BUPRENORPHINE TREATMENT

Curriculum Infusion Package (CIP) For Infusion into Graduate Level Courses

Using Buprenorphine in the Treatment of Opioid Addiction

Developed by the Mountain West ATTC

blending initiative
NIDA • SAMHSA
Introduction

This is a two-hour presentation to provide graduate students an introduction to buprenorphine. 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 to have 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).

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Slide 1: Title Slide

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.
Slide 2: NIDA-SAMHSA Blending Initiative: Blending Team Members
Note that the membership consisted of three ATTC representatives and three NIDA researchers.

Slide 3: Additional Contributors
Acknowledge additional contributors to the Blending Team product.

Slide 4: Topics included in this Curriculum Infusion Package (CIP)

Slide 5: 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.

Slide 6: 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.
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.


Transition

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.

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?

- 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?

- Among people seeking treatment for abuse of other opiates, 1/2 was 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.

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.

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.

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

Until recently, the Controlled Substances Act limited 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.**
<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>Tablet formulations of buprenorphine (Subutex®) and buprenorphine-naloxone (Suboxone®) were approved by the Food and Drug Administration (FDA).</td>
</tr>
<tr>
<td>2004</td>
<td>Sale and distribution of ORLAAM® is discontinued.</td>
</tr>
</tbody>
</table>

**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.
Slide 15: Four Reasons for Not Entering Opioid Treatment

The previous 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.
Slide 16: A Need for Alternative Options
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:

- More patients may be willing to seek treatment;
- More patients will have access to treatment; and
- Stigma may be reduced by broadening the definition and locations of available treatment options.

Transition

Slide 17: 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.

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 which 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

**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.

**Slide 20: DATA 2000: Physician Qualifications**

Summarize each bullet point.
Anyone who takes opioids for a period of time will develop physical dependence on them. For instance, a patient who is taking vicodin over a period of time for pain will experience withdrawal symptoms if they stop taking in suddenly. This does not mean that they are addicted. It just means that their body has adapted to the medication. Generally, the prescribing physician will help the patient gradually taper down on the dose once the medication is no longer needed.

However, if a person has an addiction to opioids—that has lost control over his/her use, and/or developed the problems associated with addiction (whether or not physical dependence is present)—it is unlikely that he/she is going to stop using without some sort of treatment. The next section of the training will look at the treatment options available for opioid addiction.
**How Can You Treat Opioid Addicts?**

**Medically-Assisted Withdrawal**

The individual is systematically withdrawn from addicting drugs. Medications (e.g., methadone, buprenorphine, clonidine) are used to alleviate withdrawal symptoms while the person gradually returns to an opioid-free state.

It can be done successfully in inpatient or outpatient settings, but the treatment plan should be carefully developed to ensure adequate structure and support.

Generally, a medical provider supervises the withdrawal to monitor medical safety and administer medications to relieve discomfort.

Generally, this approach is not sufficient by itself to transition someone to maintaining an ongoing opioid-free life. Longer-term treatment that helps the person to develop new behaviors and strategies for coping is critical.

Patients who are not successful in withdrawing or who choose not to withdraw from opioids should be considered for treatment with medications as part of the treatment plan (either short- or long-term).

**Long-Term Residential Treatment**

Provides a highly structured environment (away from the person’s usual environment) in which treatment occurs.

Residential treatment may employ a variety of models, including Therapeutic Communities and cognitive behavioral therapy.

TCs focus on the resocialization of the individual and use the program’s entire community, including other residents, staff, and the social context, as active components of treatment.
How Can You Treat Opioid Addicts?

Outpatient Psychosocial Treatment

- Varies in types and intensity of services offered
- Costs less than residential or inpatient treatment
- Often more suitable for individuals who are employed or who have extensive social supports


Slide 25: How Can You Treat Opioid Addiction?

Outpatient Psychosocial Treatment

People involved in outpatient psychosocial treatment continue to live in the community while receiving their treatment.

The exact structure and elements of treatment vary greatly from program to program.

Generally, outpatient treatment is less costly than residential treatment.

Outpatient programs also offer increased flexibility, allowing people to continue to hold down jobs and make use of social supports in the community.

Group counseling is emphasized

Detox often done with clonidine

Ancillary medications used to help with withdrawal symptoms

People often report being uncomfortable

Often people cannot tolerate withdrawal symptoms and discontinue treatment


Slide 26: How Can You Treat Opioid Addiction?

Outpatient Psychosocial Treatment

Group counseling is generally the primary treatment in these programs.

Medically assisted withdrawal is generally done using clonidine and other non-narcotic medications.

People often report being very uncomfortable during the withdrawal process.

For this reason, many people leave treatment prematurely because they cannot tolerate the symptoms.
Behavioral therapies are designed to help individuals change their thought patterns around drug use and learn new behaviors to help them stop using and avoid relapse.

Two general strategies have shown a great deal of promise:

Contingency management:
- Helps the patient to adopt new behaviors by reinforcing behaviors that move them toward their treatment goals.

Cognitive-behavioral interventions:
- Help the patient to change the way they think and behave with regards to drug use.
- Increase positive coping strategies.

Many different types of behavioral therapies have been used successfully for substance abuse disorders. These include:
- Motivational Enhancement Therapy
- The Matrix Model
- Cognitive and Cognitive-Behavioral Therapy
- Community Reinforcement Approach
- Self-Help Programs

MENTION THE FOLLOWING FREE RESOURCES:
- SAMHSA’s Treatment Improvement Protocol (TIP) series includes a number of documents that contain best-practice guidelines for the provision of interventions and therapies for individuals with substance abuse disorders.
- The Principles of Drug Addiction Treatment: A Research-Based Guide (a.k.a., the NIDA Blue Book) reviews treatment approaches that have empirical support for their efficacy.

Agonist maintenance helps to stabilize people so that they don’t constantly experience the cycles of use and withdrawal. This allows them to function more normally.

The negative behaviors associated with use are diminished.

The person can immediately engage in the treatment experience while interested and motivated to receive treatment, rather than feeling sick (withdrawal) for a week or more and then beginning the treatment process.
How Can You Treat Opioid Addicts?

Agonist Maintenance Treatment

Usually conducted in outpatient settings
Treatment provided in opioid treatment programs or, with buprenorphine, in office-based settings
Use a long-acting synthetic opioid medication, usually methadone
Administer the drug orally for a sustained period at a dosage sufficient to prevent opioid withdrawal, block the effect of illicit opiate use, and decrease opioid craving


Slide 29: How Can You Treat Opioid Addiction?

Agonist Maintenance Treatment

These treatments have been conducted primarily on an outpatient basis in specific opioid treatment programs. With the addition of buprenorphine to the treatment system, patients can also receive treatment through physicians in the offices.

Generally, a long-acting opioid (traditionally methadone, now also buprenorphine) is used. These medications prevent the occurrence of withdrawal symptoms and block the effects of illicit opioids if they are used. They also help to decrease craving for the drug.

Slide 30: How Can You Treat Opioid Addiction?

Agonist Maintenance Treatment

Maintenance programs are most effective if they are combined with an effective behavioral treatment program.

Additionally, patients may need treatment for other medical or psychological conditions. They may also need a variety of social support services. Social services include:

- Vocational rehabilitation
- Employment
- Education
- Housing
- Case management
- Parenting
- Socialization skills
- Anger management

Benefits of Methadone Maintenance Therapy

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

Slide 31: Benefits of Methadone Maintenance Therapy

Review and summarize bullet points.
### How Can You Treat Opioid Addicts?

#### Antagonist Maintenance Treatment

**Slide 32:** How Can You Treat Opioid Addiction?

**Antagonist Maintenance Treatment**

Use of opioid antagonists can also be effective. As with agonist treatment, antagonist treatment is generally conducted through an outpatient setting.

The antagonist is prescribed after medical withdrawal from opioids is complete.

If antagonists are administered before complete withdrawal, the person may experience immediate and intense withdrawal.

**Repeated lack of desired opioid effects, as well as the perceived futility of using the opiate, will gradually over time result in breaking the habit of opiate addiction.**

**Patient noncompliance is a common problem.** A favorable treatment outcome requires that there also be a positive therapeutic relationship, effective counseling or therapy, and careful monitoring of medication compliance.

**One problem with antagonist treatment is that patients stop taking them because they want to get the experience of taking an agonist.**

Effective antagonist maintenance therefore requires:

- A positive therapeutic relationship with the treatment provider;
- Ongoing counseling; and
- Monitoring of medication to determine level of compliance.

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**Slide 33:** How Can You Treat Opioid Addiction?

**Antagonist Maintenance Treatment**

Antagonists block the effects of any illicit opioid. Over time, this helps the person to break the pattern and desire of use.

**Use of opioid antagonists often begins after medical detoxification in a residential setting.**

**Individuals must be medically detoxified and opioid-free for several days before naltrexone is taken (to prevent precipitating an opioid withdrawal syndrome).**

**How Can You Treat Opioid Addicts?**

**Antagonist Maintenance Treatment**


**Slide 34:** How Can You Treat Opioid Addiction?

**Antagonist Maintenance Treatment**

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Effective antagonist maintenance therefore requires:

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- Ongoing counseling; and
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Treatment Options for Opioid-Addicted Individuals

Behavioral treatments educate patients about the conditioning process and teach relapse prevention strategies.

Medications such as methadone and buprenorphine operate on the opioid receptors to relieve craving.

Combining the two types of treatment enables patients to stop using opioids and return to more stable and productive lives.

The successful treatment for opioid addiction requires both management of physical withdrawal symptoms and behavioral and cognitive changes that encourage the patient to abstain from using the drug of abuse in the future. Providing psychosocial and counseling services along with pharmaceutical treatment increases the likelihood of achieving long-term, comprehensive lifestyle changes and preventing relapse. You want to help the patient restore a degree of normalcy to brain function and behavior, thereby leading to increased employment rates, reduced criminal behavior, and lowered risk of HIV, hepatitis C, and other diseases.

Stress the importance of combining both treatment approaches (Bullet #3).

The bottom line is that you need to tailor the treatment to meet the particular needs of the patient (e.g., deciding between inpatient and outpatient, behavioral and pharmacological, etc.).

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

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.

Opioids affect the brain globally, including areas that control:

- Automatic bodily functions such as breathing, blood pressure, pulse;
- Emotions, especially the areas of the brain responsible for feeling pleasure;
- Pain – opioids block the transmission of pain messages from the body to the brain thereby diminishing or stopping the experience of the pain.
Opioid Addiction and the Brain

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 effect 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.

Opioid Addiction and the Brain

At first, using opioids results in PLEASURE. But repeated exposure to opioids causes long-lasting changes in brain functioning, resulting in TOLERANCE (a need to keep using more and more in an attempt to feel the pleasure that was once felt).

If you stop using opioids after you’ve used them for a prolonged period of time, you go through WITHDRAWAL.

Environmental cues associated with drug use activate the brain and cause craving, which often leads back to drug use (RELAPSE).

Mention that craving/triggers will be discussed in greater detail in Module VI.
What Happens When You Use Opioids?

People report that the experience of taking opioids is intensely pleasurable. However, even early in the use cycle, people report negative side effects from use.

**Acute effects** include the euphoria and sedative effects; people also report constipation, itching, nausea and decreased pulse and respiration.

With **chronic use**, tolerance and withdrawal symptoms develop and the above symptoms may become more significant.

Withdrawal symptoms from opioids are quite unpleasant and include sweating, runny nose, diarrhea, nausea, and muscle and joint pain.

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Opiate/Opioid: What's the Difference?

- **Opiate** refers only to drugs or medications that are derived directly from the opium poppy. Examples include heroin, morphine, and codeine.
- **Opioid** is a broader term referring to opiates and other synthetically-derived drugs or medications that operate on the opioid receptor system and produce effects similar to morphine. Examples include buprenorphine and methadone.

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Basic Opioid Facts

- **Description**: Opium-derived, or synthetics which relieve pain, produce morphine-like addiction, and relieve withdrawal from opioids
- **Medical Uses**: Pain relief, cough suppression, diarrhea
- **Methods of Use**: Intravenously injected, smoked, snorted, or orally administered

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Throughout this training, we are using the term opioid to define the class of drug with which we are dealing. It is important to understand what this term means.

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What's What? Agonists, Partial Agonists, and Antagonists

**Agonist**
- Morphine-like effect (e.g., heroin)

**Partial Agonist**
- Maximum effect is less than a full agonist (e.g., buprenorphine)

**Antagonist**
- No effect in absence of an opiate or opiate dependence (e.g., naloxone)

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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/respiratory depression) effects.

In individuals who are not physically dependent on opioids, buprenorphine produces typical opioid agonist effects, such as analgesia, sedation, nausea, and dizziness, but these reach a “ceiling” in most individuals with sublingual doses of 24 to 32 mg.

**Antagonists** also bind to receptors, but rather than activating them, they block the receptors by preventing them from being activated by an agonist.

**Key and Lock Analogy:**
One can consider an antagonist to be a key that fits snugly into a lock, but does not open it. It also prevents another key from opening the lock. When people take an antagonist and an agonist in combination, they do not feel the agonist effects. Patients who take naltrexone (an antagonist), for example, do not feel the effects of heroin or other agonists.

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Dependence vs. Addiction: What's the Difference?
Terminology

Dependence versus Addiction

The DSM-IV defines problematic substance use with the term substance dependence. It does not use the term addiction. This has been the source of much confusion.

According to the DSM-IV definition, substance dependence is defined as continued use despite the development of negative outcomes including physical, psychological or interpersonal problems resulting from use.

Most providers refer to this as addiction and addiction is the term we will use throughout the rest of the training.

Addiction may occur with or without the presence of physical dependence. Physical dependence results from the body’s reaction to the presence of an addictive substance—that is physical dependence on the substance.

Physical dependence is one symptom of addiction, but it is important to remember that addiction can occur with or without physical dependence.

Physical dependence is defined by the presence of tolerance and/or withdrawal.

Let’s look at the specific definitions of these terms.

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

Tolerance deals with the body’s adaptation to a drug or medication. With repeated exposure, the response to the substance lessens. It therefore requires a higher dose to get the same effect.
Withdrawal: a period during which somebody addicted to a drug or other addictive substance stops taking it, causing the person to experience painful or uncomfortable symptoms OR a person takes a similar substance in order to avoid experiencing the effects described above.

Let's look at the problems that the DSM-IV identifies:

According to the DSM-IV, substance use disorders occur on a continuum. The less severe form of the problem is called abuse and is defined as having repeated problems associated with use, but generally the individual is still at least somewhat functional in their lives. As the problem worsens, the person moves on to addiction (or what the DSM-IV calls substance dependence), in which functioning is markedly impaired.

Addiction is based on clusters of behaviors and physical effects. It is defined as a “maladaptive pattern of substance use leading to clinically significant impairment or distress as manifested by three (or more) of seven symptoms occurring at any time during a 12-month period.”

Read the bullets aloud.

Additional points to mention:

Bullet #3: “taking larger amounts” – indicates a loss of control over moderating your drug use. “Over time” can also be stated as “longer periods than intended.”

For clarity, let’s review the terms again:

Read slide aloud.
Slide 50: Buprenorphine: An Exciting New Option
Buprenorphine represents an exciting addition to the available opioid treatment options.

Slide 51: Development of Tablet Formulations for Buprenorphine
Subutex® = a sublingual tablet containing buprenorphine hydrochloride only
Suboxone® = a sublingual tablet containing both buprenorphine hydrochloride and naloxone hydrochloride in a 4:1 ratio

Suboxone® is the focus of U.S. marketing efforts, even though both formulations are available in the U.S.

These medications have a tremendous amount of research behind them to show that they are both safe and effective in the treatment of opioid addiction.

Slide 52: Moving Science-Based Treatments into Clinical Practice
Many treatments that are developed never make it into real-world practice.

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.

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.
## 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. 1994b; Schottenfeld et al. 1997; Fischer et al. 1999)
- Methadone and LAAM (Johnson et al. 2000)

### Slide 53:

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:

- Is more effective than placebo; and
- Has similar effectiveness to moderate doses of methadone and LAAM.

## 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

### Slide 54:

Several factors make buprenorphine a good option for some people.

Buprenorphine is a partial agonist, resulting in a good safety profile for the medication.

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.
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.
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.

**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.

**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.

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. Physical dependence IS NOT the same thing as addiction. This is a really important concept that we will spend more time on later in the training.

**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.

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 euphoric effect at higher doses.

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.

### Who is Appropriate for Buprenorphine Treatment?

The following set of slides will review assessment questions, situations in which multidisciplinary addiction professionals should consult with the treating physician, and additional issues relating to patient selection.
Slide 62: 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 (e.g. 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?

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

1. High level of dependence on high doses of opioids
2. High risk for relapse based on psychosocial or environmental conditions
3. Pregnancy
4. Poor support system

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

1. HIV and STDs
2. Hepatitis or impaired liver function

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.
Slide 67: 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.

Slide 68: 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.
Slide 69: Patient Selection
There are instances in which patients do not meet criteria for current opioid addiction may be candidates for buprenorphine treatment.

Read the two examples aloud.

Slide 70: The Use of Buprenorphine in the Treatment of Opioid Addiction (Induction, Maintenance, Tapering Off/Medically Assisted Withdrawal)
Now let’s look at how people are transitioned onto buprenorphine and then examine the two primary treatment options: maintenance and medically assisted withdrawal.

Slide 71: Induction
The term induction refers to the procedures used to transition someone from other opioids onto buprenorphine.

Slide 72: Induction Phase
During induction, the physician works with the patient to figure out the most effective dose so that he/she can stop other opioid use with minimal withdrawal symptoms.

While the physician primarily guides this process, the multidisciplinary team is critical in providing supportive care and counseling to help the patient through the process.
Ask patient to abstain from short-acting opioid (e.g., heroin) for at least 6 hrs. and be in mild withdrawal before administering buprenorphine-naloxone.

When transferring from a short-acting opioid, be sure the patient provides a methadone-negative urine screen before 1st buprenorphine dose.


Slide 73: Direct Buprenorphine Induction from Short-Acting Opioids

People who are using either short- or long-acting opioids can be inducted onto buprenorphine/naloxone. The PHYSICIAN is responsible for this aspect of the patient’s care.

The multidisciplinary addiction professional should be available, however, during the induction process to provide supportive counseling.

In order to be inducted onto buprenorphine, the person must be in mild withdrawal. This ensures that they have a smooth transition onto the medication and will not have unexpected withdrawal symptoms. Due to the high receptor affinity (removing other opioids from the receptor) and the ceiling effect at higher doses (causing a lowered experience of the drug), if patients transition immediately from heroin to buprenorphine, for example, buprenorphine will replace the heroin at the receptor and the patient will have the experience of suddenly having much less opioids in their system than they are used to – they will go into withdrawal. However, if they are already in mild withdrawal, the buprenorphine will have the expected agonist effects and the person will experience a comfortable transition.

The patient should also be monitored for methadone use, as this can complicate the transition, as well.

Slide 74: Direct Buprenorphine Induction from Long-Acting Opioids

Less is known about how to transition people from long-acting opioids such as methadone.

Clinical trials are needed to determine the most effective procedures and which formulation to use for these patients.

Slide 75: Direct Buprenorphine Induction from Long-Acting Opioids

Clinical experience has indicated that these patients can be successfully inducted using similar procedures as those used for short-acting opioids.

The time interval between the last dose should be increased to allow for the longer active duration of the drug (24-48 hours).
Transition

Slide 76: Stabilization and Maintenance
Once the person is on the medication, the next step is to make sure he/she is stabilized.

Slide 77: Stabilization Phase
By stabilization, we mean that they do not experience any negative symptoms or craving.

At this point, the decision can be made to either move on to the maintenance phase or to withdraw with medically assisted withdrawal.

Slide 78: Maintenance Phase
Cessation of illicit drug use and problematic alcohol use.

The treatment professional should address any underlying issues, such as psychiatric co-morbidity and psychosocial issues (employment, legal, family/social, etc.).

Slide 79: Maintenance Phase
During maintenance treatment, providers should assess the patient and provide treatment for other issues that the person is facing, to help get him/her stabilized and live a more fulfilled life.

Read/summarize the bullet points.

Slide 80: Buprenorphine Maintenance: Summary
Use of take-home dosing is desired by many patients, but ongoing monitoring is critical to determine compliance.

Dosing every day is not necessary. Researchers have demonstrated that a three-time-per-week dosing schedule was safe and effective.

In order to be effective, it is imperative that counseling be incorporated into the treatment plan and supported by the entire multidisciplinary team.
Medically Assisted Withdrawal (a.k.a. Dose Tapering)

Transition

Slide 81: Medically Assisted Withdrawal (a.k.a. Dose Tapering; a.k.a. Detoxification)
Not all patients are appropriate for withdrawal from the medications. Unstable living situations, multiple relapses, previous failed detoxification attempts, or lack of desire to withdraw from opioids, may indicate that maintenance is a better treatment option.

Slide 82: Buprenorphine Withdrawal
However, if appropriate, the goal of medically assisted withdrawal is to help patients transition off of opioids so that they are no longer physically dependent.

Psychosocial treatment is a critical component of this (and all treatments) to help them avoid relapse.

Slide 83: Medically Assisted Withdrawal
Medically assisted withdrawal can be successful in either inpatient or outpatient settings. It is important for the multidisciplinary treatment professional to provide supportive wrap-around services to get the patient through this difficult stage.

This is done by transitioning the person onto a long-acting opioid like buprenorphine and then tapering him/her off over a period of time.

Other medications may be helpful if withdrawal symptoms are present to help the person to stay comfortable.

Slide 84: Counseling Buprenorphine Patients

The one major issue left to cover in this awareness-building training is a discussion of strategies to treat patients who have begun to take buprenorphine as part of their opioid treatment.
<table>
<thead>
<tr>
<th>Slide 85: Counseling Buprenorphine Patients</th>
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<tr>
<td><strong>Address issues of the necessity of counseling with medication for recovery.</strong></td>
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<tr>
<td><strong>Recovery and Pharmacotherapy:</strong></td>
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<tr>
<td>- Patients may have ambivalence regarding medication.</td>
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<td>- The recovery community may ostracize patients taking medication.</td>
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<td>- Counselors need to have accurate information.</td>
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<th>Slide 86: Counseling Buprenorphine Patients</th>
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<tbody>
<tr>
<td><strong>Recovery and Pharmacotherapy:</strong></td>
</tr>
<tr>
<td>- Focus on &quot;getting off&quot; buprenorphine may convey taking medicine is &quot;bad.&quot;</td>
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<td>- Suggesting recovery requires cessation of medication is inaccurate and potentially harmful.</td>
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<td>- Support patient's medication compliance</td>
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<td>- &quot;Medication,&quot; not &quot;drug&quot;</td>
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<th>Slide 87: Counseling Buprenorphine Patients</th>
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<tr>
<td><strong>Dealing with Ambivalence:</strong></td>
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<tr>
<td>- Impatience, confrontation, &quot;you're not ready for treatment&quot;</td>
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<tr>
<td>- Deal with patients at their stage of acceptance and readiness</td>
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**Slide 85:** Counseling Buprenorphine Patients

Again, it is important to stress that the multidisciplinary addiction professional should work with, not against, the medication.

**Slide 86:** Counseling Buprenorphine Patients

Suggesting the need to discontinue medication can convey the idea that the medication is a necessary evil and somehow wrong. It is important to refer to buprenorphine as a medication and frame it as one component of the comprehensive opioid treatment plan.

**Slide 87:** Counseling Buprenorphine Patients

Some patients are ambivalent about or averse to medication. They may acquire negative attitudes from previous treatment experiences, methadone-related stigma, or from other people in recovery who are using medications.

Medication is not essential to a treatment plan, and effective treatment can occur without it. However, it is important to talk with the patient about the realities of withdrawal and the low success rate of people who try it without medical assistance. Counselors can help patients by dispelling myths about buprenorphine and providing accurate information about the use of buprenorphine for treating opioid addiction.
Counseling Buprenorphine Patients

**Slide 88: Counseling Buprenorphine Patients**

**Be flexible:** An opioid-addicted person’s life is often out of control. The transition from active drug use to recovery via buprenorphine treatment is a major lifestyle change. Patients may be late for appointments, reschedule, or fail to show. Applying rigid standards and expressing disapproval may prompt patients to feel negatively about counseling, and they may choose to avoid appointments or discontinue psychosocial treatment altogether.

**Don’t impose high expectations:** Patients who have taken steps to address their drug addiction have already achieved a significant accomplishment. An immediate major change in the person’s general lifestyle may be an unrealistic expectation.

**Don’t confront:** Instead of being confrontational, it is better to develop discrepancy (which is a gentler counseling approach). Direct and harsh confrontation is more likely to drive a person out of treatment than to maintain them in treatment.

**Non-judgmental acceptance:** Drug addiction is associated with many unappealing behaviors, such as lying, stealing, and unreliability. Some of these behaviors may continue during treatment. View these behaviors as symptoms of the drug problem. Do not be critical or judgmental.

**Utilize a motivational interviewing approach** (*this topic is covered in more detail in a few more slides*).
What is the 12-Step program?: Two men who were unable to deal with their own alcoholism through psychiatry or medicine founded Alcoholics Anonymous (AA) in the 1930s. They discovered several principles that helped people overcome their addictions. They founded AA to introduce alcoholics to these principles of self-help.

The AA principles and concepts have been adapted for addiction to opioids, stimulants, other drugs, and even to compulsive behaviors such as gambling, overeating, and sex.

Benefits of participating in 12-Step meetings: Many treatment providers believe that participating in 12-Step meetings can be an important component of buprenorphine treatment. People addicted to alcohol and drugs have found that other addicted persons in recovery can provide enormous support and help to one another. In addition, meetings are free, and are generally available throughout the day and in the evening. 12-Step meetings can be found throughout the world.

Types of meetings: Speaker meetings (recovering person tells his/her story); topic meetings (discuss a specific topic, such as fellowship, honesty, acceptance, or patience); and step/tradition meetings (the 12 steps and 12 traditions are discussed).

Some people are able to stop using substance through 12-Step participation alone. However, for many, this self-help approach is not enough. In this case, participation in 12-step meetings may be a valuable adjunct to other medical and/or psychosocial treatment.
Some patients may have had negative experiences in the past at 12-Step meetings because they were taking medication for their drug addiction or for psychiatric disorders.

Although 12-Step programs accept people who are taking medications, some 12-Step participants do not discriminate between drugs of abuse and appropriately used medications, and are therefore intolerant of medication-taking individuals.

AA has developed an AA-approved publication called “The AA Member – Medications and Other Drugs.” Addiction professionals should become familiar with this publication.

Addiction professionals can help patients by educating them about the official position of 12-Step programs regarding the use of prescribed medications, describing the benefits of 12-Step programs, and promoting the use of these self-help programs as part of their overall recovery process.

Despite the official views of 12-Step programs, patients may need to seek 12-Step meetings that include members who are accepting of the use of properly prescribed medication.

12-Step Meetings are one source of social support. However, these meetings may not work for everyone. Providers generally recommend to these patients in treatment that they find some source of support to help them in the recovery process (e.g., other self-help meetings, churches, recreational groups, etc.).
Slide 92: Principles of Motivational Interviewing
With MI, the counselor has certain goals in mind when conducting patient interviews. These goals are formulated with an awareness of the underlying principles of the approach. When strategizing an intervention, the counselor should try to:

• Express empathy;
• Develop discrepancy;
• Avoid argumentation; and
• Support self-efficacy.

Achieving these goals and helping people to move through the Stages of Change are accomplished by using the microskills of motivational interviewing. They are:

• Asking open-ended questions;
• Being affirming;
• Listening reflectively; and
• Summarizing.

Becoming adept in the use of MI takes practice. For more information on the use of MI visit http://ncadi.samhsa.gov and review TIP 35: Enhancing Motivation for Change in Substance Abuse Treatment.

Slide 93: Counseling Buprenorphine Patients
Early Recovery Skills: Addiction professionals can help patients by educating them about the importance of developing skills related to drug cessation, early recovery, and relapse prevention.

Professionals can help patients through the recovery process by educating them about the need to discard drug paraphernalia, address triggers and cravings, understand addictive behaviors and thinking, avoid relapse drift, not focus on willpower, and address ignored responsibilities. Likewise, addiction professionals have an important role in helping patients to resume optimal health and hygiene, make amends, deal with intense emotions, and engage in healthy recreation activities.
Counseling Buprenorphine Patients

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

Relapse Prevention involves the following:

Review the bullet points.

Slide 94: Counseling Buprenorphine Patients
Relapse does not suddenly occur. It occurs gradually and with warning signs. The gradual movement can be subtle and easily explained away or denied, and therefore, relapse can feel as if it occurred suddenly and without warning.

Slide 95: Counseling Buprenorphine Patients
Because relapse is a common occurrence during the process of substance abuse recovery, it is imperative that it be examined carefully.

Read through the sample topics quickly and move on to the next slide.

Slide 96: Counseling Buprenorphine Patients

Read through the sample topics quickly and move on to the next slide.

Slide 97: Counseling Buprenorphine Patients

Read through the sample topics quickly and move on to the next slide.

Slide 98: Counseling Buprenorphine Patients

Read through the sample topics quickly and move on to the next slide.
Counseling Buprenorphine Patients

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

Slide 99: Counseling Buprenorphine Patients

Read through the sample topics quickly and move on to the next slide.

Slide 100: Stages of Change

As was previously stated, patients receiving buprenorphine treatment may not be ready to stop using all illicit drugs and alcohol. Even patients expressing the desire to stop using will have ambivalent feelings about the change process.

Patients enter treatment at varying stages of readiness for treatment and openness to counseling. Interventions effective at one stage of readiness may not be as effective when used during another stage.

Each stage will be described in greater detail in the following couple of slides.

Slide 101: Stages of Change

Pre-Contemplation: Provide the patient with factual information; explore the meaning of events that brought the patient to treatment and the results of previous treatments; explore the pros and cons of using alcohol and other illicit drugs.

Contemplation: Talk about the patient’s sense of self-efficacy (the belief that you can influence your own thoughts and behavior) and expectations regarding treatment; summarize self-motivational statements; continue exploring pros and cons of substance use.

Determination: Offer a menu of options for change or treatment; negotiate a change (treatment) plan and behavioral contract; identify and lower barriers to change; help patients enlist social support; have patients publicly announce plans to change.
Stages of Change, Continued

**Action**: Taking steps to change but hasn’t reached a stable state.

**Maintenance**: Has achieved abstinence from illicit drug use and is working to maintain previously set goals.

**Recurrence**: Has experienced a recurrence of symptoms, must cope with the consequences of the relapse, and must decide what to do next.

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**Slide 102: Stages of Change, Continued**

**Action**: Support a realistic view of change through small steps; help patients identify high-risk situations and develop appropriate coping strategies; help patients find new reinforcers of positive change; help patients access family and social support.

**Maintenance**: Help patients identify and try drug-free sources of pleasure; maintain supportive contact with patients; encourage patients to develop a “fire escape” plan; work with patients to set new short- and long-term goals.

**Recurrence**: Explore with patients the meaning and reality of recurrence as a learning opportunity; explain the stages of change, and encourage patients to remain engaged in the process; help patients to find alternative coping strategies.

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**Slide 103: Patient Management Issues**

**Bullet #1**: Recovery is more than medication. Many buprenorphine patients may feel that once they have dealt with the physical aspect of their opioid addiction and have received a medication, they do not need additional treatment in the form of psychosocial counseling. At the same time, the addiction professional should not diminish the importance of medication compliance.

**Bullet #2**: Despite the fact that physicians must have the “capacity” to refer their patients for additional counseling, they may not have knowledge of the psychosocial treatment providers that are located in their local community. Therefore, treatment providers may need to perform outreach to inform local physicians of their existence and of their willingness to collaborate in treating patients receiving buprenorphine.

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**Slide 104: Patient Management: Treatment Monitoring**

*Read the goals for treatment aloud. Mention that this list is not exhaustive, and ask the trainees to provide additional components of a comprehensive treatment plan.*

**Goals for treatment should include:**
- No illicit opioid drug use
- No other drug use
- Absence of adverse medical effects
- Absence of adverse behavioral effects
- Responsible handling of medication
- Adherence to treatment plan

**Bullet #2** (“no other drug use” may also include alcohol use) – Treatment programs handle the issue of alcohol use very differently. The important issue to keep in mind is that possible alcohol use should be assessed and the goals for treatment should be agreed upon by all of the treating professionals (physician, substance abuse counselor, etc.) and the patient.
Slide 105: Patient Management: Treatment Monitoring
Weekly visits are important – at least early on in the treatment and recovery process.

If medical issues come up throughout the course of psychosocial treatment, be sure to refer those questions back to the treating physician.

Slide 106: Patient Management: Treatment Monitoring

**Bullet #1:** Drug testing is a common practice and is conducted primarily to assess treatment efficacy. The physician, counselor, and/or other staff may conduct urine testing. Testing provides the patient with an additional tool to prevent drug use. Counselors should stress that testing is a standard procedure that can help their treatment and is not a surveillance tool based on an assumption of patients’ dishonesty.

Bullet #2: It is not up to the substance abuse counselor to decide whether or not buprenorphine should be discontinued. Tapering off of buprenorphine is a medical decision, and should be reserved for the treating physician and patient to discuss.

Bullets #3-5: The take-home message here is that lines of communication between all treatment providers should remain open at all times, to ensure that the patient is receiving high-quality, comprehensive care.
Bullet #1: Introducing 12-Step meetings to a patient can be considered a coaching process; the addiction professional should walk the patient through potential scenarios they may encounter at a 12-Step meeting. The patient should be encouraged to choose a sponsor who is supportive of their use of buprenorphine as part of their overall opioid treatment plan.

Bullet #2: Counselors can help patients by educating them about the importance of disposing of drugs and related paraphernalia, as well as ways to address triggers and cravings, understand addictive behaviors and thinking, and avoid relapse drift.

Bullet #4: Relapse prevention involves a series, or process, of learning the skills necessary to stay away from drugs. Relapse prevention techniques help the patient learn these skills.

Relapse prevention techniques will be covered in more detail later on in this module.

Slide 109: Triggers and Cravings

This is a process; it is not automatic. Patients need to be told that they can control their thoughts, but it will take time and practice. It helps if the addiction professional finds a constructive way for patients to deconstruct the thought/using process.

To the actively using substance abuser and those in early recovery, the Trigger-Thought-Craving-Use sequence feels as if it happens simultaneously. You feel triggered, and you immediately want to use. Knowing about the specifics of this process can be very helpful to the recovering addict/alcoholic. The successful key in dealing with the process is to avoid it getting started.

It is extremely important to stop the thought when it first begins and to prevent it from building into an overpowering craving. It is vitally important to do this as soon as the patient recognizes the thought is occurring. This can be accomplished by using a number of Thought-Stopping techniques.
Slide 110: Thought-Stopping Techniques

It is necessary to interrupt the thought process, by finding something to replace the drug/alcohol the patient uses. Here are examples of thought-stopping techniques:

- **Visualization**: Picture a switch or lever in your mind. Imagine yourself actually moving it from ON to OFF to stop the drug or alcohol thoughts. Have another picture ready to think about in place of those thoughts. You may have to change what you are already doing to make the switch.

- **Snapping**: Wear a rubber band loosely on your wrist. Each time you become aware of drug or alcohol thoughts, snap the band and say “NO” to the thoughts as you make yourself think about another subject.

- **Relaxation**: Feelings of hollowness, heaviness, and cramping in the stomach are cravings. These can often be relieved by breathing in deeply and breathing out slowly.

- **Call someone**: Talking to another person provides an outlet for your feelings and allows you to hear your own thought process.

Slide 111: Special Populations

The following discussion highlights a few of the many special populations, including patients with co-occurring psychiatric disorders, pregnant women, and adolescents.
Co-occurring Psychiatric Disorders

Opioid users frequently demonstrate concurrent psychiatric diagnoses, ranging from anxiety or depressive disorders to antisocial personality disorder. However, drug use effects and drug withdrawal symptoms can sometimes mimic psychiatric symptoms. It is necessary to consider the duration, recentness, and amount of drug use when making a psychiatric diagnosis.

Counselors should consult with the DSM-IV to review “substance-induced disorders.” It is also necessary to review the patient’s psychiatric history, and consult with the buprenorphine-prescribing physician and other mental health providers.

Any of the following should prompt further action:
- Suicidal thoughts or plans;
- Extreme changes in mood;
- Extreme changes in sleep or activity patterns;
- Hyperactivity;
- Paranoid thinking;
- Hallucinations;
- Unresponsiveness; and/or
- Confusion.

Pregnancy-Related Considerations

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

Opioid-addicted adolescents and young adults are often unavailable and/or hard to find. Clinicians report that the outcome leaves much to be desired. States have different requirements for admitting clients under age 18 to addictions treatment. It is important to know the local requirements.
Currently, buprenorphine is NOT approved for treatment of opioid-addicted adolescents. But researchers are in the process of studying the safety and efficacy of buprenorphine treatment for adolescents.
Slide 116: Only physicians can prescribe the medication. However, the entire treatment system should be engaged.

*Read slide aloud.*

Slide 117: 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.

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.

The Benefits of Coordinated Care

- Capacity for physician to refer to treatment is required under the law (DATA 2000)
- Substance abuse treatment providers have expertise in managing and coordinating care for substance using clients
- Combines goals of the medical and behavioral health systems— holistic care rather than compartmentalized care
- Treatment modality (e.g., inpatient vs. outpatient), type (e.g., methadone vs. buprenorphine), and setting (office based vs. OTP) can be made to maximize fit with patient needs

Review the benefits of coordinated care, as stated on the slide.
Slide 120: Roles of the Physician

Read the roles aloud.

The medical system has physical health as its primary goal. In this system, the physician may focus on alleviating the discomforts of withdrawal by helping the person to taper off of opioids or providing medication on an ongoing basis to help stabilize the patient. Additionally, the physician may focus on a longer goal of helping the person to maintain abstinence from illicit opioids.

The physician’s choice of treatment should be determined by the intensity of intervention necessary to support the recovery of an individual patient. The continuum of treatment intensities ranges from episodic office-based therapy to intensive inpatient therapy.
Slide 121: Roles of the Multidisciplinary Team

Read the roles aloud.

The treatment process is complex. The missions of substance abuse treatment and recovery agencies generally focus on helping individuals make positive changes in their lives. Various treatment services may come under the auspices of the health care system; others are affiliated with mental health systems; still others function as independent, separate agencies. Funding sources, client referrals, staffing, facilities, and many other aspects of treatment programs often vary markedly from agency to agency.

The Center for Substance Abuse Treatment’s vision for publicly funded addiction treatment and recovery services requires that the treatment and recovery infrastructure and individual community-based programs be empowered to:

1. Comprehensively assess the needs of individuals who request assistance;
2. Match individual needs with the interventions and recovery services that best suit their requirements, as well as the needs of their families and significant others;
3. Provide an appropriate array of specific treatment and recovery services along a sustained continuum of care for both the individual and his/her collaterals; and
4. Determine the outcome of specific treatment and recovery services.

Two additional points to reiterate:

- Encourage practitioners to stay within their scope of practice. One of the benefits of coordinated care is the linkage to other individuals/agencies who have the necessary expertise to treat various aspects of the patient’s condition.
- There is NO wrong door for treatment.

Slide 122: Roles of the Community Support Provider

Read the roles aloud. Ask the audience to provide examples of community support providers that are available in their area.
Slide 123: Roles of the 12-Step Program
The stigma associated with opioid maintenance therapy may be an issue in 12-Step meetings. Patients are very likely to require coaching in this area. Each professional will need to develop an effective approach with which they feel comfortable. For example, professionals might coach their patients that there is no need to disclose their medical history or medications they are taking in public settings such as 12-Step meetings. Addiction professionals may also link patients up with 12-Step support people who are understanding of and supportive of their buprenorphine treatment.

More information on 12-Step meetings will be covered in Module VI.

Addiction professionals may also want to develop special support groups for patients who are participating in buprenorphine treatment and attending 12-Step meetings.

Slide 124: A Model of Coordinated Care
All involved systems and their key players have a role in care coordination. Often, agency personnel develop informal means of collaboration, as one staff member becomes familiar with the programs and service providers in another agency. These staff members, and sometimes their agencies, may work very closely to meet the needs of mutual patients because of such voluntary efforts.

Reiterate that effective coordination combines the strengths of various systems and professions.

The roles of addiction counselors and community support providers may vary by state, depending upon the identified scope of practice for each profession.
Slide 125: Use the SAMHSA Physician Locator Service to Find a Physician Authorized to Prescribe Buprenorphine in Your State

The Substance Abuse and Mental Health Services Administration (SAMHSA) provides a registry of physicians who have received a waiver that authorizes them to prescribe buprenorphine. Community treatment providers can locate physicians in their local area by checking out this web site.

If there are no physicians within a local community, the community treatment provider may attempt to recruit a physician who is willing to pursue the waiver process if there will be a sufficient number of patients to warrant the effort. Also note that some physicians who are authorized to prescribe buprenorphine may choose not to be listed in the SAMHSA directory. So the number of physicians included in the directory may be an underestimate of the actual number authorized to prescribe buprenorphine.

Slide 126: SAMHSA’s Buprenorphine Physician Locator

**Review each feature of the Physician Locator website.**

Slide 127: 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).
Combination tablet is being marketed for U.S. use
6. Discourages IV use
7. Diminishes diversion
8. Allows for take-home dosing

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
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).
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.

Medications operating through the opioid receptors, such as buprenorphine, prevent withdrawal symptoms and help the person function normally. Various empirically-supported therapeutic approaches are available for use in counseling buprenorphine patients. Buprenorphine patients need to learn the skills to stop drug thoughts before they become full-blown cravings.

Opioid addiction has both physical and behavioral dimensions. As a result, a clinical partnership consisting of a physician, counselor and other supportive treatment providers is an ideal team approach. The addiction professionals should work to ensure the successful coordinated functioning of this partnership.