Addiction and Mental Health

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What's New ??

- Screening (SBIRT)
- Diagnosis: The Transition to DSM-V
- Synthetic Cathinones
  - "Bath Salts"
- Rx Drug Misuse/Abuse Epidemiology
  - Prescription Opioids
  - Treatment of Rx Opioid Dependence
    - POATS study – NIDA Clinical Trials Network (CTN)

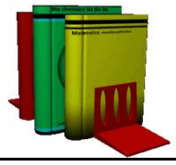
Screening, Brief Intervention and Referral to Treatment

(SBIRT)

SBIRT = Still the Gold Standard

"A comprehensive and integrated approach to the delivery of early intervention and treatment services through universal screening for persons with substance use disorders and those at risk."

(Babor et al., 2007)



Why SBIRT?

- Doesn't require people trained in addiction/treatment
- Views alcohol and drug use along a continuum – not categorical yes/no ("addicted"/"not addicted")
- Uses a non-confrontational style that places responsibility for change on the patient

Increased Recognition that:

- SBIRT has prevention **and** treatment components
  - seeks to prevent negative consequences of alcohol/drugs
  - Tries to intervene earlier in development/ progression of problems
  - It **IS** Treatment for some individuals

SBIRT is Being Used…

In More Settings……

- Primary care
- Trauma centers
- Hospital emergency rooms
- Community health centers
- ***…..and many more***

SBIRT

Screening

What's Important?

- **HOW** you ask about alcohol/drugs
  - matter-of-fact
  - Non-judgmental
- Use items that are reliable and valid

It is like your GPS….

- You have the short route, the fast route, and the scenic route…

The Old Favorites……

- **AUDIT** ***(Alc)***
- **CAGE** ***(Alc and Drugs)***
- **ASSIST** ***(Alc and Drugs)***
- **CRAFFT** ***(Alc and Drugs)***
- **T-ACE/TWEAK** ***(Alc – Pregnant Women)***

CAGE

1. Have you ever felt you should Cut down on your drinking (drug use)? **Yes/No**
2. Have people Annoyed you by criticizing your drinking (drug use)? **Yes/No**
3. Have you ever felt bad or Guilty about your drinking (drug use)? **Yes/No**
4. Have you had an Eye opener first thing in the morning to steady nerves or get rid of a hangover? **Yes/No**

Scoring: A score of 1 (women) or 2 (men) = screen positive

(Ewing, 1984)

AUDIT-C

1. **How often do you have a drink containing alcohol?**
   - ☐ a. Never
   - ☐ b. Monthly or less
   - ☐ c. 2-4 times a month
   - ☐ d. 2-3 times a week
   - ☐ e. 4 or more times a week

AUDIT-C

2. **How many standard drinks containing alcohol do you have on a typical day?**
   - ☐ a. 1 or 2
   - ☐ b. 3 or 4
   - ☐ c. 5 or 6
   - ☐ d. 7 to 9
   - ☐ e. 10 or more

AUDIT-C

3. **How often do you have six or more drinks on one occasion?**
   - ☐ a. Never
   - ☐ b. Less than monthly
   - ☐ c. Monthly
   - ☐ d. Weekly
   - ☐ e. Daily or almost daily

AUDIT-C

Scoring

The AUDIT-C is scored on a scale of 0-12.

Each AUDIT-C question has 5 answer choices. Points allotted are:
a = 0 points, b = 1 point, c = 2 points, d = 3 points, e = 4 points

- **In men**, a score of 4 or more is considered positive, optimal for identifying hazardous drinking or active alcohol use disorders.
- **In women**, a score of 3 or more is considered positive (same as above).

Bradley et al., 2003; Bush et al., 1998

Brief Intervention (BI)

- Any time-limited effort to provide:
  - information or advice
  - increase motivation to avoid substance use (Motivational Interviewing (MI)
  - teach behavior change skills to reduce substance use and chances of negative consequences

(Babor et al., 2007)

In Some Settings: Brief Treatment

- Delivery of time-limited, structured therapy for a substance use disorder
- Requires trained clinician
- Targets those at higher risk or in early stages of dependence
- Generally involves 2-6 sessions
  - cognitive-behavioral
  - motivational enhancement therapy
- Could also involve use of pharmacotherapies

(Babor, McRee, Kassebaum, Grimaldi, Ahmed and Bray, 2011)

Referral to Treatment (RT): Integration +

- Creating a coordinated system of services that link specialized community treatment programs with network of early intervention and referral activities through medical and social service settings

MH Screening

Modified Mini Screen (MMS)

- Generic screener for mood, anxiety, and psychotic spectrum disorders.
- 22 questions with yes/no responses
- Takes 15 minutes to complete.

1. Have you been consistently depressed or down, most of the day, nearly every day, for the past two weeks?
2. In the past two weeks, have you been less interested in most things or less able to enjoy the things you used to enjoy most of the time?
9. Have you worried excessively or been anxious about several things over the past six months?
20. Have your relatives or friends ever considered any of your beliefs strange or unusual?
21. Have you ever heard things other people couldn't hear, such as voices?

Alexander et al. 2008. Mental Health Screening in Addiction, Corrections and Social Service Settings: Validating the MMS. International Journal on the Addictions 6 (1): 105–19.

MMS Scoring

- 1 point per yes response
- Score of ≥ 6 indicates the likely presence of a psychiatric disorder.

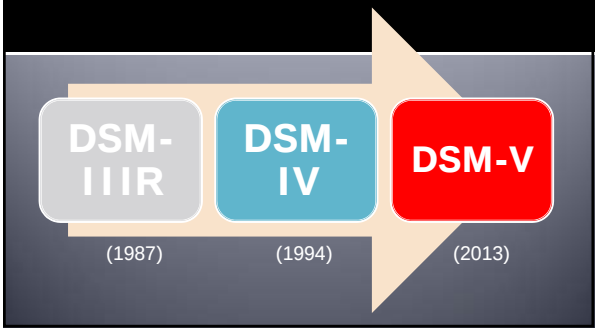
A patient who answers yes to question 4 should be monitored for suicidality.

A patient who answers yes to questions 14 and 15 should be assessed for trauma.

Alexander et al. 2008. Mental Health Screening in Addiction, Corrections and Social Service Settings: Validating the MMS. International Journal on the Addictions 6 (1): 105–19.

Diagnosis

What's new??



Why Change?

- Term "Dependence" was problematic
  - Confusion between dependence and addiction
  - Tolerance and withdrawal in patients who are prescribed medications that affect the CNS = very normal
  - In contrast, addiction is compulsive drug-seeking behavior (O'Brien, 2010)
- Studies didn't support diagnosis of Abuse (single criterion of Hazardous Use)
- No category for people who met 2 Dependence criteria but no Abuse criteria

The Facts

- No evidence of a distinction between Abuse and Dependence
- Solution:
  - Combine Abuse & Dependence into a single diagnosis with ***graded clinical severity***
- New DSM V Category: Substance Use and Addictive Disorders

Substance Use and Addictive Disorders

We will still have:
Substance Intoxication (adding caffeine)
Substance Withdrawal (adding caffeine)
Substance Induced Disorders
Mild and Major Neurocognitive Disorder …Associated with SUDs

Primary Changes

- **Added craving as a criterion for diagnosis**

+

- **Dropped encounters with law enforcement as a criterion**

+

Substance Use Disorder

- *A maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by 2 (or more) of the following, occurring within a 12-month period*
  - Recurrent substance use resulting in a **failure to fulfill major role obligations at work, school or home** (repeated absences or poor work performance related to SU; substance-related absences, suspensions or expulsions from school; neglect of children or household)

#1

Substance Use Disorder

- Recurrent substance use in situations in which it is **physically hazardous** (e.g., driving an automobile or operating a machine when impaired by SU)
- Continued substance use despite having **persistent or recurrent social or interpersonal problems** caused or exacerbated by the effects of the substance (e.g., arguments with spouse about consequences of intoxication, physical fights)

2 & 3

Substance Use Disorder

- **Tolerance**, as defined by either of the following:
  - A need for markedly increased amounts of the substance to achieve intoxication or desired effect
  - Markedly diminished effect with continued use of the same amount of the substance
    - (Note: Tolerance is not counted for those taking medications under medical supervision (e.g., analgesics, antidepresssants or anti anxiety medications or beta blockers)

#4

Substance Use Disorder

- **Withdrawal**, as manifested by either of the following:
  - The characteristic withdrawal syndrome for the substance
  - The same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms
    - (Note: Withdrawal is not counted for those taking medications under medical supervision (e.g., analgesics, antidepresssants or anti anxiety medications or beta blockers)

#5

Substance Use Disorder

- The substance is often taken in **larger amounts or over a longer period** than was intended
- There is a persistent desire or unsuccessful efforts to **cut down** or control SU
- A great deal of time is spent in activities necessary to **obtain** the substance, use the substance, or **recover** from its effects
- Important social, occupational, or recreational **activities are given up or reduced** because of SU

6 - 9

Substance Use Disorder

- The substance use is **continued despite knowledge of having** a persistent or recurrent physical or psychological **problem** that is likely to have been caused or exacerbated by the substance
- **Craving** or a strong desire or urge to use a specific substance.

10 & 11

Severity Specifiers

- **Severity** (of each SUD) based on:
  - 0 criteria or 1 criterion: No diagnosis
  - 2 – 3 criteria Mild Substance Use Disorder
  - 4 – 5 criteria Moderate Substance Use Disorder
  - 6 or more criteria Severe substance Use Disorder
- *With or without physiological dependence*

Course Specifiers (under review)

- Early Full Remission
- Early Partial Remission
- Sustained Full Remission
- Sustained Partial Remission
- On Agonist Therapy
- In a Controlled Environment

Added Behavioral Addictions

- Only one entry: Gambling Addiction
  - Previously Impulse Control Disorder Not Elsewhere Classified
  - Now Addictive Disorder (along with substance use)

Needing Further Study

- Caffeine Use Disorder
- Internet Use Disorder
- Neurobehavioral Disorder Associated with Prenatal Alcohol Exposure

Bath Salts
(aka Synthetic Cathinones)

Acknowledgements:
- Lori Keyser-Marcus, PhD
- Lauretta Safford-Cathers, MSW

- Virginia Commonwealth University (VCU) HIV/AIDS Center
- Virginia HIV/AIDS Resource and Consultation Center, Central and Southwest Regional provider
- Southern Virginia Local Performance Site of the Pennsylvania/Mid Atlantic AIDS Education and Training Center
- NIDA Clinical Trials Network, Mid-Atlantic Node, VCU Component

In the Media……

What are Bath Salts?

- An emerging family of drugs that contain one or more synthetic chemicals related to cathinone
  - An amphetamine-like stimulant found naturally in the Khat plant
  - Khat plant is widely grown in Yemen and east African countries of Ethiopia, Eritrea, and Somalia.

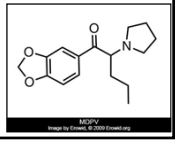
Bath Salts Can…..

- Energizing and agitating effects in many people
- Also euphoria, greater sociability and a higher sex drive
- But can produce paranoia and hallucinatory delirium
  - Instances of psychotic and violent behavior
  - Several instances of death

How Do they Affect the Brain?

- Common synthetic cathinones in bath salts include:

  Methylenedioxypyrovalerone* (MDPV) mephedrone, and pyrovalerone
- Work by stimulating release and inhibiting reuptake of dopamine, norepinephrine, serotonin
- Mimic effects of cocaine, methamphetamine, LSD, ecstasy



Drug Effects

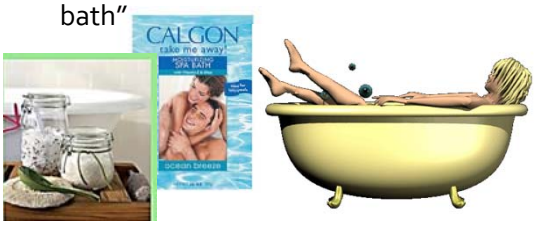
Small amounts of dopamine are constantly released	Blocks dopamine re-uptake	Releases a surge of dopamine	Releases a surge of dopamine, Then blocks re-uptake

Buying Bath Salts

- Sold in small plastic or foil packages
- White or brown crystalline powder
- Labeled "not for human consumption"
- Sometimes marketed as plant food

Not to be Confused with…

- Bath (Epsom) salts
  - Only enhancement related to "taking a bath"



Where Can you Get Bath Salts?

- Commonly sold:
  - On line (internet)
  - Drug paraphernalia stores
  - Gas stations
- Brand names include:
  - *Ivory Wave*
  - *Bloom*
  - *Cloud Nine*
  - *Lunar Wave*
  - *Vanilla sky*
  - *Scarface*
  - *White Lightning*

Dose and Route of Administration

- Often sold in 300 mg packets
  - Average dose is 5-20 mgs
  - Effects seen at 3-5 mg
- Routes of Administration
  - Typically snorted or swallowed
  - Can also be smoked or injected

How much do they Cost?

- Relatively cheap high
  - $25-50/packet
  - Available as tablets, capsules, powders

The Evolution of Bath Salts

- 2007-08: Popular European club drug
  - 2010: Made illegal across Europe
- 2010: Made appearance in USA
  - Rapidly popular as "legal high"
  - That same year: US poison control centers received 302 bath salts related calls
- October, 2011: 3 synthetic cathinones put under emergency ban by US DEA
  - July 2012 – President Obama made 2 of them (mephedrone and MDPV) illegal

"Legal High" ??

- Labeled "not for human consumption"
  - Avoids FDA regulation
- MDPV and mephedrone = Illegal in US (2011/12)
  - **AND** new ban prohibits "chemically similar analogues"
  - **BUT** Manufacturers still try to avoid prosecution
    - Modifying compounds – making them "different enough" to be "technically LEGAL"

Example from United Kingdom:
Mephedrone banned in 2010
Chemical called Naphyrone replaced it
Now sold as jewelry cleaner under name "Cosmic Blast"

Intoxication from Bath Salts

- Effects occur within 15 minutes
  - Often peak at 1.5 hours
- High can last from 2-6 hours
- Re-dosing is common
  - usually 45 to 120 minutes after initial ingestion

The Subjective Experience of a Bath Salt "High"

- Increased alertness
- Increased energy
- Euphoria
- Sexual stimulation
- Positive mood

Recent survey of (N=1506) of mephedrone users: effects most similar to ecstasy

Links to High-Risk Behavior

- **Injection Drug Use**
- **High-risk sexual behavior**
  - related to drugs sexual arousal effects
- **Risk of blood and other bodily fluid exposure**
  - due to violent behavior

Overdose and ER Admission

What are the presenting symptoms and how are they treated?

ER Admissions : Common Symptoms

- Cardiac symptoms
  - Heart racing
  - High blood pressure
  - Chest pains

- Psychiatric symptoms
  - Paranoia
  - Hallucinations
  - Panic attacks

Overdoses

- May be combative, violent, self-destructive
- Similar to PCP psychosis and cocaine or amphetamine OD
- Hallucinations may persist for 48+ hours
- Agitation may persist for several days

Detox and Thereafter…

- **Common withdrawal symptoms:**
  - fatigue
  - depression
  - decreased appetite
  - inability to sleep (due to anxiety and psychotic –like symptoms)
- **As psychosis resolves:**
  - depression and suicidal ideation may occur
- **Persistent mood changes**
  - can last days or even weeks
- **Potential for flashbacks ????**

Case Review

Michigan ED cases
(N=35)

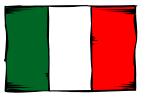
- 54% male
- Age range: 20-55 years
- 69% history of drug abuse (by self-report)
- 31% history of poly-substance use
- 34% history of IV drug use
- 46% history of mental illness (by med record)

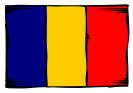
CDC MMR (2011), Vol 60 (19)

European Use

Survey of > 2000 clubbers

- over 40% had used some form of bath salts
- more than 30% had used within past month





Dargan et al 2010

Can We Stop Calling them Bath Salts?

"While it certainly doesn't have the ring of 'Ecstasy' or 'Spice'……

It is still MUCH easier to say than:

3,4-Methylenedioxypyrovalerone.

The Daily Beast, May, 2012

Prescription Drug Misuse

Trends and Treatment

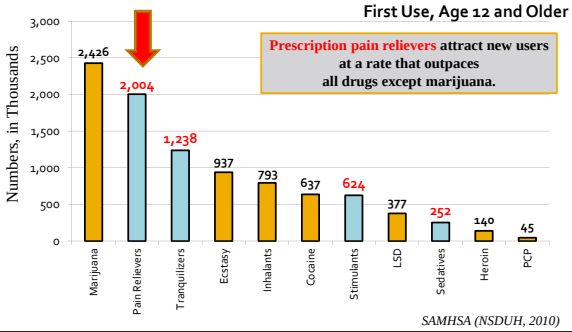
Thank you: SAMHSA, ATTC and NIDA CTN

Prescription Drug Use/Abuse

- **In USA**:
  - Since 2002, every year between 2.5 - 2.8 million Americans abused prescription drugs for the first time
  - On average, there are 7,000 new users of prescription drugs each day

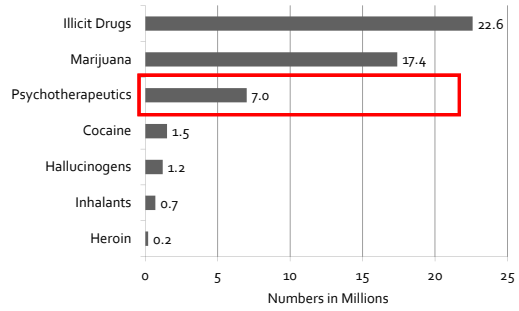
(NSDUH, SAMHSA, 2010)

Past Year Drug Use Initiation



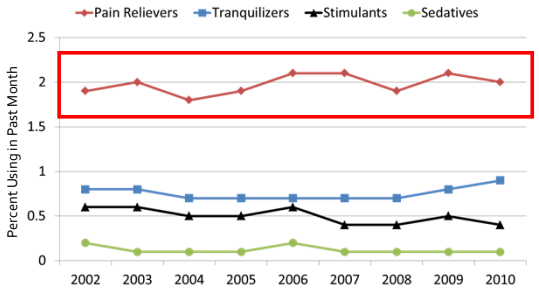
SAMHSA (NSDUH, 2010)

Past Month Illicit Drug Use among Persons Aged 12 or Older: U.S., 2010



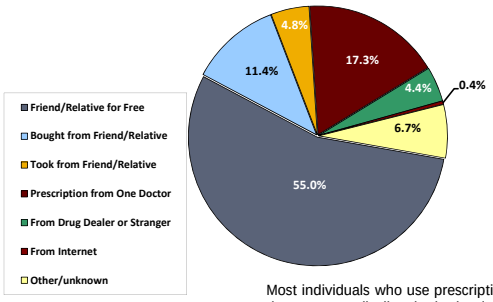
SOURCE: SAMHSA, OAS, NSDUH, 2010 results.

Percentage of U.S. Population with Past Month Non-Medical Use of Prescription Medications, by Type



SOURCE: SAMHSA, OAS, NSDUH, 2010 results.

Sources Where Pain Relievers were Obtained: Past Year Non-Medical Users Aged 12 or Older: 2010



Most individuals who use prescription drugs non-medically, obtain the drugs from friends or family members

SOURCE: SAMHSA, NSDUH, 2010 results.

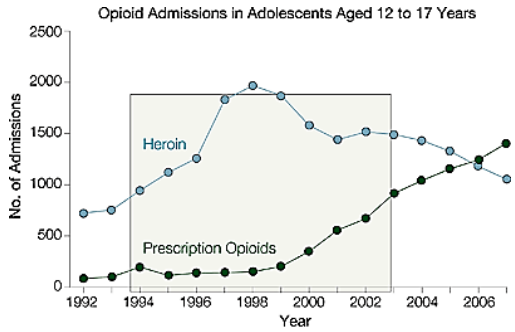
Changing Substance Abuse Treatment Profiles

- While the overall rate of alcohol/drug abuse treatment admissions (persons ages 12 +) in the U.S.A. has remained fairly constant from 1999 to 2009,

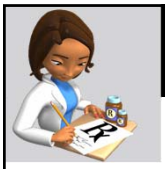
There has been a dramatic rise in the rate of treatment admissions for the abuse of prescription pain relievers during this period

- The rate of treatment admissions linked to these drugs went from:
  10 per 100,000 in the population (1999)
  to
  53 per 100,000 population (2009)

(SAMHSA TEDS Data 1999-2009)



Source: Subramaniam G. Treatments for adolescents/young adults with opioid use disorder. Presented at: 8th National Institute on Drug Abuse Blending Conference; April 22, 2010; Albuquerque, NM.



Rx Pain Medications and Drug Overdose

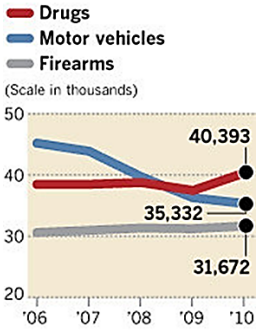
- In 2008, nearly 15,000 prescription painkiller overdose deaths occurred in the United States.
  - (more than triple the 4,000 killed in 1999)
- **Prescription painkillers were involved in more overdose deaths than heroin and cocaine combined.**
- According to the CDC, **40 Americans die every day from prescription painkiller abuse**.

"Deaths Tied to Painkillers Rising in the USA"

- Despite law enforcement and public health efforts to curb Rx drug abuse, drug-related deaths in US continued to rise
- Drug fatalities increased 3% in 2010 (CDC) and preliminary data suggest same in 2011
- Increase propelled primarily by Rx painkillers (OxyContin, Vicodin)

(LA Times, March 29, 2013)

Causes of Death



Drugs overtook traffic accidents as a Cause of Death in 2009..

And the gap continued to widen in 2010.

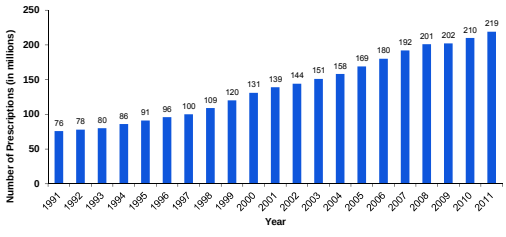
Overdose deaths involving Rx painkillers rose to 16,651 in 2010.

That was 43% of all fatal overdoses.

CDC, 2013

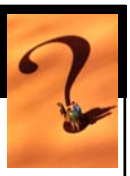
Why the Increase?

- Steady and consistent rise in opioid prescriptions (1991-2011)



IMS Vector One. From "Prescription Drug Abuse: It's Not what the doctor ordered." Nora Volkow National Prescription Drug Abuse Summit, April 2012. Available at http://www.slideshare.net/OPUNITE/nora-volkow-final-edits.

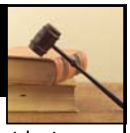
Why more prescriptions?



- Increase in chronic pain
- Pain declared the "fifth vital sign"
- Opioids often prescribed after relatively minor accidents, injuries, surgery
- Other factors contributing to access:
  - Liberalization of laws regulating opioid prescription
  - New pain medication standards
  - Aggressive marketing

Manchikanti L, 2012

New Legislation….?



- US Food and Drug Administration is considering proposal to limit daily doses of painkillers
  - restrict use to 90 days or less for non-cancer patients.
- *"The data supporting long term use of opiates for pain, other than cancer pain, is scant to nonexistent"* *(Frieden, CDC, 2013)*
- Many state Rx drug monitoring programs do **not** proactively seek out problem patients or physicians
  - Investigations are often launched only when there is a complaint

What's New in Treatment of Rx Opioid Misuse?

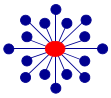
Prescription Opioid Addiction Treatment Study (POATS)

NIDA Clinical Trials Network (CTN) Study

Roger Weiss, MD, Principal Investigator

Harvard Medical School, McLean Hospital

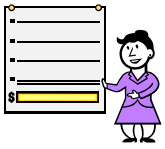
NIDA CTN



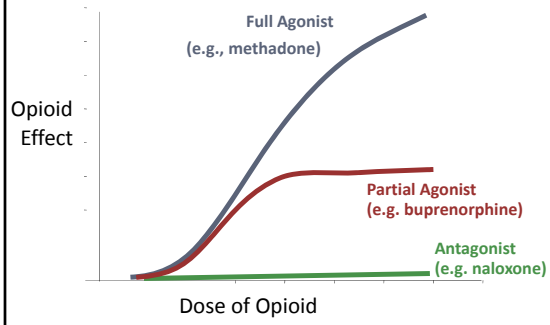
- Established in 1999
- Means by which NIDA, treatment researchers, and community-based service providers **cooperatively develop, validate, refine, and deliver new treatment options** to patients in Community Treatment Programs (CTPs), and ultimately to the SUD treatment field at large.
- Network of 13 University-based Regional Research and Training Centers (RRTCs) involving 240 CTPs in 38 states, Washington D.C., and Puerto Rico

POATS

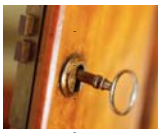
- First RCT using medication (buprenorphine) for treatment of Rx opioid addiction
- **The Bottom Line**: Long-term buprenorphine-naloxone treatment reduces opioid use by those dependent on prescription opioids



Partial vs. Full Opioid Agonist and Antagonist



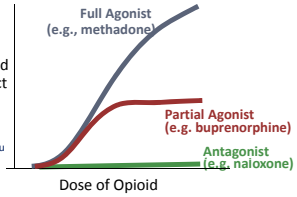
The Metaphor…



Opioid agonists work like having the right key to a door. You put the key in the lock, the lock turns and the door opens completely.

Opioid antagonists work like having the wrong key to a door. You put the key in the lock; the door remains locked and will not open. Additionally, since the key is in the lock, no other key can be put in the lock (even if it is the right key for that door) until the wrong key is removed.

Opioid partial agonists work like having the right key to a door, but the chain is on the door. The key goes in and opens the door, but it will only open so far.



Buprenorphine

- **Partial Opioid Agonist**
  - Has effects of **typical opioid agonists at lower** doses
  - Produces a **ceiling effect at higher** doses
  - Binds to opioid receptors and is **long-acting**
- **Safe and effective** therapy for opioid maintenance and detoxification in adults
- **FDA approved** for use with opioid dependent persons aged **16** and older

Formulations of Buprenorphine

- Buprenorphine is marketed for opioid treatment under the trade names:

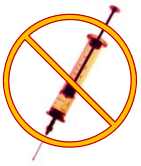
Subutex®
(buprenorphine)

Suboxone®
(buprenorphine/naloxone)

- Why did they make two formulations?

Advantages of Buprenorphine/Naloxone

- **Discourages IV use**



- **Diminishes diversion**

Buprenorphine: A Science-Based Treatment

- **Sublingual buprenorphine/naloxone as safe and effective** treatment for opioid dependence
- Most studies focused **exclusively or predominantly on heroin** users
- Increased **concerns about prescription opioid abuse/dependence**

POATS Study - Background

- **Largest study ever conducted for prescription opioid dependence – 653 participants enrolled**
- Compared treatments for prescription opioid dependence, using buprenorphine-naloxone and counseling
- Examined detoxification as initial treatment strategy, THEN for those unsuccessful, how well buprenorphine stabilization worked
  - *Go from less-intensive to more intensive tx*

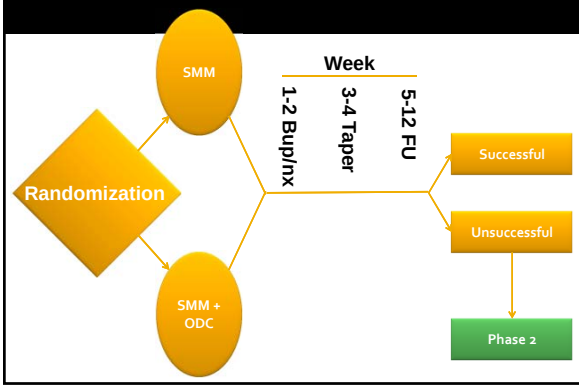
POATS Study Questions

- Does adding individual drug counseling to buprenorphine-naloxone (BUP-NX) + standard medical management (SMM) improve outcome?

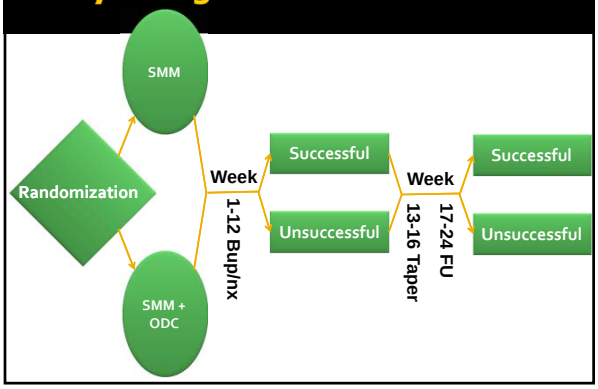
Overall Design

- Subjects who succeed in ***Phase 1*** (1-month taper plus 2-month follow-up) are successfully finished with the study
- Subjects who relapse may go into ***Phase 2***:
  - Re-randomized in Phase 2
  - 3 months of BUP-NX stabilization,
  - 1- month taper off BUP-NX,
  - 2 months of follow-up

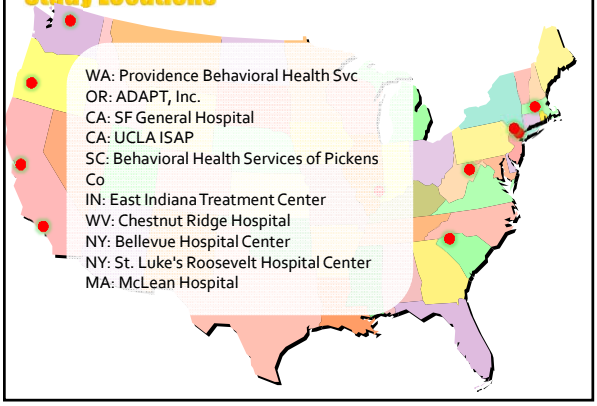
Study Design - Phase 1



Study Design - Phase 2



Study Locations



Inclusion/Exclusion Study Criteria

Inclusion
- Informed Consent
- Age ≥ 18
- Birth control
- Able to meet study requirements
- Opioid Dependence
- Medical help for withdrawal
- Stable physical health
- Psychiatrically stable
- Locator Information
- Prior to inductions, COWS >8
- For pain, clearance to withdraw
- Methadone for pain <40mg/day

Exclusion
- Medical condition
- Allergy/sensitivity to meds
- Severe psychiatric condition
- Suicide risk in past 30 days
- ETOH/Sed/Stim dependence
- Clinical trial participant (30 d)
- Opioid maintenance tx (30 d)
- Pending legal issues
- Preg/lactating/no birth control
- Leaving local area during study
- LFT > 5x upper normal limit
- Surgery scheduled (6 m)
- Current SUD treatment

Standard Medical Management

- Manualized treatment*
- Weekly visits with buprenorphine-certified physician
- Initial visit: 45-60 min; f/u visits 15-20 min
- Assess substance use, craving, medication response
- Recommend abstinence, self-help

*SOURCE: Fiellin et al. (1999).

Individual Opioid Drug Counseling

- Manualized drug counseling*, based on previous successful counseling manuals
- 45-60 min visits
- Phase 1: 2x/week
- Phase 2: 2x/wk for 6 weeks, 1x/wk for 6 weeks

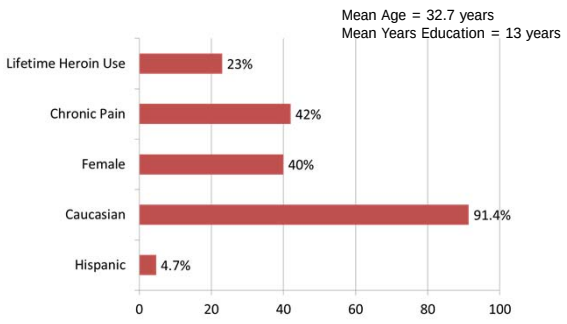
*SOURCE: Pantalon et al. (1999).

Individual Opioid Drug Counseling *(cont.)*

- Provide education about addiction and recovery
- Recommend abstinence
- Recommend self-help
- Provide skills-based interactive exercises and take-home assignments
- Address relapse prevention issues including: high-risk situations, managing emotions, and dealing with relationships

SOURCE: Pantalon et al. (1999).

Baseline Characteristics

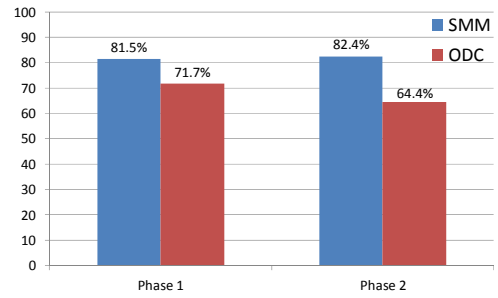


Buprenorphine Doses Prescribed

Phase 1	
8 mg	8%
12 mg	18%
16 mg	38%
20 mg	10%
24 mg	13%
32 mg	-
Other	13%

Phase 2	
8 mg	-
12 mg	14%
16 mg	27%
20 mg	14%
24 mg	16%
32 mg	11%
Other	18%

Counseling Attendance*



* Not significantly different

Results

Primary Question

Does adding :
Opioid Drug Counseling (ODC) to
Buprenorphine-Naloxone
+
Standard Medical Management (SMM)
improve outcomes?

96

Study Findings

	SMM+ ODC	SMM	p-value
Phase 1	6%	7%	0.45
Phase 2 Week 12 (end of stabilization)	52%	47%	0.30
Week 16 (end of taper)	28%	24%	0.40
Week 24 (8 wks post-taper)	10%	7%	0.20

Subjects with Chronic Pain: Study Outcomes

41.9% of participants reported chronic pain (N=274)

- No more likely to drop-out or terminate from Phase 1
- Equally likely to enter Phase 2
- No more likely to have an adverse or serious adverse event

98

What Have We Learned?

- Tapering from buprenorphine-naloxone, whether initially or after a period of substantial improvement, led to nearly universal relapse
- SMM produced outcomes equal to SMM + individual opioid drug counseling
- Patients with chronic pain had outcomes equal to those without chronic pain

Questions?