BUPRENORPHINE and Office-Based Treatment of Opioid Use Disorder

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Disclosures

• Dr. Wyatt - No disclosures

• Dr. Kushner – Speaker, Alkermes Pharmaceuticals
Course Goal

Goal is to provide specific information on the pharmacology and clinical use of buprenorphine, and on the resources needed to set up office-based treatment of opioid dependence using buprenorphine.
Program Outline

2. General Opioid Pharmacology & Pharmacology of Buprenorphine
3. Patient Assessment and Selection
4. Efficacy and Safety of Buprenorphine
5. Clinical Use of Buprenorphine, Induction & Stabilization
6. Confidentiality, Medical Records, Office Policies & Procedures
7. Clinical Management
8. Evidence-Based Counseling
9. Pain Patients and Other Special Populations
Evaluations and Completion of the Waiver Application
Course Syllabus

• Legislation and Waiver Application

• Regulations and FSMB Policies

• Clinical Tools and Diagnostic Criteria

• TIP 40 and Medication Guides

• DEA, Billing, Reading List, Websites
Housekeeping Issues

Sign-in

Notification Forms

Course Evaluations

Pagers and cell phones

Questions?
OVERVIEW OF OPIOID USE DISORDERS
Overview of DATA 2000
Physicians had been liberal prescribers of morphine in late 1800s/early 1900s, leading to rising rates of addiction.

Harrison Act of 1914 prohibited physicians from prescribing narcotics to addicts, with criminal prosecution for violations.

This legislation drove down morphine prescribing, even for severe pain cases.
History of Medical Practice for Opioid Addiction in the U.S.

- Opioids continued to be sold by criminal elements in the United States. Addiction, including imported heroin, continued to be a large problem.
- Methadone clinics to treat opioid addiction were established in 1974 and highly regulated at the federal level.
- Ongoing need for access to care for opioid addiction led to DATA 2000.
Number of U.S. Drug Poisoning Deaths
CDC 1999–2013

Other Opiates
Methadone
Other Synthetics
Benzodiazepines
Heroin

Figure 2.16 Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older: 2012-2013

Source Where User Obtained

- More than One Doctor (2.6%)
- Free from Friend/Relative (53.0%)
- One Doctor (21.2%)
- Other\(^1\) (4.3%)
- Bought on Internet (0.1%)
- Drug Dealer/Stranger (4.3%)
- Bought/Took from Friend/Relative (14.6%)

Source Where Friend/Relative Obtained

- One Doctor (83.8%)
- More than One Doctor (3.3%)
- Free from Friend/Relative (5.1%)
- Bought/Took from Friend/Relative (4.9%)
- Drug Dealer/Stranger (1.4%)
- Other\(^1\) (1.2%)
- Bought on Internet (0.3%)

\(^1\) The Other category includes the sources "Wrote Fake Prescription," "Stole from Doctor's Office/Clinic/Hospital/Pharmacy," and "Some Other Way."

Note: The percentages do not add to 100 percent due to rounding.
Opioid agonist treatment

Most effective treatment for opioid dependence

Controlled studies have shown that with long term maintenance treatment using appropriate doses, there are significant:

✓ Decreases in illicit opioid use
✓ Decreases in other drug use

(continued on next slide)
Rationale for Opioid Agonist Treatment

Opioid agonist treatment (continued)

✓ Decreases in criminal activity
✓ Decreases in needle sharing and HIV transmission
✓ Improvements in pro-social activities
✓ Improvements in mental health
History of Medical Practice for Opioid Addiction in the U.S.

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- Ongoing need for access to care for opioid addiction led to DATA 2000.
U.S. Legislation Enabling Office-Based Treatment of Opioid Dependence

Amended Controlled Substances Act: DATA 2000

• Revision in legislation now allows a physician to prescribe narcotic drugs in schedules III, IV, V, or combinations of such drugs, for the treatment of opioid dependence

• However:
  ▪ Drugs and practitioners must meet certain requirements
Amended Controlled Substances Act: DATA 2000

- Narcotic drug requirements:
  - Drug must be approved by the US FDA for use in maintenance or detoxification treatment of opioid dependence
  - Must be in Schedule III, IV, or V
- Applies to single opioid or combination of opioids
Amended Controlled Substances Act: DATA 2000

- Practitioners requirements:
  - Must be “Qualifying physician” (i.e. subspecialty addiction psychiatry or ABAM certification)
  - Must affirm the capacity to refer patients for appropriate counseling and ancillary services that are needed to treat opioid addiction
Amended Controlled Substances Act: DATA 2000

- Practitioners requirements:
  - Must register with SAMHSA and DEA.
  - No more than 30 patients in Year 1. Now can increase to 100 patients per practitioner after Year 1 of having waiver, but those who undertake the higher patient number must notify CSAT of their intent to do so by completing a second waiver.
  - Group practices: each waivered physician can have up to 100 patients after 1 year.
Amended Controlled Substances Act

• Qualifying physicians:
  ▪ A licensed physician who meets one or more of the following:
    – ABPN Added Qualification in Addiction Psychiatry
    – Certified in Addiction Medicine by ABAM
    – Certified in Addiction Medicine by AOA
    – Investigator in buprenorphine clinical trials
Amended Controlled Substances Act

• Qualifying physicians:
  ▪ Meets one or more of the following:
    - Has completed 8 hours training provided by ASAM, AAAP, AMA, AOA, APA (or other organizations which may be designated by HHS)
    - Training/experience as determined by state medical licensing board
    - Other criteria established through regulation by the Secretary of Health and Human Services
Amended Controlled Substances Act

- Practitioner requirements:
  - Qualifying physician”
  - Waiver application requires physicians to endorse that they have the capacity to refer patients for appropriate counseling and ancillary services
  - Psychosocial interventions  *in addition to* medication treatment are standard of care for treatment of severe opioid use disorders (opioid addiction)
Amended Controlled Substances Act: DATA 2000

• State legislation:
  ▪ A state may not preclude a practitioner from dispensing or prescribing buprenorphine for opioid dependence treatment unless the state enacts a law prohibiting the practitioner from doing so.
Amended Controlled Substances Act: DATA 2000

- DHHS has evaluated:
  - Whether the treatment is effective in the office setting
  - Whether access to treatment has been increased
  - Whether there have been adverse consequences for the public health
Amended Controlled Substances Act: DATA 2000

- DEA has evaluated:
  - Extent of violations of the 30/100 patient limit
  - Extent of diversion of the medication
  - Physician record keeping and security measures related to on-site medication storage
  - DEA will continue to visit two prescribers in each DEA district every 18 months
Amended Controlled Substances Act: DATA 2000

- Evaluation period:
  - On the basis of these evaluations, DHHS and DEA decided the law should remain in effect
  - Office-based treatment of opioid dependence continues as a treatment option for patients who need it
  - It is expected that number of providers offering this treatment will continue to grow as the treatment modality becomes more familiar to clinicians and patients
Opioid Treatment Programs

• 2013: Change in regulations now allows opioid treatment programs (OTPs, methadone maintenance programs) to dispense buprenorphine in same manner as office-based practitioners
• (Previously, OTPs had to dispense buprenorphine as they did for methadone with restricted take-home doses)
• OTPs could be a potential referral source in communities that have provided methadone maintenance. Can provide structure to patients who need closer observation than an office-based practitioner can provide; counseling is available; and some provide medical/mental health services
Amended Controlled Substances Act: DATA 2000

- Mandatory evaluation period:
  - During the first three years of buprenorphine approval, DHHS and DEA evaluated efficacy and safety
  - Safety included protection of the public health against diversion of the drug
HHS Rule Change for

• Patient limit increase to 275
• Current waiver to treat up to 100 patients, for at least one year
• Hold “additional credentialing”
• Board certification in addiction medicine or addiction psychiatry by:
  - American Board of Addiction Medicine (ABAM) or
  - American Board of Medical Specialties (ABMS) or
  - Certification by American Osteopathic Academy of Addiction Medicine, ABAM or ASAM; or
Practice in a Qualifying Practice Setting

- Provides 24 hours medical emergency coverage during off hours;
- Provides case-management services including referral, follow-up services; financial services, medical, behavioral, social, housing, employment, educational, or other related services;
- Uses health technology: electronic health records, if required in practice setting.
- Registered with State prescription drug monitoring program (PDMP) where operational and follows in accordance with Federal and State law.
- Accepts third-party payment for costs in providing health services, including written billing, credit, and collection policies and procedures, or Federal health benefits.
- Provider may not have had Medicare enrollment and billing privileges revoked under 42 CFR 424.535 nor have violated the Controlled Substances Act pursuant to 21 U.S.C. 824(a) to be eligible for the higher limit.
Authorizing NP’s and PA’s Prescribing

- Waivered to prescribe buprenorphine five year period expires 2021
- Newly waivered PAs and NPs, and physician to treat 30 patients in year one
  - May increase to 100 after one year with certain conditions
- NP and PA’s must complete 24 hours addition education with accredited, authorized providers
  - HHS secretary may waive/adjust requirements for those working in addiction
- Collaborative/supervised relationship required based on state law
  - If supervision required by state law must be a waivered provider
Summary

The need for opioid treatment far exceeds current capacity. Office-based buprenorphine is intended to address this unmet treatment need and to place the treatment of opioid dependence in the mainstream of medical practice.
SUMMARY

Legislation sets up relatively minor requirements for a physician to provide office-based buprenorphine treatment of opioid dependence.

However, if difficulties arise (e.g., diversion, misuse), it will be relatively easy for government agencies to end office-based treatment of opioid dependence with buprenorphine.
SUMMARY

It is important for physicians to know and abide by the rules – and not risk losing this valuable treatment option.
GENERAL OPIOID PHARMACOLOGY
and the Pharmacology of Buprenorphine
Outline for this talk

I. GENERAL OPIOID PHARMACOLOGY

II. The pharmacology of buprenorphine

III. The pharmacology of buprenorphine/naloxone

IV. Summary: Buprenorphine pharmacology
Opioids constitute a class of drugs found within opium as well as semi-synthetic and synthetic compounds that resemble the structure and/or function of the naturally occurring forms.

Opioids are medically used for relief of pain and cough suppression, and many have an abuse potential.
Opioid Receptors

Types of opioid receptors:

- Mu
- Kappa
- Delta
Opioid Receptors

Drugs and medications that activate mu receptors:

- Morphine
- Hydromorphone
- Oxymorphone
- Fentanyl
- Methadone
- Codeine
- Hydrocodone
- Oxycodone
- LAAM
- Buprenorphine
Function at Receptors: Full Opioid Agonists

1. activates the mu receptor
2. is highly reinforcing
3. is the most abused opioid type
4. includes heroin, codeine, & others
Function at Receptors: Partial Opioid Agonists

- **Mu receptor**
- **Partial agonist binding ...**

1. activates the receptor at lower levels
2. is relatively less reinforcing
3. is a less abused opioid type
4. includes buprenorphine
Function at Receptors: Opioid Antagonists

- **Mu receptor**
  - occupies without activating
  - is not reinforcing
  - blocks abused agonist opioid types
  - includes naloxone and naltrexone
Efficacy: Full Agonist (Methadone),
Partial Agonist (Buprenorphine), Antagonist (Naloxone)
Repeated Administration and Withdrawal

SPONTANEOUS WITHDRAWAL

- For short-acting opioids (e.g., heroin, oxycodone): usually begins 6-12 hours after last dose, peaks at 36-72 hours, and lasts about 5 days (with possible protracted withdrawal?)

- For opioids with longer half-lives (e.g., methadone): usually begins 36-72 hours after last dose, longer period before peak effects occur, less severe spontaneous withdrawal syndrome.
Repeated Administration and Withdrawal

PRECIPITATED WITHDRAWAL

- Occurs with administration of an opioid antagonist to a person physically dependent upon mu agonist opioids.
- Is qualitatively similar to spontaneous withdrawal, but has a faster onset.
Precipitated Withdrawal

- Buprenorphine will precipitate withdrawal only when it displaces a full agonist off the mu receptors.
- Buprenorphine only partially activates the receptors, therefore a net decrease in activation occurs and withdrawal develops.

![Graph showing the effects of drug doses on mu receptor intrinsic activity.](image-url)
Pharmacokinetics of Opioid Antagonists
Oral vs. Extended Release Naltrexone

Mean steady-state naltrexone concentration following monthly XR-NTX 380 mg compared to daily oral dosing

Dean RL. *Front Biosci.* 2005 Jan 1;10:643-655.
Data on File, Alkermes, Inc.
Outline for this talk

I. General opioid pharmacology

II. THE PHARMACOLOGY OF BUPRENORPHINE

III. The pharmacology of buprenorphine/naloxone

IV. Summary: Buprenorphine pharmacology
Buprenorphine

- Opioid partial agonist
- Schedule III (vs. methadone: Schedule II)
- Treatment modalities for buprenorphine:
  - Office-based treatment
    - Primary Care
    - Specialty (e.g.: Infectious Disease, GI, Psychiatry)
    - Substance abuse treatment clinics
  - Methadone maintenance programs
How Does Buprenorphine Work?

- AFFINITY is the strength with which a drug physically binds to a receptor
  - Buprenorphine has strong affinity; will displace full mu receptor agonists like heroin and methadone
  - Receptor binding strength (strong or weak), is NOT the same as receptor activation
How Does Buprenorphine Work?

• DISSOCIATION is the speed (slow or fast) of disengagement or uncoupling of a drug from the receptor
  ▪ Buprenorphine dissociates slowly

  Buprenorphine Dissociates Slowly

<table>
<thead>
<tr>
<th>Mu Receptor</th>
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  Full Agonists: Reduced Binding

  ▪ Therefore buprenorphine stays on the receptor a long time and blocks heroin, methadone and other opioids from binding to those receptors
How Does Buprenorphine Work?

• Buprenorphine may reduce the effects of other opioids taken due to its high affinity for, and slow dissociation from, the mu receptor.
• However, buprenorphine is unlikely to block all effects from an opioid taken after initiation of buprenorphine treatment.
• This is because the availability of mu receptors is a dynamic process; while effects may be less, they are not likely to be completely eliminated.
Buprenorphine is a Partial Agonist

Graph showing the relationship between drug dose and mu receptor intrinsic activity. The graph compares full agonists (e.g., heroin) with partial agonists (e.g., buprenorphine) and antagonists (e.g., naloxone).
### Pharmacology of Full vs. Partial Agonists

- Buprenorphine can precipitate withdrawal if it displaces a full agonist from the mu receptors.
- Buprenorphine only partially activates the receptors; therefore, a net decrease in activation occurs and withdrawal develops.

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**Graph: A Net Decrease in Receptor Activity if a Partial Agonist displaces Full Agonist**

- **X-axis:** Drug dose
  - no drug
  - low dose
  - high dose
- **Y-axis:** % Mu Receptor Intrinsic Activity
  - 0
  - 10
  - 20
  - 30
  - 40
  - 50
  - 60
  - 70
  - 80
  - 90
  - 100
- **Legend:**
  - Full Agonist
  - Heroin/Methadone
  - Partial Agonist
  - Buprenorphine

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A Net Decrease in Receptor Activity if a Partial Agonist displaces Full Agonist
Formulations of Buprenorphine

- Parenteral form for treatment of moderate to severe pain (not approved for opioid dependence treatment)
- 7-day Transdermal Patch (5, 10, and 20 μg/hour) for severe pain
- Sublingual forms (tablets and films) for treatment of opioid addiction; not approved for pain management
- Implant
  - 6 month implant for patients previously stabilized on 8mg or less of the SL product.
Buprenorphine Formulation

- Buprenorphine/naloxone combination is recommended formulation for treatment of opioid dependence
- Naloxone is present to reduce diversion to injected abuse
- Naloxone plays no role in the patient’s medication treatment:
  - Active by parenteral route
  - Not well absorbed by GI route
Formulations of Buprenorphine

- **Sublingual film or tablets** for treatment of opioid dependence
  - **Film Strengths:**
    - Bup 2mg/Nlx 0.5mg, Bup 4 mg/Nlx 1 mg, Bup 8mg/Nlx 2mg, Bup 12 mg/Nlx 3 mg
  - **Tablets:** 2/0.5 mg and 8/2 mg
    - (5.7/1.4mg, 1.4/0.36)
  - **Dose Range:** 4/1-24/6 mg daily; most stabilize on 12/3-16/4 mg daily
  - **Combination of buprenorphine/naloxone (Bup/Nlx)** is preferred drug for opioid addiction
    - developed to decrease diversion to injected abuse
      - Precipitated withdrawal if injected by opioid-dependent person
Buprenorphine/Naloxone Tablets

2mg/0.5 mg

8mg/2mg
### Buprenorphine/naloxone Film (Suboxone)

<table>
<thead>
<tr>
<th>Strength</th>
<th>Composition</th>
<th>Image</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2 mg</strong></td>
<td>buprenorphine/0.5 mg naloxone</td>
<td><img src="image1" alt="Image" /></td>
</tr>
<tr>
<td><strong>4 mg</strong></td>
<td>buprenorphine/1 mg naloxone</td>
<td><img src="image2" alt="Image" /></td>
</tr>
<tr>
<td><strong>8 mg</strong></td>
<td>buprenorphine/2 mg naloxone</td>
<td><img src="image3" alt="Image" /></td>
</tr>
<tr>
<td><strong>12 mg</strong></td>
<td>buprenorphine/3 mg naloxone</td>
<td><img src="image4" alt="Image" /></td>
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</tbody>
</table>

For complete Prescribing Information, visit suboxone.com.

SUBOXONE® Sublingual Film is a registered trademark of Reckitt Benckiser (UK) Ltd.
Buprenorphine/naloxone Sublingual Tablets (Zubsolv)

Available doses (BUP/NX): 1.4 mg / 0.36 mg; 5.7 mg / 1.4 mg
Recommended maintenance dose: 11.4 mg/ 2.8 mg
Buccal Film (Bunavail)

Available dosages (BUP/NX): 2.1 mg / 0.3 mg; 4.2 mg/0.7 mg; 6.3 mg/ 1.0mg

Recommended maintenance dose: 8.4mg / 1.4mg
Clinical Forms of Buprenorphine

- There is also a sublingual tablet that is available as buprenorphine alone (without naloxone)
  - Bup 2mg or Bup 8 mg
  - For use in pregnancy
  - Available only as a generic
  - Has more diversion potential than the bup/nlx combination; hence, the combination is the recommended form for treatment of opioid addiction except in pregnant, opioid dependent, women
Buprenorphine: Side Effects

- Nausea/vomiting (consider precipitated withdrawal)
- Constipation
- Sedation (use of other sedating drugs or in those not currently dependent, but eligible for buprenorphine treatment by history)
- Elevations in liver transaminases possible (Hep C at higher risk)
Public Health Issues with Buprenorphine

- **Diversion**: is illegal
  - Selling or giving a medication prescribed to another person
  - Using the medication in a way other than it was prescribed.
- Significant dangers for diversion of buprenorphine.
  - Abuse of the drug (known to occur widely in countries mainly using the buprenorphine-only formulation)
  - Buprenorphine/nlx is being increasingly diverted in the U.S. Smaller doses minimize risk of precipitated withdrawal when injected.
Public Health Issues with Buprenorphine

- Adverse events: buprenorphine abuse, overdoses/deaths:
  - Lack of tolerance to opioids
  - Drug-drug interactions since use of other drugs (licit and illicit) and/or alcohol occur frequently
- Important to understand the diversion/abuse potential of buprenorphine and not to give larger doses than patients need to treat their opioid addiction
- Favorable safety profile:
  - Ceiling effect of partial agonist protects against overdose when buprenorphine is taken on its own;
  - Lower risk (vs. methadone) of prolonged QT, Torsades de Pointes
  - Minimal subjective effects when used sublingually: clear-headed, improved energy/sleep
Diversion and Misuse

• Three ways to consider diversion.
  ▪ Injection diversion
    ▪ Persons physically dependent on illicit opioids
    ▪ Persons on prescribed opioids (e.g., methadone), with this history concealed from bup/nx prescriber
  ▪ Diversion to the street
    ▪ Persons maintained on buprenorphine/naloxone at higher-than-needed doses
    ▪ Persons abusing, but not physically dependent on, opioids
  ▪ Drug dealers with intent to sell buprenorphine/naloxone
Diversion and Parenteral Misuse

- Persons physically dependent on short-acting opioids like heroin or pain meds (prescribed or illicit):
  - If have short-acting full agonist on receptors:
    - Then injection of buprenorphine/naloxone will precipitate opioid withdrawal syndrome
  - If no short-acting full agonist on receptors:
    - By definition will already be experiencing some level of opioid withdrawal syndrome
    - Then injection of buprenorphine/naloxone will provide withdrawal relief and give agonist effects
Diversion and Parenteral Misuse

- Persons physically dependent on long-acting opioids like methadone (prescribed or illicit):
  - If have long-acting full agonist on receptors:
    - Then injection of buprenorphine/naloxone will precipitate opioid withdrawal syndrome
    - Methadone occupies receptors for days ($T_{1/2} = \text{up to 36 hrs}$). Cannot confirm absence of methadone and thus readiness for buprenorphine/naloxone without negative urine toxicology and/or naloxone challenge.
Diversion and Parenteral Misuse

- Persons physically dependent on sublingual buprenorphine/naloxone (prescribed or illicit):
  - If have long-acting buprenorphine/naloxone on receptors:
    - Then injection of buprenorphine/naloxone will not cause as severe withdrawal, but instead give agonist effects
  - If no long acting buprenorphine/naloxone on receptors
    - Then injection of buprenorphine/naloxone will provide agonist effects
  - Note that this population may dissolve and inject buprenorphine/naloxone film, since they will have a ready supply if in maintenance treatment
  - Intranasal and rectal routes of abuse are also possible
Diversion and Parenteral Misuse

• Persons abusing, but not physically dependent on opioids:
  ▪ Then injection of buprenorphine/naloxone will give agonist effect because the low dose of naloxone will not completely block the buprenorphine.
Diversion and Sublingual Misuse

- Sublingual abuse may be less likely because agonist effect onset is slower and magnitude of effect is lower.
- Two groups that might abuse by the sublingual route include:
  - Persons who are physically dependent on full agonist opioids
    - Periodic abuse to control full agonist opioid withdrawal syndrome is most likely pattern
  - Persons who are NOT physically dependent on any type of opioids
    - Experimental abuse for agonist effect is more likely in this group
Buprenorphine is a partial mu agonist opioid with a profile of effects similar to other mu agonists, but has less risk of respiratory depression and a lower level of physical dependence.

Patients who are physically dependent on opioids can develop a precipitated withdrawal with buprenorphine.

The buprenorphine/naloxone combination is the preferred form for unsupervised dosing to diminish the likelihood of diversion to injected use.
Patient Assessment and Selection
For Office Based Care
Background

• How does one assess and select appropriate patients for office-based treatment for opiate addiction?

• What types of patients are not good candidates for office-based opiate addiction treatment with buprenorphine?

• Understand that success for both the patient and the practitioner to treat opiate addiction will depend, in part, on initial steps of assessment and selection of treatment
OUTLINE

I. Identify opioid use/abuse
II. Establish the diagnosis of opioid dependence
III. Assess for other conditions
IV. Determine appropriateness for office-based buprenorphine
V. Match the treatment plan and treatment resources
VI. Summary
Commonly Abused Opioids

- Opioids are abused by all routes of administration including oral, inhalation, smoking, and injection.
- Heroin is most commonly used intravenously, but can be inhaled, smoked, or injected intramuscularly or subcutaneously.
- Opium is usually smoked.
- The pharmaceutical opioids are usually taken orally (but may also be injected).
Identify Opioid Use

• Commonly used opioids
  - Heroin
  - Fentanyl

• Prescription
  - Increased use
  - Properties influence use
Common Prescription Opioids

- Diacetylmorphine (Heroin)
- Hydromorphone (Dilaudid)
- Oxycodone (OxyContin, Percodan/Percocet)
- Meperidine (Demerol)
- Hydrocodone (Lortab, Vicodin)
- Morphine (MS Contin, Oramorph)
- Fentanyl (Sublimaze)
- Propoxyphene (Darvon)
- Methadone (Dolophine)
- Codeine
- Opium
Evaluation of the Patient

• The ATTITUDE of the interviewer is important

• It should be:
  - Matter-of-fact
  - non-judgmental
  - Curious
  - Respectful
  - Interested
  - professional
Evaluation of the Patient

• History of drug use:
  - Start with first substance used
  - Ask about all substances (including licit and illicit)
  - Determine changes in use over time (frequency, amount, route)
  - Assess recent use (past several weeks)

• Relapse/Attempts to abstain:
  - Determine if the patient has tried to abstain, and what happened
  - Ask what was the longest period of abstinence
  - Identify triggers to relapse
Evaluation of the Patient

- Tolerance, intoxication, withdrawal:
  - Explain what is meant by tolerance
  - Determine the patient’s tolerance and withdrawal history
  - Ask about complications associated with intoxication and withdrawal

- Consequences of use:
  - Determine current and past levels of functioning
  - Identify consequences to drug/alcohol use:
    - Medical, family, employment, legal, other consequences
Evaluation of the Patient

• Craving and control:
  - Ask if the patient experiences craving to use and/or a compulsive need to use
  - Determine if patient sees loss of control over use

• Substance abuse treatment history:
  - Treatment episodes (detoxifications – medically and non-medically supervised; maintenance; counseling)
  - Response following each treatment intervention
  - Attendance at 12 step (or other self-help) meetings
Evaluation of the Patient

• Psychiatric history:
  - Inpatient and/or outpatient treatment episodes
  - Untreated episodes of psychiatric illness
  - Treatment with psychiatric medications

• Medical history:
  - Past and/or present:
    - Significant medical illnesses, Hospitalizations, Operations, and Accidents/injuries
  - Drug allergies
  - Current medications & herbal medicines
Evaluation of the Patient

• Family history:
  - Substance abuse disorders
  - Medical and psychiatric conditions

• Personal (or social) history:
  - Birth and early development
  - Education
  - Employment and occupations
  - Marital status and children
  - Living situation
The categories of substance abuse and dependence have been combined into a new category of Substance Use Disorders. The DSM-5 Substance Use Disorder criteria combine the abuse and dependence criteria of DSM-IV with the elimination of recurrent legal problems and the addition of craving. Using the resulting 11 criteria (see following slide) the severity of the disorder – either mild (2-3), moderate (4-5), or severe (6 or more) is rated based on the number of criteria endorsed.
**DSM-5: Opioid Use Disorder**

Patients meeting the DATA 2000 criteria for buprenorphine treatment would be diagnosed as **Opioid Use Disorder, Moderate or Severe** (4 or more criteria)

- Tolerance
- Withdrawal
- Substance taken in larger amounts or for longer periods than intended
- Unsuccessful efforts to control or cut down
- Excessive time spent seeking, using or recovering from the substance
- Important activities given up
- Continued use despite knowledge of problems
- Failure to fulfill major obligations
- Recurrent use in physically dangerous situations
- Continued use despite problems caused by substance
- Craving
Assess for Other Conditions

- Medical co-morbidity
- Psychiatric co-morbidity
- Other substance use, abuse, dependence
  - Reason to assess for other substance use
  - Detecting other substance use
  - Types of other substance use
Other Substance Use, Abuse, Dependence

- Detecting substance use
  - Screening instruments
  - Self-report of use, reason
  - Multiple trauma
  - Hospitalization
  - Infections
Other Substance Use, Abuse, Dependence

• Detecting substance use
  - Track or puncture marks
  - Infection (abscesses, cellulitis)
  - Constricted pupil (opioid intoxication)
  - Dilated pupil (opioid withdrawal)
  - Confusion, disorientation

• Laboratory methods:
  - Blood
  - Urine
  - Hair
Other Substance Use, Abuse, Dependence

• Types of other substance use
  - Alcohol
  - Sedative-hypnotics
  - Cocaine
  - Cannabis
Appropriateness for Office-based Treatment

- Factors to keep in mind when considering a patient for office-based buprenorphine treatment

- Some factors indicate the patient is less likely to be an appropriate candidate for office-based buprenorphine treatment and should be referred elsewhere
Appropriateness for Office-based Treatment

• Consider these factors:
  - Does the patient meet criteria for an opioid use disorder?
  - Is the patient interested in office-based buprenorphine treatment?
  - Does the patient understand the risks/benefits of buprenorphine treatment?
  - Would methadone or ER naltrexone be an appropriate alternative?
  - Is he/she expected to be reasonably compliant?
  - Is he/she expected to follow safety procedures?
  - Is the patient psychiatrically stable?
Appropriateness for Office-based Treatment

• Consider these factors (continued)
  - High level of physical dependence (risk for severe withdrawal)
  - Patient needs cannot be addressed with existing office-based resources
  - Are the psychosocial circumstances of the patient stable and supportive?
  - Can the office provide the needed resources for the patient (either on or off site)?
  - Is the patient taking other medications that may interact with buprenorphine?
Appropriateness for Office-based Treatment

- Patient is less likely to be an appropriate candidate for office-based treatment:
  - Dependence on high doses of benzodiazepines, alcohol, or other CNS depressants
  - Significant psychiatric co-morbidity
  - Active or chronic suicidal or homicidal ideation or attempts
  - Multiple previous treatments and relapses
  - Non-response to buprenorphine in the past
Appropriateness for Office-based Treatment

- Patient is less likely to be an appropriate candidate for office-based treatment:
  - High risk for relapse
  - Pregnancy
  - Current medical condition(s) that could complicate treatment
  - Poor support systems
Match Treatment Plan and Resources

• Determine appropriateness of patient for office based buprenorphine treatment by considering the needs of the patient and the available resources

• ASAM patient placement criteria can help guide
  - Acute intoxication/withdrawal potential
  - Biomedical conditions, complications
  - Emotional/behavioral/cognitive conditions and complications
Match Treatment Plan and Resources

- ASAM patient placement criteria (PCP) can help guide
  - Acute intoxication/withdrawal potential
  - Biomedical conditions, complications
  - Emotional/behavioral/cognitive conditions and complications
  - Readiness to change
  - Continued use or continued problem potential
  - Recovery environment

- Can the needs of the patient be addressed by available resources?
SUMMARY

- Determination of suitability for office-based buprenorphine treatment begins with the presence of a diagnosis of opioid use disorder.

- In addition, many patient factors (such as co-morbid conditions) will guide the decision of whether or not to treat in the office with buprenorphine.

- Final decision is whether the patient’s needs can be addressed by the resources available through the office.