

# BUPRENORPHINE TREATMENT

Curriculum Infusion Package (CIP)  
For Infusion Into Undergraduate  
Generalist's Courses

A Generalist's Course  
Developed by the Mountain West ATTC



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- The ATTC National Office developed and contributed the Buprenorphine Bibliography.
- The O.A.S.I.S. Clinic developed and granted permission for inclusion of the video, "Put Your Smack Down! A Video about Buprenorphine."



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## Topics included in this Curriculum Infusion Package (CIP)

- Understand the history of opioid treatment in the U.S.
- 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

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## Prevalence of Opioid Use and Abuse in the United States



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## Who Uses Heroin?

### Individuals of all ages use heroin:

- More than 3 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. Nearly 2 percent of US high school seniors used the drug at least once in their lifetime, and nearly half of those injected the drug.

SOURCE: National Survey on Drug Use and Health; Monitoring the Future Survey.

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## 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.

SOURCE: SAMHSA, National Survey on Drug Use and Health, 2002.

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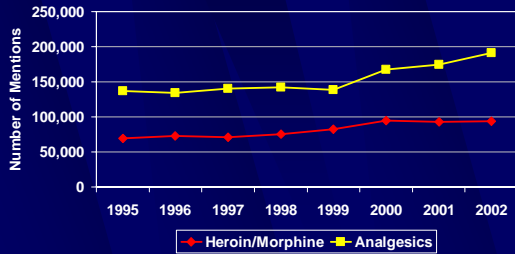
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## Estimated Total Number of *Heroin/Morphine- and Analgesic-Related Hospital Emergency Department Mentions*



SOURCE: SAMHSA, Drug Abuse Warning Network, 2003.

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## Treatment Admissions for Opioid Addiction

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### Where Are Opioid-Addicted Patients Seen?

- Pain clinics
- Doctors' offices
- Psychiatric clinics
- Outpatient treatment centers
- Residential treatment programs
- Methadone clinics
- Health care clinics
- Infectious disease clinics
- Courts
- Etc...

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### Who Enters Treatment for Heroin Abuse?

- 90% of opioid admissions in 2000 were for heroin
- 67% male
- 47% White; 25% Hispanic; 24% African American
- 65% injected; 30% inhaled
- 81% used heroin daily

SOURCE: SAMHSA, Treatment Episode Data Set, 1992-2000.

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### Who Enters Treatment for Heroin Abuse?

- 78% had at least one prior treatment episode; 25% had 5+ prior episodes
- 40% had a treatment plan that included methadone
- 23% reported secondary alcohol use; 22% reported secondary powder cocaine use

SOURCE: SAMHSA, Treatment Episode Data Set, 1992-2000.

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## Who Enters Treatment for *Other Opiate Abuse?*

(Non-prescription use of methadone, codeine, morphine, oxycodone, hydromorphone, opium, etc.)

- 51% male
- 86% White
- 76% administered opiates orally
- 28% used opiates other than heroin after age 30
- 19% had a treatment plan that included methadone
- 44% reported no secondary substance use; 24% reported secondary alcohol use

SOURCE: SAMHSA, Treatment Episode Data Set, 1992-2000.

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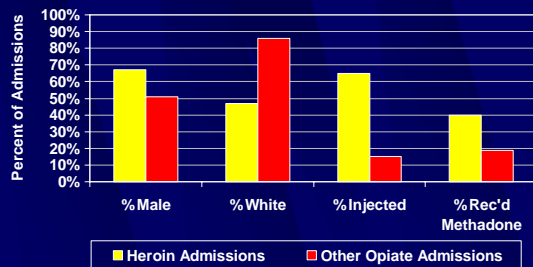
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## Primary Heroin Treatment Admissions vs. Primary Other Opiate Treatment Admissions: A Side-by-Side Comparison



SOURCE: SAMHSA, Treatment Episode Data Set, 1992-2000.

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## Four Reasons for Not Entering Opioid Treatment

- Limited treatment options
  - Methadone or Naltrexone
  - Drug-Free Programming
- Stigma
  - Many users don't want methadone
    - "It's like going from the frying pan into the fire"
    - Fearful of withdrawing from methadone
  - Concerned about being stereotyped
- Settings have been highly structured
- Providers subscribe to abstinence-based model

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## A Need for Alternative Options

- Move outside traditional structure to:
  - Attract more patients into treatment
  - Expand access to treatment
  - Reduce stigma associated with treatment
- Buprenorphine is a potential vehicle to bring about these changes.

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## A Brief History of Opioid Treatment

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## 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.

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## A Brief History of Opioid Treatment, Continued

- 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.

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## Understanding DATA 2000

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## 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

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## Development of Subutex®/Suboxone®

- U.S. FDA approved Subutex® and Suboxone® *sublingual tablets* 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.

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## Buprenorphine Treatment: The Myths and The Facts



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## MYTH #1: Patients are still addicted

**FACT:** Addiction is pathologic use of a substance and *may* or *may not* include physical dependence.

- Physical dependence on a medication for treatment of a medical problem **does not** mean the person is engaging in pathologic use and other behaviors.

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**MYTH #2: Buprenorphine is simply a substitute for heroin or other opioids**

**FACT:** Buprenorphine *is* a replacement medication; it is *not simply* a substitute

- Buprenorphine is a legally prescribed medication, not illegally obtained.
- Buprenorphine is a medication taken sublingually, a very safe route of administration.
- Buprenorphine allows the person to function normally.

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**MYTH #3: Providing medication alone is sufficient treatment for opioid addiction**

**FACT:** Buprenorphine is an important treatment option. However, the *complete* treatment package must include other elements, as well.

- Combining pharmacotherapy with counseling and other ancillary services increases the likelihood of success.

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**MYTH #4: Patients are still getting high**

**FACT:** When taken sublingually, buprenorphine is slower acting, and does not provide the same “rush” as heroin.

- Buprenorphine has a ceiling effect resulting in lowered experience of the euphoria felt at higher doses.

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## Buprenorphine: An Exciting New Option

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### Moving Science-Based Treatments into Clinical Practice

- A challenge in the addiction field is moving science-based treatment methods into clinical settings.
- NIDA and CSAT initiatives are underway to bring research and clinical practice closer.
- Buprenorphine treatment represents an achievement in this effort.

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### Buprenorphine: A Science-Based Treatment

Clinical trials have established the effectiveness of buprenorphine for the treatment of heroin addiction. Effectiveness of buprenorphine has been compared to:

- Placebo (Johnson et al. 1995; Ling et al. 1998; Kakko et al. 2003)
- Methadone (Johnson et al. 1992; Strain et al. 1994a, 1994b; Ling et al. 1996; Schottenfield et al. 1997; Fischer et al. 1999)
- Methadone and LAAM (Johnson et al. 2000)

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## 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

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## 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

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## Clinical Case Studies Involving Buprenorphine

- Buprenorphine is equally effective as moderate (60 mg per day) doses of methadone.
- It is unclear if buprenorphine can be as effective as higher doses of methadone.
- Buprenorphine is as effective as moderate doses of LAAM.

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## Clinical Case Studies Involving Buprenorphine

- Buprenorphine is mildly reinforcing, encouraging good patient compliance.
- After a year of buprenorphine plus counseling, as many as 75 percent have been retained in treatment compared to none in a placebo plus counseling condition.

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Only physicians can prescribe the medication.

However, the entire treatment system should be engaged.



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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

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## 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.



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## 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
3. Minimal subjective effects (e.g., sedation) following a dose
4. Available for use in an office setting
5. Lower level of physical dependence

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## Advantages of Buprenorphine/Naloxone in the Treatment of Opioid Addiction

- Combination tablet is being marketed for U.S. use
6. Discourages IV use
  7. Diminishes diversion
  8. Allows for take-home dosing

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## 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. Not detectable in most urine toxicology screenings

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## Summary

- Use of medications as a component of treatment can be an important in helping the person to achieve their treatment goals.
- DATA 2000 expands the options to include both opioid treatment programs and the general medical system.
- Opioid addiction affects a large number of people, yet many people do not seek treatment or treatment is not available when they do.
- Expanding treatment options can
  - make treatment more attractive to people;
  - expand access; and
  - reduce stigma.

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