BUPRENORPHINE TREATMENT

Curriculum Infusion Package (CIP) Based on the Work of Dr. Thomas Freese of the Pacific Southwest ATTC

Drug Addiction Treatment Act of 2000 (DATA 2000)

Developed by Mountain West ATTC

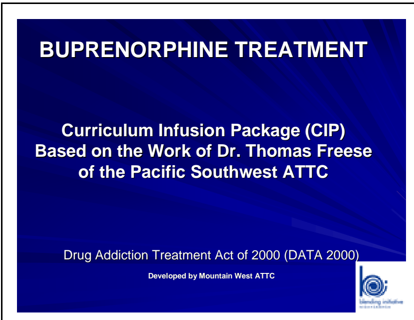
Introduction

The Drug Addiction Treatment Act of 2000 (DATA 2000) is a brief presentation (about 10 minutes) that describes the role of Buprenorphine in Addiction treatment.

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

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

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



Slide 1: Title Slide

It is important to note that this training is introductory and is focused on building awareness and encouraging multidisciplinary addiction professionals to learn more about buprenorphine and its role in opioid treatment. It is NOT designed to provide an expert level of competency in utilizing buprenorphine for the treatment of opioid addiction.

NIDA-SAMHSA Blending Initiative: 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	**Slide 2: NIDA-SAMHSA Blending Initiative: Blending Team Members** *Note that the membership consisted of three ATTC representatives and three NIDA researchers.*
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 developed and contributed the Buprenorphine Bibliography. 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 3: Additional Contributors** *Acknowledge additional contributors to the Blending Team product.*

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 4: Drug Addiction Treatment Act of 2000 (DATA 2000)

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

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

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

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

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

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

DATA 2000:
Physician Qualifications

Physicians must:

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

Slide 5: DATA 2000: Physician Qualifications

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

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

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

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

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

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

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

DATA 2000:
Physician Qualifications

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

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

Slide 6: DATA 2000: Physician Qualifications

Summarize each bullet point.

Buprenorphine as a Treatment for Opioid Addiction

- A synthetic opioid
- Described as a mixed opioid agonist-antagonist (or partial agonist)
- Available for use by certified physicians outside traditionally licensed opioid treatment programs

Slide 7: Buprenorphine as a Treatment for Opioid Addiction

Several factors make buprenorphine a good option for some people. Buprenorphine is a partial agonist, resulting in a good safety profile for the medication.

With the changes in the treatment legislation, this medication becomes the first available outside of the OTP system. This expands both the availability of and access to treatment.

Factors for Addiction Professionals to Consider

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

Slide 8: Factors for Addiction Professionals to Consider

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

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

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

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

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

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

Factors for Addiction Professionals to Consider 6. Is the patient expected to follow safety procedures? 7. Is the patient psychiatrically stable? 8. Are the psychosocial circumstances of the patient conducive to treatment success? 9. Are there resources available to ensure the link between physician and treatment provider? 10. Is the patient taking other medications that may interact adversely with buprenorphine?	**Slide 9: Factors for Addiction Professionals to Consider** #6: Can the patient manage his/her medication appropriately (e.g. keep it away from children in the home) and take it as prescribed? #7: Is the patient so unstable psychiatrically that he/she needs to be treated in a psychiatric hospital or receive additional treatment for co-occurring disorders? #8: What stressors, relationships, supports, living situation, etc., does the patient have that can contribute to or undermine the success of the treatment plan? #9: Has a comprehensive treatment plan been developed and coordinated between the psychosocial treatment team and the physician? What additional resources need to be brought on board in order to facilitate coordinated care? #10: Another way of asking this question is, “Is this an appropriate medication for the person to be taking?” Additional medications and health conditions should be brought to the attention of the physician, so that the physician is fully informed in making the decision to prescribe buprenorphine or any other medication.
Induction Phase *Working to establish the appropriate dose of medication for patient to discontinue use of opiates with minimal withdrawal symptoms, side-effects, and craving*	**Slide 10: Induction Phase** During induction, the physician works with the patient to figure out the most effective dose so that he/she can stop other opioid use with minimal withdrawal symptoms. While the physician primarily guides this process, the multidisciplinary team is critical in providing supportive care and counseling to help the patient through the process.

Direct Buprenorphine Induction from Short-Acting Opioids

- Ask patient to abstain from short-acting opioid (e.g., heroin) for at least 6 hrs. and be in mild withdrawal before administering buprenorphine-naloxone.
- When transferring from a short-acting opioid, be sure the patient provides a methadone-negative urine screen before 1st buprenorphine dose.

SOURCE: Amass, et al., 2004, Johnson, et al. 2003.

Slide 11: Direct Buprenorphine Induction from Short-Acting Opioids

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

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

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

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

Maintenance Phase

Goals of Maintenance Phase:

Help the person stop and stay away from illicit drug use and problematic use of alcohol

1. Continue to monitor cravings to prevent relapse
2. Address psychosocial and family issues

Slide 12: Maintenance Phase

Cessation of illicit drug use and problematic alcohol use.

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

Buprenorphine Withdrawal

- Working to provide a smooth transition from a physically-dependent to non-dependent state, with medical supervision
- Medically supervised withdrawal (detoxification) is accompanied with and followed by psychosocial treatment, and sometimes medication treatment (i.e., naltrexone) to minimize risk of relapse

Slide 13: Buprenorphine Withdrawal

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

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

Medically Assisted Withdrawal (Detoxification) ▪ Outpatient and inpatient withdrawal are both possible ▪ How is it done? • Switch to longer-acting opioid (e.g., buprenorphine) • Taper off over a period of time (a few days to weeks depending upon the program) • Use other medications to treat withdrawal symptoms • Use clonidine and other non-narcotic medications to manage symptoms during withdrawal	**Slide 14: Medically Assisted Withdrawal** Medically assisted withdrawal can be successful in either inpatient or outpatient settings. It is important for the multidisciplinary treatment professional to provide supportive wrap-around services to get the patient through this difficult stage. This is done by transitioning the person onto a long-acting opioid like buprenorphine and then tapering him/her off over a period of time. Other medications may be helpful if withdrawal symptoms are present to help the person to stay comfortable.
Counseling Buprenorphine Patients	**Slide 15: Counseling Buprenorphine Patients**
Counseling Buprenorphine Patients ▪ Address issues of the necessity of counseling with medication for recovery. ▪ Recovery and Pharmacotherapy: • Patients may have ambivalence regarding medication. • The recovery community may ostracize patients taking medication. • Counselors need to have accurate information.	**Slide 16: Counseling Buprenorphine Patients** *Again, it is important to stress that the multidisciplinary addiction professional should work with, not against, the medication.*
Counseling Buprenorphine Patients ▪ Recovery and Pharmacotherapy: • Focus on "getting off" buprenorphine may convey taking medicine is "bad." • Suggesting recovery requires cessation of medication is inaccurate and potentially harmful. • Support patient's medication compliance • "Medication," not "drug"	**Slide 17: Counseling Buprenorphine Patients** Suggesting the need to discontinue medication can convey the idea that the medication is a necessary evil and somehow wrong. It is important to refer to buprenorphine as a medication and frame it as one component of the comprehensive opioid treatment plan.