

# **Module I**

## **Introduction**



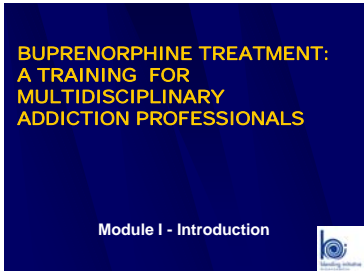
## Module I: Introduction




*The main goal of Module I is to provide the context for the rest of the training. 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 the trainer keeps a balanced perspective and does NOT 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.*

*Module I can also be presented as a stand-alone presentation (e.g., a one-hour workshop) by including slides 38-50. If the entire training package is being delivered, these slides should be omitted and the trainer(s) should end Module I after slide 36 and precede with Module II.*

*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 trainer(s).*

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|  | <p><b>Slide 1: Title Slide</b></p> <p><i>Briefly describe the development of the Blending Team product, as well as the purpose of the training as described above in the introduction to this manual.</i></p> <p><i>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.</i></p> <p><i>Reiterate that throughout the training, the term “patient” has been used to refer to the individual seeking treatment. This terminology reflects the medicalized nature of buprenorphine treatment and underscores the fact that the treatment is largely physician-driven. The use of this term may be inconsistent with the vocabulary in common usage in the addiction treatment setting.</i></p> |
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| <p><b>NIDA-SAMHSA Blending Initiative:<br/>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><br/> <i>Acknowledge the members of the Blending Team who created these materials.</i></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> <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><br/> <i>Acknowledge additional contributors to the Blending Team product.</i></p>   |
| <p><b>Introductions</b></p> <ul style="list-style-type: none"> <li>■ Introduce yourself by briefly providing the following information: <ul style="list-style-type: none"> <li>● Your name and the agency in which you work</li> <li>● Experience with opioid treatment</li> <li>● What you expect from the training</li> </ul> </li> </ul>    | <p><b>Slide 4: Introductions</b><br/> <i>Begin the training by asking participants to briefly introduce themselves by providing their name and the agency for which they work, their experience with opioid treatment, and what they expect to gain from the training.</i></p> <p>Example Ice Breaker – Raise your hand if you:</p> <ul style="list-style-type: none"> <li>• Work primarily or exclusively with opioid addicted individuals</li> <li>• Work as a substance abuse counselor</li> <li>• Work as medical personnel</li> </ul> |
| <p><b>What do we know?</b></p> <ul style="list-style-type: none"> <li>■ What are your thoughts about buprenorphine?</li> <li>■ What hopes/concerns do you have about buprenorphine coming to your community?</li> </ul>   | <p><b>Slide 5: What Do We Know?</b><br/> <i>Next, ask the group to share their thoughts about buprenorphine and any hopes/concerns they may have about buprenorphine being introduced in their local community. This will provide the trainer(s) with a sense of the audience's background and experience with opioid treatment in general, and with buprenorphine in particular.</i></p> <p><i>This exercise also allows the trainer(s) to become familiar with the expectations of the group.</i></p>                                    |

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| <p><b>Module I – Goals for the Module</b></p> <p>This module will help participants to:</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 6: Goals for the Module</b><br/> <i>State the goals for the module:</i></p> <ul style="list-style-type: none"> <li>• Understand the history of opioid treatment in the United States.</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>Buprenorphine Treatment: The Myths and The Facts</b></p>   | <p style="text-align: center;"><b>Transition</b></p> <p><b>Slide 7: 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 or 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 <b>does not</b> mean the person is engaging in pathologic use and other behaviors.</li> </ul>  | <p><b>Slide 8: 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>  |

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| <p><b>MYTH #2: Buprenorphine is simply a substitute for heroin or other opioids</b></p> <p><b>FACT:</b> Buprenorphine <i>is</i> a replacement medication; it is <i>not simply</i> a substitute</p> <ul style="list-style-type: none"> <li>■ Buprenorphine is a legally prescribed medication, not illegally obtained.</li> <li>■ Buprenorphine is a medication taken sublingually, a very safe route of administration.</li> <li>■ Buprenorphine allows the person to function normally.</li> </ul> | <p><b>Slide 9: Myth #2: Buprenorphine is simply a substitute for heroin or other opioids</b></p> <p>Fact: Buprenorphine is a replacement medication in that it prevents the occurrence of withdrawal. However, it is not simply a substitute.</p> <p>Buprenorphine is a legally prescribed medication. When taken sublingually, under medical supervision, it is very safe and allows the person to function normally.</p> <p>Buprenorphine is a controlled substance, produced and distributed under close supervision and quality controls.</p> <p>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.</p> |
| <p><b>MYTH #3: Providing medication alone is sufficient treatment for opioid addiction</b></p> <p><b>FACT:</b> Buprenorphine is an important treatment option. However, the <i>complete</i> treatment package must include other elements, as well.</p> <ul style="list-style-type: none"> <li>■ Combining pharmacotherapy with counseling and other ancillary services increases the likelihood of success.</li> </ul>   | <p><b>Slide 10: Myth #3: Providing medication alone is sufficient treatment for opioid addiction</b></p> <p>The combination of pharmacotherapy with counseling provides critical clinical advantages, such as improvements to patients' psychosocial functioning, employment stability, and general lifestyle issues.</p> <p>This is an extremely important point for this particular audience. Law or regulation does not <i>require</i> 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.</p>  |
| <p><b>MYTH #4: Patients are still getting high</b></p> <p><b>FACT:</b> When taken sublingually, buprenorphine is slower acting, and does not provide the same "rush" as heroin.</p> <ul style="list-style-type: none"> <li>■ Buprenorphine has a ceiling effect resulting in lowered experience of the euphoria felt at higher doses.</li> </ul>  | <p><b>Slide 11: Myth #4: Patients are still getting high</b></p> <p>There is a ceiling effect in terms of the rushing euphoria.</p> <p>When taken sublingually as prescribed, patients feel more stable than when they take heroin or other full agonists.</p> <p>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.</p> <p>When the dose is adjusted adequately, patients prescribed buprenorphine should function without sedation or intoxication.</p>  |

## Transition

### A Brief History of Opioid Treatment

#### Slide 12: A Brief History of Opioid Treatment

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.

### 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 13: 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 14: 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 15: 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 16: 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.

**DATA 2000:  
Physician Qualifications**

Physicians must:

- Be licensed to practice by his/her state
- Have the capacity to refer patients for psychosocial treatment
- Limit their practice to 30 patients receiving buprenorphine at any given time
- Be qualified to provide buprenorphine and receive a license waiver

**Slide 17: DATA 2000: Physician Qualifications**

**\*\*Nurse practitioners and physician assistants MAY NOT prescribe buprenorphine under the terms of DATA 2000.\*\***

Bullet #2: Psychosocial treatment may include counseling and ancillary services (medical care, employment and education, etc.).

There is no mandate for people who are prescribed buprenorphine to receive psychosocial counseling. The fact that physicians have the capacity to refer patients for psychosocial treatment does not mean they will actually make the referrals or that patients will follow through. It is critical that multidisciplinary addiction professionals be proactive in developing linkages with physicians in their local areas.

Bullet #3: The type of practice does not matter (the cap of 30 applies to an individual or group practice).

The 30-patient limit does not apply to opioid treatment programs that prescribe buprenorphine. However, OTPs must follow the same regulations as those set up for the provision of methadone.

*This is a good place to briefly discuss the waiver process all physicians must go through before they are able to prescribe buprenorphine.*

A physician must (1) meet the training requirements or be otherwise “qualified”; and (2) complete a waiver notification form and submit it to SAMHSA/CSAT. CSAT then reviews and evaluates the form. If approved, a special, unique license number is issued and added to the physician’s existing DEA license number.

**DATA 2000:  
Physician Qualifications**

A physician must meet one or more of the following qualifications:

- Board certified in Addiction Psychiatry
- Certified in Addiction Medicine by ASAM or AOA
- Served as Investigator in buprenorphine clinical trials
- Completed 8 hours of training by ASAM, AAAP, AMA, AOA, APA (or other organizations that may be designated by Health and Human Services)
- Training or experience as determined by state medical licensing board
- Other criteria established through regulation by Health and Human Services

**Slide 18: DATA 2000: Physician Qualifications**

*Summarize each bullet point.*

**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.

**Slide 19: Development of Subutex®/Suboxone®**

Prior to 2002, buprenorphine was only available in the US in an injectable form and was only approved for the treatment of pain.

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.

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.



Only physicians can prescribe the medication.

However, the entire treatment system should be engaged.



**Slide 20: 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 21: 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.



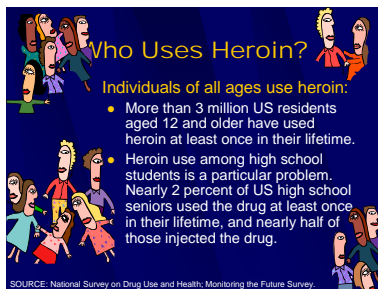
### Prevalence of Opioid Use and Abuse in the United States



## Transition

**Slide 22: Prevalence of Opioid Use and Abuse in the United States**

So how significant is the problem of opioid use in the U.S.? Let's look at some of the available statistics.



### 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.

**Slide 23: Who Uses Heroin?**

- More than 3 million people over the age of 12 have used heroin at least one time.
- Among high school students:
  - Almost 2% have used heroin at least once.
  - Almost half of those who had tried it had injected the drug.

### Heroin Use in a Household Survey Population

- Since the mid-1990s, the prevalence of lifetime heroin use increased for both adolescents and young adults.
- From 1995 to 2002, the rate among adolescents aged 12 to 17 increased from 0.1 percent to 0.4 percent.
- Among young adults aged 18 to 25, the rate rose from 0.8 percent to 1.6 percent.

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

### Slide 24: Heroin Use in a Household Survey Population

- Since the mid-1990s, heroin use has been increasing among young people.
- From 1995-2002:
  - Among 12-17 year olds, the rate increased from 1 in 1,000 to 4 in 1,000.
  - Among 18-25 year olds, the rate increased from 8 in 1,000 to 16 in 1,000.

### 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 25: 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.

### Other Opioid Use in a Household Survey Population

According to the 2002 National Survey on Drug Use and Health:

- An estimated 6.2 million persons (2.6% of the U.S. population aged 12 or older) were currently using certain prescription drugs nonmedically.
- An estimated 4.4 million were current users of pain relievers.
- Approximately 1.9 million persons had used OxyContin nonmedically at least once in their lifetime.
- Pain reliever incidence increased from 1990 (628,000 initiates) to 2000, when there were 2.7 million new users.

SOURCE: SAMHSA, 2002.

### Slide 26: Other Opioid Use in a Household Survey Population

Heroin is only one of the types of opioids for which people seek substance abuse treatment. Prescription opioids are also prone to abuse.

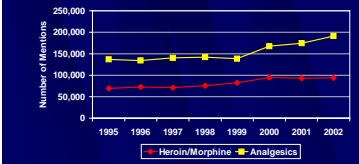
The National Household Survey on Drug Abuse provides information on the prevalence of substance use in the United States and associated problems resulting from use. The survey is conducted on a nationwide sample and collects information on the demographics, patterns of use, treatment, perception of risk, criminal behavior, and mental health issues.

In 2002, the survey estimated that 2.6% of the U.S. population was currently using certain prescription drugs nonmedically (this category includes prescription pain relievers, tranquilizers, stimulants, or sedatives).

Approximately 1.8% of Americans (4.4 million people) were currently using pain relievers nonmedically, and approximately 2 million people had used OxyContin for nonmedical purposes at least once in their lives.

Pain reliever use increased nearly fourfold in the decade between 1990 and 2000.

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



SOURCE: SAMHSA, Drug Abuse Warning Network, 2003.

**Slide 27: 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.

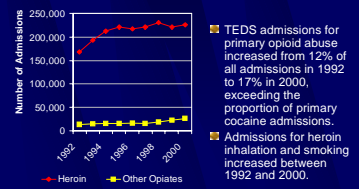
**Treatment Admissions for Opioid Addiction**

**Transition**

**Slide 28: 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.

**Heroin & Other Opioid Treatment Admissions**



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

**Slide 29: Heroin and Other Opioid Treatment Admissions**

- Information from SAMHSA's Treatment Episode Data set showed that admissions for primary opioid abuse increased from 12% to 17% between 1992 and 2000.
- Admissions for other opioids were fairly stable between 1992 and 1997, but began increasing in 1998.

**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.

**Slide 30: Who Enters Treatment for Heroin Abuse?**

- In 2000, 90% of all admissions for opioid treatment were for heroin.
- 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.

### 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.

### Slide 31: Who Enters Treatment for Heroin Abuse?

- 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.
- 40% were seeking treatment that included methadone.
- Secondary drug use among people seeking treatment for heroin addiction included alcohol (23%) and cocaine (22%).

### Who Enters Treatment for Other Opiate Abuse?

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

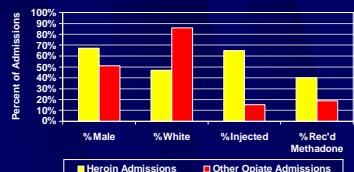
- 51% male
- 86% White
- 76% administered opiates orally
- 28% used opiates other than heroin after age 30
- 19% had a treatment plan that included methadone
- 44% reported no secondary substance use; 24% reported secondary alcohol use

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

### Slide 32: Who Enters Treatment for Other Opiate Abuse?

- 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.
- One in five had a treatment plan that included methadone.
- 44% reported no use of other drugs, and 24% reported alcohol use.

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



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

### Slide 33: 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 34: 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.

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|  <p><b>N.I.M.B.Y. Syndrome</b><br/>Methadone clinics are great, but<br/><b>Not In My Back Yard</b></p> <ul style="list-style-type: none"> <li>■ New opioid treatment programs are difficult to open.</li> <li>■ Zoning regulations and community reaction often create delays or prevent programs from opening.</li> </ul>  | <p><b>Slide 35: N.I.M.B.Y. Syndrome</b><br/>Another factor that limits the availability to treatment is the “NIMBY” syndrome. This stands for “Not In My Back Yard.” Even people who recognize the importance of providing opioid treatment may not want a new program opening up in their neighborhood. This makes opening new programs very difficult.</p>   |
| <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 36: A Need for Alternative Options</b><br/>DATA 2000 allows for a new treatment option. 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>Introduction Summary</b></p> <ul style="list-style-type: none"> <li>■ Use of medications as a component of treatment can be an important in helping the person to achieve their treatment goals.</li> <li>■ DATA 2000 expands the options to include both opioid treatment programs and the general medical system.</li> <li>■ Opioid addiction affects a large number of people, yet many people do not seek treatment or treatment is not available when they do.</li> <li>■ Expanding treatment options can <ul style="list-style-type: none"> <li>● make treatment more attractive to people;</li> <li>● expand access; and</li> <li>● reduce stigma.</li> </ul> </li> </ul> | <p><b>Slide 37: Introduction Summary</b></p> <p><i>Review each bullet.</i></p>   |
|   | <p><b>Slide 38: Transition</b></p> <p><i>NOTE TO TRAINER(s):<br/>This slide is purposefully blank. If you are conducting the full training, end here and skip to Module II. If you are doing Module I as a stand-alone training, please continue to the next slide.</i></p>  |
| <p><b>Review of Opioid Pharmacology, Buprenorphine Treatment, and the Role of the Multidisciplinary Treatment Team</b></p>   | <p><b>Slide 39: Review of Opioid Pharmacology, Buprenorphine Treatment, and the Role of the Multidisciplinary Treatment Team</b><br/>So let’s review some specific information about opioids and the role of buprenorphine in the treatment system. Then we will discuss the critical role of the multidisciplinary team in providing this treatment.</p>  |

### 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.

### Slide 40: Opioid Addiction and the Brain

First, here are a few basic facts about opioids and how they affect the brain.

- Opioids bind to receptors in the brain that are specifically designed for them.
- Once opioids bind to these receptors, they cause an intense euphoric rush, which is experienced as extremely pleasurable.
- With repeated administration of the drug, the body begins to adapt, and tolerance develops. This means that it requires more of the drug to get the same affect and withdrawal occurs if the amount of use is decreased or stopped.

*NOTE TO TRAINER(s): It is important to emphasize that the presence of tolerance or withdrawal is not enough to say that someone is addicted to the drug. Addiction requires continued use in spite of negative consequences resulting from use. Physical dependence may or may not be present.*

### Buprenorphine: An Exciting New Option

### Slide 41: Buprenorphine: An Exciting New Option

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

### 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 42: 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 43: 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.*

### Patient Selection

- Counselors can screen and recommend patients for referral to qualified physicians.
- Physicians will consider the following questions:
  - Is the patient currently opioid addicted?
  - Is buprenorphine the best medication?
  - Is the office the best setting for treating the patient?

### Slide 44: Patient Selection

The patient's appropriateness for treatment may change during the course of treatment.

Potential patients or other treatment providers may ask the counselor about appropriateness for treatment.

The physician will do the final screening prior to prescribing the medication. He/she will look at current opioid use, appropriateness for buprenorphine versus other medications, and the most appropriate setting for the treatment to occur (office-based vs. OTP).

Useful and informed communication with the physician is enhanced by a complete knowledge of the entire treatment process.

### Factors for Addiction Professionals to Consider

1. Is the patient addicted to opioids?
2. Is the patient interested in office-based buprenorphine treatment?
3. Is the patient aware of other treatment options?
4. Does the patient understand the risks and benefits of this treatment approach?
5. Is the patient expected to be reasonably compliant?

### Slide 45: Factors for Addiction Professionals to Consider

Not all patients who are opioid addicted are good candidates for buprenorphine treatment. The addiction professional should understand that the physician will consider several questions in making the decision about whether or not to prescribe buprenorphine.

#1: Patients with a history of good response to buprenorphine who have had their medication discontinued (such as due to incarceration) and are now at high risk for relapse (because they were recently released from prison) may be good candidates, even if they are not currently addicted to opioids.

#2: Even if the patient is a suitable candidate for buprenorphine treatment, he/she may not be best treated in an office setting. Stability and structure of the patient's living situation will help the treatment team to determine the most appropriate setting.

#3: Patients should be made aware of all of the options available to them and be assisted in making a decision regarding their treatment. Their willingness to participate is critical to compliance with any treatment regimen.

#4: Has the patient had the opportunity to ask the physician about any medical concerns associated with the treatment? Have cost issues been explained and compared with other treatment options?

#5: Is the person in a situation where he/she can be expected to attend sessions as required and take the medication as prescribed? If the answer is "no," the treatment team should explore the possibility of conducting the treatment in a highly structured environment (e.g., residential, partial hospitalization).

**Factors for Addiction Professionals to Consider**

- 6. Is the patient expected to follow safety procedures?
- 7. Is the patient psychiatrically stable?
- 8. Are the psychosocial circumstances of the patient conducive to treatment success?
- 9. Are there resources available to ensure the link between physician and treatment provider?
- 10. Is the patient taking other medications that may interact adversely with buprenorphine?

**Slide 46: Factors for Addiction Professionals to Consider**

#6: Can the patient manage his/her medication appropriately (e.g., keep it away from children in the home), and take it as prescribed?

#7: Is the patient so unstable psychiatrically that he/she needs to be treated in a psychiatric hospital or receive additional treatment for co-occurring disorders?

#8: What stressors, relationships, supports, living situation, etc., does the patient have that can contribute to or undermine the success of the treatment plan?

#9: Has a comprehensive treatment plan been developed and coordinated between the psychosocial treatment team and the physician? What additional resources need to be brought on board in order to facilitate coordinated care?

#10: Another way of asking this question is, "Is this an appropriate medication for the person to be taking?" Additional medications and health conditions should be brought to the attention of the physician, so that the physician is fully informed in making the decision to prescribe buprenorphine or any other medication.

**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

**Slide 47: Issues Requiring Consultation with the Physician**

Bullet #1: CNS depressants can interact negatively with buprenorphine, potentially resulting in death. Use of these substances must be carefully evaluated and brought to the attention of the physician if they are discovered.

Bullet #2: This may or may not be an issue (case-specific), but should be evaluated to determine appropriate course of treatment for drug addiction and other psychiatric conditions.

Bullet #3: Again, not exclusionary, but understanding what led to previous treatment failures may help to shape the current treatment plan. This may, in fact, be a good thing. Changing to a new treatment, rather than continuing an unsuccessful one, may work well for them.

**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

**Slide 48: Issues Requiring Consultation with the Physician**

Bullet #1: Level of opioid use needs to be evaluated carefully to determine if buprenorphine is appropriate, and if so, the best way to transition the person onto the medication. This is a medical decision, but the addiction professional should bring all the information that they have to the physician and work with the physician in the development of the treatment plan.

Bullet #2: This may be an issue of timing; the patients may need more containment (e.g., residential care), or they may be saying that they are not ready to enter treatment.

Bullet #3: Buprenorphine is not currently approved for the treatment of opioid-addicted pregnant women. Clinical trials are ongoing and it looks promising, but right now, pregnant women should be treated with methadone. A physician who discovers that a patient on buprenorphine has become pregnant will likely develop a plan to transition her onto methadone. However, if buprenorphine is determined to be the best treatment after weighing all of the pros and cons, the physician may still prescribe buprenorphine.

Bullet #4: A poor social support system is not ideal for any treatment process. The treatment team should work with the patient to develop a plan to help the person strengthen and engage effective support.

**Issues Requiring Consultation with the Physician**

- HIV and STDs
- Hepatitis or impaired liver function



**Slide 49: Issues Requiring Consultation with the Physician**

It is important to consult with a physician and coordinate care to make appropriate treatment decisions.

Bullet #1: There is a common concern that patients with these conditions often take a variety of medications and, therefore, a potential for medication interactions may exist.

Bullet #2: Medication interaction is a concern here, as well. However, buprenorphine has not been shown to have negative effects on the liver.

### Issues Requiring Consultation with the Physician

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

### Slide 50: Issues Requiring Consultation with the Physician

Combining benzodiazepines and buprenorphine, especially if injected in an overdose attempt, may result in death.

Since alcohol is a sedative-hypnotic, patients should be cautioned to avoid alcohol use while taking buprenorphine.

Patients who abuse more than one drug present unique problems. Abuse of other drugs may interfere with overall treatment adherence. Persons with multiple addictions may need to be referred for further or more intensive treatment.

### General Counseling Issues

- Confidentiality
- Urine testing
- Working with, not against, medication
- Patient comfort during withdrawal

### Slide 51: General Counseling Issues

Confidentiality: Care should be taken to execute appropriate professional service agreements and releases of information in order to comply with confidentiality and HIPAA regulations.

Drug testing: In traditional opioid treatment programs, positive drug tests may or may not result in dismissal from treatment. In the case of office-based buprenorphine treatment, the physician and the treatment provider must come to a common understanding of how drug testing will be used and what will happen if the person has a positive test.

Working with, not against, the medication: Recovery is more than medication. But counselors should not diminish the importance of medication compliance or suggest the need to discontinue the medication.

Psychosocial treatment: Counselors and administrators in such programs should consider their treatment philosophy before accepting patient referrals from physicians prescribing buprenorphine or referring current clients to a physician for buprenorphine treatment.

Patient comfort: Counseling patients during withdrawal can be frustrating. Patients who are physically sick may have trouble being receptive to the cognitive and behavioral issues involved in the counseling process. Patients who are on buprenorphine, however, are generally not distracted by their own physical distress.