Module I Introduction



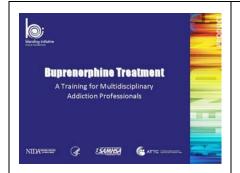
Module I: Introduction

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).



Slide 1: Buprenorphine Treatment: A Training for Multidisciplinary Addiction Professionals

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.



Slide 2: NIDA/SAMHSA Blending Initiative

Share the definition of "blend" based upon the Webster dictionary.

Reference:

Blend. (2010). In *Merriam-Webster Online Dictionary*. Retrieved March 16, 2010, from http://www.merriam-webster.com/dictionary/blend









NIDA/SAMHSA Blending Initiative Developed in 2001 by NIDA and SAMHSA/CSAT, the initiative was designed to meld science and practice to improve addiction treatment. "Blending Teams," include staff from CSAT's ATTCs and NIDA researchers who develop methods for dissemination of research results for adoption and implementation into practice. Scientific findings are able to reach the frontline service providers treating people with substance use disorders. This is imperative to the success of drug abuse treatment programs throughout the country.

Slide 3: NIDA/SAMHSA Blending Initiative

Slide 3

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.

Blending Team Members Leslie Amass, Ph.D. – Friends Research Institute, Inc. Greg Brigham, Ph.D. – CTN Ohio Valley Node Glenda Clare, M.A. – Central East ATTC Gail Dixon, M.A. – Southern Coast ATTC Beth Finnerty, M.P.H. – Pacific Southwest ATTC Thomas Freese, Ph.D. – Pacific Southwest ATTC Eric Strain, M.D. – Johns Hopkins University ATTC representative ATTC representative ATTC representative NEDA researcher/Community Greatment provider

Slide 4: Blending Team Members

Slide 4

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.



Additional Contributors

Judith Martin, M.D. – 14th Street Clinic, Oakland, CA Michael McCann, M.A. – Matrix Institute on Addictions Jeanne Obert, MFT, MSM – Matrix Institute on Addictions Donald Wesson, M.D. – Independent Consultant The ATTC National Office The O.A.S.I.S. Clinic

- developed and granted permission for inclusion of the video.
- "Put Your Smack Down! A Video about Buprenorphine"

Slide 5: Additional Contributors

Acknowledge additional contributors to the Blending Team product.

Slide 5



Goals for the 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 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 6

Introduction

- Please introduce yourself:
- Your name and the organization in which you work
- Experience with opioid treatment
- Your expectations for this training

Slide 7: Introductions

<u>For smaller groups (20 or less):</u> 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.

<u>For larger groups</u>: 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.



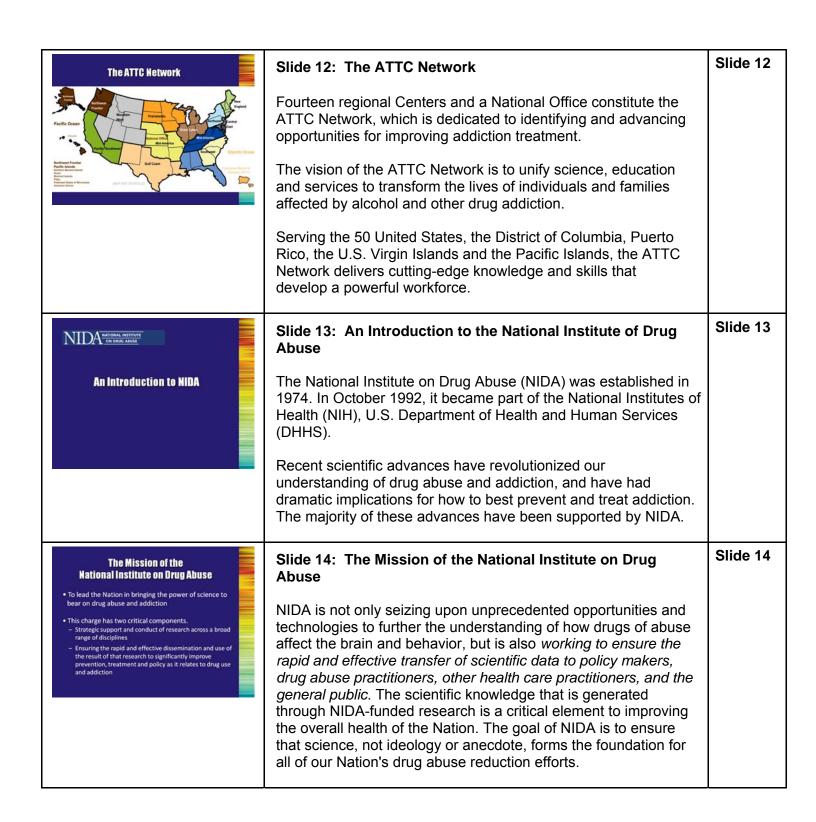
Who is:

- A direct treatment provider
- A counselor
- A nurse
- A physician
- A social worker
- An administrator
- An educator
- Anyone that I missed?





So who are the participants in this endeavor?	Slide 8: So who are the participants in this endeavor? So now we will introduce the key participants who helped put these materials together.	Slide 8
An Introduction to SAMHSA/CSAT	Slide 9: An Introduction to SAMHSA/CSAT 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.	Slide 9
SAMHSA/CSAT CSAT's Mission: To improve the lives of individuals and families affected by alcohol and drug abuse by ensuring access to clinically sound, cost-effective addiction treatment that reduces the health and social costs to our communities and the nation. CSAT's initiatives and programs are based on research findings and the general consensus of experts in the addiction field that, for most individuals, treatment and recovery work best in a community-based, coordinated system of comprehensive services. Because no single treatment approach is effective for all persons, CSAT supports the nation's effort to provide multiple treatment modalities, evaluate treatment effectiveness, and use evaluation results to enhance treatment and recovery approaches.	Slide 10: SAMHSA/CSAT Read CSAT mission. 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.	Slide 10
ATTC Information and administration of particular to perform two. The ATTC Network	Slide 11: The ATTC Network One of the major vehicles that SAMHSA has for ensuring that the workforce is adequately trained is the Addiction Technology Transfer Center (ATTC) Network.	Slide 11



So what is this thing called the CTN?	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 15
NIDA's Glinical Trials Network Established in 1999 NIDA's largest initiative to blend research and clinical practice by bringing promising therapies to community treatment providers Network of 16 University-based Regional Research and Training Centers (RRTCs) involving 240 Community Treatment Programs (CTPs) in 23 states, Washington D.C., and Puerto Rico	 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 16
Community Treatment Program Treatment Program Treatment Program Treatment Program	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 17



MYTH #2: Buprenorphine is simply a substitute for heroin or other opioids FACT: Buprenorphine is a replacement medication; it is not simply a substitute / Buprenorphine is a legally prescribed medication, not illegally obtained. / Buprenorphine is a medication taken sublingually, a very safe route of administration. / Buprenorphine allows the person to function normally.

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

Slide 21

<u>Fact:</u> 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: Buprenorphine is an important treatment option. However, the complete treatment package must include other elements, as well.

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

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

<u>Fact:</u> 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.



MYTH #4: Patients are still getting high FACT: When taken sublingually, buprenorphine is slower acting, and does not provide the same "rush" as heroin. ✓ Buprenorphine has a ceiling effect resulting in lowered experience of the euphoria felt at higher doses.	Slide 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 23
A Brief History of Opioid Treatment	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 24

A Brief History of Opioid Treatment

- 1964: Methadone is approve
- 1974: Narcotic Treatment Act limits methadone treatment to specifically licensed Opioid Treatment Programs (OTPs).
- 1984: Naltrexone is approved, but has continued to be rarely used (approved in 1994 for alcohol addiction)
- 1993: LAAM is approved (for non-pregnant patients only), but is underutilized.

Slide 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

- 2000: Drug Addiction Treatment Act of 2000 (DATA 2000) expands the clinical context of medicationassisted 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 cardiacrelated 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.



Slide 26: A Brief History of Opioid Treatment, Continued Slide 26 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: Maremmani, I., Pacini, M., Cesaroni, C., Lovrecic, M., Perugi, G., & Tagliamonte, (2005), QTc interval prolongation in patients on long-term methadone maintenance therapy. European Addiction Research, 11, 44-49. Pimentel, L. & Mayo, D. (2008). Chronic methadone therapy complicated by torsades de pointes: A case report. Journal of Emergency Medicine, 34(3), 287-290. Slide 27 Slide 27: Understanding DATA 2000 (Transition Slide) The Drug Addiction Treatment Act of 2000 (DATA 2000) changed the available options for providing treatment for opioid Understanding DATA 2000 addiction and is critical in the discussion of buprenorphine and how it can be used.

Drug Addiction Treatment Act of 2000 (DATA 2000)

- Expands treatment options to include both the general health care system and opioid treatment programs.
- Expands number of available treatment slots
- Allows opioid treatment in office settings
- Sets physician qualifications for prescribing the medication

Slide 28: Drug Addiction Treatment Act of 2000 (DATA 2000)

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.

DATA 2000: Physician Qualifications

Physicians mus

- Be licensed to practice by his/her state
- Have the capacity to refer patients for psychosocial treatment
- Limit number of patients receiving buprenorphine to 30 patients for a least the first year
- File for a new waiver after first year to increase their limit to 100 patients.
- Be qualified to provide buprenorphine and receive a license waiver

Slide 29: DATA 2000: Physician Qualifications

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

Bullet #2: Psychosocial treatment may include counseling and ancillary services (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 <u>do not apply</u> 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.



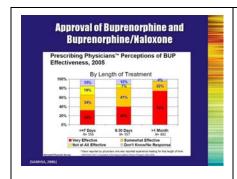


Slide 30 DATA 2000: Slide 30: DATA 2000: Physician Qualifications **Physician Qualifications** Summarize each bullet point. . Board certified in Addiction Psychiatry Certified in Addiction Medicine by ASAM or AOA Served as Investigator in buprenorphine clinical trials Completed 8 hours of training by ASAM, AAAP, AMA, AOA, APA (or other organizations that may be designated by Health and Human Services) ASAM – American Society of Addiction Medicine AOA – American Osteopathic Association Training or experience as determined by state medical licensing board AAAP – American Academy of Addiction Psychiatry Other criteria established through regulation by Health and Human Services AMA – American Medical Association APA – American Psychiatric Association Slide 31 **Approval of Buprenorphine and** Slide 31: Approval of Buprenorphine and Buprenorphine/Naloxone **Buprenorphine/Naloxone** U.S. FDA approved buprenorphine (marketed as as Suboxone*) for opioid addiction treatment on Prior to 2002, buprenorphine was only available in the United October 8, 2002. States in an injectable form and was only approved for the Product launched in U.S. in March 2003 Interim rule changes to federal regulation (42 CFR) treatment of pain. Part 8) on May 22, 2003 enabled Opioid Treatment Programs (specialist clinics) to offer buprenorphine 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.

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.

When the regulations went into effect in 2002, the medication was only approved for prescription in physicians' offices. Office-based implementation requires that a <u>physician complete the necessary training requirements and secure a waiver</u>. Following one year of experience, they are allowed to treat up to 100

patients.



Slide 32: Approval of Buprenorphine and Buprenorphine/Naloxone

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 postmarketing risk management program.

Reference:

Westat and The Avista Group. (2006). *The SAMHSA evaluation of the impact of the DATA waiver program. Final summary report* (Task Order 277-00-6111). Rockville, MD: Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration.



Slide 32



Slide 33: Only physicians can prescribe the medication. However, the entire treatment system should be engaged.

Read slide aloud.



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

- Manage physical withdrawal symptoms
- Understand the behavioral and cognitive changes resulting from drug use
- · Achieve long-term changes and prevent relapse
- Establish ongoing communication between physician and community provider to ensure coordinated care
- Engage in a flexible treatment plan to help them achieve recovery

Slide 34: 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

Slide 35: 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.

Slide 34





Slide 36: Rates of Current Heroin Use

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:

Substance Abuse and Mental Health Services Administration. (2009). *Results from the 2008 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-36, HHS Publication No. SMA 09-4434). Rockville, MD.

National Drug Intelligence Center. (2007). *National Drug Threat Assessment 2008.* (Document ID: 2007-Q0317-003). Washington, DC: U.S. Department of Justice







Who Uses Heroin? Individuals of all ages use heroin: • More than 3.8 million Us residents aged 12 and older have used heroin at least once in their lifetime. • Heroin use among high school students is a particular problem. Slightly more than 2% percent of US high school seniors used heroin at least once during their lifetime. • Approximately 1.6% of young adults (ages 19-28) reported lifetime use

Slide 37: Who Uses Heroin?

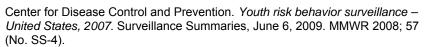
According to the 2008 NSDUH, more than 3.8 million people over the age of 12 have used heroin at least one time. Approximately 453,000 (0.2%) reported past year heroin use and 213,000 (0.1%) reported past month heroin use (SAMHSA, 2009).

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:

Substance Abuse and Mental Health Services Administration. (2009). *Results from the 2008 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-36, HHS Publication No. SMA 09-4434). Rockville, MD.







Prevalence of Use Rates of heroin use are declining among youth 8th grade use peaked in 1996 10th grade use peaked in 1997 12th grade use peaked in 2000 Rates of non-medical use of opioids are increasing Rates in all ages peaked in 2007 Rates highest in 18-25 year olds

Slide 38: Prevalence of Use

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-.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:

Johnston, L. D., O'Malley, P. M., Bachman, J. G., & Schulenberg, J. E. (2009). *Monitoring the Future national survey results on drug use, 1975-2008. Volume I: Secondary school students* (NIH Publication No. 09-7402). Bethesda, MD: National Institute on Drug Abuse.

Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (February 5, 2009). *The NSDUH Report: Trends in Nonmedical Use of Prescription Pain Relievers: 2002 to 2007.* Rockville, MD.

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,





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 uses was consistently greater than 100,000.
- Between 2002 and 2008, the number of new heroin users ranged from 91,000 to 114,000.

AND DESCRIPTION OF THE PERSON NAMED IN COLUMN

Slide 39: 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.
- 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:

Substance Abuse and Mental Health Services Administration, Office of Applied Studies (2008). Results from the 2007 National Survey on Drug Use and Health: National Findings (NSDUH Series H-34, DHHS Publication No. SMA 08-4343). Rockville, MD.



Slide 39

Substance Abuse and Mental Health Services Administration. (2009). *Results from the 2008 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-36, HHS Publication No. SMA 09-4434). Rockville, MD.

Cither Opioia Use in a National Survey Population According to the 2007 National Survey on Drug Use and Health: An estimated 6.9 million persons (2.8% of the U.S. population aged 12 or older) were currently using certain prescription drugs nonmedically. An estimated 5.2 million were current users of pain relievers for nonmedical purposes. Approximately 4.4 million persons had used OxyContin nonmedically at least once in their lifetime. Hon-medical pain reliever incidence increased from 1990 (628.000 initiates) to 2007, when there were 2.1 million new users.

Slide 40: *Other Opioid* Use in a Household Survey Population

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

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

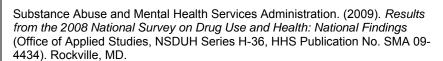
In 2007, approximately 2.1% of Americans (5.2 million people) were currently using pain relievers nonmedically, and approximately 4.4 million people had used OxyContin for nonmedical purposes at least once in their lives (SAMHSA, 2009b).

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:

Substance Abuse and Mental Health Services Administration, Office of Applied Studies (2008). *Results from the 2007 National Survey on Drug Use and Health: National Findings* (NSDUH Series H-34, DHHS Publication No. SMA 08-4343). Rockville, MD.



Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (2009). *The NSDUH Report: Trends in Nonmedical Use of Prescription Pain Relievers: 2002 to 2007.* Rockville, MD.



Emergency Department Visits Related to Heroin/Other Opioids According to the Drug Abuse Warning Network - 2004-2008: *An estimated 200,666 drug misuse/abuse ED visits were related to heroin. *One-third (33%) of nonmedical use ED visits were related to Central Nervous System (CNS) agents. *Among CNS agents, the most frequent drugs were opiates/opioid analgesics, specifically: - Hydrocodone/combinations (22,912 visits) - Oxycodone/combinations (44,489 visits) - Methadone (23,498 ED visits)

Slide 41: Emergency Department Visits Related to *Heroin and Other Opioids*

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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:

Drug Abuse Warning Network, 2004–2008: Selected Tables of National Estimates of Drug-Related Emergency Department Visits. Rockville, MD: Office of Applied Studies, SAMHSA, 2009



New Non-Medical Users of Pain Relievers In 2008 – 2.2 million new non-medical users (a decline from 2.5 million in 2003, but still a lot!) 6,000 new users per day Among youth aged 12-17, females more likely to use non-medically Among young adults aged 18-25, males more likely to use non-medically

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:

Substance Abuse and Mental Health Services Administration, Office of Applied Studies. *Drug Abuse Warning Network, 2006: National Estimates of Drug-Related Emergency Department Visits.* DAWN Series D-30, DHHS Publication No. (SMA) 08-4339, Rockville, MD, 2008.

Substance Abuse and Mental Health Services Administration. (2009). *Results from the 2008 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-36, HHS Publication No. SMA 09-4434). Rockville, MD.

Slide 43

Slide 42

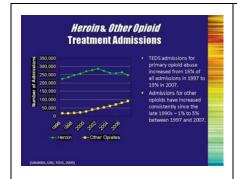


Slide 43: Treatment Admissions for Opioid Addiction (Transition Slide)

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.





Slide 44: Heroin and Other Opioid Treatment Admissions

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.

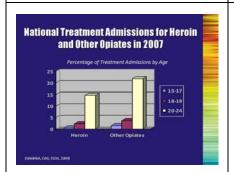
Reference:

Substance Abuse and Mental Health Services Administration, Office of Applied Studies. *Treatment Episode Data Set (TEDS). Highlights - 2007. National Admissions to Substance Abuse Treatment Services*, DASIS Series: S-45, DHHS Publication No. (SMA) 09-4360, Rockville, MD, 2009.



Slide 45

Slide 44



Slide 45: National Treatment Admissions for Heroin and Other Opiates in 2007

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:

Substance Abuse and Mental Health Services Administration, Office of Applied Studies. *Treatment Episode Data Set (TEDS). Highlights - 2007. National Admissions to Substance Abuse Treatment Services*, DASIS Series: S-45, DHHS Publication No. (SMA) 09-4360, Rockville, MD, 2009.



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

Slide 46: Who Enters Treatment for *Heroin* Abuse?

- 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:

Substance Abuse and Mental Health Services Administration, Office of Applied Studies. *Treatment Episode Data Set (TEDS). Highlights - 2007. National Admissions to Substance Abuse Treatment Services*, DASIS Series: S-45, DHHS Publication No. (SMA) 09-4360, Rockville, MD, 2009.





Slide 47

Slide 46

Who Enters Treatment for HeroinAhuse? • 51% of patients entering treatment for heroin abuse primary heroin abuse in 2007 had at least one prior treatment episode; 26% had 5+ prior episodes • 29% had a treatment plan that included medication-assisted opioid therapy • 65% reported secondary drug use - cocaine – 51% - alcohol – 18% - marijuana- 11%

Slide 47: Who Enters Treatment for Heroin Abuse?

- 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:

Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (August 27, 2009). *The TEDS Report: Heroin and Other Opiate Admissions to Substance Abuse Treatment*. Rockville, MD.





Slide 48: Who Enters Treatment for Other Opioid Abuse?

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

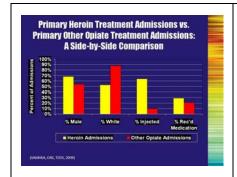
- 47% had at least one prior treatment admission; 9% reported 5 or more previous treatment admissions.
- slightly more than 1/2 (53%) were male.
- the great majority (88%) was non-Hispanic White; 4% Hispanic, and 4% non-Hispanic Black.
- about 72% took the drug orally; 16% inhaled; and 10% injected.
- 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:

Substance Abuse and Mental Health Services Administration, Office of Applied Studies. *Treatment Episode Data Set (TEDS). Highlights - 2007. National Admissions to Substance Abuse Treatment Services*, DASIS Series: S-45, DHHS Publication No. (SMA) 09-4360, Rockville, MD, 2009.







Slide 49: Primary Heroin Treatment Admissions vs. Primary Other Opioid Treatment Admissions: A Side-by-Side Comparison

Slide 49

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.

huse and Mental Health Services Administration, Office of Applied



Substance Abuse and Mental Health Services Administration, Office of Applied Studies. *Treatment Episode Data Set (TEDS). Highlights - 2007. National Admissions to Substance Abuse Treatment Services*, DASIS Series: S-45, DHHS Publication No. (SMA) 09-4360, Rockville, MD, 2009a.

References:

Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (August 27, 2009). *The TEDS Report: Heroin and Other Opiate Admissions to Substance Abuse Treatment*. Rockville, MD.

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

Slide 50: Four Reasons for Not Entering Opioid Treatment

The above information clearly indicates that opioid use has been increasing, and that a large number of people are seeking treatment for opioids. Data have also been collected that indicate that there are many more users of heroin than people seeking and/or receiving treatment. This raises the question: "Why are some people not entering treatment?"

- #1: The current treatment system involves either a 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.



Slide 51: N.I.M.B.Y. Syndrome

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.

A Need for Alternative Options Move outside traditional structure to: - Attract more patients into treatment - Expand access to treatment - Reduce stigma associated with treatment Buprenorphine is a potential vehicle to bring about these changes. Module I - Summary

Slide 52: A Need for Alternative Options

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.

Slide 54: Transition Slide

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.

Slide 54

Slide 52

Slide 53



- 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

Slide 53: Module I - Summary

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Review of Opioid Pharmacology, Buprenorphine Treatment, and the Role of the Multidisciplinary Treatment Team	Slide 55: 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.	Slide 55
Opioid Addiction and the Brain Opioids attach to specific receptors in the brain called mu receptors. Activation of these receptors causes a pleasure response. Repeated stimulation of these receptors creates a tolerance – requiring more drug for same effect.	 Slide 56: Opioid Addiction and the Brain First, here are a few basic facts about opioids and how they affect the brain: Opioids bind to receptors in the brain that are specifically designed for them. Once opioids bind to these receptors, they cause an intense euphoric rush, which is experienced as extremely pleasurable. With repeated administration of the drug, the body begins to adapt, and tolerance develops. This means that it requires more of the drug to get the same affect and withdrawal occurs if the amount of use is decreased or stopped. Note to 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. 	Slide 56
Buprenorphine: An Exciting New Option	Slide 57: Buprenorphine: An Exciting New Option Buprenorphine represents an exciting addition to the available opioid treatment options.	Slide 57

Buprenorphine Research Outcomes

- Buprenorphine is as effective as moderate doses of methadone picture et al., 1999; Johnson, Inflier, 8 Tookda, 1997; Ling et al., 1996;
- Buprenorphine is as effective as moderate doses of LAAM (Interconnect al., 2000).
- Buprenorphine's partial agonist effects make it mildly reinforcing, encouraging medication compliance (1844) 1990.
- After a year of buprenorphine plus counseling, 75% of patients retained in treatment compared to 0% in a placebo-plus-counseling condition (Make et al., 2003)

Slide 58: Buprenorphine Research Outcomes

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

Slide 58

References: Bullet#1

Fischer, G., Gombas, W., Eder, H., Jagsch, R., Peternell, A., Stuhlinger, G., ... Kasper, S. (1999). Buprenorphine versus methadone maintenance for the treatment of opioid dependence. *Addiction*, *94*(9), 1337-1347.

Johnson, R. E., Jaffe, J. H., & Fudala, P. J. (1992). A controlled trial of buprenorphine treatment for opioid dependence. *Journal of the American Medical Association*, 267, 2750–2755.

Schottenfeld, R. S., Pakes, J. R., Oliveto, A., Ziedonis, D., & Kosten T. R. (1997). Buprenorphine vs methadone maintenance treatment for concurrent opioid dependence and cocaine abuse. *Archives of General Psychiatry*, *54*, 713–720.

Strain, E. C., Stitzer, M. L., Liebson, I. A., & Bigelow, G. E. (1994). Comparison of buprenorphine and methadone in the treatment of opioid dependence. *American Journal of Psychiatry*, *151*, 1025–1030.

Reference: Bullet #2

Johnson, R. E., Chutuape, M. A., Strain, E. C., Walsh, S. L., Stitzer, M. L., & Bigelow, G. E. (2000). A comparison of levomethadyl acetate, buprenorphine, and methadone for opioid dependence. *New England Journal of Medicine*, *343*(18), 1290-1297. Reference: Bullet #3

Ling, W., Charuvastra, C., Collins, J. F., Batki, S., Brown, L. S., Jr., Kintaudi, P., ... Segal, D. (1998) Buprenorphine maintenance treatment of opiate dependence: A multicenter, randomized clinical trial. *Addiction*, *93*, 475–486.

Reference: Bullet #4

Kakko, J., Svanborg, K., Kreek, M., & Heilig, M. (2003). 1-year retention and social function after buprenorphine-assisted relapse prevention treatment for heroin dependence in Sweden: A randomised, placebo-controlled trial. *The Lancet*, *361*(9358), 662-668.

The Role of Buprenorphine in Opioid Treatment Partial Opioid Agonist Produces a ceiling effect at higher doses Has effects of typical opioid agonists—these effects are dose dependent up to a limit Binds strongly to opiate receptor and is long-acting Safe and effective therapy for opioid maintenance and detoxification

Slide 59: The Role of Buprenorphine in Opioid Treatment

Slide 59

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.

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

Slide 60: Patient Selection

Slide 60

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.

Patient Selection Assessment Questions

- Is the patient addicted to opioids?
- Is the patient aware of other available treatment options?
- Does the patient understand the risks, benefits, and limitations of buprenorphine treatment?
- Is the patient expected to be reasonably compliant?
- Is the patient expected to follow safety procedures?

Slide 61: Patient Selection: Assessment Questions

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.



Slide 61: Patient Selection: Assessment Questions, Continued

Slide 61

Bullet #3: Does the patient understand the risks, benefits, and the limitations of bu0prenorphine 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?

Patient Selection: Assessment Questions

- Is the patient psychiatrically stable?
- Is the patient taking other medications that may interact with buppenorphine?
- Are the psychosocial circumstances of the patient stable and supportive?
- Is the patient interested in office-based buprenorphine treatment?
- Are there resources available in the office to provide appropriate treatment?

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:

Center for Substance Abuse Treatment. *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction.* Treatment Improvement Protocol (TIP) Series 40. DHHS Publication No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004.

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?





Slide 62: Patient Selection: Assessment Questions, Continued

Slide 62



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.

Issues Requiring Consultation with the Physician

- Dependence upon high doses of benzodiazepines or other CNS depressants
- · Significant psychiatric co-morbidity
- Multiple previous opioid treatment episodes with frequent relapse

Slide 63: Issues Requiring Consultation with the Physician

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.



Issues Requiring Consultation with the Physician

- · High level of dependence on high doses of opioids
- High risk for relapse based on psychosocial or environmental conditions
- Pregnancy
- · Poor support system

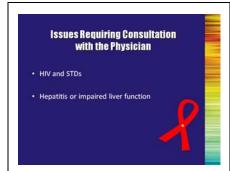
Slide 64: Issues Requiring Consultation with the Physician

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:

Carrieri, M. P., Vlahov, D., Dellamonica, P., Gallais, H., Lepeu, G., Spire, B., & Obadia, Y. (2000). Use of buprenorphine in HIV-infected injection drug users: Negligible impact on virologic response to HAART. The Manif-2000 Study Group. *Drug and Alcohol Dependence, 60*(1), 51–54.







Issues Requiring Consultation with the Physician

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

Slide 66: Issues Requiring Consultation with the Physician

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:

Reynaud, M., Petit, G., Potard, D., & Courty, P. (1998). Six deaths linked to concomitant use of buprenorphine and benzodiazepines. *Addiction*, *93*(9), 1385–1392.

Reynaud, M., Tracqui, A., Petit, G., Potard, D., & Courty, P. (1998). Six deaths linked to misuse of buprenorphine-benzodiazepine combinations. *American Journal of Psychiatry*, *155*(3), 448–449.





General Counseling Issues

- Confidentiality
- Urine toxicology testing
- Working with, not against, medication
- Psychosocial treatment
- Supporting medication maintenance
- · Patient comfort during withdrawal

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 (<u>drug testing</u>) 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

Slide 67

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.