Module I

Introduction
Module I: Introduction

The 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 55-67. If the entire training package is being delivered, these slides should be omitted and the trainer(s) should end Module I after slide 53 and proceed 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).
Welcome participants and take care of housekeeping details such as location of restrooms, turning off cell phones, participate actively, etc.

Briefly describe the development of the Blending Team product, as well as the purpose of the training as described in the introduction to this manual.

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.

Reiterate that throughout the training, the term “patient” has been used to refer to the individual seeking treatment. This terminology reflects the medical 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.

Also reiterate that throughout the training, the term “medication” is used to refer to buprenorphine and buprenorphine/naloxone. This terminology again reflects the medical nature of buprenorphine treatment and underscores the difference between a drug of abuse and medication used for the treatment of opioid treatment and medically-assisted withdrawal.

Share the definition of “blend” based upon the Webster dictionary.

Reference:
Slide 3: NIDA/SAMHSA Blending Initiative

Developed in 2001 by the National Institute on Drug Abuse (NIDA) and the Substance Abuse and Mental Health Services Administration’s (SAMHSA) Center for Substance Abuse Treatment (CSAT), the **NIDA/SAMHSA Blending Initiative** is designed to meld science and practice together to improve substance use disorder treatment. The primary goal of this initiative is to develop methods for disseminating research findings that will accelerate the adoption and implementation of research-based drug abuse treatment into community-based practice.

Blending Products are designed to shorten the time that it takes scientific findings to become available in a usable way for frontline service providers. This is imperative for successful outcomes of clients in addiction treatment programs throughout the country.

---

Slide 4: Blending Team Members

Blending Teams are composed of NIDA-funded researchers, community-based substance abuse treatment practitioners and trainers from SAMHSA's Addiction Technology Transfer Center (ATTC) Network who work closely together to develop the NIDA/SAMHSA Blending Products.

**Note to the Trainer(s):** Acknowledge the members of the Blending Team who created this module. Note that the membership consisted of four ATTC representatives and three NIDA-funded researchers and community treatment providers.
Slide 5: Additional Contributors

Acknowledge additional contributors to the Blending Team product.

Slide 6: Goals for the Training

There are four primary objectives for this training:

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

Slide 7: Introductions

For smaller groups (20 or less): 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.

For larger groups: Personal introductions will take too much time to complete. Omit this slide and proceed by asking people to identify their role in the treatment system by raising their hand.

At minimum, ask:

Who is:
- A direct treatment provider
- A counselor
- A nurse
- A physician
- A social worker
- An administrator
- An educator
- Anyone that I missed?
<table>
<thead>
<tr>
<th>Slide 8:</th>
<th>So who are the participants in this endeavor?</th>
</tr>
</thead>
<tbody>
<tr>
<td>So now we will introduce the key participants who helped put these materials together.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 9:</th>
<th>An Introduction to SAMHSA/CSAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Center for Substance Abuse Treatment (CSAT) of the Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services (DHHS), was created in October 1992 with a congressional mandate to expand the availability of effective treatment and recovery services for alcohol and drug problems.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 10:</th>
<th>SAMHSA/CSAT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CSAT’s Mission:</strong></td>
<td></td>
</tr>
<tr>
<td>• To improve the lives of individuals and families affected by alcohol and drug abuse by promoting access to effective and cost-effective addiction treatment that reduces the health and social consequences of these disorders.</td>
<td></td>
</tr>
<tr>
<td>• CSAT’s initiatives and programs are based on research findings and the general consensus of experts in the addiction field that:</td>
<td></td>
</tr>
<tr>
<td>• the need for evidence-based treatment and recovery services is real;</td>
<td></td>
</tr>
<tr>
<td>• the need for a comprehensive system of services is real;</td>
<td></td>
</tr>
<tr>
<td>• because no single treatment approach is effective for all persons, CSAT supports the provision of treatment that is tailored to the needs of the individual.</td>
<td></td>
</tr>
<tr>
<td><strong>Read CSAT mission.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Highlight the importance of the research base in all of CSAT’s programming and educating the field about the advances of science to continually improve the quality of services provided.</strong></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 11:</th>
<th>The ATTC Network</th>
</tr>
</thead>
<tbody>
<tr>
<td>One of the major vehicles that SAMHSA has for ensuring that the workforce is adequately trained is the Addiction Technology Transfer Center (ATTC) Network.</td>
<td></td>
</tr>
</tbody>
</table>
Slide 12: The ATTC Network

Fourteen regional Centers and a National Office constitute the ATTC Network, which is dedicated to identifying and advancing opportunities for improving addiction treatment.

The vision of the ATTC Network is to unify science, education and services to transform the lives of individuals and families affected by alcohol and other drug addiction.

Serving the 50 United States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands and the Pacific Islands, the ATTC Network delivers cutting-edge knowledge and skills that develop a powerful workforce.

Slide 13: An Introduction to the National Institute of Drug Abuse

The National Institute on Drug Abuse (NIDA) was established in 1974. In October 1992, it became part of the National Institutes of Health (NIH), U.S. Department of Health and Human Services (DHHS).

Recent scientific advances have revolutionized our understanding of drug abuse and addiction, and have had dramatic implications for how to best prevent and treat addiction. The majority of these advances have been supported by NIDA.

Slide 14: The Mission of the National Institute on Drug Abuse

NIDA is not only seizing upon unprecedented opportunities and technologies to further the understanding of how drugs of abuse affect the brain and behavior, but is also working to ensure the rapid and effective transfer of scientific data to policy makers, drug abuse practitioners, other health care practitioners, and the general public. The scientific knowledge that is generated through NIDA-funded research is a critical element to improving the overall health of the Nation. The goal of NIDA is to ensure that science, not ideology or anecdote, forms the foundation for all of our Nation's drug abuse reduction efforts.
Slide 15: So what is this thing called the CTN?

To date, the efficacy of new treatments for drug addiction has been demonstrated primarily in specialized research settings, with somewhat restricted patient populations. This presents a problem when trying to apply these findings about new treatments into community-based treatment programs, which typically serve diverse populations. To address this problem, NIDA established the National Drug Abuse Treatment Clinical Trials Network (CTN).

Slide 16: NIDA’s Clinical Trials Network

The mission of the CTN is twofold:
- Conduct studies of behavioral, pharmacological, and integrated behavioral and pharmacological interventions to determine therapeutic effectiveness in rigorous, multisite clinical trials across a broad range of community-based treatment settings and diversified patient populations; and
- Transfer the research results to physicians, providers, and their patients to improve the quality of drug abuse treatment throughout the country using science as the vehicle.

Slide 17: CTN Node

The CTN comprises Nodes that are dispersed across the country. Each Node has one Regional Research Training Center (RRTC) and 5-10 affiliated community treatment programs (CTPs). CTN research is conducted in the CTPs. CTPs are chosen to participate in a given research protocol based on match between the study questions and requirements, and the populations served by the CTP. For instance, in the buprenorphine studies, a CTP could be chosen if they served an opioid dependent population from whom they could recruit study participants.
Slide 18: What Do We Know?

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.

This exercise also allows the trainer(s) to become familiar with the expectations of the group.

---

Slide 19: Buprenorphine Treatment: The Myths and the Facts (Transition Slide)

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.

---

Slide 20: Myth #1: Patients are still addicted

Fact: 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.
**Slide 21: Myth #2: Buprenorphine is simply a substitute for heroin or other opioids**

**Fact:** Buprenorphine is a replacement medication in that it prevents 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.

---

**Slide 22: Myth #3: Providing medication alone is sufficient treatment for opioid addiction**

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

**Note to the Trainer(s):** 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 other multidisciplinary addiction professionals.
Slide 23: Myth #4: Patients are still getting high

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

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

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

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

Slide 24: A Brief History of Opioid Treatment (Transition Slide)

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.
Slide 25: 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 allowed the use of narcotics for addiction treatment to only those opioid drugs approved by the U.S. Food and Drug Administration (FDA) for the detoxification or maintenance treatment of addiction. These drugs could only be dispensed by physicians in programs regulated by the Substance Abuse and Mental Health Services Administration (SAMHSA) and the U.S. Drug Enforcement Administration (DEA). These programs are usually called “methadone maintenance” or “opioid treatment programs (OTPs).”

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, levo-α-acetylmethadol (LAAM) or Orlaam (trade name), a synthetic opioid similar in structure to methadone, 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

- 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 26: A Brief History of Opioid Treatment

Define the Drug Addiction Treatment Act of 2000 (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 Laboratories 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.

Notes about Methadone:

Currently, there is significant controversy about potential harmful effects of methadone on cardiac conduction. Although several reports suggest that some patients receiving methadone are at increased risk for QTc prolongation and a potentially fatal arrhythmia (torsade de pointes; Maremmani et al., 2005; Pimentel & Mayo, 2008), others have not replicated these findings.
Most of the uncertainty is due to the lack of large controlled studies. Until large controlled studies become available, caution should prevail.

Currently, it is suggested that patients entering methadone therapy (MT) be screened for cardiac risk factors. An electrocardiogram (ECG), which is an electrical recording of the heart and is used in the investigation of heart disease, might be considered in new patients with a history of known heart disease or recent symptoms like unexplained seizures, exertional chest pain or discomfort, exertional shortness of breath, unexplained syncope or heart palpitations. During MT, an ECG evaluation might be considered before starting QT-prolonging medications (particularly psychotropic drugs in dually diagnosed patients). There is no consensus on when to perform an ECG during MT.

References:


The Drug Addiction Treatment Act of 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.
DATA 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 DEA places all drugs and medications 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.

DATA 2000 preempts individual state laws unless a state passed a new law before October 8, 2005.
**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 (e.g., medical care, employment and education, etc.).

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

Bullet #3: While originally limited to 30 patients for individual or group practices, the regulations were changed so that individual physicians (not groups), were limited to 30 for their first year. After gaining at least one year of experience, they can apply for an additional waiver that will allow them to increase their number of patients to 100.

The patient limits do not apply to opioid treatment programs (OTPs) that prescribe buprenorphine. However, OTPs must follow the same regulations as those set up for the provision of methadone.

*Note to the Trainer(s): 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 30: DATA 2000: Physician Qualifications

Summarize each bullet point.

ASAM – American Society of Addiction Medicine
AOA – American Osteopathic Association
AAAP – American Academy of Addiction Psychiatry
AMA – American Medical Association
APA – American Psychiatric Association

Slide 31: Approval of Buprenorphine and Buprenorphine/Naloxone

Prior to 2002, buprenorphine was only available in the United States 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 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. Office-based implementation requires that a physician complete the necessary training requirements and secure a waiver. Following one year of experience, they are allowed to treat up to 100 patients.

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. OTPs.
SAMHSA began a 3-year evaluation of DATA 2000 starting on the date of FDA approval (October 8, 2002).

Evaluation findings regarding the effectiveness of buprenorphine treatment for opioid dependence provided under the Waiver Program can be summarized as follows:

- Most prescribing physicians perceived buprenorphine to be effective, particularly for treatment of longer duration.
- Positive treatment outcomes were observed among patients treated in a variety clinical practice settings.
- Outcomes are consistent with the results of numerous clinical trials that have found buprenorphine to be effective in research contexts.
- Buprenorphine treatment appeared to be somewhat more effective for patients who were dependent on prescription opioids than for those primarily dependent on heroin.

In addition, the buprenorphine manufacturer is conducting a post-marketing risk management program.

Reference:

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)

So how significant is the problem of opioid use in the United States? Let’s look at some of the available statistics.
The National Survey on Drug Use and Health (NSDUH) 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.

Data from multiple NSDUH surveys indicate that rates of heroin use have been stable or have declined for most age groups. These data show that past year rates of heroin use did not significantly change in any measured age group during that same period. The exception is for 18-25 year olds, where the 2008 estimate was significantly higher than the 2003 estimate, with the highest level of usage among young adults aged 18-25 (SAMHSA, 2009).

Additional Information for the Trainer(s):
The National Drug Intelligence Center (U.S. Department of Justice) reports that although heroin use is stable, it could increase as more prescription narcotic abusers switch to heroin. Officials who were surveyed in treatment facilities throughout the country reported that many abusers of prescription opiates, such as OxyContin, Percocet, and Vicodin, eventually begin abusing heroin because it is typically cheaper and easier to obtain, and it provides a more intense high. Treatment officials also reported that once an individual switches from prescription opiates to heroin, he or she rarely switches back to exclusively abusing prescription opiates (National Drug Intelligence Center, 2007).

References:

According to the 2008 NSDUH, more than 3.8 million people over the age of 12 have used heroin at least one time. Approximately 453,000 (0.2%) reported past year heroin use and 213,000 (0.1%) reported past month heroin use (SAMHSA, 2009).

The number of heroin users that reported past month heroin use decreased from 338,000 in 2006 to 153,000 in 2007.

- Among high school students surveyed as part of the 2007 Centers for Disease Control and Prevention’s (CDC) Youth Risk Behavior Surveillance System (YRBSS), 2.3% have used heroin at least once during their lifetime.
- Approximately 0.5% of college students and 1.6% of young adults (ages 19-28) reported lifetime use of heroin (CDC, 2008).

References:


Recent concern has focused on opioid use among young people. Rates of heroin use are on the downturn among youth, however, rates of non-medical use of opioids have been steadily increasing.

The annual prevalence of heroin use among youth rose in the mid- and late 1990s, reaching peak levels in 1996 among 8th graders (1.6%), in 1997 among 10th graders (1.4%), and in 2000 among 12th graders (1.5%). Since those peak levels, heroin use has declined among students in all three grade levels to 0.7-0.09% (Johnston, O’Malley, Bachman, & Schulenberg, 2009).

However, for the general population over 12 years of age, recent data showed that 13.4% of individuals who reported new use of heroin in the past 13 to 24 months also met criteria for substance dependence (SAMHSA, Office of Applied Studies, 2008).

References:


Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (March 27, 2008). The NSDUH Report: Substance Use and Dependence Following Initiation Following Alcohol or Illicit Drug Use. Rockville, MD.
During the latter half of the 1990s, the annual number of heroin initiates rose to a level not reached since the late 1970s.

- In 1974, there were an estimated 246,000 heroin initiates.
- Between 1988 and 1994, the annual number of new users ranged from 28,000 to 80,000.
- Between 1995 and 2001, the number of new heroin users was consistently greater than 100,000.
- Between 2002 and 2007, the number of new heroin users ranged from 91,000 to 117,000.

In 2007, there were 106,000 first-time users of heroin aged 12 or older; the average age at first use of heroin was 21.8 years.

In 2008, there were 114,000 persons aged 12 or older who had used heroin for the first time within the past 12 months. The average age at first use among recent initiates aged 12 to 49 was 23.4 years in 2008. There were no significant changes in the number of initiates or in the average age at first use from 2007 to 2008. (SAMHSA, 2008)

The number of heroin initiates in 2008 was not significantly different from the number in 2002 (117,000) (SAMHSA, 2008).

References:


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

Prescription pain reliever use increased nearly fourfold in the decade between 1990 and 2000, and has continued to consistently increase.

In 2007, approximately 2.1% of Americans (5.2 million people) were currently using pain relievers nonmedically, and approximately 4.4 million people had used OxyContin for nonmedical purposes at least once in their lives (SAMHSA, 2009b).

In 2008, a small decline was noted in the percentage (1.9%) of individuals using pain relievers nonmedically; however this decline is not statistically significant (SAMHSA, 2009).

Overall, between 2004 and 2008, the percentage and the number of persons dependent on or abusing pain relievers increased from 0.6 to 0.7 percent and from 1.4 to 1.7 million (SAMHSA, 2009).

References:


The Drug Abuse Warning Network (DAWN) collects data from emergency departments (ED) 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.

In 2008, of 993,370 drug misuse/abuse ED visits, an estimated 200,666 were related to heroin. This is an increase from 2006 at which time 189,780 drug misuse/abuse ED visits were related to heroin.

One-third (33%) of the nonmedical use ED visits were related to medications that affect the central nervous system (CNS), such as prescription pain killers and sedatives. Among those, the most frequently mentioned were hydrocodone/combinations, oxycodone/combinations, and methadone.

According to the DAWN system, other opiates/opioids included, but were not limited to narcotic analgesics/combinations such as codeine combinations, hydrocodone combinations, methadone, morphine combinations, opium combinations, and oxycodone combinations.

Reference:

Slide 42: Non-Medical Users of Pain Relievers

Data from the 2008 NSDUH show that 2.2 million people, aged 12 or older, initiated nonmedical use of prescription pain relievers within the past year. This averages to approximately 6,000 initiates (new users) per day (SAMHSA, 2009).

Among youth aged 12 to 17, females were more likely than males to have used pain relievers non-medically in the past year, whereas males aged 18 to 25 and males aged 26 to 34 had higher rates than their female counterparts (SAMHSA, OAS, 2009).

Data from DAWN (SAMHSA, 2008) showed that ED visits involving hydrocodone/combinations increased 44% and oxycodone/combinations increased 56% from 2004 to 2006.

References:


Slide 43: Treatment Admissions for Opioid Addiction (Transition Slide)

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.

Note to the Trainer(s): In the next series of slides, trainers are encouraged to add slides containing state-specific data following each of the national data slides.
The Treatment Episode Data Set (TEDS) is part of SAMHSA’s Drug and Alcohol Services Information System (DASIS). TEDS is a compilation of data on the demographic and substance abuse characteristics of admissions to (and more recently, on discharges from) substance abuse treatment.

- Information from TEDS showed that admissions for primary opioid abuse increased from approximately 16% to 19% between 1997 and 2007.
- Admissions for other opioids have increased consistently since the late 1990s – 1.0% to 5.0% between 1997 and 2007.

Reference:

The TEDS also reported that, from 1997 to 2007, the number of persons who were admitted to treatment programs across the United States with a primary problem with opiates other than heroin increased from 16,274 to 90,516. The table shows the “primary drug” data for treatment admissions in 2007 by age breakouts for adolescents and young adults. Of the age categories shown on this slide, the highest percentage of treatment admissions are among young adults aged 20 to 24 for both heroin (14.5%) and other opiates (21.8%).

Reference:
Who Enters Treatment for Heroin Abuse?

- 68% male
- 53% non-Hispanic White; 22% Hispanic; 22% non-Hispanic Black
- 64% injected; 32% inhaled
- Average age at admission – 36 years
- 71% used heroin daily

In 2007, admissions for opiate abuse (primarily heroin) accounted for nearly one-fifth of all substance abuse treatment admissions.

Patients entering treatment were about 2/3 male (68%); just over half (53%) were non-Hispanic White, 22% were Hispanic, and 22% were non-Hispanic Black.

Two-thirds (64%) of patients seeking treatment used by injection, 32% inhaled, and 2% reported smoking.

Average age at admission was 36 years.

Nearly three quarters (71%) used heroin on a daily basis.

References:


Who Enters Treatment for Heroin Abuse?

- 51% of patients entering treatment for heroin abuse in 2007 had at least one prior treatment episode; 26% had 5+ prior episodes
- 20% had a treatment plan that included medication-assisted opioid therapy
- 65% reported secondary drug use:
  - cocaine – 51%
  - alcohol – 18%
  - marijuana – 11%

Approximately 1/2 (51%) of patients entering treatment for heroin abuse in 2007 had at least one prior treatment admission, and 26% of heroin admissions reported 5 or more previous treatment admissions.

Twenty-nine percent were seeking treatment that included medication-assisted opioid therapy.

Approximately 65% of heroin admissions reported secondary drug use. Most commonly reported were cocaine (51%), alcohol (18%), and marijuana (11%).

Reference:
In 2007, among those entering treatment for abuse of other opiates:

- 47% had at least one prior treatment admission; 9% reported 5 or more previous treatment admissions.
- slightly more than 1/2 (53%) were male.
- the great majority (88%) was non-Hispanic White; 4% Hispanic, and 4% non-Hispanic Black.
- about 72% took the drug orally; 16% inhaled; and 10% injected.
- 20% had a treatment plan that included medication-assisted opioid therapy.
- Average age at admission was 32 years.
- Approximately 63% reported secondary drug use; most commonly reported were alcohol (22%), marijuana (22%), and cocaine (18%).

References:


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.

References:


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 medical model (e.g., OTPs) 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 suggests 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: OTPs 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.

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.
DATA 2000 allows for a new treatment option. Opioid treatment will continue to be offered through opioid treatment programs as it has been in the past. DATA 2000 allows for treatment in physician offices, and expands beyond the structure in place for methadone. 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.

Review each bullet.
- Use of medications as a component of treatment can be important in helping the person 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 treatment may not available to treatment-seekers or many do not seek treatment at all.  
- Expanding treatment options can  
  - make treatment more attractive to people;  
  - expand access; and  
  - reduce stigma.

Note to the Trainer(s): 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.
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.

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 effect and withdrawal occurs if the amount of use is decreased or stopped.

Note to the 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. For further discussion of dependence versus addiction, please refer to Module II.

Buprenorphine represents an exciting addition to the available opioid treatment options.
Clinical trials have established the effectiveness of buprenorphine for the treatment of opioid addiction. The clinical studies have shown the following about buprenorphine:

Bullet #1: Patients on buprenorphine did as well as patients on a moderate dose of methadone (e.g., 60mg). However, 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).

Bullet #2: Patients on buprenorphine did as well as patients on a moderate dose of LAAM (70mg/70mg/85mg on a Monday/Wednesday/Friday schedule).

Note to the Trainer(s): LAAM is no longer being marketed in the United States due to safety concerns. This information is provided as evidence of efficacy of buprenorphine.

Bullet #3: Patients found that taking buprenorphine was a pleasant experience, which encouraged them to be compliant.

Bullet #4: When compared to placebo-plus-counseling, 3/4 of the patients receiving buprenorphine and counseling were still in treatment after one year. None of the placebo patients were retained.
Slide 58: Buprenorphine Research Outcomes, Continued

References: Bullet#1


Reference: Bullet #2


Reference: Bullet #3


Reference: Bullet #4

Slide 59: The Role of Buprenorphine in Opioid Treatment

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

The effects of the medication at lower doses are virtually the same as that of full agonists. However, as the dose is increased, the effects level out for buprenorphine (especially respiratory suppression), whereas 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.

Slide 60: 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 complete knowledge of the entire treatment process.
The patient selection process includes determining if the patient is addicted to opioids, if buprenorphine is the optimal medication for the patient, and if an office or a clinic is the optimal site for treatment. Once a thorough assessment is conducted, the physician can determine if addiction to opioids is present using DSM-IV-TR criteria. Treatment success is enhanced by good patient assessment and selection. Ten simple criteria can help to guide patient assessments of appropriateness of office-based buprenorphine treatment.

**Read criteria aloud and discuss as follows:**

**Bullet #1:** Is the patient addicted to opioids? Treatment with buprenorphine will generally be conducted with individuals who meet criteria for opioid addiction. However, a physician may consider buprenorphine treatment for a patient with problematic opioid use that has not progressed to addiction. An example of this might be if, in the physician’s clinical judgment, the patient has a high risk of progression to addiction or is injecting opioids. Additional candidates include patients with a history of good response to buprenorphine who have had their medication discontinued (perhaps due to incarceration) and are now at risk of relapse (released from prison).

**Bullet #2:** Is the patient aware of other available treatment options? Even if a patient is addicted to opioids and a suitable candidate for buprenorphine treatment, he/she may not be best treated in an office setting. 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.

Co-occurring disorders (other substance use disorders, psychiatric disorders, or medical conditions) may lead to the decision to not treat the individual in an office-based setting, since that office cannot provide the other needed services. For example, a physician’s office may not be able to provide psychotherapy needed by a patient with a severe personality disorder or the monitoring needed for a patient with AIDS.
<table>
<thead>
<tr>
<th>Slide 61: Patient Selection: Assessment Questions, Continued</th>
</tr>
</thead>
</table>

**Bullet #3:** Does the patient understand the risks, benefits, and the limitations of buprenorphine treatment? The patient needs to be conscious/aware of what buprenorphine **WILL** and **WILL NOT** do. Are there indications to suggest that the patient is reliable (i.e., steady employment, showing up on time for appointments, taking other medications as prescribed)? Have cost issues been explained and compared with other treatment options?

**Bullet #4:** Is the patient expected to be reasonably compliant? Is the patient in a situation where he/she can be expected to attend sessions as required, manage the medication appropriately, and take it 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).

**Bullet #5:** Is the patient expected to follow safety procedures? Can the patient manage his/her medication appropriately (e.g., keep it away from children in the home), and take it as prescribed?
**Slide 62: Patient Selection: Assessment Questions**

**Read the remaining criteria aloud.**

**Bullet #1:** Is the patient psychiatrically stable? Do they need to be stabilized first? Do they need treatment for co-occurring disorders?

**Additional Information for Trainer(s):** According to the Buprenorphine Treatment Guidelines (TIP 40), the presence and severity of co-morbid psychiatric conditions must be assessed prior to initiating buprenorphine treatment, and a determination made whether referral to specialized behavioral health services is necessary. The psychiatric disorders most commonly encountered in patients addicted to opioids are other substance abuse disorders, depressive disorders, posttraumatic stress disorder, substance-induced psychiatric disorders, and antisocial and borderline personality disorder.

Reference:


**Bullet #2:** Is the patient taking other medications that may interact with buprenorphine? Other medications may include naltrexone, benzodiazepines, or other sedative hypnotics. 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.

**Bullet #3:** Are the psychosocial circumstances of the patient stable and supportive? What stressors, relationships, supports, living situation, etc. does the patient have that can contribute to or undermine the success of the recovery plan?
Read the remaining criteria aloud.

Bullet #4: Is the patient interested in office-based buprenorphine treatment? Even if a 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 determine the most appropriate setting.

Bullet #5: Are there resources available in the office to provide appropriate treatment? Has a comprehensive recovery plan been developed and coordinated between the psychosocial treatment team and the physician? What additional resources need to be added in order to facilitate coordinated care?

If resources are not available in the physician’s office, attempts should be made to work in cooperation with a local substance abuse treatment program.
The multidisciplinary addiction professional should be aware of the following factors and inform the physician of any changes or arising information.

**Read factors aloud.**

**Bullet #1:** Patients taking high doses of benzodiazepines, alcohol or other CNS depressants. The use of benzodiazepines in combination with 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 while taking buprenorphine.

**Bullet #2:** Significant psychiatric co-morbidity. 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:** Multiple previous opioid addiction treatment episodes with frequent relapse during those episodes (may also indicate a perfect candidate). Again not exclusionary, but understanding what led to previous treatment failures may help to shape the current recovery plan. Changing to a new treatment, rather than continuing an unsuccessful one, may work well for them.

**Bullet #4:** Non-response or poor response to buprenorphine treatment in the past.
Slide 64: Issues Requiring Consultation with the Physician

Bullet #1: High level of dependence on high doses of opioids. 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 recovery plan.

Bullet #2: High risk for relapse to opioid use. For example, living in a place where others are consuming heroin or other opioids. This may be an issue of timing; the patient may need a more structured environment (e.g., residential care), or they may be saying that they are not ready to enter treatment.

Bullet #3: Pregnancy - 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. For additional information regarding buprenorphine and pregnant women, refer to Modules IV and VI.

Bullet #4: Poor social support system. A poor social support system is not ideal for any recovery process. The treatment team should work with the patient to develop a plan to help the person strengthen and engage effective support.
Slide 65: Issues Requiring Consultation with the Physician

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

Bullet #1: Human immunodeficiency virus (HIV) and sexually transmitted diseases (STDs): Of particular concern for opioid-addicted patients are issues regarding HIV/AIDS and hepatitis C virus (HCV). Multidisciplinary addiction professionals should ask patients about their HIV and HCV status, and when they were last tested. If patients have not been tested recently, they should be referred to a physician or given information on how to locate a testing site. If patients are positive for HIV or HCV, they should be asked about the medications they are taking and encouraged to comply with their medication regimen. The treatment team should communicate any new information to the physician regarding the patient’s medications in order to monitor potential medication interactions with buprenorphine.

Additional Information for Trainer(s): Buprenorphine should be used cautiously in combination with HIV antiretroviral medications that may inhibit, induce, or be metabolized by the same liver enzyme system involved with the buprenorphine (cytochrome P450 3A4) enzyme system. Protease inhibitors inhibit cytochrome P450 3A4. Metabolism of buprenorphine and/or the antiretroviral medications may be altered when they are combined. Therefore, therapeutic blood levels may need to be monitored. Note that this is a precaution, not a contraindication; successful treatment of addiction with buprenorphine in HIV-infected patients has been well demonstrated (Carrieri et al., 2000).

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

Reference:
Bullet #1 through Bullet #3: Use of alcohol, sedative-hypnotics, and stimulants: As was previously mentioned, the combination of other drugs should be carefully evaluated, especially given the fact that reported overdoses have been related to a combination of CNS depressants and buprenorphine (Reynaud, Petit, Potard, & Courty, 1998; Reynaud, Tracqui, Petit, Potard, & Courty, 1998).

Bullet #4: Other drugs: Buprenorphine is a treatment for opioid addiction, not other substance use disorders. Addiction to other drugs (e.g., stimulants or sedatives) is common among opioid-addicted patients and may interfere with overall treatment adherence. Patients should be encouraged to abstain from the use of all non-prescribed drugs while receiving buprenorphine treatment. However, although a predictor of poor adherence, use of other drugs IS NOT an absolute contraindication to buprenorphine treatment. They may need to be referred for more intensive treatment.

References:

Slide 67: General Counseling Issues

Bullet #1: Confidentiality: Care should be taken to execute appropriate professional service agreements and releases of information in order to comply with confidentiality and HIPAA regulations.

Bullet #2: Urine toxicology testing (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. 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.

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 #3: Working with, not against, the medication: 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.
**Slide 67: General Counseling Issues, continued**

**Bullet #4:** 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.

**Bullet #5:** Supporting medication maintenance: Patients who are being maintained on buprenorphine need ongoing counseling to reduce the risk of relapse, and assist them in addressing ongoing psychosocial, mental health and other substance use issues.

**Bullet #6:** 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.