rash
 - swelling of your face, eyes, mouth, or tongue
 - trouble breathing or wheezing
 - chest pain
 - feeling dizzy or faint

Common side effects of VIVITROL may include:

- nausea. Nausea may happen after your first VIVITROL injection and usually improves within a few days. Nausea is less likely with future injections of VIVITROL.
- sleepiness
- headache
- dizziness
- vomiting
- decreased appetite
- painful joints
- muscle cramps
- cold symptoms
- trouble sleeping
- toothache

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the side effects of VIVITROL. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about VIVITROL

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. This Medication Guide summarizes the most important information about VIVITROL. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about VIVITROL that is written for health professionals.

For more information about VIVITROL, call 1-800-848-4876, Option #1 or go to www.vivitrol.com.

What are the ingredients in VIVITROL?

Active ingredient: naltrexone

Inactive ingredient: polylactide-co-glycolide (PLG)

Diluent ingredients: carboxymethylcellulose sodium salt, polysorbate 20, sodium chloride, and water for injection

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured and marketed by:

Alkermes, Inc.

852 Winter Street

Waltham, MA 02451-1420

Revised: July 2013; VIV-001409

Alkermes® and VIVITROL® are registered trademarks of Alkermes, Inc.

The Future

- Detoxification for opiates unless paired with a long acting antagonist (Vivitrol, Naltrexone Implant), longitudinal monitoring and CM will not be seen as medically appropriate
- Treating depression and other co-occurring disorders will become more important
- The use of agonists for opiate dependency will be seen through a medical lens rather than a spiritual lens
- Agonist therapy by itself will never suffice – low retention, high co-occurring substance misuse

What Doesn't Work?

- Detox by itself
 - No better than no treatment
- Medications for cocaine, stimulants
- Oral naltrexone for opiate dependency – OD risk
- SBIRT (Screening, Brief Intervention, Referral to Treatment)
 - You must do more

Drug Treatments: What Works?

- Standard treatment – counseling and community support
- Longer treatment is always better than shorter treatment but the setting may be less important
- UDS Monitoring + rewards/consequences improves outcomes across a range of drug dependencies
- No single medication treatment works better than 40% of the time at 1 year
- Reduced use is more common and stable than abstinence in the first year following treatment

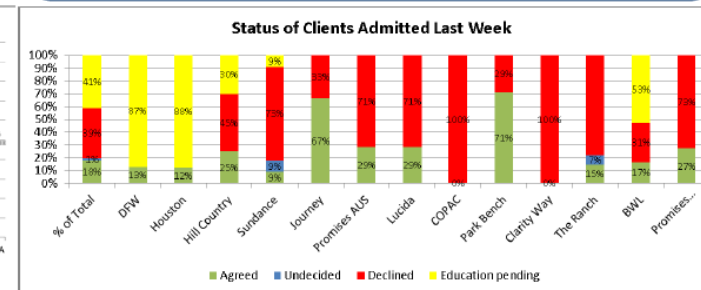
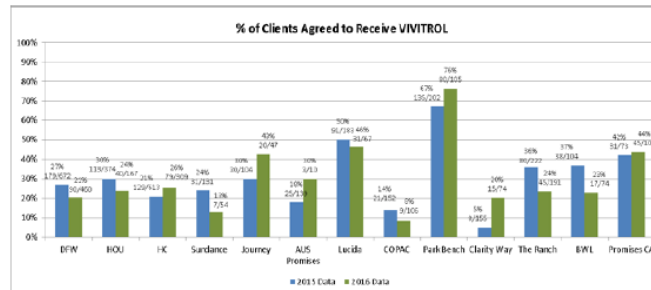
Ensuring Opiate Clients Get Medications

VIVITROL – Summary

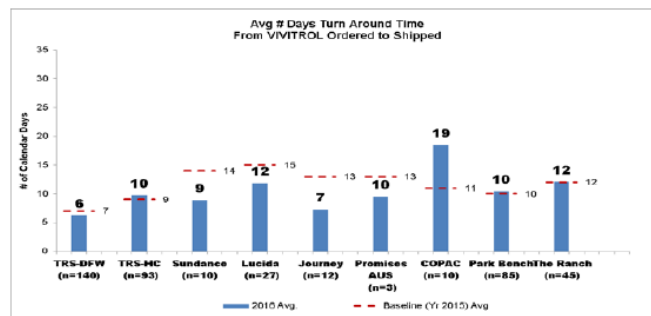
June 2016

Comments:

- 57 clients agreed to receive VIVITROL (does not include refills)
- Clients that agreed to use VIVITROL for this period decreased from 28% to 18%
- Refresher training given to The Ranch staff in July
- Due to change in staff at TRS HOU and DFW, some of the metrics were not available. Metrics for these facilities were based off of census and # of enrollments received. At this time, we're unable to determine how many clients received the education, declined or are considering VIVITROL



Client - VIVITROL Status (Eligible Clients)															
Status of Eligible Clients	% of Total	Total	DFW	HOU	HC	Sundance	Journey	AUS Prom	Lucida	COPAC	Park Bench	Clarity Way	The Ranch	BWL	Promises CA
Agreed	18%	57	8	5	15	1	4	2	2	0	5	0	6	6	3
Undecided	1%	4			0	1	0	0	0	0	0	0	3	0	0
Declined	39%	123			27	8	2	5	5	18	2	5	32	11	8
Education pending	41%	128	54	36	18	1	0	0	0	0	0	0	0	19	0
All		312	62	41	60	11	6	7	7	18	7	5	41	36	11



Turn Around Time (Calendar Days)				
Request Type	# of samples	Min TAT	Max TAT	Avg. TAT
Touchpoints	354	0 ²	59*	10
Specialty Pharmacy ¹	67	0 ²	29*	6

*Client placed order temporarily on hold (hold time was approx. 1 1/2 month)

¹ TAT for facilities processing own requests directly with specialty pharmacy not included

² Some refills were shipped on the same day of request

³ Includes orders shipped this year regardless of order date

Method of VIVITROL Request		
SP or Touchpoint	# Clients	Comment
Specialty Pharmacy	9	
Touchpoint	48	Clients need to be referred to an injector

Opioid Use Disorder

-addiction is a brain disorder its symptoms may be drugs, alcohol, gambling, sex.....

-long term treatment is needed as in traditional “medical disease states”

Diabetes model/CVD

-Return to functioning and treatments may change with time.

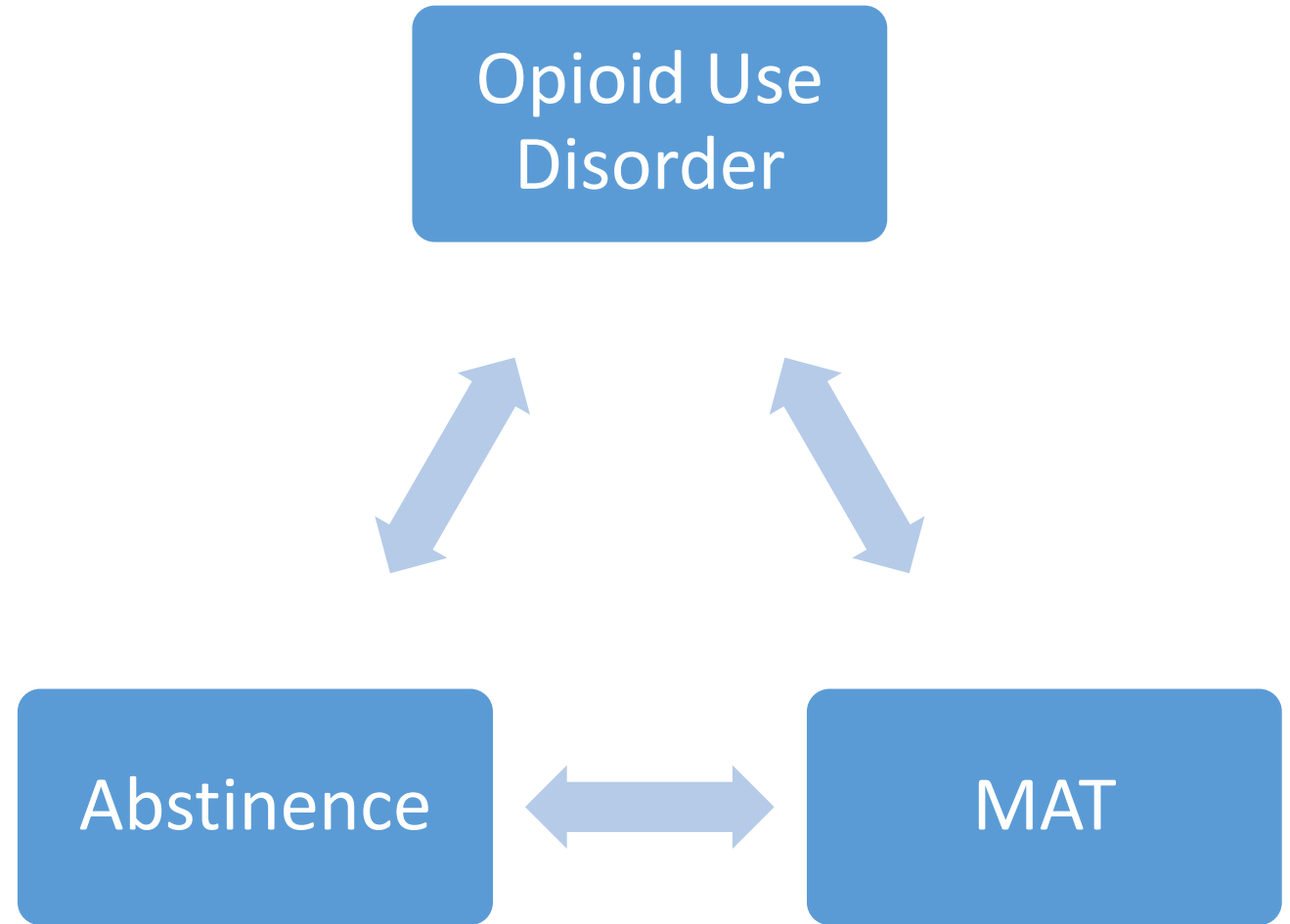
-Medication alone is never the answer

-Treat co-occurring MH diagnoses

MDD, BP, Mood DO, ADD,PTSD

-Treat co-occurring Medical diagnoses

DM2,HTN,CAD,MS,DJD



Treatment Concerns

- Inpatient treatment is becoming increasingly difficult even with tools such as ASAMs PPC. Every benefits plan is different. Be prepared for quick discharges and transfers to lower levels of care.
- Include the patient in the treatment plan so they are not surprised.
- We can no longer NOT discuss treatment options with our patients. Informed consent is expected.
- Change happens slowly and is often bidirectional.
- Treatments will change over time. Fostering those changes is our responsibility as providers

Questions?

Thoughts?

MAT is not drug substitution

MAT is not effective without a complete treatment plan

Detox only is not treatment

Not one treatment works for everyone

Cravings are real and relapse is real

AEDs save lives. Narcan saves lives too