Clinical Management
Clinical management encompasses a wide variety of subjects, and many of them are addressed in other sections (such as the assessment of co-morbid conditions, the importance of consent, and the evaluation for a diagnosis of opioid dependence).

This section focuses on
- Interactions with the patient
- Managing problematic behaviors
- Urine testing
Regarding problematic behaviors, this talk stresses the importance of preparation and anticipation, so that the clinician is not making sudden decisions about how to handle these situations.

Note that problematic behaviors are rare, especially in stable patients, and can occur in patients being treatment for any condition (not only opioid dependence)
Outline for This Talk

I. INTERACTIONS WITH THE PATIENT

II. Managing problematic behavior

III. Urine testing

IV. Summary
Prior to the Initial Visit

In a phone call with the patient:

• Briefly discuss your office’s general treatment philosophy

• Screen for issues which would exclude the patient from your office, depending on the criteria you have established (e.g., untreated or unstable psychiatric conditions, need for opioid agonist medications for pain)
Prior to the Initial Visit

In a phone call with the patient:

• Determine insurance coverage

• Find out the pharmacy he/she uses

• Explain cost of medication (if uninsured), urine testing, etc.

• Explain amount of time that may be required for the initial visit
The Initial Visit with the Patient

- Establish foundation of trust at first visit
- Establish a relationship in which patient can be open and confident that he/she can report difficulties
- Physician must be open, understanding, and willing to listen – straightforward and non-judgmental
The Initial Visit with the Patient

- Be prepared for defensiveness
- Address concerns about disclosure, confidentiality
- Start the interview with questions not likely to increase defensiveness
- Use open-ended or quantifiable rather than “yes-no” questions
- Assumptive questioning may yield more accurate responses
Assumptive questioning may yield more accurate responses

- “When was the last time you were high?”
- “How many times did you use this past week?”
The Initial Visit with the Patient

Part of the initial visit is to review rules and expectations with the patient, making sure that the patient understands them before buprenorphine treatment is initiated.

Part of the patient assessment is to form a judgment about whether the person can comply with the rules – whether the medication will be taken as prescribed and will be kept safe.
Rules and Expectations for the Patient

General principles for rules and expectations

• Must be clear and concrete
• Must be logical and easily justifiable
• Provide clear guidelines and expectations for patients
• Must clearly outline consequences of infractions
Rules and Expectations for the Patient

General principles for rules and expectations (continued)

• Lay the groundwork for confronting patients about problematic behaviors

• Must be clear to all involved with patient’s care

• Must be flexible, when necessary

• If you are uncertain, ask a colleague and/or lawyer
Rules and Expectations for the Patient

Staff: Rules and expectations

• Address staff concerns and preconceptions

• Help staff understand relevant issues before the patient’s first visit

• As a group, determine reasonable and realistic consequences of unacceptable behavior

• Assure that everyone is on board
Examples of items addressed in rules and expectations

• The treatment philosophy in your office or clinic
• Prescription procedures
  How many day’s medication is provided in a prescription
  How you respond to lost buprenorphine prescriptions
• How to store the medication safely
Rules and Expectations for the Patient

Examples of items addressed in rules and expectations (continued)

• Need for full and prompt disclosure of use of non-prescriptive psychoactive substances
• Urine testing procedures
• Illicit drug, problematic alcohol use
• If the patient cancels an appointment
Conveying rules and expectations

• Do both in writing and verbally

• Ask the patient to sign a copy of the rules and give her or him a copy

• Convey that failure to comply will result in consequences

• Review periodically (as needed) with patients

• Review (and revise as needed) periodically with staff
Boundaries in Patient-Staff Interactions

Boundaries are important for the physician and the physician’s office staff to consider

- Maintain professional relationship
- Acknowledge away from office only if patient does so
- Careful avoidance of excessive familiarity with patients
- Do not accept gifts from patients
I. Interactions with the patient
II. MANAGING PROBLEMATIC BEHAVIOR
III. Urine testing
IV. Summary
General Principles

- Preparation and anticipation are crucial, as are consistency and flexibility in responding to problems
- Evaluate the problem
- Consider the length of time in treatment; history of patient’s treatment success, patient’s motivation, options available
- Set limits and use contingencies
- Be aware of impact on staff and other patients if it is perceived that there is no consequence to the patient
Consider a range of options tailored to the specific problematic behaviors:

• Increased office visits, to physician or counselor
• Increased frequency of urine tests
• Referral to more intensive level of service such as counseling or intensive outpatient program
• Change in dosing schedule
• Transfer to opioid treatment program (OTP)
General Principles

Negotiating skills and problematic behaviors

• Negotiate from strength
• Defend the integrity of treatment
• Consider violations in the context of the patient’s condition and situation
• Be aware of your own feelings
Examples of Problematic Behaviors

- Intoxication at the office
- Loitering
- Diversion of medication
- Drug dealing
- Aggressive acts

Such actions occur rarely – but if they do occur, it is important that the office be prepared to respond in a therapeutically appropriate and consistent way.
Outline for This Talk

I. Interactions with the patient
II. Managing problematic behavior
III. URINE TESTING
IV. Summary
Urine Testing

Why conduct urine drug testing?

• Drug abuse is a chronic disorder – relapse can occur
• Patients may deny or minimize use
• Urine testing is an integral part of on-going evaluation and treatment planning
• Purpose is not to punish the patient, but to provide a therapeutically appropriate response
Urine Testing

Different laboratory methods for drug screening and testing

• Thin Layer Chromatography (TLC)
  positive result on this screening test should be confirmed using another method
• Gas chromatography/mass spectrometry
• Enzyme immunoassay (EIA)
• Point-of-care testing
Detection time limits for drugs of abuse using urine testing

- Amphetamine/methamphetamine: 2-4 days
- Benzodiazepines: up to 30 days
- Cocaine: 1-3 days
- Heroin/morphine: 1-3 days
- Methadone: 2-4 days
- Marijuana: chronic use, up to 30 days
  occasional use, 1-3 days
Urine Testing

Detection of drugs of abuse using urine testing

• Note that standard opioid screens do not test for synthetic or semi-synthetic pharmaceuticals such as oxycodone, methadone or buprenorphine

• For oxycodone and methadone, you must make a specific request to the testing laboratory

• Buprenorphine dipstick test is now available
Urine Testing

Practical issues of urine testing

• In-office versus off site collection
• Sending specimens out for testing versus quick test in office
• Random versus scheduled collection
• Observed versus non-observed
• Maintaining a Chain of Custody
Other Body Fluid Testing

- **Buccal tests**
  - Less intrusive
  - Not yet as sensitive

- **Sweat patch testing**
  - Less intrusive
  - Not yet as sensitive
  - ? Easier to manipulate
Outline for This Talk

I. Interactions with the patient

II. Managing problematic behavior

III. Urine testing

IV. SUMMARY
Most patients treated in an office-based setting will be cooperative, stable.

Having rules and regulations helps patients and office staff prepare responses to problematic acts.

The physician should have options in how to respond – discharge from treatment should never be the first response.
Case Study #2

ROBERT, A 35-YEAR OLD TEACHER
Robert, a 35-year old teacher

The patient is a 35-year-old school teacher. He has been injecting heroin on and off since he was 16. He has never been arrested. He has been through many episodes of heroin detoxification, mostly outpatient methadone detoxification but has also been in three inpatient drug treatment programs. The last inpatient program was a 28-day, drug-free recovery program, and he remained both heroin and alcohol free for about 6 months following treatment. He teaches math at a junior high school and is in some difficulty because of “calling in sick too much.” His wife is in recovery, and insisted that he return to treatment after she discovered he was taking large quantities of codeine pills from several doctors for a back injury following an automobile accident. She is unaware that he is also injecting heroin at least once daily. He has been alcohol abstinent for the past two years. His only current medical problem is that he is hepatitis C positive and he has been so for at least 10 years. He states “Doc, I know I’m an addict. My wife cleaned up when she was pregnant with our daughter, and she just got her 12-year chip. She moved on with her life, but I’m stuck. My back injury threw me into a tailspin. At first, I really needed the codeine, but now I’m just using them to stave off heroin withdrawal. I really need your help. If my wife finds out I’m back on the needle, she’ll leave me this time.”
Robert, a 35-year old teacher

1. Does this patient meet DSM-V criteria for opioid dependence?

2. What are the treatment options for this patient?

3. How would you assess the need for pharmacotherapy for this patient?

4. Is this patient a candidate for buprenorphine?
EVIDENCE-BASED COUNSELING
Outline for This Talk

EVIDENCED-BASED COUNSELING TECHNIQUES

• The Impact of Counseling on Recovery
• Evidenced-based Practice
• Practical Counseling Models:
  - Brief Intervention / FRAMES
  - Twelve Step Facilitation
  - Cognitive Behavioral Therapy
  - Motivational Enhancement Therapy
Effect of counseling in buprenorphine treatment
(Fiellin, 2002)
Effect of counseling in buprenorphine treatment
(Fiellin, 2006)

- Patients can receive efficacious care in a primary care, office-based setting with weekly brief counseling and medication dispensing is important.

- Availability of buprenorphine–naloxone attracts new patients to treatment for opioid dependence provides support for federal efforts to expand access to the treatment.

- Findings also show that supervised nurses can provide appropriate counseling.
Efficacy of Psychosocial Counseling

EVIDENCED BASED PRACTICE

INSUFFICIENT EVIDENCE OF EFFECTIVENESS

• Confrontational Counseling
• Non-specific Psychotherapy
• Alcohol Counseling
• Educational Films / Lectures
• Court-ordered AA Meeting
• Relaxation Therapy, Hypnosis
• Meds: psychodelics, anxiolytics, Ca carbimide
EVIDENCED BASED PRACTICE

INDETERMINATE EVIDENCE OF EFFECTIVENESS

- Non-behavioral Marital Counseling
- Stress Management
- Relapse Prevention
- Meds: lithium, SSRI’s (for craving)
EVIDENCED BASED PRACTICE

Strong Evidence of Effectiveness

- Brief Interventions
- Motivational Enhancement
- Cognitive Therapy
- 12-Step Facilitation
- Behavioral Marital
- Patient-Centered
- Behavioral Contracting
- Self-Control Training
- Nausea Aversion
- Social Skills Training
- CRA
- Medications:
  - Disulfiram
  - Acamprosate
  - Naltrexone
FRAMES
A MODEL FOR BRIEF INTERVENTION

- Feedback about the problem (CAGE; Lab data, etc.)
- Responsibility placed on client
- Advice given to make a change
- Menu of options for treatment
- Empathy for the patient’s struggle
- Self-efficacy – stress patient’s competence

Miller & Sanchez, 1993
Twelve-Step Facilitation
Choosing a Sponsor

• Role model / mentor / counselor
  - Support recovery
  - Confront risky behavior / denial

• Active member of AA/NA

• Minimum one year sobriety

• Same gender

• Is comfortable with medication-assisted treatment
CBT / Relapse Prevention
The “Seeking Safety” Protocol

- Manualized Group Therapy
- 25 sessions
- **Integrated** PTSD & Subst. Abuse Treatment
- Focuses on “Safety”
  - No Acting Out
  - No Substance Use
- Combines Cognitive Behavioral approaches to both disorders
- Useful for a variety of Dual Diagnosis Patients

Najavits, 2002
Motivational Enhancement Therapy (MET)

1. The Stages of Change Paradigm
2. Basic Concepts
3. Moving Patients One Step at a Time
4. Matching Strategies to the Stages
Stages of Change
The Basis for Motivational Interviewing

- Pre-contemplation
- Contemplation
- Determination / Preparation
- Action
- Maintenance

Prochaska & DiClemente, 1992
The Basic Therapeutic Task:

- Identify the patient’s stage in the model
- Match treatment strategy to the patient’s specific stage
- Goal: Move patient one step
Motivational Enhancement
Basic Concepts

• Therapist Style Determines Resistance / Change
• Confrontation: a Goal, not a Style
• Avoid Argumentation
• Resistance Prevents Change
• Treatment can Increase Motivation
• Motivation Emerges from Patient-Doctor Interaction
Motivational Enhancement

BASIC CONCEPTS:

• Ambivalence is normal

• **Helping patients resolve ambivalence is the key to change**
Motivational Enhancement

The Basic Techniques

• Express Empathy
• Develop Discrepancy
• Avoid Argumentation
• Roll with the Resistance
• Support Self-Efficacy

Miller & Rollnick, 1991, 2002
Moving from Pre-Contemplation to Contemplation

• PROVIDE FEEDBACK
  - data specific to patient: labs, CAGE, BAC
  - review patient’s drug/alcohol consumption
  - compare results to normals

• SUMMARIZE FINDINGS; DRAW CONCLUSIONS

• NEVER ARGUE

• GIVE APPROPRIATE ADVICE
Moving from Pre-Contemplation to Contemplation

• WORKING WITH RESISTANT PATIENTS:
  - medical visits to assess “the problem”
  - listen to complaints
  - supportive, client-centered approach
  - avoid behavioral or non-directive analytic techniques

• START TO TREAT “THE PROBLEM” / ESTABLISH SOLID DOCTOR-PATIENT RELATIONSHIP

• GOAL: HELP PATIENT SEE CONNECTION BETWEEN PROBLEMS AND SUBSTANCE USE
Moving from Contemplation to Determination

• EXPLORE AMBIVALENCE & FANTASIES
  - begin with the positive: what do they gain?
  - then consider the negative:
    - Is there another side to this story?
    - Have you ever had second thoughts?

• INTERNALIZE THE CONFLICT
  - avoid conflict with patient
  - talk thru the anger, guilt, humiliation, fantasies about return to controlled use
Moving from Determination to Action

- CLARIFY INITIAL TREATMENT GOALS
  - to explore? - continue evaluation
  - to control? - refer for psychotherapy or addiction counseling
  - to stop? - refer to substance abuse treatment
Moving from Determination to Action

• SA TREATMENT ACTION PLAN
  
  - explore options
  
  - develop menu
  
  - let patient choose
Moving from Determination to Action

• NEGOTIATING TREATMENT OPTIONS
  - Brief Detoxification vs. Gradual Taper
  - Detoxification vs. Maintenance
  - NA vs. AA
  - Individual vs. Group or Family Therapy

• SUPPORT SELF-EFFICACY
Active Quitting Begins (Action)

- TREATMENT STRATEGIES
  - Buprenorphine therapy as a treatment platform
  - Encouraged twelve-step participation
  - Avoid passive non-directive strategies
  - Expect relapses

- QUITTING IS A TRIAL & ERROR PROCESS
Active Quitting Begins (Action)

- MANAGING RELAPSES
  - normal part of the recovery process
  - therapeutic optimism
  - relapse as an opportunity for learning
    - reassess recovery program
    - identify hidden triggers
    - identify defective coping skills
  - REDEFINE STRATEGIES & GOALS
    - intensify treatment activities
### Overview
Using the Stages of Change Model

<table>
<thead>
<tr>
<th>STAGE OF CHANGE</th>
<th>STRATEGIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-contemplation</td>
<td>Feedback</td>
</tr>
<tr>
<td>Contemplation</td>
<td>Resolve Ambivalence</td>
</tr>
<tr>
<td>Determination</td>
<td>Define Goals</td>
</tr>
<tr>
<td>Action</td>
<td>Choose from Menu</td>
</tr>
<tr>
<td>Maintenance</td>
<td>Relapse as Learning Opportunity</td>
</tr>
</tbody>
</table>
Patient Management Techniques

- Sobriety is the Primary Goal
- Structured therapies work best (CBT/TSF/MET) to achieve sobriety
- Learn to work with NA/AA
- Relapse Prevention: use relapses as learning tools
- Avoid excessive dependency
- Integrate buprenorphine therapy into recovery program
- Use Stages of Change to guide therapy choices
Keys to Successful Treatment

• Screen carefully for psychiatric co-morbidity
• Refer to skilled, empathetic therapists using MET
• Long-term treatment rather than high-intensity care
• Integrate self-help programs and family therapy
• Prompt return to therapy after any relapse
• External pressure (court, job, family, medical board) can be very helpful
REFERENCES


Project MATCH series, 1995

Volume 1-Twelve Step Facilitation Therapy Manual, NIH Pub. No. 94-3722


Pain Patients and Other Special Populations
Outline for This Talk

I. ADOLESCENTS (UNDER 18 YEARS OF AGE)

II. Pregnant patients

III. Geriatric patients

IV. Patients with acute or chronic pain

V. Patients with renal failure

VI. Patients appropriate for ER Naltrexone

VII. Summary
Special Considerations

- Consider including the parents in the assessment and treatment.
- Age of consent varies from state to state.
- DATA 2000 authorizes treatment of individuals age 16 and older.
Use of Buprenorphine in Adolescents

- While we have extensive studies of buprenorphine in adults, there are limited data in adolescents.
- Guidelines for dose induction and withdrawal for adults should, in general, be used with adolescents.
- Buprenorphine should be considered for adolescents who have failed previous attempts at abstinence.
- Oral Naltrexone should also be considered if family members are available to monitor medication ingestion.
- ER Naltrexone has not been studied in this population.
Use of Buprenorphine in Adolescents

- Other issues to consider when treating adolescents with buprenorphine include:
  - Supervision of take-home doses of medication
  - The risk of diversion and abuse
  - Providing other levels of treatment beyond medication (for example, individual or family counseling)
  - Assessing for pregnancy. It is necessary to test all adolescent females for pregnancy before buprenorphine is administered.
Outline for This Talk

I. Adolescents (under 18 years of age)
II. PREGNANT PATIENTS
III. Geriatric patients
IV. Patients with acute or chronic pain
V. Patients with renal failure
VI. Patients appropriate for ER Naltrexone
VII. Summary
Each year, 5,000-10,000 infants are born to opioid dependent mothers.

- Learn about specialized treatment services for pregnant, opioid dependent patients in your community.
- Management of the patient will depend on the availability of such services.
Initial Management of the Pregnant Patient

If the physician has been following the patient for some time on buprenorphine/naloxone, and she becomes pregnant:

- Switch the patient to buprenorphine monotherapy to minimize risk of naloxone exposure.

- Give strong consideration to referring the patient to a specialized treatment program and to a prenatal care provider as well, if prenatal services are not provided in the program.

- Refer the patient to a prenatal care provider immediately if there is any delay in access to the specialized program or no such program is available.
Use of Buprenorphine vs. Methadone in the Pregnant Patient

• Methadone has been the standard of care for pregnancy
  • Safe and effective for both the pregnant woman and the neonate.
  • Pregnant, opioid-using patients should be offered the possibility of referral to specialized services in methadone maintenance treatment program in it exists in your community
    • Induction onto methadone should be carefully monitored, although it has been found to be tolerated and safe for both the mother and the fetus.

• There is now strong evidence of the safety and reduced NAS in mothers treated with buprenorphine vs methadone

• Undergoing medically supervised opioid withdrawal during pregnancy has not been indicated, given the high rate of relapse that occurs during withdrawal.
Use of Buprenorphine

If the patient elects buprenorphine treatment during pregnancy:

• No reports of teratogenic effects (but limited number of cases are studied).

• Avoid naloxone, which is classified as Category B.

• Use the “mono” (buprenorphine) product instead of the “combo” (buprenorphine/naloxone) product in any pregnant patient.
Buprenorphine Dosing during Pregnancy

• No reports suggesting altered metabolism of buprenorphine during pregnancy (as commonly seen with methadone).

• Pregnant women treated with buprenorphine have had good withdrawal suppression with QD dosing.

• Maintain clinical flexibility during pregnancy and consider dose increases or split-dosing if indicated.
Recent double-blind, double-dummy randomized controlled trial of buprenorphine v. methadone indicates:

- Equivalent reductions in illicit opioid and other substance use
- Less satisfaction with and more dropout from buprenorphine group
- Mothers on methadone had higher rates of medical complications at delivery
- Buprenorphine has milder withdrawal syndrome for infant

(MOTHER study / Jones et al., NEJM 2010)

Reminder – Tobacco and alcohol use during pregnancy causes greater long term fetal development problems than opioids.
In Utero Exposure to Buprenorphine

Figure 2. Mean Neonatal Morphine Dose, Length of Neonatal Hospital Stay, and Duration of Treatment for Neonatal Abstinence Syndrome.
Buprenorphine in Lactation

- Plasma to breast milk ratio is approximately 1 (on the basis of limited data)
- Poor oral bioavailability when buprenorphine is swallowed.
Outline for This Talk

I. Adolescents (under 18 years of age)

II. Pregnant patients

III. GERIATRIC PATIENTS

IV. Patients with acute or chronic pain

V. Patients with renal failure

VI. Patients appropriate for ER Naltrexone

VII. Summary
Special Considerations

- Our index of suspicion is likely too low; we don’t usually think of drug use in the elderly.
- Effects of drug use may be mistakenly attributed to aging.
- The usual diagnostic criteria may be less appropriate for the elderly (for example, those related to violations of social norms).
Use of Buprenorphine

• No data on buprenorphine for opioid dependence in the elderly.

• Consider more gradual dose induction and closer monitoring (versus routine practice in non-elderly). They could have different sublingual absorption rates for this medication.

• Increase concern for medication interactions.

• Hepatic metabolism is slowed in the elderly, so maintenance buprenorphine doses may be lower than those used in younger patients.

• There is increased incidence of pain in the elderly. Treatment of pain may complicate the use of buprenorphine.
Elderly-Specific Considerations

- In addition, close observation during induction should also include monitoring of other medical conditions, to ensure no exacerbation of their symptoms occurs upon treatment with buprenorphine.

- Because the literature on the use of buprenorphine among the elderly is extremely limited, care should be exercised when choosing buprenorphine maintenance due to changes or differences in body composition and the metabolism of other medications.

- At the onset of treatment, more frequent monitoring of the patient should occur and should include assessment for medication side effects/interactions, including increased sensitivity to lower doses of buprenorphine.
Outline for This Talk

I. Adolescents (under 18 years of age)
II. Pregnant patients
III. Geriatric patients
IV. PATIENTS WITH ACUTE OR CHRONIC PAIN
V. Patients with renal failure
VI. Patients appropriate for ER Naltrexone
VII. Summary
“Opioid Debt”

- Patients who are physically dependent on opioids (i.e. methadone or buprenorphine) must be maintained on daily equivalence before ANY analgesic effect is realized with opioids used for acute pain management.

- Opioid analgesic requirements are often higher due to increased pain sensitivity and opioid cross tolerance.

Peng PW, Tumber PS, Gourlay D: Can J Anaesthesia 2005
Buprenorphine is an effective parenteral analgesic, but duration of analgesia is relatively short (necessitating multiple dosing daily).

In United States, the sublingual form has not been developed or approved for analgesic purposes.

Use of full opioid agonists to treat pain in patients maintained on buprenorphine can be complicated.
Acute Pain in Buprenorphine Maintained Patients

• Make sure some form of opioid maintenance medication is continued

• The patient’s acute pain will not be treated by their once daily maintenance dose of buprenorphine – other management of pain will be required

• Initially try non-opioid analgesics (ketorolac, NSAIDs, Cox-II inhibitors)

• If opioid analgesic is required, consider titrating a short-acting opioid analgesic in addition to their daily buprenorphine
Managing **Moderate Acute Pain** in Buprenorphine Maintained Patients

- Alternately, could try to obtain analgesic effect for acute pain with an increased dose of buprenorphine

- First divide maintenance buprenorphine dose to every 6-8 hours

- Add small supplemental doses of sublingual buprenorphine/naloxone 2/0.5 mg or 4/1.0 mg every 6-8 hour as needed
Peri-procedure management **WITH** expected need for opioid analgesics

- **Post-procedure**: Opioids analgesics should be started using standard dosing protocols but pain management should be carefully monitored since patients with opioid dependence often have decreased pain tolerance and cross-tolerance to opioid analgesics resulting in a need for higher opioid doses and shorter dosing intervals.

- **Because of its high affinity at the opioid receptor** fentanyl should be the opioid of choice for analgesia during surgery and in PACU for these patients.
Post-procedure OUTPATIENT analgesia with opioids

- Continue to hold buprenorphine
- All patients should be continued on ER/LA opioid
- Treat patient’s breakthrough pain with IR/SA opioids e.g., oxycodone, morphine.
- Schedule patient to seen by their buprenorphine provider within 1 week to be considered for restarting buprenorphine maintenance
Summary: Buprenorphine & Acute Pain

- **Options for severe pain:**
  - Regional anesthesia
  - Continue buprenorphine and titrate short-acting opioid analgesic
  - D/C buprenorphine, use opioid analgesic, then re-induce
- **Options for moderate pain:**
  - Consider non opioid alternatives first line
  - Divide buprenorphine to every 6-8 hours
  - Increase dose by 25%; divide total dose to every 6-8 hours
  - Use supplemental doses of buprenorphine (2/0.5 or 4/1.0 mg)
- **Additional option if inpatient,**
  - D/C buprenorphine
  - start methadone 20-40mg (or other extended-release, long-acting opioid)
  - use short-acting, immediate-release opioid analgesics
  - then re-induce w/ buprenorphine when acute pain resolves

Alford DP. Handbook of Office-Based Buprenorphine Treatment of Opioid Dependence. 2010
Macintyre PE et al. Anaesth Intensive Care 2013
Chronic Pain in Patients on Buprenorphine

➢ Consider coordinating care with a multidisciplinary team of pain management specialists where all approaches can be employed.

➢ Consider trials of all non-pharmacological approaches (e.g., physical therapy) and non-opioid medications appropriate to the clinical situation (e.g., NSAIDs, corticosteroids, tricyclic antidepressants, anticonvulsants).
Chronic Pain in Patients on Buprenorphine

- Treatment of chronic pain may be better achieved by maintaining patient on methadone rather than buprenorphine, and adding short acting opioids for pain control.

- Maintaining a patient on methadone requires transferring the patient to an Opioid Treatment Program (OTP), i.e., a methadone maintenance treatment program.
If chronic opioid analgesics are required for pain control:

- Buprenorphine may make it difficult to get analgesia from full mu agonists
- However, standard buprenorphine maintenance doses if divided into a q. 6-8 hr dosing schedule may provide adequate pain control
- These patients may require higher total daily doses in the range of 24 to 32 mg

Patient’s opioid dependence may be better treated with methadone maintenance (avoids complications of possible precipitated withdrawal by buprenorphine or difficulty obtaining effective analgesia)
Managing **Chronic Pain** in Buprenorphine Maintained Patients

In general, when treating a patient with chronic pain:

- Consider consulting a pain medicine specialist
- Consider multidisciplinary team approach
- Begin with non-pharmacologic therapies
- Try non-opioids and adjuvant analgesics
- If pain persists try splitting buprenorphine dose
- If no relief, transfer to methadone program and add concurrent long-acting opioid analgesics as needed
Outline for This Talk

I. Adolescents (under 18 years of age)
II. Pregnant patients
III. Geriatric patients
IV. Patients with acute or chronic pain
V. PATIENTS WITH RENAL FAILURE
VI. Patients appropriate for ER Naltrexone
VII. Summary
Patients with Renal Failure

- No significant difference in kinetics of buprenorphine in patients with renal failure versus healthy controls.
- No significant side effects in patients with renal failure.
- It should be suitable to use buprenorphine in patients with renal failure – consistent with buprenorphine’s metabolism being hepatic (not renal).
Buprenorphine undergoes hepatic metabolism, primarily by the CYP450 3A4 system.

Patients with compromised hepatic function could have reduced metabolism of buprenorphine, with resultant higher blood levels of the medication.

No specific hepatotoxicity has been demonstrated for either methadone or buprenorphine (NIDA CTN 0027 START Study).

However patients with impairments in hepatic function should be monitored closely.
I. Adolescents (under 18 years of age)

II. Pregnant patients

III. Geriatric patients

IV. Patients with acute or chronic pain

V. Patients with renal failure

VI. PATIENTS APPROPRIATE FOR ER NALTREXONE

VII. Summary
2 Groups of patients are appropriate for use of ER Naltrexone

- Patients entering treatment in active addiction OR after short-term detoxification/rehabilitation

- Patients who have succeeded on methadone or buprenorphine and successfully tapered off agonist medication
ER Naltrexone for Opioid Dependence: Dosing

• ER Naltrexone is only available in 1 dose, 380 mg IM
• Administered by a health care professional
  • Given as a 4-mL gluteal intramuscular injection
  • Delivering 380 mg of medication every 4 weeks or once a month

• ER Naltrexone must not be given intravenously, subcutaneously, or into adipose tissue
  • Inadvertent subcutaneous injection of naltrexone may increase the likelihood of severe injection site reactions
- Steady state by 2\textsuperscript{nd} dose
- Minimal accumulation 6β-naltrexol
- Limited 1\textsuperscript{st} pass metabolism by liver
Adverse Reactions Opiates
• severe injection site reactions (induration/pain)
• eosinophilic pneumonia
• serious allergic reactions
• unintended precipitation of opioid withdrawal
• accidental opioid overdose
• depression and suicidality
• hepatic enzyme abnormalities
• nasopharyngitis, insomnia, and toothache
Vulnerability to Opioid Overdose:
Because naltrexone blocks the effects of exogenous opioids for approximately 28 days after administration, reduced tolerance to opioids after opioid detoxification.

As the blockade dissipates, use of previously tolerated doses of opioids could result in potentially life-threatening opioid intoxication (respiratory compromise or arrest, circulatory collapse, etc).

Cases of opioid overdose with fatal outcomes have been reported in patients who used opioids at the end of a dosing interval, after missing a scheduled dose, or after discontinuing treatment.
Outline for This Talk

I. Adolescents (under 18 years of age)
II. Pregnant patients
III. Geriatric patients
IV. Patients with acute or chronic pain
V. Patients with renal failure
VI. Patients appropriate for ER Naltrexone
VII. SUMMARY
Summary

- We have limited information about the use of buprenorphine for the treatment of opioid dependence in these populations.
- This reflects, in part, the lack of studies with these groups (for any treatment intervention, not just buprenorphine).
- While caution should be exercised in the use of buprenorphine with any of these groups, buprenorphine’s safety profile is an advantage to its use in these populations.
Case Study #3

19-YEAR-OLD UNIVERSITY STUDENT
19-year-old university student
A 19-year-old woman university student comes to you asking for treatment of her heroin use. She has been using heroin intranasally for the last 15 months, daily for the last 3 months. She is now using about 1 gram daily. Some of her friends are now switching to intravenous use because it takes less heroin to keep from getting sick. She says she does not want to do that but may be “forced” to because she cannot keep paying the “extra cost” of nasal use. She has used all the money her parents gave her for school expenses to buy heroin, her credit cards are maxed out, and she has borrowed money from her friends. Until last semester, she had an overall B average, but this semester she is in academic difficulty. When she doesn’t use heroin, she has muscle aches, diarrhea, insomnia, and anxiety. She recognizes the symptoms as heroin withdrawal and was surprised because thought she could not develop dependence with nasal use. She has no prior history of drug treatment.

What is the diagnosis?
Is this patient a candidate for treatment with buprenorphine?
What are the treatment goals?
What is the initial treatment plan?
19-year-old university student

Part II
The clinic physician gives her a prescription for 6 day supply of buprenorphine (4 mg/day), and she is told to participate in the clinic’s relapse prevention workshop six days a week and to schedule individual counseling at the clinic once a week. She returns 3 days later having taken 8 mg/day for 3 days. She has not attended the relapse prevention workshop nor scheduled an individual counseling session. The counselor is not available to see her when she comes

What is the treatment plan at this point?
19-year-old university student

Part III
She returns the following day at a time when neither the group nor the counselor is available. She is told she has to attend the relapse prevention workshop in order to get medication. She does not return to the clinic for 4 weeks. When she does, she is smoking more heroin than before, but having no difficulty with finances because she has dropped out of school and is working as a stripper at a local “gentlemen’s club.”

*What would you recommend at this point?*
BUPRENORPHINE
Waiver Notification Form

Entering a 30 Patient Notification
Submitting a 30 patient Notification form on line

Before you begin
Before starting this application, please make sure you have
- Your DEA Number
- Your State Medical License Number
- Your Training Certificate Information

Do you work for the US military, Veterans Administration, or Indian Health Service?

- Yes
- No

Answer the question yes or no and click the Next button.
Check your eligibility

• Use the drop down menu to select your licensing state.
• Enter your medical license number, letter and numbers only. No spaces or dashes.
• Enter your DEA number, letter and numbers only.
• Click the Submit button.
Eligible?

The system will indicate the number of patients you are eligible to submit a Notification for. Click the Next button.

Eligible For Waiver Level 30
It appears your information is not in our database. Recheck your data, or click next to apply for the Notification of Intent (30 patient limit).

The state, medical license and DEA number will be pre-populated.
Complete Notification Form

1A. Enter your name and suffix. (M.D. or D.O.)
1B. Medical license number will be pre-populated
1C. License state will be pre-populated
1D. DEA number will be pre-populated

**Buprenorphine Waiver Notification 30**

Notification of Intent to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction under 21 USC § 823(g)(2)

Note: Notification is required by § 363(g)(2), Controlled Substances Act (21 USC § 823(g)(2)). See instructions below.

1A. NAME OF PRACTITIONER

First Name  
Middle Name  
Last Name  
Suffix  

1B. State Medical License Number  
25ma03737400

License State  
New Jersey

1D. DEA Registration Number
AT9264664

SMA-167 Form Approved: 0930-0234
Date: 07/31/2018
See OMB Statement Below
2. **Address** – if you are planning to store buprenorphine on site, you will need to provide the address you are listed under with DEA. Otherwise, you may provide an address in your licensing state. Do not enter a P.O. Box as your street address.

3. **Enter phone number**
4. **Enter fax number**
5. **Enter email address**, twice. Please provide an email address you regularly access. All correspondence from SAMHSA will be via email.
6. Purpose of Notification
the New box will be pre-checked
7. Check box, that you will only use approved Schedule III, IV, & V medications
8. Certification of Qualifying Criteria
Check the appropriate box if you have a sub-specialty in Addiction medicine or psychiatry.
Check the appropriate box for the 8 hour training course you completed.
Enter the date the training was completed.
Enter the city where the training was completed. If you have complete an on-line course type “web” for your city
The state will be pre-populated but you may change it if it does not correspond with where you complete on site training.
9. Certification of Capacity
   Check box – must certify that you will refer patients for counseling.

10. Certification of Maximum Patient Load – button is pre-populated

11. Consent to Release Contact Information – click the “consent” or “do not consent” button

12. Check the box which states that you have not knowingly given false information.

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<table>
<thead>
<tr>
<th>Certification of Capacity</th>
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<tr>
<td>I certify that I have the capacity to refer patients for appropriate counseling and other appropriate ancillary services.</td>
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<tr>
<th>Certification of Maximum Patient Load</th>
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<tbody>
<tr>
<td>I certify that I will not exceed 30 patients for maintenance or detoxification treatment at one time.</td>
</tr>
<tr>
<td>I certify that I will not exceed 100 patients for maintenance or detoxification treatment at one time.</td>
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The SAMHSA Buprenorphine Physician and Treatment Program Locator Web site is publicly accessible at [http://buprenorphine.samhsa.gov/bwks_locator](http://buprenorphine.samhsa.gov/bwks_locator). The Locator Web site lists the names and practice contact information of physicians with DATA waivers who agree to be listed on the site. The Locator Web site is used by the treatment-seeking public and health care professionals to find physicians with DATA waivers. The Locator Web site additionally provides links to many other sources of information on substance abuse. No physician listings on the SAMHSA Buprenorphine Physician and Treatment Program Locator Web site will be made without the express consent of the physician.

<table>
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<tr>
<th>Consent to Release Identifying Information to SAMHSA Buprenorphine Physician and Treatment Program Locator Web Site</th>
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</thead>
<tbody>
<tr>
<td>I consent to the release of my name, primary address, and phone number to the SAMHSA Buprenorphine Physician and Treatment Program Locator Web site.</td>
</tr>
<tr>
<td>I do not consent to the release of my name, primary address, and phone number to the SAMHSA Buprenorphine Physician and Treatment Program Locator Web site.</td>
</tr>
</tbody>
</table>

I certify that the information presented above is true and correct to the best of my knowledge. I certify that I will notify SAMHSA at the address below if any of the information contained on this form changes. Note: Any false, fictitious, or fraudulent statements or information presented above or misrepresentations relative thereto may violate Federal laws and could subject you to prosecution, and/or monetary penalties, and/or denial, revocation, or suspension of DEA registration. (See 18 USC § 1001; 31 USC §§ 3801–3812; 21 USC § 824.)
Type you name in the box as your signature. Type in your DEA number matching the one you entered initially. Click the Submit button.
When the Notification is submitted successfully you will receive a confirmation. If it has not, an error message will indicate what needs to be correct.
Physician Clinical Support Systems (PCSS)

• To get involved - go to the websites:
  • Prescriber’s Clinical Support System for Opioid Therapies
    - www.pscce-o.org
  • Prescriber’s Clinical Support System for Medication Assisted Therapies
    - www.pcssmat.org
Introduction to PCSS-MAT
Target Audience

- The overarching goal of PCSS-MAT is to make available the most effective medication-assisted treatments to serve patients in a variety of settings, including primary care, psychiatric care, and pain management settings.
Training Modalities

PCSS-MAT offers FREE training activities with CME to health professionals through the use of:

- **Live Webinars**: [http://pcssmat.org/education-training/webinars/](http://pcssmat.org/education-training/webinars/)


- **Online Modules**: [http://pcssmat.org/education-training/modules/](http://pcssmat.org/education-training/modules/)

In addition, PCSS-MAT offers clinical resources that can be accessed here: [http://pcssmat.org/resources/essential-materials/](http://pcssmat.org/resources/essential-materials/)
PCSS-MAT Mentoring Program

- PCSS-MAT Mentor Program is designed to offer general information to clinicians about evidence-based clinical practices in prescribing medications for opioid addiction. PCSS-MAT Mentors comprise a national network of trained providers with expertise in medication-assisted treatment, addictions and clinical education.

- Our 3-tiered mentoring approach allows every mentor/mentee relationship to be unique and catered to the specific needs of both parties.

- NEW: Small Group Discussions allow for an interactive round table talk between mentor and mentees

- The mentoring program is available at no cost to providers.

For more information on requesting or becoming a mentor visit: pcssmat.org/mentoring
PCSSMAT is a collaborative effort led by American Academy of Addiction Psychiatry (AAAP) in partnership with: American Osteopathic Academy of Addiction Medicine (AOAAM), American Psychiatric Association (APA) and American Society of Addiction Medicine (ASAM).

For more information visit: www.pcssmat.org
For questions email: pcssmat@aaap.org

Twitter: @PCSSProjects

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