

# **BUPRENORPHINE TREATMENT**

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

***A Generalist's course***

***Developed by the Mountain West ATTC***




## Introduction





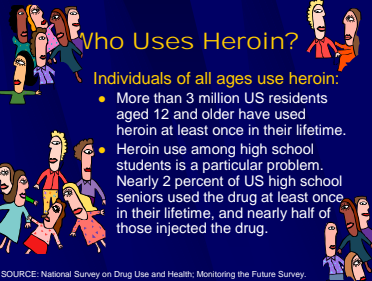
*The main goal of this course is to provide information on buprenorphine in a broad context for students who are in introductory classes. The material contained within this module should help to demystify opioid treatment, provide an overview of the problem of opioid addiction in the United States, and set the stage for understanding the utility of medication treatment in general and buprenorphine treatment specifically.*

*It is important that there is a balanced perspective and NOT to come across with the message that buprenorphine is better than or replaces methadone or other forms of opioid treatment. The message should be that buprenorphine represents an important advance in opioid treatment that provides another option for treatment.*

*This package is designed to be infused into addiction education curricula based on the specifics of the course set by the Addiction Educator(s). Addiction Educators are encouraged to make adaptations to the materials as needed.*

*The notes below contain information that can be presented with each slide. This information is designed as a guidepost and can be adapted to meet the needs of the local training situation. Information can be added or deleted at the discretion of the Addiction Educator(s).*

	<p><b>Slide 1: Title Slide</b></p> <p>It is important to note that this training is introductory and is focused on building awareness and encouraging multidisciplinary addiction professionals to learn more about buprenorphine and its role in opioid treatment. It is NOT designed to provide an expert level of competency in utilizing buprenorphine for the treatment of opioid addiction.</p>
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<p><b>NIDA-SAMHSA Blending Initiative: Blending Team Members</b></p> <ul style="list-style-type: none"> <li>■ Leslie Amass, Ph.D. – Friends Research Institute, Inc.</li> <li>■ Greg Brigham, Ph.D. – CTN Ohio Valley Node</li> <li>■ Glenda Clare, M.A. – Central East ATTC</li> <li>■ Gail Dixon, M.A. – Southern Coast ATTC</li> <li>■ Beth Finnerty, M.P.H. – Pacific Southwest ATTC</li> <li>■ Thomas Freese, Ph.D. – Pacific Southwest ATTC</li> <li>■ Eric Strain, M.D. – Johns Hopkins University</li> </ul> 	<p><b>Slide 2: NIDA-SAMHSA Blending Initiative: Blending Team Members</b></p> <p><i>Note that the membership consisted of three ATTC representatives and three NIDA researchers.</i></p>
<p><b>Additional Contributors</b></p> <ul style="list-style-type: none"> <li>■ Judith Martin, M.D. – 14th Street Clinic, Oakland, CA</li> <li>■ Michael McCann, M.A. – Matrix Institute on Addictions</li> <li>■ Jeanne Obert, MFT, MSM – Matrix Institute on Addictions</li> <li>■ Donald Wesson, M.D. – Independent Consultant</li> </ul> <ul style="list-style-type: none"> <li>■ The ATTC National Office developed and contributed the Buprenorphine Bibliography.</li> <li>■ The O.A.S.I.S. Clinic developed and granted permission for inclusion of the video, "Put Your Smack Down! A Video about Buprenorphine."</li> </ul> 	<p><b>Slide 3: Additional Contributors</b></p> <p><i>Acknowledge additional contributors to the Blending Team product.</i></p>
<p><b>Topics Included in this Curriculum Infusion Package (CIP)</b></p> <ul style="list-style-type: none"> <li>● Understand the history of opioid treatment in the U.S.</li> <li>● Understand changes in the laws regarding treatment of opioid addiction and the implications for the treatment system</li> <li>● Identify groups of people who are using opioids</li> <li>● Understand how buprenorphine will benefit the delivery of opioid treatment</li> </ul>	<p><b>Slide 4: Topics included in this Curriculum Infusion Package (CIP)</b></p>
<p><b>Prevalence of Opioid Use and Abuse in the United States</b></p>  	<p><b>Transition</b></p> <p><b>Slide 5: Prevalence of Opioid Use and Abuse in the United States</b></p> <p>So how significant is the problem of opioid use in the U.S.? Let's look at some of the available statistics.</p>
<p><b>Who Uses Heroin?</b></p> <p>Individuals of all ages use heroin:</p> <ul style="list-style-type: none"> <li>● More than 3 million US residents aged 12 and older have used heroin at least once in their lifetime.</li> <li>● 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.</li> </ul> <p><small>SOURCE: National Survey on Drug Use and Health; Monitoring the Future Survey.</small></p> 	<p><b>Slide 6: Who Uses Heroin?</b></p> <ul style="list-style-type: none"> <li>● More than 3 million people over the age of 12 have used heroin at least one time.</li> <li>● Among high school students: <ul style="list-style-type: none"> <li>● Almost 2% have used heroin at least once.</li> <li>● Almost half of those who had tried it had injected the drug.</li> </ul> </li> </ul>

### 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.

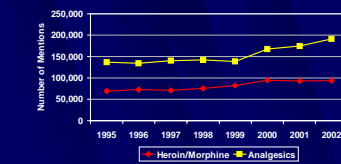
SOURCE: SAMHSA, National Survey on Drug Use and Health, 2002.

### Slide 7: Initiation of Heroin Use

The number of new people initiating heroin use has also increased to a level comparable to that seen 30 years ago.

- In 1974, there were 246,000 new heroin users.
- That number dropped to between 28,000-80,000 between 1988 and 1998.
- Between 1994 and 2001, the number of new heroin initiates was about 100,000 per year.

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



SOURCE: SAMHSA, Drug Abuse Warning Network, 2003.

### Slide 8: Estimated Total Number of Heroin/Morphine and Analgesic-Related Hospital Emergency Department Mentions

The Drug Abuse Warning Network (DAWN) collects data from emergency departments to determine if drugs are mentioned as a factor contributing to the ED visit. Examination of these data provides an indicator of changes in the level of use in the population.

As can be seen from this slide, both heroin and other analgesics have been trending upward since 1995.

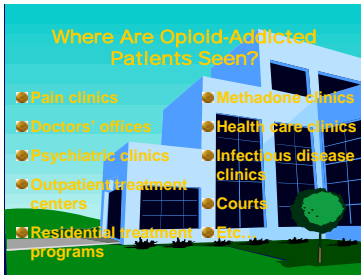
According to the DAWN system, analgesics include: narcotic analgesics/combinations (codeine combinations, methadone, morphine combinations, opium combinations, oxycodone combinations), Cox-2 inhibitors, anti-migraine agents, non-steroidal anti-inflammatory agents, salicylates/combinations, etc.

### Treatment Admissions for Opioid Addiction

### Transition

### Slide 9: Treatment Admissions for Opioid Addiction

Another indicator of a drug problem is to look at the number and demographics of people seeking treatment for particular drugs. These data will provide another way to look at the populations affected by particular drugs.



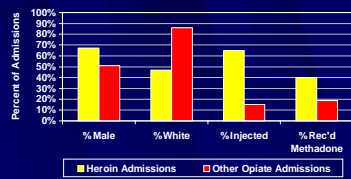
**Slide 10: Where Are Opioid-Addicted Patients Seen?**

*Read the list aloud, or have a trainee(s) volunteer to read the settings aloud. Ask to identify other settings in which opioid users may be encountered.*

Other settings may include: emergency rooms, schools/colleges, church/faith-based organizations, workplace/corporate world (EAP), and insurance companies.

<p><b>Who Enters Treatment for Heroin Abuse?</b></p> <ul style="list-style-type: none"> <li>■ 90% of opioid admissions in 2000 were for heroin</li> <li>■ 67% male</li> <li>■ 47% White; 25% Hispanic; 24% African American</li> <li>■ 65% injected; 30% inhaled</li> <li>■ 81% used heroin daily</li> </ul> <p><small>SOURCE: SAMHSA, Treatment Episode Data Set, 1992-2000.</small></p>	<p><b>Slide 11: Who Enters Treatment for Heroin Abuse?</b></p> <ul style="list-style-type: none"> <li>• In 2000, 90% of all admissions for opioid treatment were for heroin.</li> <li>• People entering treatment were 2/3 male; just under half were White, 1/4 were Hispanic, and 1/4 were African American; 2/3 of the people seeking treatment used by injection; and 4 out of 5 used heroin on a daily basis.</li> </ul>
<p><b>Who Enters Treatment for Heroin Abuse?</b></p> <ul style="list-style-type: none"> <li>■ 78% had at least one prior treatment episode; 25% had 5+ prior episodes</li> <li>■ 40% had a treatment plan that included methadone</li> <li>■ 23% reported secondary alcohol use; 22% reported secondary powder cocaine use</li> </ul> <p><small>SOURCE: SAMHSA, Treatment Episode Data Set, 1992-2000.</small></p>	<p><b>Slide 12: Who Enters Treatment for Heroin Abuse?</b></p> <ul style="list-style-type: none"> <li>• Approximately 3/4 of those entering treatment for heroin in 2000 had at least one prior treatment episode, and 1/4 had 5 or more previous episodes.</li> <li>• 40% were seeking treatment that included methadone.</li> <li>• Secondary drug use among people seeking treatment for heroin addiction included alcohol (23%) and cocaine (22%).</li> </ul>
<p><b>Who Enters Treatment for Other Opiate Abuse?</b></p> <p><small>(Non-prescription use of methadone, codeine, morphine, oxycodone, hydromorphone, opium, etc.)</small></p> <ul style="list-style-type: none"> <li>■ 51% male</li> <li>■ 86% White</li> <li>■ 76% administered opiates orally</li> <li>■ 28% used opiates other than heroin after age 30</li> <li>■ 19% had a treatment plan that included methadone</li> <li>■ 44% reported no secondary substance use; 24% reported secondary alcohol use</li> </ul> <p><small>SOURCE: SAMHSA, Treatment Episode Data Set, 1992-2000.</small></p>	<p><b>Slide 13: Who Enters Treatment for Other Opiate Abuse?</b></p> <ul style="list-style-type: none"> <li>• Among people seeking treatment for abuse of other opiates, 1/2 were male, the great majority (86%) was White; and 3/4 took the drug orally.</li> <li>• One in five had a treatment plan that included methadone.</li> <li>• 44% reported no use of other drugs, and 24% reported alcohol use.</li> </ul>

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



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

**Slide 14: Primary Heroin Treatment Admissions vs. Primary Other Opiate Treatment Admissions: A Side-by-Side Comparison**

A side-by-side graphic comparison helps to illustrate the differences in the demographics of heroin users and other opiate users.

Injection continues to be the predominant method of heroin use among addicted users seeking treatment; however, researchers have observed a shift in heroin use patterns. As the purity of heroin has increased, users have begun to use alternative methods of administration, such as smoking and snorting/inhaling.

### Four Reasons For Not Entering Opioid Treatment

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

### Slide 15: Four Reasons for Not Entering Opioid Treatment

The above information clearly indicates that opioid use has been increasing, and that a large number of people are seeking treatment for opioids. Data have also been collected that indicate that there are many more users of heroin than people seeking and/or receiving treatment.

This raises the question: why are some people not entering treatment?

#1: The current treatment system involves either a medicalized model (e.g., the opioid treatment programs) or psychosocial programming. Many OTPs do not have large behavioral treatment components and many psychosocial programs do not provide adequate medical intervention to help the person through the withdrawal process.

#2: Anecdotal evidence exists to suggest that people may feel that getting off methadone is much harder than getting off heroin. Lack of understanding about how methadone should be used, as well as the possibility for illicit use of methadone, contributes to this feeling.

Additionally, people are afraid of being labeled and stereotyped due to their opioid addiction (e.g., "junkies").

#3. Opioid treatment programs have very structured rules requiring regular attendance. Programs often open early in the morning and close by mid-afternoon. Clients who are not able to follow the rules or attend the program during operating hours may not be able to receive the treatment.

#4: Many providers believe that treatment requires abstinence from all drugs. However, many opioid users are not able to stop using opioids. They often cannot tolerate the withdrawal experience, and even if they can, may be drawn back to using. Using a medication such as methadone or buprenorphine to assist with the withdrawal process or to prevent people from going through withdrawal will help them to participate in treatment and function more normally in their daily lives.

<p><b>A Need for Alternative Options</b></p> <ul style="list-style-type: none"> <li>● Move outside traditional structure to: <ul style="list-style-type: none"> <li>● Attract more patients into treatment</li> <li>● Expand access to treatment</li> <li>● Reduce stigma associated with treatment</li> </ul> </li> <li>● Buprenorphine is a potential vehicle to bring about these changes.</li> </ul>	<p><b>Slide 16: A Need for Alternative Options</b>  DATA 2000 allows for a new treatment options. Opioid treatment will continue to be offered through OTPs as it has been in the past. DATA 2000 allows for expansion beyond the structure in place for methadone to allow for treatment in physician offices. By doing so:</p> <ul style="list-style-type: none"> <li>● More patients may be willing to seek treatment;</li> <li>● More patients will have access to treatment; and</li> <li>● Stigma may be reduced by broadening the definition and locations of available treatment options.</li> </ul>
<p><b>A Brief History of Opioid Treatment</b></p>	<p style="text-align: center;"><b>Transition</b></p> <p><b>Slide 17: A Brief History of Opioid Treatment</b>  Before we can understand the role that buprenorphine can play in the treatment system, we need to do a quick review of how the treatment of opioid addiction has developed.</p>

### 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.

### Slide 18: A Brief History of Opioid Treatment

1964: Methadone was the first medical intervention approved for the treatment of drug addiction.

Until recently, the Controlled Substances Act the use of narcotics for addiction treatment to only those opioid drugs approved by the food and drug administration for the detoxification or maintenance treatment of addiction. These drugs could only be dispensed by physicians in programs regulated by SAMHSA and the DEA. These programs are usually called “methadone maintenance” or “opioid treatment programs.”

Additional medications have been shown to be effective in the treatment of opioid addiction. However, use of these medications was not widespread, due, in part, to the failure to adequately transfer the technology to the field.

For example, LAAM had trouble making it into the opioid treatment system – people were already using methadone and the way that LAAM was introduced to them was ineffective. The goal in developing new medications is not to replace the old ones, but to increase the available treatment options.

*\*\*Some states do not have methadone maintenance available to its opioid addicted individuals. Be sure to find out the local methadone-related policies that exist in your State.\*\**

**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.

**Slide 19: A Brief History of Opioid Treatment, Continued**

*Define DATA 2000 and note that we will talk more about that in just a minute.*

*Note the approval of buprenorphine and buprenorphine/ naloxone in 2002, which set the stage for the implementation of DATA 2000.*

**Notes about LAAM:**

ORLAAM® was withdrawn from the European market in March 2001.

Extensive changes (including additional warnings and contraindications) were made to U.S. package insert in April 2001.

Roxane announced the discontinuation of LAAM on August 23, 2003 (due, in part, to reports of severe cardiac-related adverse events, including slowing of cardiac conduction [QT interval prolongation] and cardiac arrest). The risks of continued distribution and use in the face of less toxic treatment alternatives outweighed the overall benefits.

**Understanding DATA 2000**

**Transition**

**Slide 20: Understanding DATA 2000**

DATA 2000 changed the available options for providing treatment for opioid addiction and is critical in the discussion of buprenorphine and how it can be used.

**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

**Slide 21: Drug Addiction Treatment Act of 2000 (DATA 2000)**

The Drug Addiction Treatment Act of 2000 amended the Controlled Substances Act, allowing qualified physicians to prescribe approved narcotic medications (in Schedules III, IV, V, or combinations of such drugs approved by the FDA for the treatment of opioid addiction) from their office settings.


The U.S. Drug Enforcement Administration places all drugs and medication on a schedule. Placement is based upon the substance's medicinal value, harmfulness, and potential for abuse or addiction. Schedule I is reserved for the most dangerous drugs that have no recognized medical use, while Schedule V is the classification used for the least dangerous drugs. Methadone is Schedule II and Buprenorphine is Schedule III.

This means that Buprenorphine is considered a safer drug with lower potential for abuse than methadone. Therefore, buprenorphine is subject to fewer prescribing restrictions than methadone.

As a result, opioid-addicted patients may receive treatment in a qualified physician's office instead of an opioid treatment program, making treatment available to persons who might otherwise not have received it.

SAMHSA began a three-year evaluation of DATA 2000 started on the date of FDA approval (10/8/02). In addition, the buprenorphine manufacturer is conducting a post-marketing risk management program.

DATA 2000 preempts individual state laws unless a state passes a new law before 10/8/05.

<p style="text-align: center;"><b>Development of Subutex®/Suboxone®</b></p> <ul style="list-style-type: none"> <li>■ U.S. FDA approved Subutex® and Suboxone® <i>sublingual tablets</i> for opioid addiction treatment on October 8, 2002.</li> <li>■ Product launched in U.S. in March 2003</li> <li>■ Interim rule changes to federal regulation (42 CFR Part 8) on May 22, 2003 enabled Opioid Treatment Programs (specialist clinics) to offer buprenorphine.</li> </ul>	<p><b>Slide 22: Development of Subutex®/Suboxone®</b></p> <p>Prior to 2002, buprenorphine was only available in the US in an injectable form and was only approved for the treatment of pain.</p> <p>Sublingual formulations of buprenorphine were approved by the FDA in late 2002 for the treatment of opioid addiction and the medication was made available by the pharmaceutical company in March 2003.</p> <p>When the regulations went into effect in 2002, the medication was only approved for prescription in physicians' offices. In May of 2003, the regulations were modified so that OTPs could use buprenorphine as well, but they have to do so under the same regulations as methadone, thereby creating two distinct implementation schemes for buprenorphine treatment, i.e., office-based vs. opioid treatment programs.</p>
<p style="text-align: center;"><b>Buprenorphine Treatment: The Myths and The Facts</b></p> 	<p style="text-align: center;"><b>Transition</b></p> <p><b>Slide 23: Buprenorphine Treatment: The Myths and the Facts</b></p> <p>When considering becoming part of a network of care that involves buprenorphine treatment, counselors may have to examine their own thinking about opioid addiction, in general, and about pharmacotherapy in particular. The following myths and facts can help to correct some of the common misconceptions regarding this type of treatment.</p>
<p><b>MYTH #1: Patients are still addicted</b></p> <p><b>FACT:</b> Addiction is pathologic use of a substance and <i>may</i> or <i>may not</i> include physical dependence.</p> <ul style="list-style-type: none"> <li>■ Physical dependence on a medication for treatment of a medical problem <i>does not</i> mean the person is engaging in pathologic use and other behaviors.</li> </ul>	<p><b>Slide 24: Myth #1: Patients are still addicted</b></p> <p>Addiction is defined by the pathological behaviors and compulsivity of use, not by the body's adaptation to a medication. Using medications as a component of opioid treatment can help a person to function normally.</p> <p>Physical dependence <b>IS NOT</b> the same thing as addiction. This is a really important concept that we will spend more time on later in the training.</p>

**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.

**Slide 25: Myth #2: Buprenorphine is simply a substitute for heroin or other opioids**

Fact: Buprenorphine is a replacement medication in that it prevents the occurrence of withdrawal. However, it is not simply a substitute.

Buprenorphine is a legally prescribed medication. When taken sublingually, under medical supervision, it is very safe and allows the person to function normally.

Buprenorphine is a controlled substance, produced and distributed under close supervision and quality controls.

Helping the person to stop the negative and compulsive behaviors associated with drug use and helping them to lead a functional normal life is the goal of any treatment. Using a medication such as buprenorphine can be an important method for helping people to achieve this goal.

**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.

**Slide 26: Myth #3: Providing medication alone is sufficient treatment for opioid addiction**

The combination of pharmacotherapy with counseling provides critical clinical advantages, such as improvements to patients' psychosocial functioning, employment stability, and general lifestyle issues.

This is an extremely important point for this particular audience. Law or regulation does not *require* the behavioral treatment (counseling) component of buprenorphine treatment. The successful dissemination of this treatment may very well hinge on the development of collaboration between physicians and multidisciplinary addiction professionals.

**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.

**Slide 27: Myth #4: Patients are still getting high**

There is a ceiling effect in terms of the rushing euphoria.

When taken sublingually as prescribed, patients feel more stable than when they take heroin or other full agonists.

Buprenorphine occupies the same receptors as full agonists, but it occupies them for a much longer period of time. It also has a ceiling effect for the "rush" experience so that even at higher doses, there is less experience of this euphoric effect.

When the dose is adjusted adequately, patients prescribed buprenorphine should function without sedation or intoxication.

**Buprenorphine: An Exciting New Option**

**Slide 28: Buprenorphine: An Exciting New Option**

Buprenorphine represents an exciting addition to the available opioid treatment options.

<p><b>Moving Science-Based Treatments into Clinical Practice</b></p> <ul style="list-style-type: none"> <li>● A challenge in the addiction field is moving science-based treatment methods into clinical settings.</li> <li>● NIDA and CSAT initiatives are underway to bring research and clinical practice closer.</li> <li>● Buprenorphine treatment represents an achievement in this effort.</li> </ul>	<p><b>Slide 29: Moving Science-Based Treatments into Clinical Practice</b></p> <p>Many treatments that are developed never make it into real-world practice.</p> <p>This has been a problem for quite some time and both the National Institute on Drug Abuse (NIDA) and the Substance Abuse Mental Health Services Administration (SAMHSA) have recognized this. The Blending Team that developed these materials resulted from one initiative designed to help move scientific findings into practical application: The NIDA-SAMHSA Blending Initiative.</p> <p>Buprenorphine is an important treatment advancement and represents an exciting opportunity for individuals to develop strategies to work with both providers and researchers to find ways to make this treatment a readily-available option.</p>
<p><b>Buprenorphine: A Science-Based Treatment</b></p> <p>Clinical trials have established the effectiveness of buprenorphine for the treatment of heroin addiction. Effectiveness of buprenorphine has been compared to:</p> <ul style="list-style-type: none"> <li>● Placebo (Johnson et al. 1995; Ling et al. 1998; Kakko et al. 2003)</li> <li>● Methadone (Johnson et al. 1992; Strain et al. 1994a, 1994b; Ling et al. 1996; Schottenfield et al. 1997; Fischer et al. 1999)</li> <li>● Methadone and LAAM (Johnson et al. 2000)</li> </ul>	<p><b>Slide 30: Buprenorphine: A Science-Based Treatment</b></p> <p>In the development of the medication, the effectiveness of buprenorphine has been compared to that of other medications that are currently available. These studies have shown that buprenorphine treatment:</p> <ul style="list-style-type: none"> <li>• Is more effective than placebo; and</li> <li>• Has similar effectiveness to moderate doses of methadone and LAAM.</li> </ul>
<p><b>Buprenorphine as a Treatment for Opioid Addiction</b></p> <ul style="list-style-type: none"> <li>● A synthetic opioid</li> <li>● Described as a mixed opioid agonist-antagonist (or partial agonist)</li> <li>● Available for use by certified physicians outside traditionally licensed opioid treatment programs</li> </ul>	<p><b>Slide 31: Buprenorphine as a Treatment for Opioid Addiction</b></p> <p>Several factors make buprenorphine a good option for some people.</p> <p>Buprenorphine is a partial agonist, resulting in a good safety profile for the medication.</p> <p>With the changes in the treatment legislation, this medication becomes the first available outside of the OTP system. This expands both the availability of and access to treatment.</p>

### 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

### Slide 32: The Role of Buprenorphine in Opioid Treatment

The partial agonist properties of the medication are important to understand.

The effects of the medication at lower doses are virtually the same as that of full agonists. However, as the dose is increased, the effects level out for buprenorphine (especially respiratory suppression), where they continue to increase with full agonist medications. This is called a “ceiling effect.” This ceiling effect greatly decreases the risk of overdose when compared to full agonists.

Buprenorphine has a very HIGH affinity for opioid receptors. It displaces morphine, methadone, and other full agonist opioids from the receptor. Additionally, buprenorphine dissociates slowly from the receptor.

This high affinity for and slow dissociation from the receptor result in buprenorphine blocking the effects of other opioids, such as heroin. Additionally, the high affinity and slow dissociation give rise to buprenorphine’s prolonged therapeutic effects.

Clinical trials have demonstrated that buprenorphine is a safe and effective medication for both opioid maintenance and medically assisted withdrawal (detoxification). Additionally, because buprenorphine is very long-acting, dosing can occur on a less-than-daily basis, as infrequently as three times per week.

### 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.

### Slide 33: Clinical Case Studies Involving Buprenorphine

Buprenorphine is equally effective as moderate doses of methadone (such as 60 mg per day) on primary outcome measures.

It is unclear if buprenorphine can be as effective as higher doses of methadone (such as 80 mg per day to more than 100 mg per day).

Buprenorphine appears to be equally effective as moderate doses of LAAM (such as 70 mg/70 mg/85 mg on a Monday/ Wednesday/Friday schedule).

### 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.

### Slide 34: Clinical Case Studies Involving Buprenorphine

Buprenorphine has a ceiling effect for the intense rush experienced with full agonists. \* However, patients do experience it as mildly reinforcing, thereby encouraging them to adhere to their dosing regimen.

Studies have shown that buprenorphine holds people in treatment much more effectively than counseling alone.

*\*Note: Increasing the dose of a full agonist produces increasing effects until the receptor is fully activated and a maximum effect is reached.*

*Partial Agonists share some characteristics of full agonists. At low doses, full and partial agonists produce effects that are essentially indistinguishable. However, increasing the dose of a partial agonist DOES NOT produce as great an effect as occurs with a full agonist. There is a CEILING to the agonist (intoxicating/euphoric) effects.*

Only physicians can prescribe the medication.

However, the entire treatment system should be engaged.

**Slide 35: Only physicians can prescribe the medication. However, the entire treatment system should be engaged.**

*Read slide aloud.*

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

**Slide 36: Effective treatment generally requires many facets. Treatment providers are important in helping the patients to:**

*Summarize bullet points.*

*Here are a few other points worth mentioning:*

- Encourage patients to abstain from further use of their drug(s) of abuse.
- Provide psychosocial and counseling services along with pharmaceutical treatment to increase the likelihood of achieving long-term, comprehensive lifestyle changes and prevent relapse.

*It is important to stress the importance of flexible partnerships.*

The multidisciplinary professional/physician relationship may take many forms, ranging from members of a common treatment team within the same facility (co-located) to geographically separated independent practitioners. The multidisciplinary professional and physician should have common treatment philosophies and goals, and have rapid access to each other.

### 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.*



### Slide 37: Effective Coordination of Care

*Read quote aloud.*

While previous opioid treatment occurred only in the context of federally regulated programs, buprenorphine treatment extends the treatment arena to the physician's office. Developing a coordinated system of care is the only means that the physician has of ensuring that his/her patient is benefiting from the drug he/she has prescribed.

Treatment is most successful when there are comprehensive and continuing services. This collaborative approach can best be achieved through care coordination.

*Important points to mention:*

- Obtaining a signed release of information is highly recommended, to prevent any delays in communication between multidisciplinary addiction professionals and treating physician.
- If you are seeing physical symptoms, you should bring a physician into the loop immediately (again, do not go beyond the scope of your practice/experience).

*Discuss what to do if a patient starts asking the professional about the side effects of buprenorphine – encourage them to discuss any medical matters with their physician.*

**When in doubt, refer the patient back to his/her treating physician.**

**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

**Slide 38: Advantages of Buprenorphine in the Treatment of Opioid Addiction**

When transitioned onto buprenorphine, patients can participate fully in treatment activities rather than being sick from withdrawal for several days. This means that treatment can begin as soon as they seek it (while motivation is high).

There are no known cases of overdose directly related to buprenorphine. To date, cases in which overdose has occurred involved use of alcohol or other respiratory depressants (e.g., benzodiazepines). *See Johnson, et al. 2003, for a more detailed discussion.*

Patients report minimal sedation following a dose.

The treatment setting can be determined to fit the needs of the patient (OPT or office-based).

**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

**Slide 39: Advantages of Buprenorphine/Naloxone in the Treatment of Opioid Addiction**

The marketing effort in the U.S. is focused on the combination formulation. This formulation has several advantages, including the following:

- It discourages injection use because, when injected, the naloxone in the product will lead to withdrawal, whereas when taken sublingually as prescribed, it will not have that effect.

Because of the above point, the combination tablet lowers the likelihood that the medication will be diverted.

**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

**Slide 40: Disadvantages of Buprenorphine in the Treatment of Opioid Addiction**

There are definitely disadvantages to the medication, as well.

Buprenorphine is more costly than methadone: According to the manufacturer, Suboxone® (16 mg/day) costs \$287.50 for a month's supply, compared to less than \$30 for a month's supply of methadone at usual doses.

Overall, the medication causes a lower level of physical dependence. While this is generally seen as an advantage of the medication, it does make it easier for patients to discontinue treatment and return to use.

Buprenorphine is not detectable in most urine tests, making monitoring for compliance difficult. However, this could also be an advantage of buprenorphine (for people who are randomly drug tested in the workplace).

**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.

**Slide 41: Summary**

*Review each bullet.*