THE USE OF BUPRENORPHINE IN TREATING OPIOID DEPENDENCE

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New England (HHS Region 1)
ATTC Addiction Technology Transfer Center Network
Funded by Substance Abuse and Mental Health Services Administration

Disclosures

The development of these training materials were supported by grant H79 TI080209 (PI: S. Becker) from the Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, United States Department of Health and Human Services. The views and opinions contained within this document do not necessarily reflect those of the US Department of Health and Human Services, and should not be construed as such.

Goals for the Training

- Understand the history of opioid treatment in the United States.
- Understand changes in the laws regarding treatment of opioid addiction and the implications for the treatment system.
- Identify groups of people who are using opioids.
- Understand how buprenorphine will benefit the delivery of opioid treatment.

SAMHSA/CSAT

CSAT's Mission:

- To improve the lives of individuals and families affected by alcohol and drug abuse by ensuring access to clinically sound, cost-effective addiction treatment that reduces the health and social costs to our communities and the nation.
- CSAT's initiatives and programs are based on research findings and the general consensus of experts in the addiction field that, for most individuals, treatment and recovery work best in a community-based, coordinated system of comprehensive services.
- Because no single treatment approach is effective for all persons, CSAT supports the nation's effort to provide multiple treatment modalities, evaluate treatment effectiveness, and use evaluation results to enhance treatment and recovery approaches.

The ATTC Network

The Mission of the National Institute on Drug Abuse

- To lead the Nation in bringing the power of science to bear on drug abuse and addiction

- This charge has two critical components.
  - Strategic support and conduct of research across a broad range of disciplines
  - Ensuring the rapid and effective dissemination and use of the result of that research to significantly improve prevention, treatment and policy as it relates to drug use and addiction

A Brief History of Opioid Treatment

A Brief History of Opioid Treatment

- 1964: Methadone is approved.
- 1974: Narcotic Treatment Act limits methadone treatment to specifically licensed Opioid Treatment Programs (OTPs).
- 1984: Naltrexone is approved, but has continued to be rarely used (approved in 1994 for alcohol addiction).
- 1993: LAAM is approved (for non-pregnant patients only), but is underutilized.

A Brief History of Opioid Treatment

- 2000: Drug Addiction Treatment Act of 2000 (DATA 2000) expands the clinical context of medication-assisted opioid treatment.
- 2002: Tablet formulations of buprenorphine (Subutex®) and buprenorphine/naloxone (Suboxone®) were approved by the Food and Drug Administration (FDA).
- 2004: Sale and distribution of ORLAAM® is discontinued.

Drug Addiction Treatment Act of 2000 (DATA 2000)

- Expands treatment options to include both the general health care system and opioid treatment programs.
  - Expands number of available treatment slots
  - Allows opioid treatment in office settings
  - Sets physician qualifications for prescribing the medication

Approval of Buprenorphine and Buprenorphine/Naloxone

- U.S. FDA approved buprenorphine (marketed as Subutex®) and buprenorphine/naloxone (marketed as Suboxone®) for opioid addiction treatment on October 8, 2002.
- Product launched in U.S. in March 2003
- Interim rule changes to federal regulation (42 CFR Part 8) on May 22, 2003 enabled Opioid Treatment Programs (specialist clinics) to offer buprenorphine.

Effective treatment generally requires many facets. Treatment providers are important in helping the patients to:

- Manage physical withdrawal symptoms
- Understand the behavioral and cognitive changes resulting from drug use
- Achieve long-term changes and prevent relapse
- Establish ongoing communication between physician and community provider to ensure coordinated care
- Engage in a flexible treatment plan to help them achieve recovery

Rates of Current Heroin Use

- Drug demand data show that, nationally, current heroin use is stable or decreasing.

Rates of Past-Year Heroin Use – NSDUH, 2009						
% of US population	2003	2004	2005	2006	2007	2008
Individuals (12 & older)	0.1	0.2	0.2	0.2	0.1	0.2
Adolescents (12-17)	0.1	0.2	0.1	0.1	0.1	0.2
Adults (18-25)	0.3	0.4	0.5	0.4	0.4	0.5
Adults (26 & older)	0.1	0.1	0.1	0.2	0.1	0.3

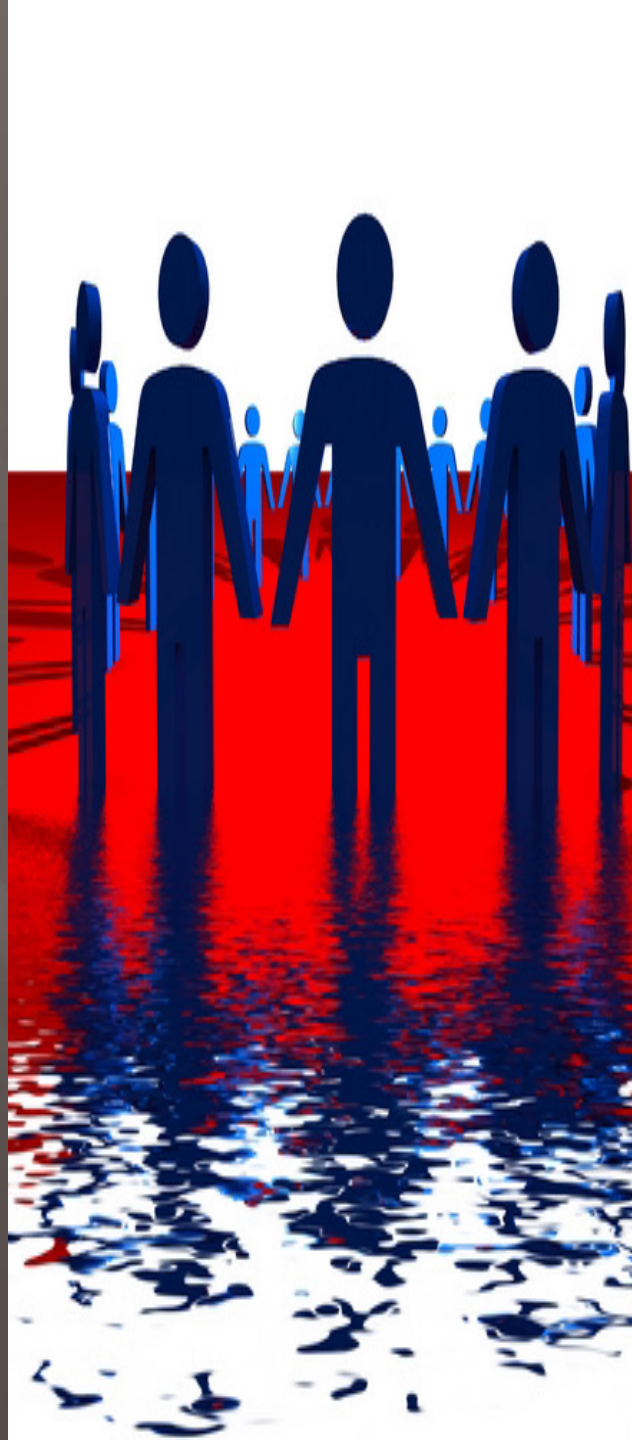
(SAMHSA, NSDUH, 2009)

Who Uses Heroin?

Individuals of all ages use heroin:

- More than 3.8 million US residents aged 12 and older have used heroin at least once in their lifetime.
- Heroin use among high school students is a particular problem. Slightly more than 2% percent of US high school seniors used heroin at least once during their lifetime.
- Approximately 1.6% of young adults (ages 19-28) reported lifetime use

(CDC, 2009; SAMHSA, NSDUH, 2007)



Prevalence of Use

- Rates of heroin use are declining among youth -
  - 8th grade use peaked in 1996
  - 10th grade use peaked in 1997
  - 12th grade use peaked in 2000

- Rates of non-medical use of opioids are increasing
  - Rates in all ages peaked in 2007
  - Rates highest in 18-25 year olds

(Johnston et al., 2009; SAMHSA, OAS, NSDUH, 2009)

Initiation of *Heroin* Use

- During the latter half of the 1990s, the annual number of heroin initiates rose to a level not reached since the late 1970s.
- In 1974, there were an estimated 246,000 heroin initiates.
- Between 1988 and 1994, the annual number of new users ranged from 28,000 to 80,000.
- Between 1995 and 2001, the number of new heroin users was consistently greater than 100,000.
- Between 2002 and 2008, the number of new heroin users ranged from 91,000 to 114,000.

(SAMHSA, OAS, 2008; SAMHSA, NSDUH, 2009)

Other Opioid Use in a National Survey Population

According to the 2007 National Survey on Drug Use and Health:

- An estimated 6.9 million persons (2.8% of the U.S. population aged 12 or older) were currently using certain prescription drugs nonmedically.
- An estimated 5.2 million were current users of pain relievers for nonmedical purposes.
- Approximately 4.4 million persons had used OxyContin nonmedically at least once in their lifetime.
- Non-medical pain reliever incidence increased from 1990 (628,000 initiates) to 2007, when there were 2.1 million new users.

(SAMHSA, OAS, 2008; SAMHSA, NSDUH, 2009)

Emergency Department Visits Related to *Heroin/Other Opioids*

According to the Drug Abuse Warning Network - 2004-2008:

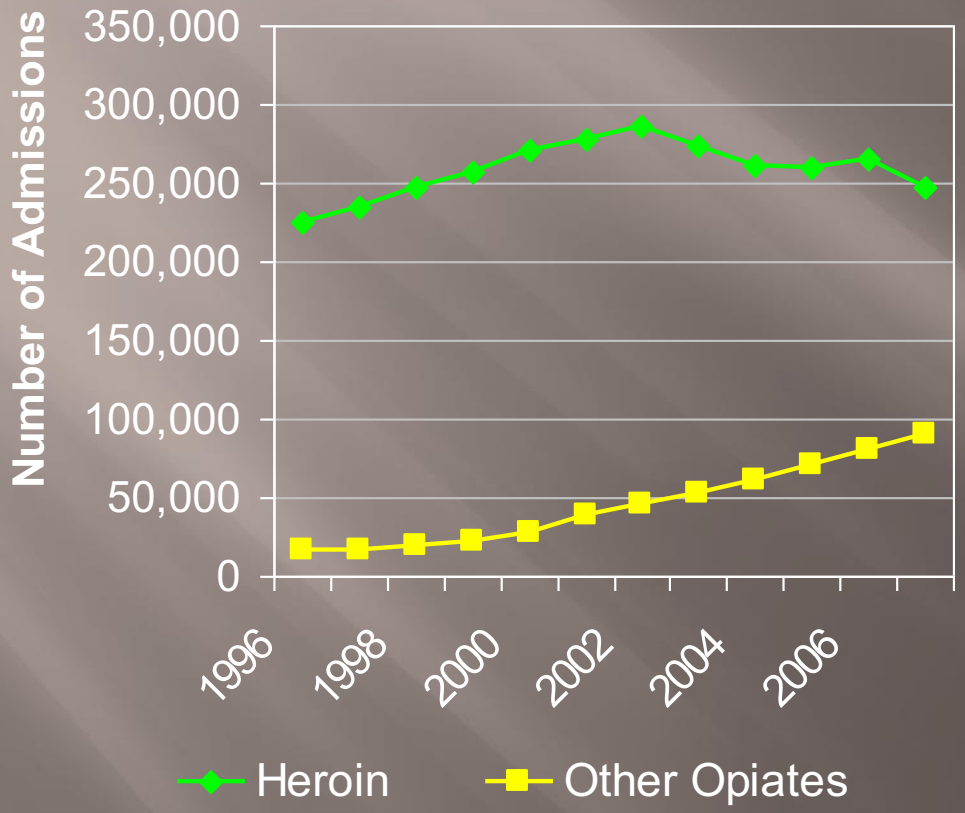
- An estimated 200,666 drug misuse/abuse ED visits were related to heroin.
- One-third (33%) of nonmedical use ED visits were related to Central Nervous System (CNS) agents.
- Among CNS agents, the most frequent drugs were opiates/opioid analgesics, specifically:
  - Hydrocodone/combinations (22,912 visits)
  - Oxycodone/combinations (44,489 visits)
  - Methadone (23,498 ED visits)

(SAMHSA, OAS, DAWN, 2009)

New Non-Medical Users of Pain Relievers

- In 2008 – 2.2 million new non-medical users (a decline from 2.5 million in 2003, but still a lot!)
- 6,000 new users per day
- Among youth aged 12-17, females more likely to use non-medically
- Among young adults aged 18-25, males more likely to use non-medically (SAMHSA, OAS, 2009)

Heroin & Other Opioid Treatment Admissions



- TEDS admissions for primary opioid abuse increased from 16% of all admissions in 1997 to 19% in 2007.
- Admissions for other opioids have increased consistently since the late 1990s – 1% to 5% between 1997 and 2007.

(SAMHSA, OAS, TEDS, 2009).

Review of Opioid Pharmacology, Buprenorphine Treatment, and the Role of the Multidisciplinary Treatment Team

Opioid Addiction and the Brain

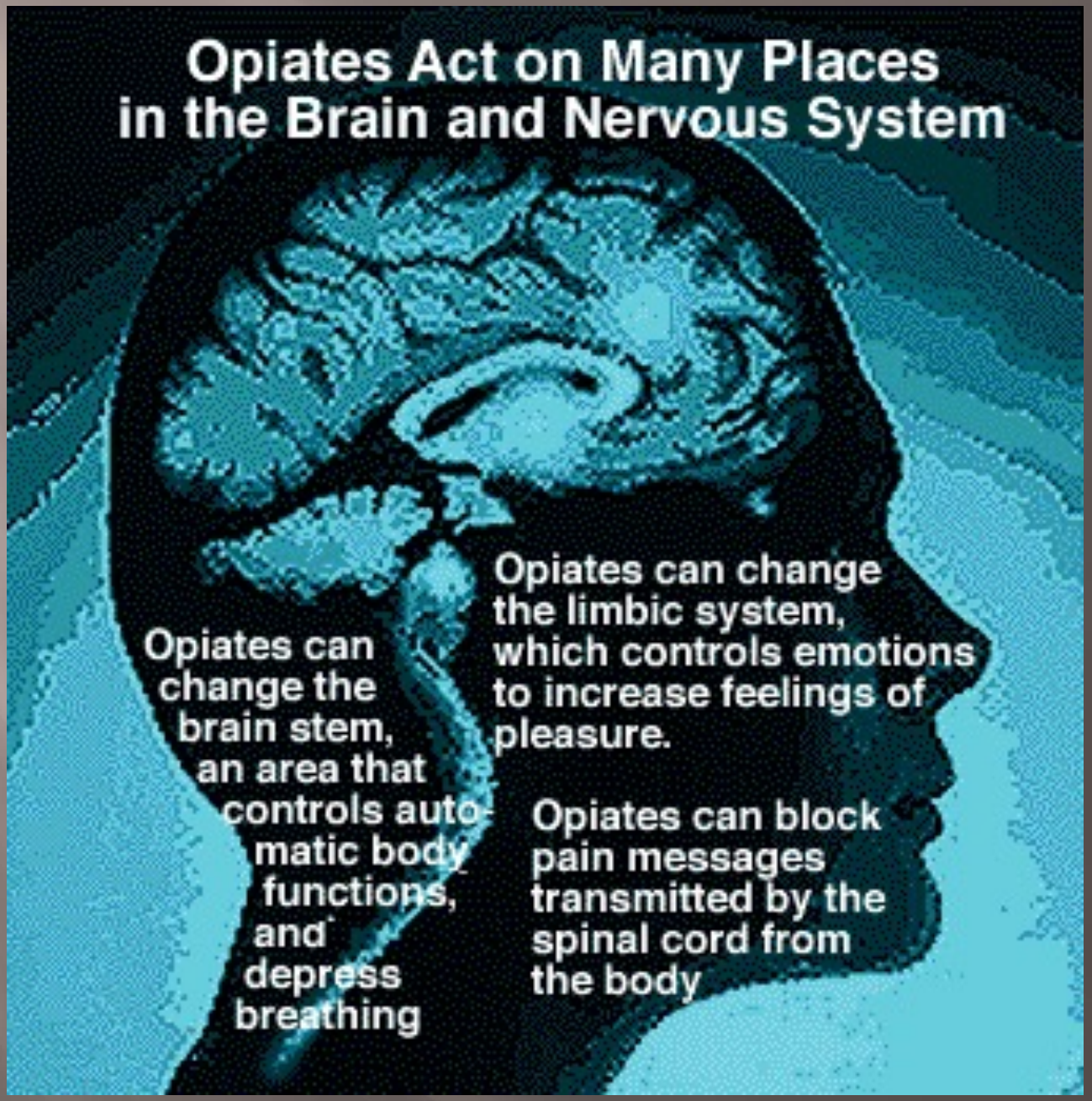
- Opioids attach to specific receptors in the brain called mu receptors.
- Activation of these receptors causes a pleasure response.
- Repeated stimulation of these receptors creates a tolerance – requiring more drug for same effect.

Basic Opioid Facts

Description: Opium-derived, or synthetics which relieve pain, produce morphine-like addiction, and relieve withdrawal from opioids

Medical Uses: Pain relief, cough suppression, diarrhea

Methods of Use: Intravenously injected, smoked, snorted, or orally administered



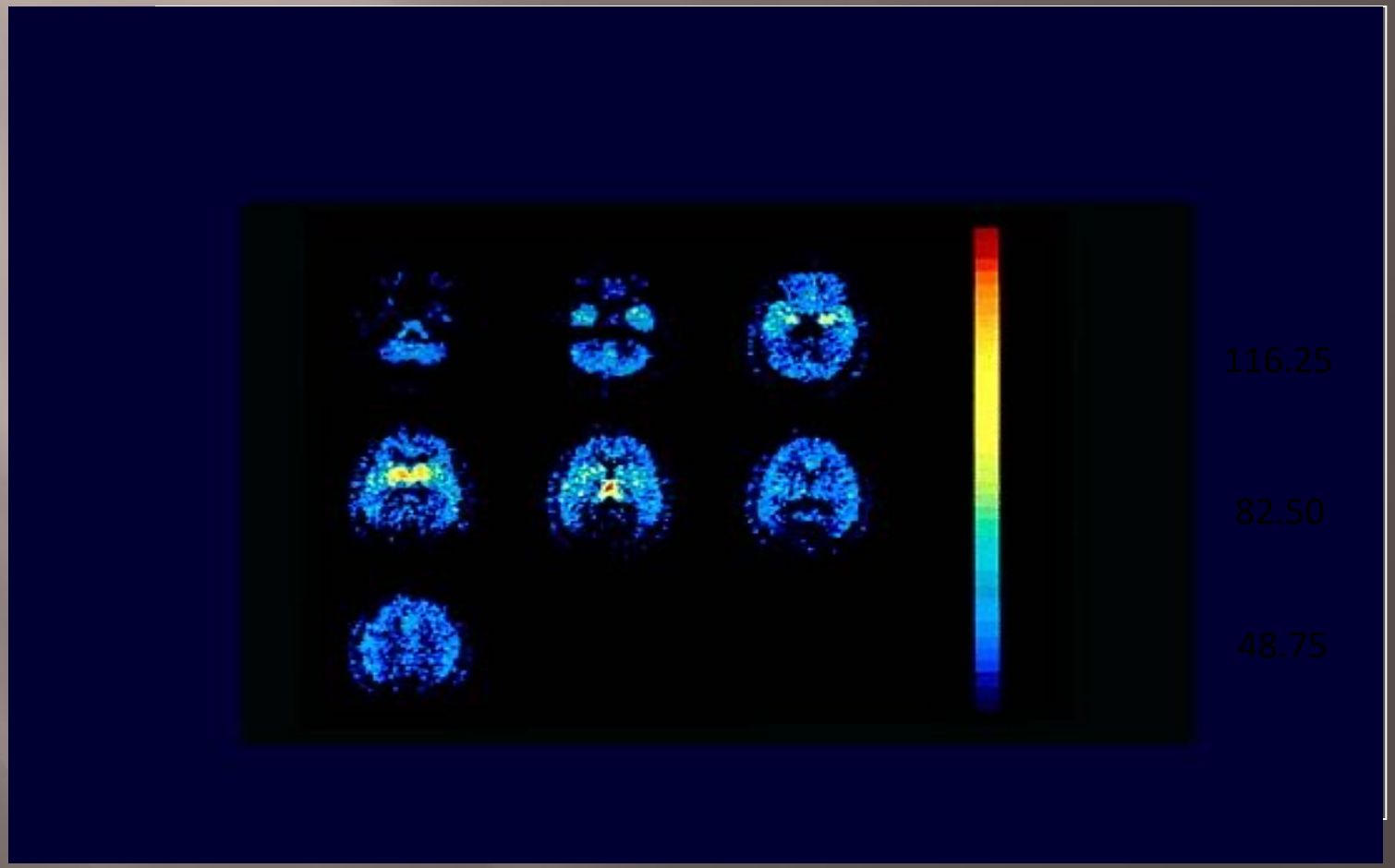
(National Institute on Drug Abuse, www.nida.nih.gov)

Terminology

Receptor:

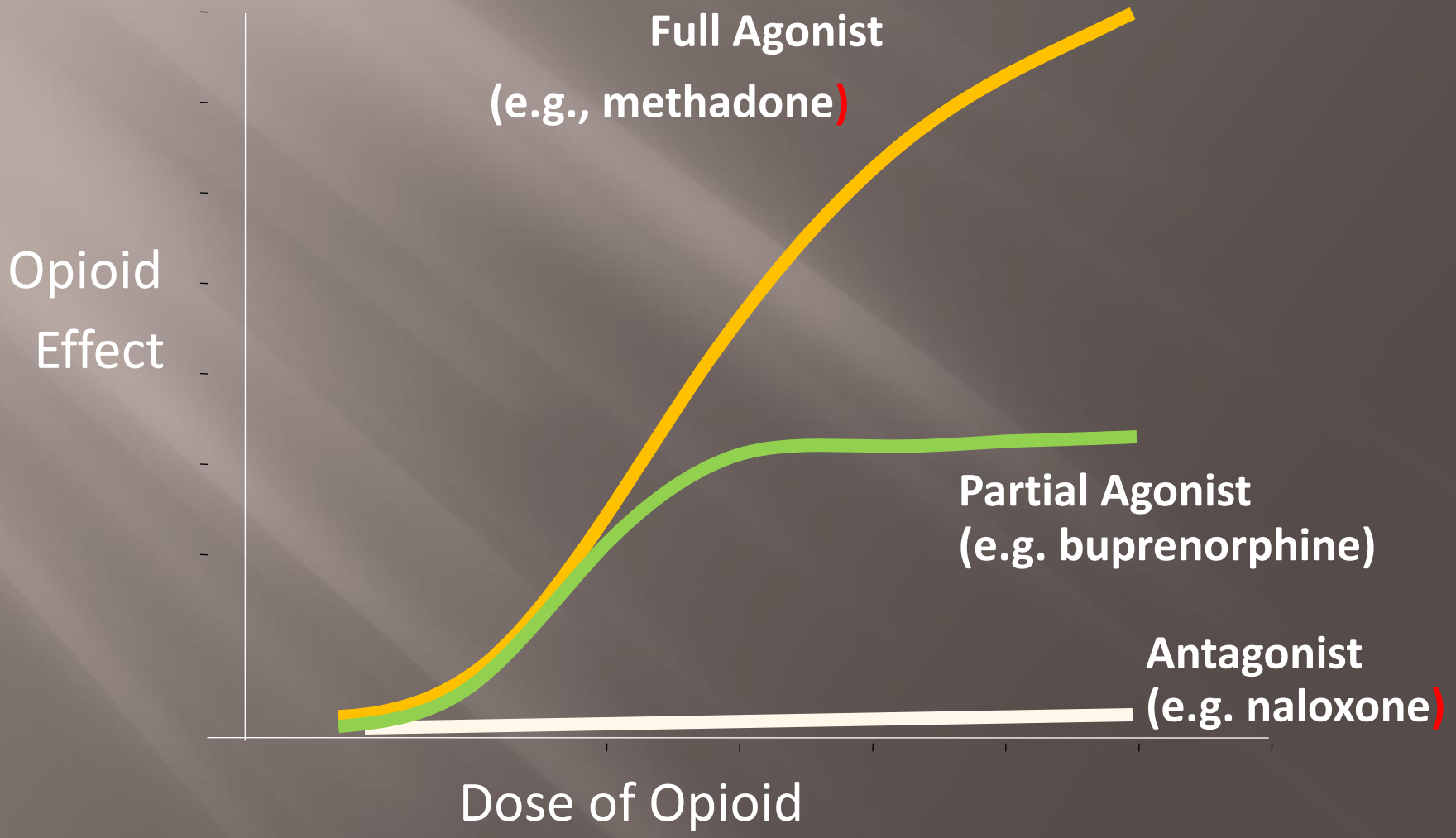
Specific cell binding site or molecule: a molecule, group, or site that is in a cell or on a cell surface and binds with a specific molecule, antigen, hormone, or antibody

[^{18}F] Cyclofoxy (a Selective Opioid Antagonist) Binding in Human Brain: Normal Volunteer PET Study - NIH



(Eckelman, Rice and the NIH PET group, 2000; Kling et al., 2000)

Partial vs. Full Opioid Agonist and Antagonist



Opioid Agonists

- Natural derivatives of opium poppy

  - Opium
  - Morphine
  - Codeine

Opium

(www.streetdrugs.org)

Morphine

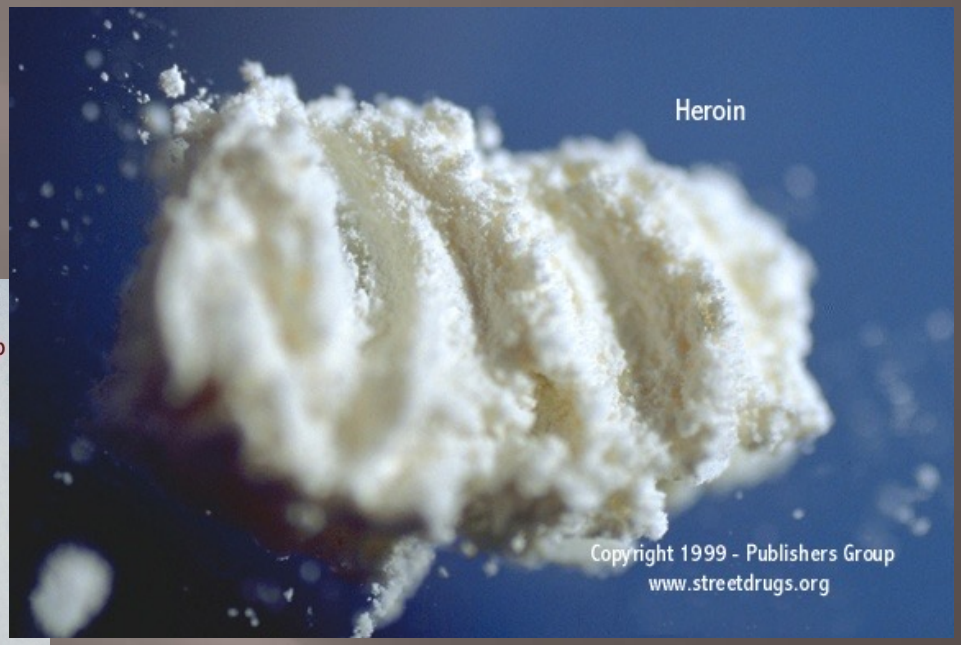
(www.streetdrugs.org)

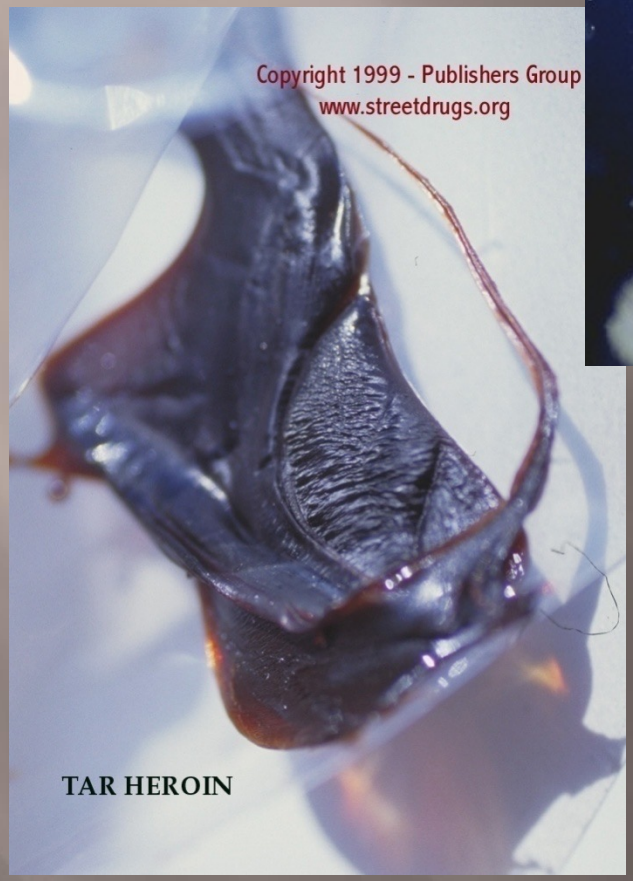
Opioid Agonists

- Semisynthetics: Derived from chemicals in opium

  - Diacetylmorphine – Heroin
  - Hydromorphone – Dilaudid®
  - Oxycodone – Percodan®, Percocet®
  - Hydrocodone – Vicodin®

Heroin





(www.streetdrugs.org)

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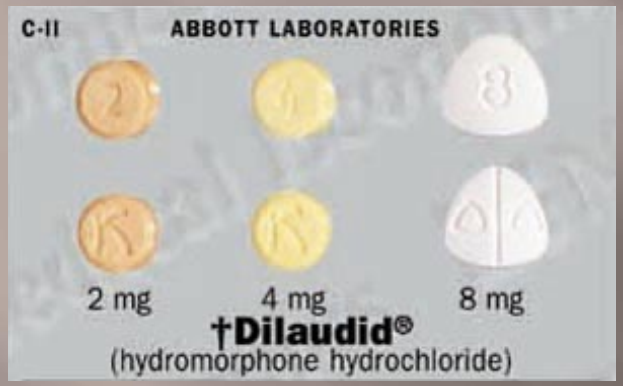
Opioid Agonists



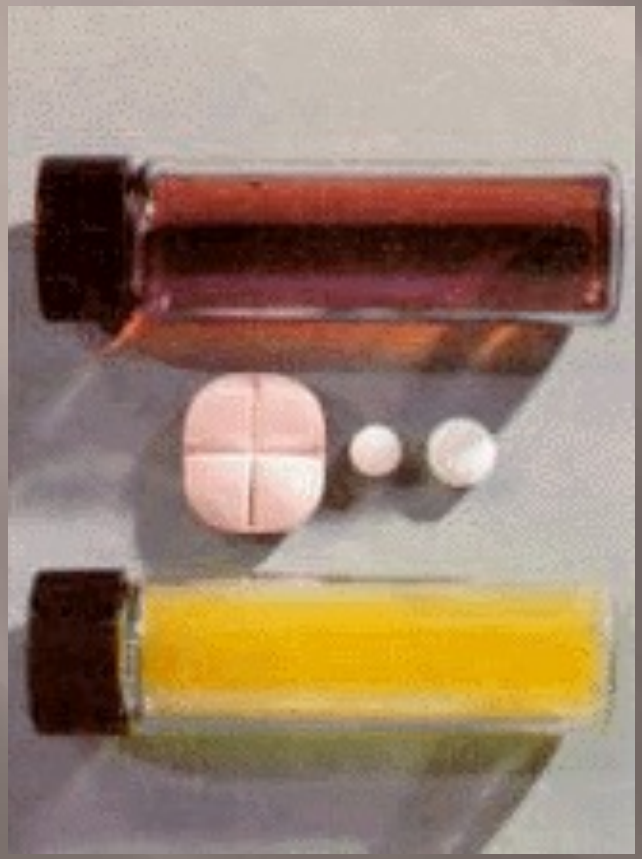
(www.pdrhealth.com)

Opioid Agonists

- Synthetics

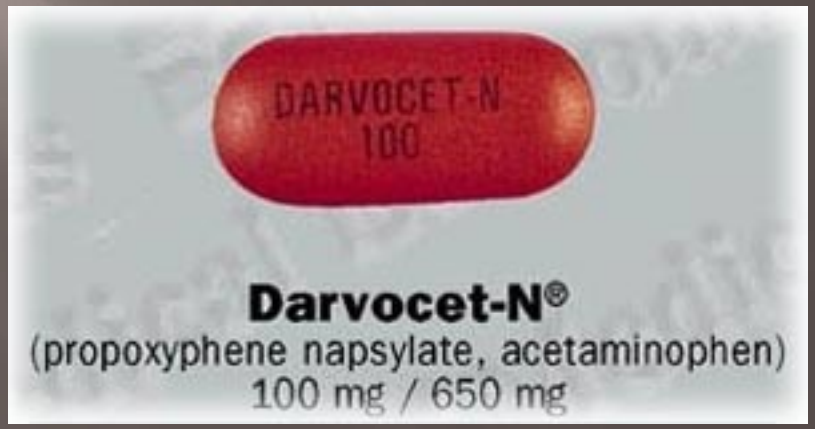
  - Propoxyphene – Darvon®, Darvocet®
  - Meperidine – Demerol®
  - Fentanyl citrate – Fentanyl®
  - Methadone – Dolophine®
  - Levo-alpha-acetylmethadol – ORLAAM®

Methadone



(www.methadoneaddiction.net/m-pictures.htm)

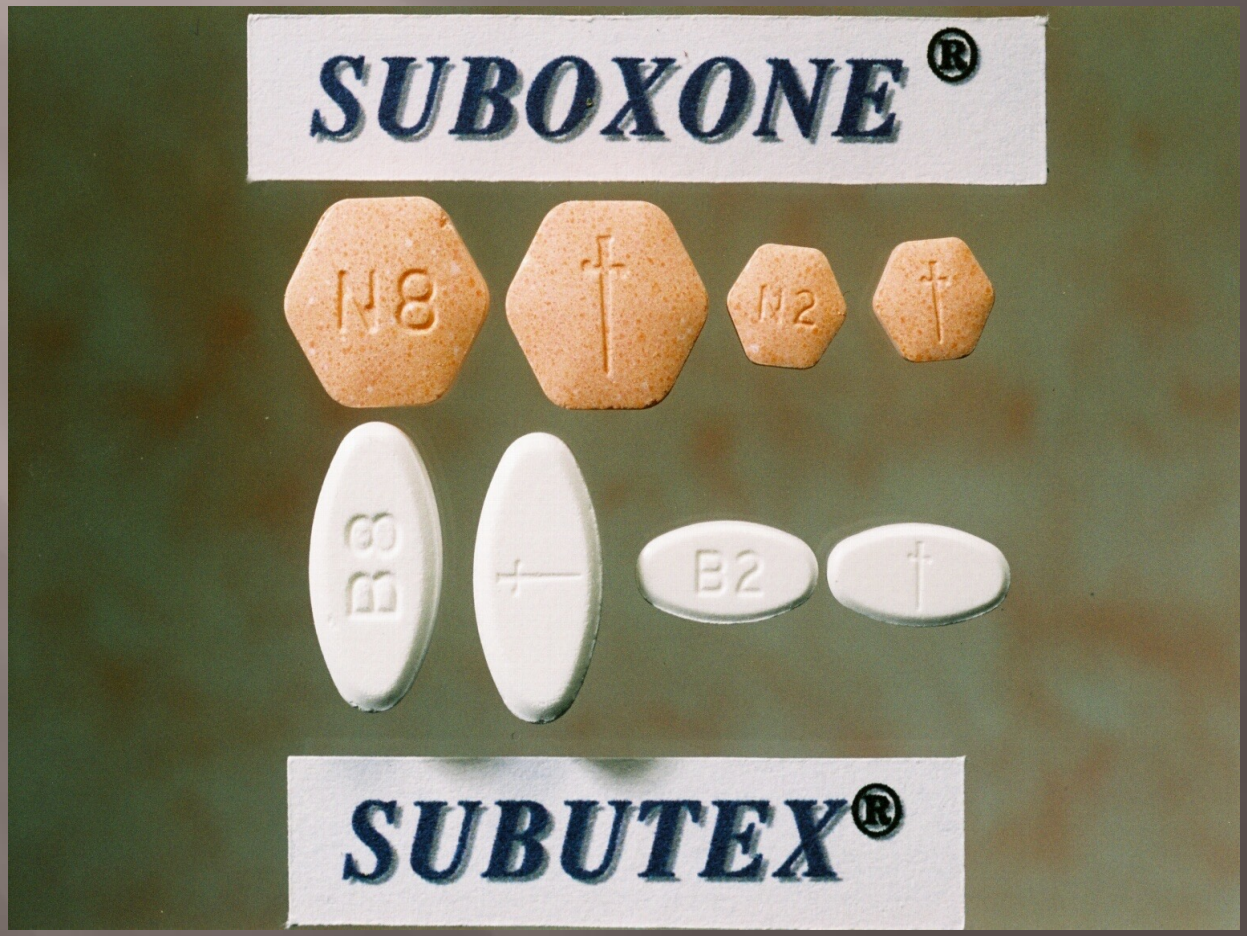
Darvocet



Opioid Partial Agonists

- Buprenorphine – Buprenex®, Suboxone®, Subutex®
- Pentazocine – Talwin®

Buprenorphine/Naloxone Combination and Buprenorphine Alone



Opioid Antagonists

- Naloxone – Narcan®
- Naltrexone – ReVia®, Trexan®

Opiate/Opioid : What's the Difference?

Opiate

- A term that refers to drugs or medications that are derived from the opium poppy, such as heroin, morphine, codeine, and buprenorphine.

Opioid

- A more general term that includes opiates as well as the synthetic drugs or medications, such as buprenorphine, methadone, meperidine (Demerol®), fentanyl—that produce analgesia and other effects similar to morphine.

Consequences of Opioid Use

- Addiction
- Overdose
- Death
- Use related (e.g., HIV infection, malnutrition)
- Negative consequences from injection:
  - Infectious diseases (e.g., HIV/AIDS, Hepatitis B and C)
  - Collapsed veins
  - Bacterial infections
  - Abscesses
  - Infection of heart lining and valves
  - Arthritis and other rheumatologic problems

Heroin Withdrawal Syndrome

- Intensity varies with level & chronicity of use
- Cessation of opioids causes a rebound in function altered by chronic use
- First signs occur shortly before next scheduled dose
- Duration of withdrawal is dependent upon the half-life of the drug used:
  - Peak of withdrawal occurs 36 to 72 hours after last dose
  - Acute symptoms subside over 3 to 7 days
  - Protracted symptoms may linger for weeks or months

Opioid Withdrawal Syndrome Acute Symptoms

- Pupillary dilation
- Lacrimation (watery eyes)
- Rhinorrhea (runny nose)
- Muscle spasms (“kicking”)
- Yawning, sweating, chills, gooseflesh
- Stomach cramps, diarrhea, vomiting
- Restlessness, anxiety, irritability

Opioid Withdrawal Syndrome Protracted Symptoms

- Deep muscle aches and pains
- Insomnia, disturbed sleep
- Poor appetite
- Reduced libido, impotence, anorgasmia
- Depressed mood, anhedonia
- Drug craving and obsession

Treatment of Opioid Addiction

Treatment Options for Opioid-Addicted Individuals

- Behavioral treatments educate patients about the conditioning process and teach relapse prevention strategies.
- Medications such as methadone and buprenorphine operate on the opioid receptors to relieve craving.
- ***Combining the two types of treatment enables patients to stop using opioids and return to more stable and productive lives.***

How Can You Treat Opioid Addiction?

Medically-Assisted Withdrawal

- Relieves withdrawal symptoms while patients adjust to a drug-free state
- Can occur in an inpatient or outpatient setting
- Typically occurs under the care of a physician or medical provider
- Serves as a precursor to behavioral treatment, because it is designed to treat the acute physiological effects of stopping drug use

(National Institute on Drug Abuse, 2009)

How Can You Treat Opioid Addiction?

Long-Term Residential Treatment

- Provides care 24 hours per day
- Planned lengths of stay of 6 to 12 months
- Models of treatment include Therapeutic Community (TC), Cognitive Behavioral Therapy.

Outpatient Psychosocial Treatment

- Less costly than residential treatment
- Varies in types and intensity of services offered
- Group counseling is emphasized
- Medically-assisted withdrawal is offered generally done with clonidine and other non-narcotic medications.

(National Institute on Drug Abuse, 2009)

How Can You Treat Opioid Addiction?

Behavioral Therapies

- Contingency management
  - Based on principles of operant conditioning
  - Uses reinforcement (e.g., vouchers) of positive behaviors in order to facilitate change
- Cognitive-behavioral interventions
  - Modify patient's thinking, expectancies, and behaviors
  - Increase skills in coping with various life stressors

(National Institute on Drug Abuse, 2009)

How Can You Treat Opioid Addiction?

Agonist Maintenance Treatment

- Usually conducted in outpatient settings
- Treatment provided in opioid treatment programs traditionally using methadone, now with buprenorphine, in office-based settings
- Patients stabilized on adequate, sustained dosages of these medications can function normally.
- Can engage more readily in counseling and other behavioral interventions essential to recovery and rehabilitation
- The best, most effective opioid agonist maintenance programs include individual and/or group counseling, as well as provision of, or referral to other needed medical, psychological, and social services.

(National Institute on Drug Abuse, 2009)

Benefits of Methadone Maintenance Therapy

- Used effectively and safely for over 30 years
- Not intoxicating or sedating, if prescribed properly
- Effects do not interfere with ordinary activities
- Suppresses opioid withdrawal for 24-36 hours

How Can You Treat Opioid Addiction?

Antagonist Maintenance Treatment

- Usually conducted in outpatient setting
- Initiation of naltrexone often begins after medical detoxification in a residential setting
- Repeated lack of desired opioid effects will gradually over time result in breaking the habit of opiate addiction.
- Patient noncompliance is a common problem. A favorable treatment outcome requires a positive therapeutic relationship, effective counseling or therapy, and careful monitoring of medication compliance.

(National Institute on Drug Abuse, 2009)

Buprenorphine Research Outcomes

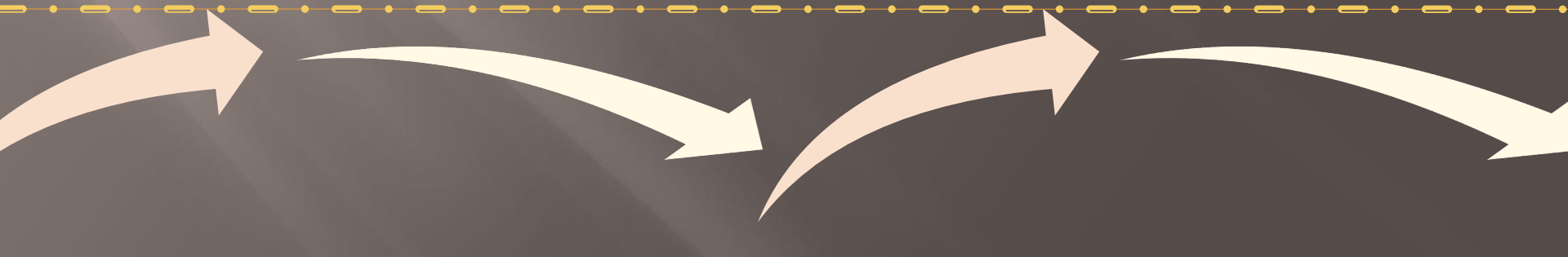
- Buprenorphine is as effective as moderate doses of methadone (Fischer et al., 1999; Johnson, Jaffee, & Fudula, 1992; Ling et al., 1996; Schottenfield et al., 1997; Strain et al., 1994).
- Buprenorphine is as effective as moderate doses of LAAM (Johnson et al., 2000).
- Buprenorphine's partial agonist effects make it mildly reinforcing, encouraging medication compliance (Ling et al., 1998).
- After a year of buprenorphine plus counseling, 75% of patients retained in treatment compared to 0% in a placebo-plus-counseling condition (Kakko et al., 2003).

Buprenorphine as a Treatment for Opioid Addiction

- A synthetic opioid
- Described as a mixed opioid agonist-antagonist (or partial agonist)
- Available for use by certified physicians outside traditionally licensed opioid treatment programs

The Role of Buprenorphine in Opioid Treatment

- Partial Opioid Agonist
  - Produces a ceiling effect at higher doses
  - Has effects of typical opioid agonists—these effects are dose dependent up to a limit
  - Binds strongly to opiate receptor and is long-acting
- Safe and effective therapy for opioid maintenance and detoxification



Advantages of Buprenorphine in the Treatment of Opioid Addiction

1. Patient can participate fully in treatment activities and other activities of daily living easing their transition into the treatment environment
2. Limited potential for overdose (Johnson et.al, 2003)
3. Minimal subjective effects (e.g., sedation) following a dose
4. Available for use in an office setting
5. Lower level of physical dependence

Disadvantages of Buprenorphine in the Treatment of Opioid Addiction

1. Greater medication cost
2. Lower level of physical dependence (i.e., patients can discontinue treatment)
3. Detectable only in specific urine toxicology screenings

What is the Ratio of Buprenorphine to Naloxone in the Combination Tablet?

- Each tablet contains buprenorphine and naloxone in a 4:1 ratio
  - Each 8 mg tablet contains 2 mg of naloxone
  - Each 2 mg tablet contains 0.5 mg of naloxone
- Ratio was deemed optimal in clinical studies
  - Preserves buprenorphine's therapeutic effects when taken as intended sublingually
  - Sufficient dysphoric effects occur if injected by some physically dependent persons to discourage abuse

Why Combining Buprenorphine and Naloxone Sublingually Works

- Buprenorphine and naloxone have different sublingual (SL) to injection potency profiles that are optimal for use in a combination product.

SL Bioavailability	Potency
Buprenorphine 40-60%	Buprenorphine ≈ 2:1
Naloxone 10% or less	Naloxone ≈ 15:1

(Chaing & Hawks, 2003)

Buprenorphine/Naloxone: What You Need to Know

- Basic pharmacology, pharmacokinetics, and efficacy is the ***same*** as buprenorphine alone
- Partial opioid agonist; ceiling effect at higher doses
- Blocks effects of other agonists
- Binds strongly to opioid receptor, long acting

Induction Phase

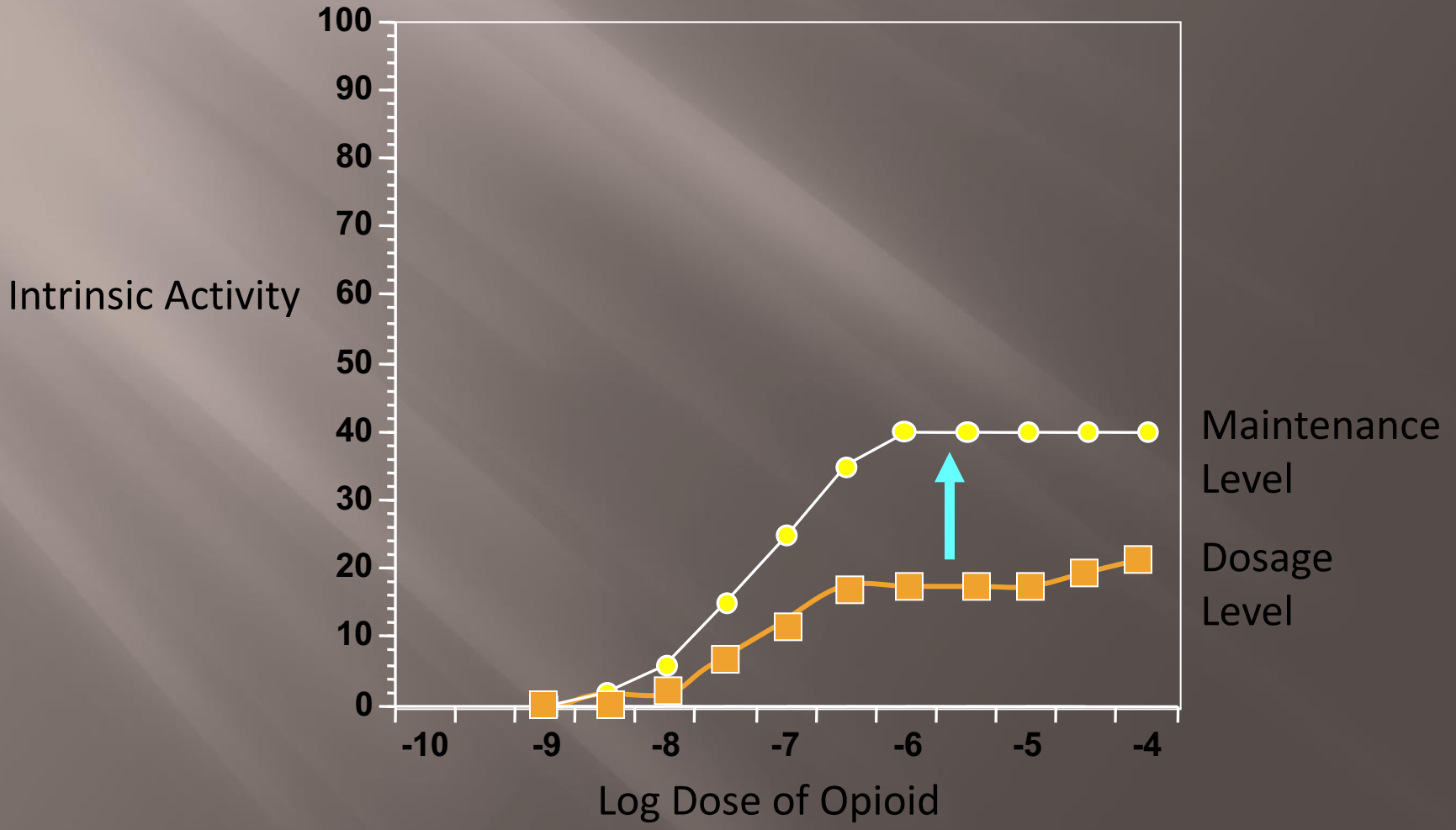
Working to establish the appropriate dose of medication for patient to discontinue use of opiates with minimal withdrawal symptoms, side-effects, and craving

Transferring Patients Onto Buprenorphine: 3 Ways Significant Withdrawal Could Occur

Dose too low?

Insufficient agonist effects

If the dose is too low, the patient will experience withdrawal



Transferring Patients Onto Buprenorphine: 3 Ways Significant Withdrawal Could Occur

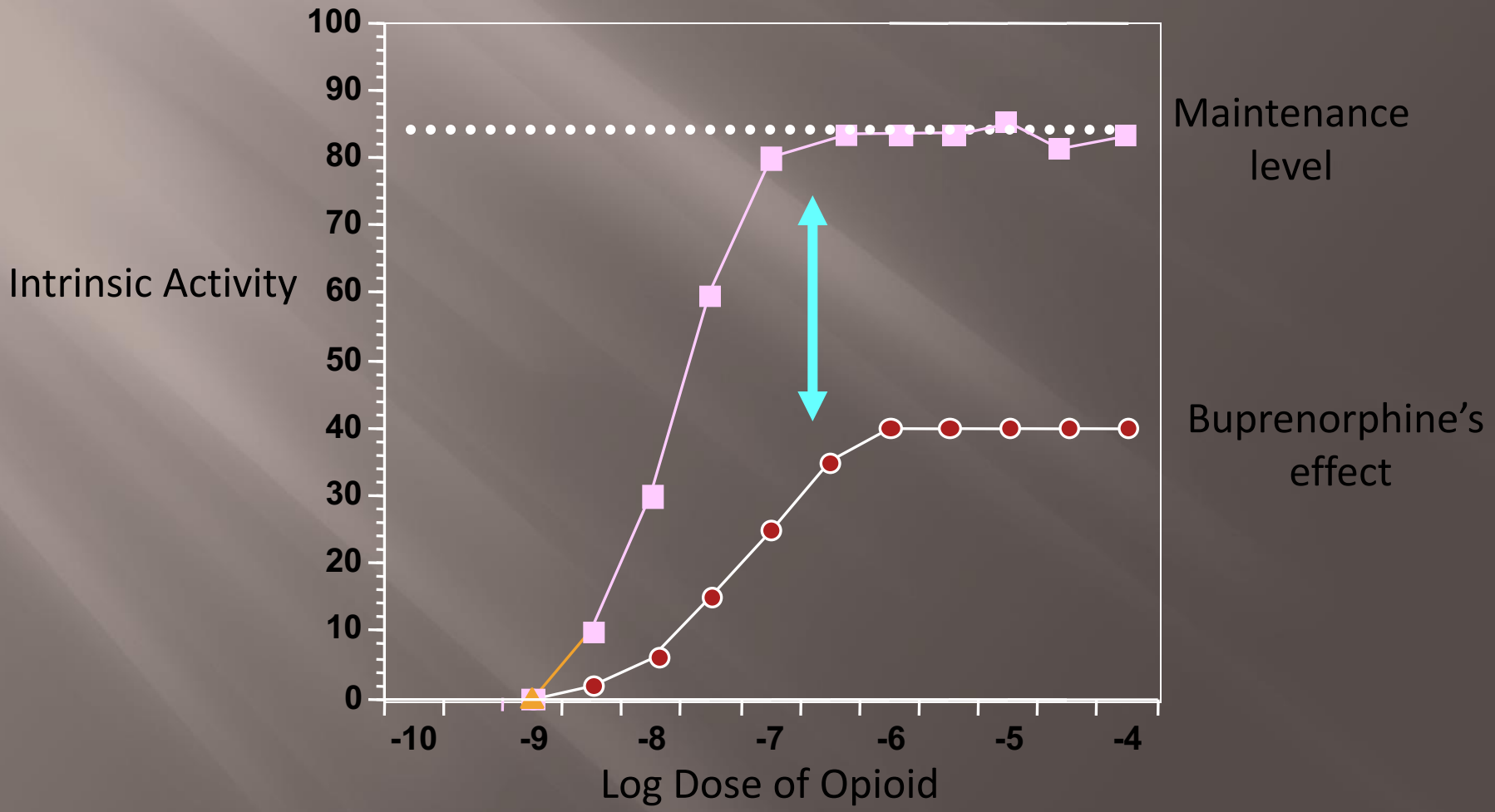
Dose too low?

Insufficient agonist effects

Not full agonist

May not fully replace

If the patient needs a high level of medication to achieve maintenance, the ceiling effect of buprenorphine may result in withdrawal



Transferring Patients Onto Buprenorphine: 3 Ways Significant Withdrawal Could Occur

Dose too low?

Insufficient agonist effects

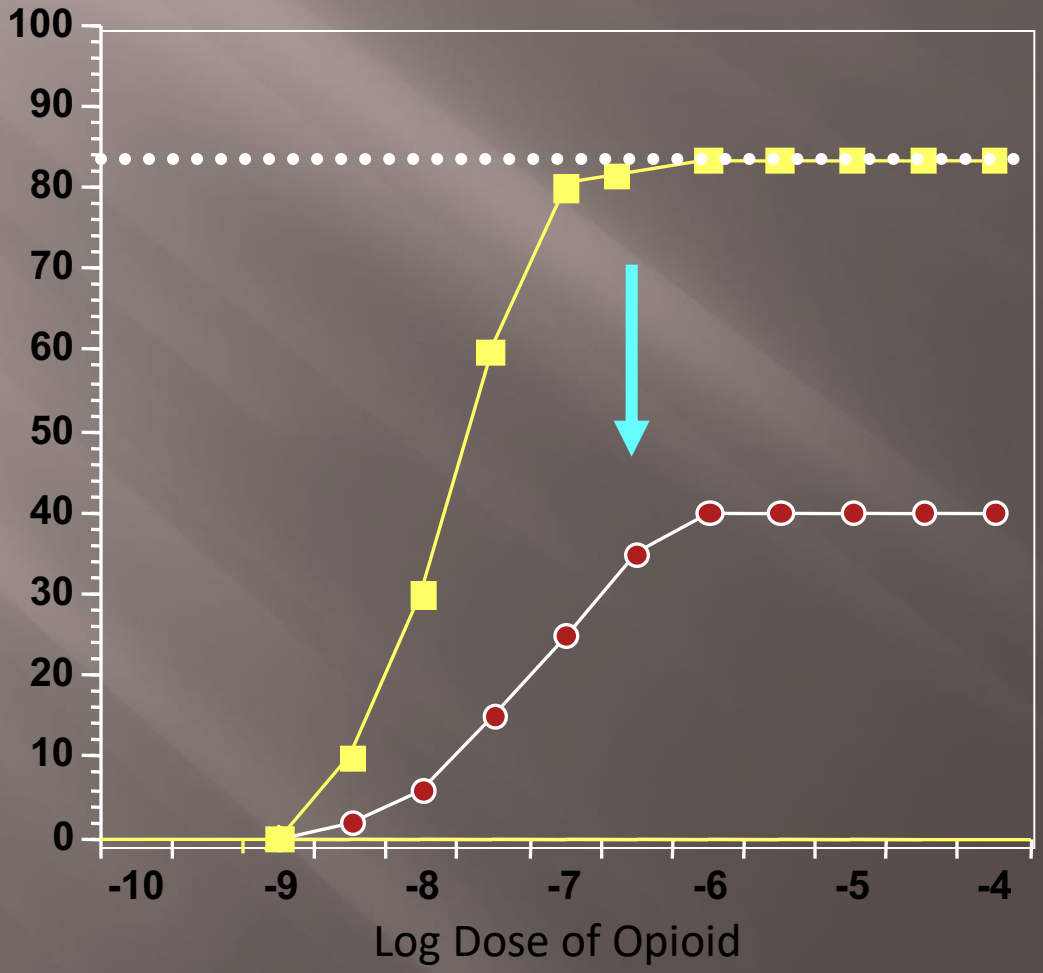
Not full agonist

May not fully replace

Precipitates Withdrawal

Ceiling effect

Buprenorphine will replace other opioids at the receptor site; therefore the patient experiences withdrawal.



Direct Buprenorphine Induction from Short-Acting Opioids

- Ask patient to abstain from short-acting opioid (e.g., heroin) for at least 6 hrs. and be in mild withdrawal before administering buprenorphine/naloxone.
- When transferring from a short-acting opioid, be sure the patient provides a methadone-negative urine screen before 1st buprenorphine dose.

(Amass et al., 2004; Johnson et al., 2003)

Small Group Exercise:

Dependence vs. Addiction: What's the Difference?

In your small groups, discuss this question.

Terminology
Dependence versus Addiction

- The DSM-IV- TR defines problematic substance use with the term substance dependence. It does not use the term addiction. This has been the source of much confusion.
- According to the DSM-IV-TR definition, substance dependence is defined as continued use despite the development of negative outcomes including physical, psychological or interpersonal problems resulting from use.
- Most providers refer to this as addiction and **ADDICTION** is the term we will use throughout the rest of the training.

(American Psychiatric Association, 2000)

Terminology
Dependence versus Addiction

- Addiction may occur with or without the presence of physical dependence.
- Physical dependence results from the body's adaptation to a drug or medication and is defined by the presence of
  - Tolerance and/or
  - Withdrawal

Terminology
Dependence versus Addiction

Tolerance:

The loss of or reduction in the normal response to a drug or other agent, following use or exposure over a prolonged period

Terminology
Dependence versus Addiction

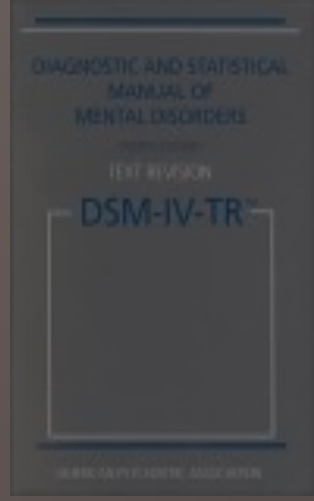
Withdrawal:

A period during which somebody dependent to a drug or other addictive substance stops taking it, causing the person to experience painful or uncomfortable symptoms

OR

a person takes a similar substance in order to avoid experiencing the effects described above.

DSM IV- TR Criteria for Substance Dependence



- Three or more of the following occurring at any time during the same 12 month period:
  - Tolerance
  - Withdrawal
  - Substance taken in larger amounts over time
  - Persistent desire or unsuccessful efforts to cut down or stop
  - A lot of time and activities spent trying to get the drug
  - Disturbance in social, occupational or recreational functioning
  - Continued use in spite of knowledge of the damage it is doing to the self

(American Psychiatric Association, 2000)

Opioid Agonists: Pharmacology

- Stimulate opioid receptors in central nervous system & gastrointestinal tract
- Analgesia – pain relief (somatic & psychological)
- Antitussive action – cough suppression
- Euphoria, stuperousness, "nodding"
- Respiratory depression

Opioid Agonists: Pharmacology

- Pupillary constriction (miosis)
- Constipation
- Histamine release (itching, bronchial constriction)
- Reduce libido
- Tolerance, cross-tolerance
- Withdrawal: acute & protracted

Possible Acute Effects of Opioid Use

- Surge of pleasurable sensation = “rush”
- Warm flushing of skin
- Dry mouth
- Heavy feeling in extremities
- Drowsiness
- Clouding of mental function
- Slowing of heart rate and breathing
- Nausea, vomiting, and severe itching

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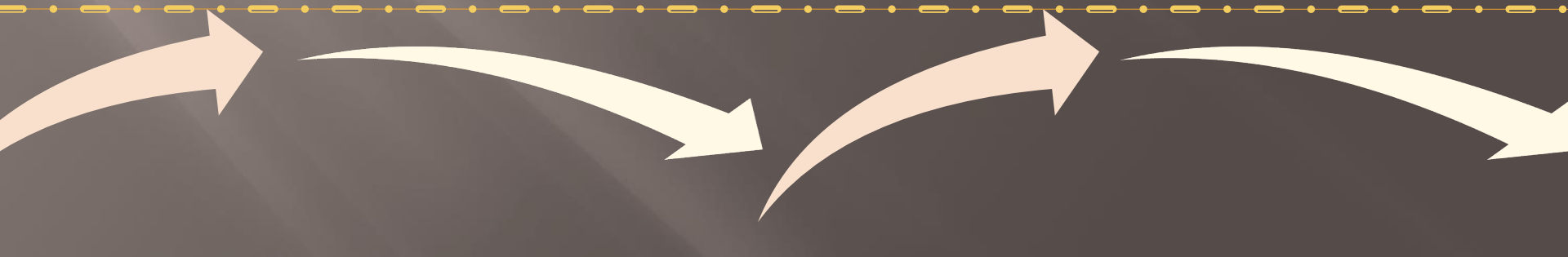
- Buprenorphine is as effective as moderate doses of methadone (Fischer et al., 1999; Johnson, Jaffee, & Fudula, 1992; Ling et al., 1996; Schottenfield et al., 1997; Strain et al., 1994).
- Buprenorphine is as effective as moderate doses of LAAM (Johnson et al., 2000).
- Buprenorphine's partial agonist effects make it mildly reinforcing, encouraging medication compliance (Ling et al., 1998).
- After a year of buprenorphine plus counseling, 75% of patients retained in treatment compared to 0% in a placebo-plus-counseling condition (Kakko et al., 2003).

The Role of Buprenorphine in Opioid Treatment

- Partial Opioid Agonist
  - Produces a ceiling effect at higher doses
  - Has effects of typical opioid agonists—these effects are dose dependent up to a limit
  - Binds strongly to opiate receptor and is long-acting
- Safe and effective therapy for opioid maintenance and detoxification



Patient Selection

- Counselors can screen and recommend patients for referral to qualified physicians.

- Physicians will consider the following questions:
  - Is the patient currently addicted to opioids?
  - Is buprenorphine the best medication?
  - Is the office the best setting for treating the patient?

Patient Selection Assessment Questions

- Is the patient addicted to opioids?
- Is the patient aware of other available treatment options?
- Does the patient understand the risks, benefits, and limitations of buprenorphine treatment?
- Is the patient expected to be reasonably compliant?
- Is the patient expected to follow safety procedures?

Patient Selection: Assessment Questions

- Is the patient psychiatrically stable?
- Is the patient taking other medications that may interact with buprenorphine?
- Are the psychosocial circumstances of the patient stable and supportive?
- Is the patient interested in office-based buprenorphine treatment?
- Are there resources available in the office to provide appropriate treatment?

Issues Requiring Consultation with the Physician

- Dependence upon high doses of benzodiazepines or other CNS depressants
- Significant psychiatric co-morbidity
- Multiple previous opioid treatment episodes with frequent relapse

Issues Requiring Consultation with the Physician

- High level of dependence on high doses of opioids
- High risk for relapse based on psychosocial or environmental conditions
- Pregnancy
- Poor support system

Issues Requiring Consultation with the Physician

- HIV and STDs
- Hepatitis or impaired liver function

Issues Requiring Consultation with the Physician

- Use of alcohol
- Use of sedative-hypnotics
- Use of stimulants
- Poly-drug addiction

General Counseling Issues

- Confidentiality
- Urine toxicology testing
- Working with, not against, medication
- Psychosocial treatment
- Supporting medication maintenance
- Patient comfort during withdrawal

Direct Buprenorphine Induction from Long-Acting Opioids

- Clinical experience has suggest that induction procedures with patients receiving long-acting opioids (e.g. methadone-maintenance patients) are basically the same as those used with patients taking short-acting opioids, except:
  - The time interval between the last dose of medication and the first dose of buprenorphine must be **increased.**
  - **At least 24 hrs should elapse** before starting buprenorphine and longer time periods may be needed (up to 48 hrs).
  - Urine drug screening should indicate no other illicit opiate use at the time of induction.

(Center for Substance Abuse Treatment, 2004)

Stabilization Phase

Patient experiences no withdrawal symptoms, side-effects, or craving

Maintenance Phase

Goals of Maintenance Phase:

Help the patient stop and stay away from illicit drug use and problematic use of alcohol

1. Continue to monitor cravings to prevent relapse
2. Address psychosocial and family issues

Maintenance Phase

Psychosocial and family issues to be addressed:

a) Psychiatric co-morbidity
b) Family and support issues
c) Time management
d) Employment/financial issues
e) Pro-social activities
f) Legal issues
g) Secondary drug/alcohol use

Buprenorphine Maintenance: Summary

- Take-home dosing is safe and preferred by patients, but patient adherence will vary and this can impact treatment outcomes.
- 3x/week dosing with buprenorphine/naloxone is safe and effective as well (Amass et al., 2001).
- *Counseling needs to be integrated into any buprenorphine treatment plan.*

Medically-Assisted Withdrawal

(a.k.a. Dose Tapering; a.k.a. Detoxification)

Buprenorphine Withdrawal

- Working to provide a smooth transition from a physically-dependent to non-dependent state, with medical supervision
- Medically supervised withdrawal (detoxification) is accompanied with and followed by psychosocial treatment, and sometimes medication treatment (i.e., naltrexone) to minimize risk of relapse.
- Medically- supervised withdrawal may lead to early treatment engagement (Brigham et al., 2007).

Medically-Assisted Withdrawal (Detoxification)

- Outpatient and inpatient withdrawal are both possible
- How is it done?
  - Switch to longer-acting opioid (e.g., buprenorphine)
    - Taper off over a period of time (a few days to weeks depending upon the program)
    - Use other medications to treat withdrawal symptoms
  - Use clonidine and other non-narcotic medications to manage symptoms during withdrawal

Issues in Recovery

- 12-Step meetings and the use of medication
- Drug cessation and early recovery skills
  - Disposing of drugs and related paraphernalia
  - Dealing with triggers and cravings
- Treatment should be delivered within a formal structure.
- Relapse prevention is not a matter of will power.

Trigger

A trigger is a stimulus which has been repeatedly associated with the preparation for, anticipation of, or use of drugs and/or alcohol. These stimuli include people, things, places, times of day, and emotional states.

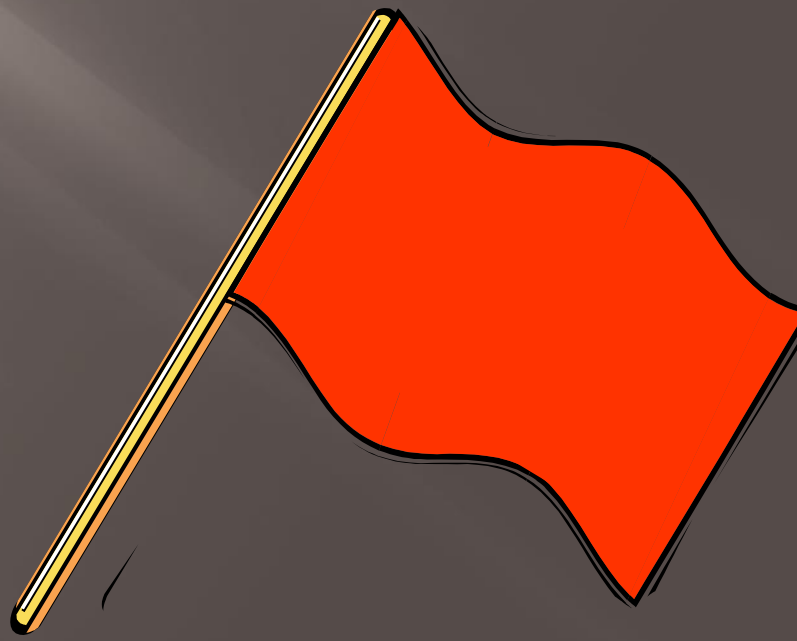
Issues in Recovery: Triggers

- People, places, objects, feelings and times can cause cravings.
- An important part of treatment involves stopping the craving process:
  - Identify triggers
  - Present exposure to triggers
  - Deal with triggers in a different way

(Center for Substance Abuse Treatment, 2006)

Issues in Recovery: Triggers

- Secondary drug use
- Internal vs. external triggers
- "Red flag" emotional states
  - Loneliness
  - Anger
  - Deprivation
  - Stress
- Others?



Issues in Recovery: Craving

- A strong desire for something
- Does not always occur in a straightforward way
- It takes effort to identify and stop a drug-use related thought.
- The further the thoughts are allowed to go, the more likely the individual is to use drugs.

(Center for Substance Abuse Treatment, 2006)

Triggers & Cravings

During addiction, triggers, thoughts, and craving can run together. The usual sequence, however, is as follows:

Trigger → ***Thought*** → ***Craving*** → ***Use***

The key to dealing with this process is to not allow for it to start. Stopping the thought when it first begins helps prevent it from building into a craving.

(Center for Substance Abuse Treatment, 2006)

Thought-Stopping Techniques

- Visualization
- Snapping
- Relaxation
- Calling someone

(Center for Substance Abuse Treatment, 2006)

Areas of Needs Assessment

- Drug use
- Alcohol use
- Social Issues
- Social Services
- Psychological history and status
- Education
- Vocational

Patient Management Issues

- Pharmacotherapy alone is insufficient to treat drug addiction.
- Physicians are responsible for providing or referring patients to counseling.
- Contingencies should be established for patients who fail to follow through on referrals.

Patient Management: Treatment Monitoring

Goals for treatment should include:

- No illicit opioid drug use
- No other drug use
- Absence of adverse medical effects
- Absence of adverse behavioral effects
- Responsible handling of medication
- Adherence to treatment plan

Patient Management: Treatment Monitoring

Weekly visits (or more frequent) are important to:

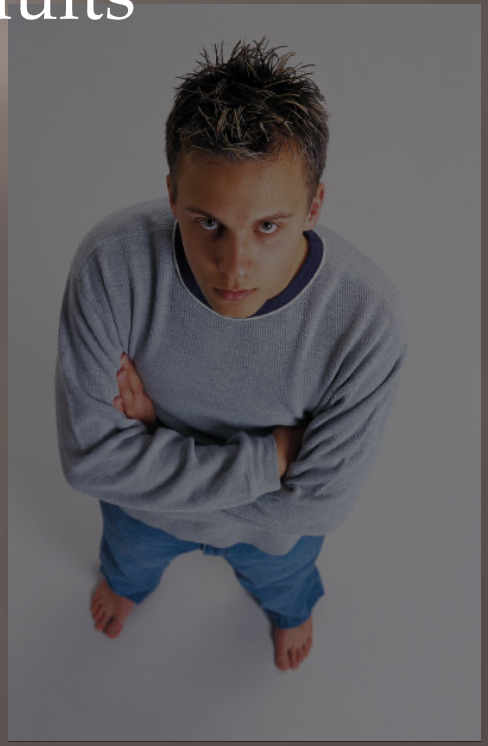
1. Provide ongoing counseling to address barriers to treatment, such as travel distance, childcare, work obligations, etc
2. Provide ongoing counseling regarding recovery issues
3. Assess adherence to dosing regimen
4. Assess ability to safely store medication
5. Evaluate treatment progress

Patient Management: Treatment Monitoring

- Urine toxicology tests should be administered at least monthly for all relevant illicit substances.
- Buprenorphine can be tapered while psychosocial services continue.
- The treatment team should work together to prevent involuntary termination of medication and psychosocial treatment.
- In the event of involuntary termination, the physician and/or other team members should make appropriate referrals.
- Physicians should manage appropriate withdrawal of buprenorphine to minimize withdrawal discomfort.

Special Populations

- Patients with co-occurring psychiatric disorders
- Pregnant women
- Adolescents and young adults



Co-Occurring Psychiatric Disorders

- Opioid users frequently have concurrent psychiatric diagnoses.
- Sometimes the effects of drug use and/or withdrawal can mimic psychiatric symptoms.
- Clinicians must consider the duration, recentness, and amount of drug use when selecting appropriate patients.
- Signs of anxiety, depression, thought disorders or unusual emotions, cognitions, or behaviors should be reported to physician and discussed with the treatment team.

Pregnancy-Related Considerations

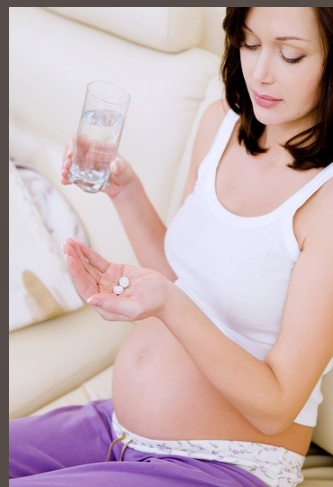
- Methadone maintenance is the treatment of choice for pregnant opioid-addicted women.
- Opioid withdrawal should be avoided during pregnancy.
- Buprenorphine may eventually be useful in pregnancy, but is currently not approved.

(Jones et al ., 2005)

The Use of Buprenorphine During Pregnancy

- Currently buprenorphine is a Category C medication. This means it is not approved for use during pregnancy.
- Studies conducted to date suggest that buprenorphine *may be* an excellent option for pregnant women.
- Randomized trials are underway to determine

  the safety and effectiveness of using buprenorphine during pregnancy.



Specific Research on Buprenorphine and Pregnancy

- Case series in France: safe and effective, possibly reducing NAS
- One preliminary study in US: examining the use of buprenorphine versus methadone in the treatment of pregnant opioid-dependent patients: effects on the neonatal abstinence syndrome **(Jones et al., 2005)**

Specific Research on Buprenorphine and Pregnancy

- Head to head randomized blinded comparison between methadone and buprenorphine in pregnant women
- Women admitted during second trimester
- One statistically significant finding: shorter stay for buprenorphine
- Other trends for buprenorphine: fewer infants treated for NAS, less NAS medication used.
- Multi-site trial in progress now.

Opioid-Addicted Adolescents and Young Adults

- Current treatments for opioid-addicted adolescents and young adults are often unavailable and when found, clinicians report that the outcome leaves much to be desired.
- States have different requirement for admitting clients under age 18 to addictions treatment. It is important to know the local requirements.

Opioid-Addicted Adolescents and Young Adults

- Buprenorphine is approved for use with opioid dependent persons age 16 and older
- Research conducted through the NIDA Clinical Trials Network (CTN 010) demonstrated that it can be safely and effectively used with young adults.
- This research also indicated that medical treatment likely needs to be longer than current standard treatment indicates.

Buprenorphine and Pain Management

Medication-Assisted Treatment and Pain Management

Common Misconceptions

- Maintenance opioid agonists provide pain relief.
- Use of opioids for pain relief may result in addiction or relapse
- Combining opioid analgesics and opioid agonist therapy may cause respiratory and central nervous system depression.
- The pain complaint may be a manipulation to obtain medications to feel “high.”

Buprenorphine and Pain Management

- Little clinical experience documented
- Acute Pain
  - Initially treat with non-opioid analgesics
  - Pain not relieved by non-opioid medications, follow usual pain management protocol
- Chronic Pain
  - May not be good candidate for buprenorphine treatment because of the ceiling effect

Buprenorphine-Related Patient Management Issues

- Discuss the benefits of maintenance treatment
- Evaluate the readiness to taper medication
- Explain issues in evaluating the discontinuation of buprenorphine treatment
- Identify the components of a healthy counselor-physician partnership

Counseling Buprenorphine Patients

- Address issues of the necessity of counseling with medication for recovery.

- Recovery and Pharmacotherapy:
  - Patients may have ambivalence regarding medication.
  - The recovery community may ostracize patients taking medication.
  - Counselors need to have accurate information.

Counseling Buprenorphine Patients

- Recovery and Pharmacotherapy:
  - Focus on "getting off" buprenorphine may convey taking medicine is "bad."
  - Suggesting recovery requires cessation of medication is inaccurate and potentially harmful.
  - Support patient's medication compliance
  - "Medication," not "drug"

Counseling Buprenorphine Patients

- Dealing with Ambivalence:
  - Impatience, confrontation, "you're not ready for treatment"

    or,
  - Deal with patients at their stage of acceptance and readiness

Counseling Buprenorphine Patients

- Counselor Responses:
  - Be flexible
  - Don't impose high expectations
  - Don't confront
  - Be non-judgmental
  - Use a motivational interviewing approach
  - Provide reinforcement

Counseling Buprenorphine Patients

- Encouraging Participation in 12-Step Meetings:
  - What is the 12-Step Program?
  - Benefits
  - Meetings: speaker, discussion, Step study, Big Book readings
  - Self-help vs. treatment

Counseling Buprenorphine Patients

- Issues in 12-Step Meetings:
  - Medication and the 12-Step program
    - Program policy
      - "The AA Member: Medications and Other Drugs"
      - NA: "The ultimate responsibility for making medical decisions rests with each individual"
    - Some meetings are more accepting of medications than others

Counseling Buprenorphine Patients

- A Motivational Interviewing Approach:
  - Dealing with other drugs and alcohol
  - Doing more than not-using
- MIA-STEP
  - Developed through the Blending Initiative
  - Empirically supported mentoring products to enhance the MI skills of treatment providers
  - Provides tools to help supervisors offer structured, focused, and effective supervision.
  - The blending products are available at www.drugabuse.gov/Blending/ www.attcnetwork.org

Principles of Motivational Interviewing

- Express empathy
- Develop discrepancy
- Avoid argumentation
- Support self-efficacy
- Ask open-ended questions
- Be affirming
- Listen reflectively
- Summarize

Using Motivational Incentives

- NIDA CTN research shows that treatment retention and drug abstinence are improved by providing low-cost reinforcement (prizes, vouchers, clinic privileges, etc.), for drug negative urine tests.
- The Blending Product Promoting Awareness of Motivational Incentives (PAMI) provides information on this effective technique.
- The blending products are available at: www.drugabuse.gov/Blending/ www.attcnetwork.org

Counseling Buprenorphine Patients

- Early Recovery Skills:
  - Getting Rid of Paraphernalia
  - Scheduling
  - Trigger Charts

Counseling Buprenorphine Patients

- Relapse Prevention:
  - Patients need to develop new behaviors.
  - Learn to monitor signs of vulnerability to relapse
  - Recovery is more than not using illicit opioids.
  - Recovery is more than not using drugs and alcohol.

Counseling Buprenorphine Patients

- Relapse Prevention: Sample Topics
  - *Relapse Prevention*
    - Overview of the concept
  - *Using Behavior*
    - Old behaviors need to change
    - Re-emergence signals relapse risk
  - *Relapse Justification*
    - "Stinking thinking"
    - Recognize and stop

Counseling Buprenorphine Patients

- Relapse Prevention: Sample Topics
  - *Dangerous Emotions*
    - Loneliness, anger, deprivation
  - *Be Smart, not Strong*
    - Avoid the dangerous people and places
    - Don't rely on will power
  - *Avoiding Relapse Drift*
    - Identify "mooring lines"
    - Monitor drift

Counseling Buprenorphine Patients

- Relapse Prevention: Sample Topics
  - *Total Abstinence*
    - Other drug/alcohol use impedes recovery growth
    - Development of new dependencies is possible
  - *Taking Care of Business*
    - Addiction is full-time
    - Normal responsibilities often neglected
  - *Taking Care of Yourself*
    - Health, grooming
    - New self-image

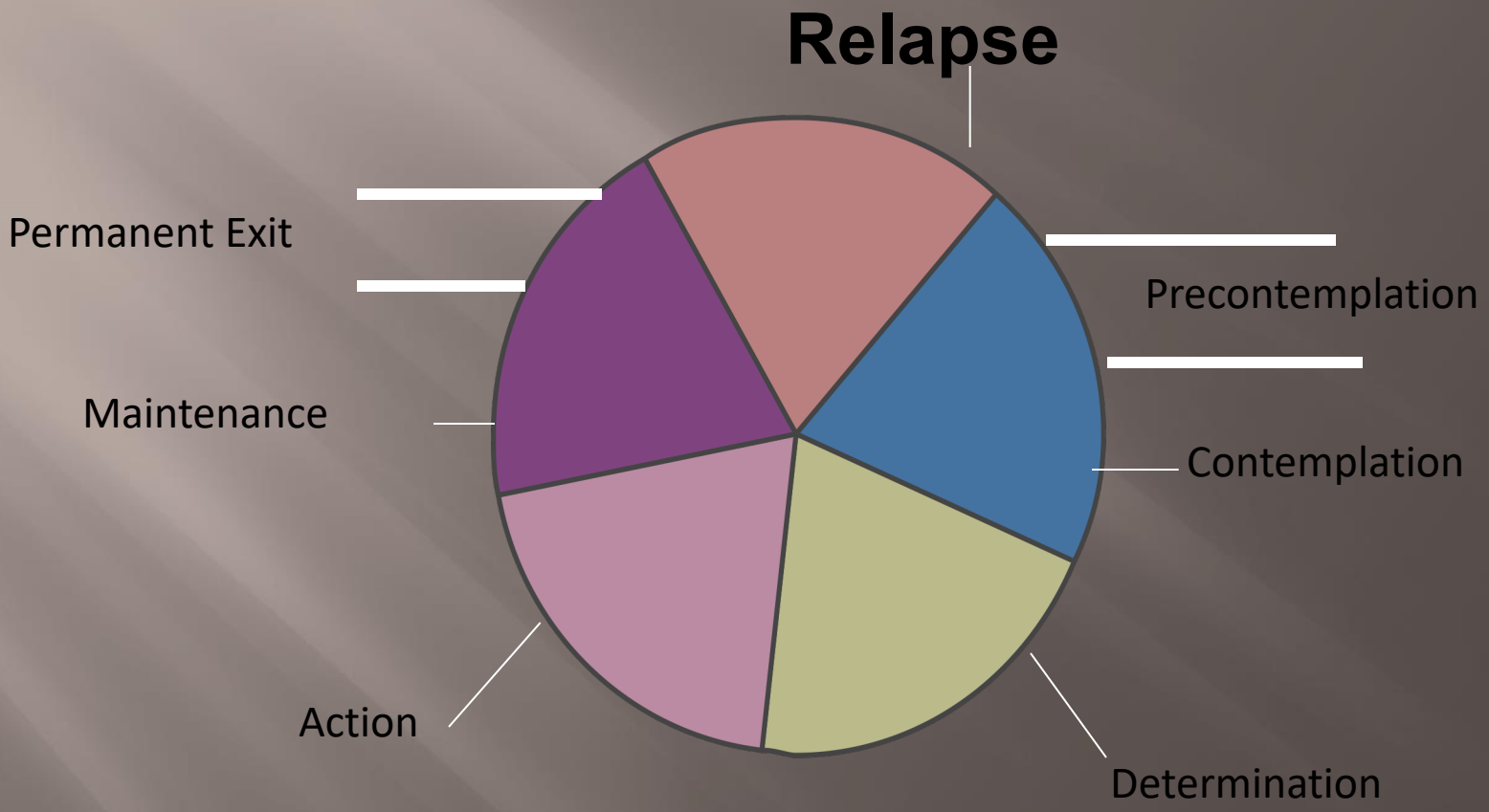
Counseling Buprenorphine Patients

- Relapse Prevention: Sample Topics
  - *Repairing Relationships*
    - Making amends
  - *Truthfulness*
    - Counter to the drug use style
    - A defense against relapse
  - *Trust*
    - Does not return immediately
    - Be patient

Counseling Buprenorphine Patients

- Relapse Prevention: Sample Topics
  - *Downtime*
    - Diversion, relief, escape without drugs
  - *Recognizing and Reducing Stress*
    - Stress can cause relapse
    - Learn signs of stress
    - Learn stress management skills

Stages of Change



(Prochaska & DiClemente, 1983)

Stages of Change

- Pre-contemplation: Not yet considering change or is unwilling or unable to change.
- Contemplation: Sees the possibility of change but is ambivalent and uncertain.
- Determination (or preparation): Committed to making change but is still considering what to do.

Buprenorphine Treatment Works in Multiple Settings

- National studies conducted through the CTN have shown that buprenorphine treatment can be integrated into diverse settings, such as specialized clinics, hospital settings and drug-free programs, and including settings with no prior experience using agonist-based therapies.
- Additional information about interventions that may be useful along with buprenorphine treatment include the MIA: STEP and PAMI Blending Products available at:
  www.attcnetwork.org
  www.drugabuse.gov/Blending/

Effective Coordination of Care

Effective coordination combines the strengths of various systems and professions, including: physicians, addiction counselors, 12-step programs, and community support service providers. The roles of certain providers may vary by state, depending upon the identified scope of practice for each profession.

Roles of the Physician

- Screening
- Assessment
- Diagnosing Opioid Addiction
- Patient Education
- Prescribing Buprenorphine
- Urinalysis Testing
- Recovery Support

Roles of the Multidisciplinary Team

- Screening
- Assessing and Diagnosing of Opioid Addiction
- Psychosocial Treatment
- Patient Education
- Referral for Treatment
- Urinalysis Testing
- Recovery Support
- Case Management and Coordination

Roles of the Community Support Provider

- Screening
- Assessment
- Referral for Treatment
- Recovery Support
- Meeting Ancillary Needs of the Patient

Roles of the 12-Step Program

- Recovery Support
  - Being on an opioid treatment medication may be an issue in some 12-step meetings.
  - Program staff should be prepared to coach patients on how to handle this issue.

Challenges for Addiction Treatment Professionals

- Not all physicians who are trained have consented to be listed on Physician locator. Community outreach is still critical.
- Linking patients to primary care who have not been within the medical mainstream
- Coordination with other professionals not accustomed to working with non-medical partners
- Covering the cost of medication

Barriers to Effective Care Coordination

- Misunderstanding respective roles
- Conflicting goals for treatment
- Confidentiality restrictions
- Control issues
- Misconception of other professional perspectives

Attributes of Successful Care Coordination

- Understanding roles for each participant in the treatment team
- Ongoing communication across professions
- Personal contact between partners in the system