Disclosures

• I have no disclosures or commercial interests to report
“In all my years as a physician, I have never, ever met an addicted person who wanted to be an addict.”

- Dr. Nora Volkow
NIDA Director

DrugAbuse.gov
DRUG OVERDOSES NOW TAKE MORE LIVES EVERY YEAR THAN TRAFFIC ACCIDENTS

PRESIDENT OBAMA’S BUDGET CALLS FOR NEW $1.1 BILLION INVESTMENT TO EXPAND TREATMENT

Deaths per year

Drug Overdoses

Traffic Accidents

SOURCE: Centers for Disease Control and Prevention, National Center for Health Statistics (NCHS). Multiple Cause of Death 1999-2014 on CDC WONDER Online Database, revised 2015.
10% of patients with substance use disorder (SUD) receive treatment over the course of a year.

Current state of SUD

- 1 out of every 11 individuals across the country has SUD.
- Opioid related deaths (40K in 2016) have surpassed peak deaths from car crashes, HIV and guns.
- MA death rate from opioids has surpassed the national average.

Opioid misuse has an estimated cost to society of $80 billion.

Source:
- SAMHSA, NSDUH survey 2014
- The Surgeon General's Report on Alcohol, Drugs, and Health, 2016
- Face It Together, Scale of Addiction
- The Upshot – Drug Deaths in America are rising faster than ever (June 5, 2017)
- "Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States", Brinbaum et al. (2011)
- McKinsey analysis
Compulsive Drug Use (Addiction)

Voluntary Drug Use
Treatment Non Compliance Rates Are Similar for Drug Dependence and Other Chronic Illnesses

Most Importantly

• Detox is not treatment!
Medication-Assisted Treatment Models of Care for Opioid Use Disorder in Primary Care Settings

Technical Briefs, No. 28
Agency for Healthcare Research and Quality
BMC Collaborative Care Model

- Patient-level outcomes comparable to physician-centered approaches
- Allows efficient use of physician time to focus on patient management (e.g., dose adjustments, maintenance vs taper)
- Improved access to OBOT and daily management of complex psychosocial needs (e.g., housing, employment, health insurance)
- Open communication between NCM and other providers including behavioral health improved compliance

Alford DP et al. Arch Intern Med. 2011
Why the Nurse Care Model Works

- Increased patient access
  - Frequent follow-ups
  - Case management
  - Able to address
    - positive urines
    - insurance issues
    - prescription/pharmacy issues
- Pregnancy, acute pain, surgery, injury
- Concrete service support
  - Intensive treatment needs, legal/social issues, safety, housing
- Brief counseling, social support, patient navigation
- Support providers with large case loads
Office-Based Opioid Treatment with Buprenorphine (OBOT-B): Implementation of Massachusetts Model

- Between 2007 and 2013, 14 community health centers (CHCs) successfully initiated OBOT
- Physicians “waivered” increased by 375%, 24 to 114 over 3 years
- Annual admissions of OBOT patients to CHCs increased from 178 to 1210

History of Opioid Agonist Regulation

- In 1914, the Harrison Narcotics Act
  - Treatment for addiction with opioids stopped
  - 1970’s methadone maintenance approved for OUD

  - Treat OUD with approved medication in office setting
  - Allowed and approved Schedule III-V for OUD
  - Buprenorphine/naloxone only approved medication
  - Methadone Scheduled II no changes in regulations
Buprenorphine—Regulatory (2)

- FDA approved for the treatment of OUD
  - DEA Schedule III (refills permitted)

- Authorized by Drug Abuse Treatment Act of 2000
  - Qualifying physician must have a waiver
  - Special registration: “X” number Controlled Substances Act opioid agonist therapy
  - X number must be included on prescription with DEA number
  - Renewed at same time as DEA
  - No additional charge
  - State systems may require a copy or proof of certification

https://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management
Responding to Treatment Barriers continued:

- Engaging RNs, and support staff
- Allowing NPs and PAs to prescribe
- Collaborative models of care expand treatment
  - Nurse care-manager models
  - Induction centers
  - Specialty supports
- Educating payers to cost benefits
- CARA Act: Expansion access to prescribe
Comprehensive Addiction and Recovery Act (CARA) 2016

- Authorizing NP’s and PA’s to prescribe under DATA 2000 revision
  - Waivered for 5-year period expires 2021
  - Newly waivered providers: treat 30 patients in year one
  - Can apply after one year to increase to 100
  - 24 hours addiction education: accredited, authorized providers
  - HHS secretary may waive/adjust requirements for those working in addiction
  - If supervision/collaboration required by state law must be with waivered provider

Role of Providers

- Multi-disciplinary team
  - Complex disease management
- Support staff: clerical, administrative
- Nurses
- Behavioral health
- Social workers, therapist
- Prescribers
Regulatory Oversight of Medication Treatment for OUD

- FDA-approved medications for OUD
  - Methadone
  - Buprenorphine (monotherapy and combination with nalaxone)
  - Naltrexone (oral and long-acting injection)

\(\text{fda.org}\)
Regulatory Differences: Methadone vs Buprenorphine

- **Location of treatment**
  - Methadone: in OTP setting
  - Buprenorphine: office-based or OTP

- **Urine drug testing**
  - Methadone: 8 or more yearly
  - Buprenorphine: as clinically indicated

- **Clinical visit frequency**
  - Methadone: federally regulated
  - Buprenorphine: as clinically indicated

- **Days’ supply of medication**
  - Methadone: slow progression
  - Buprenorphine: as clinically indicated
Buprenorphine Clinical Visit Frequency

- Visit frequency individualized
- More frequent visits: initiation, relapse, medical, social, or mental health issues
- Rationale for frequency should be documented
- Frequency of visits adjusted with clinical status changes
- Link visits to medication
Regulatory and Administrative Concerns

- Patient should be informed of your rationale for recommending buprenorphine
- The risks, benefits, and alternatives should be discussed and summarized in the medical record
- Recommendation for appropriate psychosocial treatment should be made
- Informed consent: opioid product
DEA Inspection: What to Expect (1)

- **Purpose:**
- Assure compliance: record keeping and security
  - Professional unannounced visit
  - 2 unarmed officers with identification
  - Will perform visit if you are present
  - Prescriber not on site when DEA arrives:
    - Will sometimes schedule return date and time
  - Issue notice of inspection
  - DEA registration, licenses, and records at location
DEA Inspection

- Log of patients: numbers being treated
  - 30 vs 100

- Log of prescriptions

- Storage

- Prescriptions:
  - Name, address, drug, strength, dose, quantity, directions
  - Dated and signed when issued
  - DEA’s numbers prescriber including X number

- Tracking tool:
  - Within EMR or create tracking tool
How Does Buprenorphine Work? (1)

Full Agonist (Methadone)

Partial Agonist (Buprenorphine)

Antagonist (Naloxone)
• **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? (2)**

Buprenorphine affinity is higher, therefore full agonist is displaced
How Does Buprenorphine Work? (3)

**DISSOCIATION** is the speed (slow or fast) of disengagement, or uncoupling, of a drug from the receptor

- Buprenorphine dissociates slowly
- Therefore buprenorphine stays on the receptor a long time and blocks heroin, methadone and other opioids from binding to those receptors

Buprenorphine dissociates slowly, so full agonist has reduced binding
Formulations

- Generic sublingual (SL) buprenorphine tablets and generic SL bup/nlx
- Buprenorphine and buprenorphine/naloxone film
- Buccal film: cheek
- Buprenorphine patch: pain only
- New formula buprenorphine/naloxone: different dosage
- Implantable buprenorphine, injectable

Buprenorphine sublingual film
https://www.suboxone.com/medical-treatment/how-to-take-suboxone
Planning for Induction

• **Build a Relationship. Build Trust:**
  - Early stages of withdrawal prior to induction
  - Review with patient ahead of time:
    - Usage history, withdrawal, last use
    - Reinforcing the goal to improve symptoms
    - Help them feel better
  - Short-acting, long-acting opioids:
    - What did they last use?
Buprenorphine Induction: Office Logistics (1)
How to Prevent Precipitated Withdrawal (1)

Opiate Withdrawal Timeline

- Last Dose
- Symptoms Begin
- Symptoms Peak
- 6-12 hours: Short-Acting Opiates
- 30 hours: Long-Acting Opiates
- 72 hours

Symptoms Peak:
- Nausea
- Vomiting
- Stomach Cramps
- Diarrhea
- Goosebumps
- Depression
- Drug Cravings

http://americanaddictioncenters.org/withdrawal-timelines-treatments/opiate/
How to Prevent Precipitated Withdrawal (2)

• **Withdrawal more likely when:**
  - Level of physical dependence is high
  - Short time since last opioid use (short- vs long-acting opioids)
  - Initial dose of buprenorphine too high

• **Prevention:**
  - Administer 1st buprenorphine dose when objective signs of withdrawal are present
Buprenorphine Induction - Day 1

• Instruct the patient to abstain from any opioid use prior to induction to avoid precipitated withdrawal:
  
  ❖ 8-12 hours for short-acting opioids
  
  ❖ 24 hours for sustained-release opioid medications
  
  ❖ 36 or > hours for methadone; assessment is critical
Buprenorphine Induction - Day 1

• If patient is not in opioid withdrawal at time of arrival in office:
  ❖ Assess last opioid use
  ❖ Consider returning another day, or wait and reassess for withdrawal.
  ❖ Ask specifically about last use (heroin, fentanyl, methadone, oxycodone)
  ❖ Short- vs long-term opioids
  ❖ Methadone requires more time
  ❖ Avoid precipitating withdrawal
Buprenorphine Induction - Day 1

- First dose: 2 to 4 mg SL buprenorphine/naloxone
- Monitor in office for 1+ hours after first dose
  - Opioid withdrawal symptoms should improve 30-45 minutes after the first dose
  - Better, worse, or the same?
  - If opioid withdrawal subsides but then reappears, re-dose every 2-3 hours
  - Aim for a dose of 8-12 mg in the first 24 hours
Buprenorphine Induction - Day 1

- If opioid withdrawal appears: may have precipitated withdrawal
- Greatest severity precipitated withdrawal:
  - First few hours (1-4) after a dose
  - Decreasing symptoms over subsequent hours
Buprenorphine Induction - Day 1

- If precipitate withdrawal:
  - Continue dosing, provide agonist effect, suppress withdrawal

  OR

  - Stop induction, provide symptomatic treatments, and have the patient return the next day

- Latter - risk losing the patient, the first option is often preferred
Buprenorphine Induction - Patient Education

- Sublingual tablets/film held under tongue until dissolved
  - Start with a moist mouth
  - Avoid acidic drinks (coffee or fruit juice)
  - No smoking immediately before or after
  - No talking during administration
  - Keep tablet or film under tongue or buccal mucosa
  - Do not swallow until entire tablet or film dissolves
Clinical Opioid Withdrawal Scale (COWS)

• Total Score:
  ❖ 5-12 Mild
  ❖ 13-24 Moderate
  ❖ 25-36 Moderately Severe
  ❖ >36 Severe
  ❖ Aim for Score: 8-10

Wesson, 2003
# Opioid Withdrawal Assessment

<table>
<thead>
<tr>
<th>Grade</th>
<th>Symptoms / Signs</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Anxiety, Drug Craving</td>
</tr>
<tr>
<td>1</td>
<td>Yawning, Sweating, Runny nose, Tearing eyes, Restlessness, Insomnia</td>
</tr>
<tr>
<td>2</td>
<td>Dilated pupils, Gooseflesh, Muscle twitching &amp; shaking, Muscle &amp; Joint aches, Loss of appetite</td>
</tr>
<tr>
<td>3</td>
<td>Nausea, extreme restlessness, elevated blood pressure, Heart rate &gt; 100, Fever</td>
</tr>
<tr>
<td>4</td>
<td>Vomiting / dehydration, Diarrhea, Abdominal cramps, Curled-up body position</td>
</tr>
</tbody>
</table>

Clinical Opiate Withdrawal Scale (COWS): pulse, sweating, restlessness & anxiety, pupil size, aches, runny nose & tearing, GI sx, tremor, yawning, gooseflesh (score 5-12 mild, 13-24 mod, 25-36 mod sev, 36-48 severe)
Timing of Induction: Short-Acting Opioids

- Abstain 8-12 hours (mild withdrawal)
  - If not in documented withdrawal:
    - Review/assess history
    - Assess, support, and wait
    - What did you use in the last 24 hours?
      - Ask specifically: methadone, oxycontin, heroin, fentanyl?
      - Urine testing prior to induction if possible
Short-Acting Opioids

8 to 12 hours

- Oxycodone (Percocet®, crushed Oxycontin®)
- Hydrocodone (Vicodin®)
- Heroin
- Morphine
Long-Acting Opioids:

- Oxycontin P.O.: 24+ hours
- Methadone: 48+ hours
- Much harder and longer process
- Patient and provider need to be engaged
Timing of Induction: Long-Acting Opioids:

Opiate Withdrawal Timeline

- **Last Dose Last Dose**
  - **Short-Acting Opiates**
  - **Long-Acting Opiates**

- **6-12 hours**
- **30 hours**
- **72 hours**

Symptoms Peak:
- Nausea
- Vomiting
- Stomach Cramps
- Diarrhea
- Goosebumps
- Depression
- Drug Cravings
Timing of Induction: Long Acting Opioids

- Abstain for at least 48+ hours
- Assess for withdrawal

Timing is often not a good indicator:
  - Need to assess symptoms
  - Slow and steady
Patient Instructions
During First dose:

- Put tablet(s) or film under tongue (sublingual), buccal form (cheek), or as instructed by formula
- Do not talk, do not swallow: saliva pools
- May use mirror, watch the tablet(s) gradually shrink as they dissolve
- Do not drink fluids immediately before, during, or after
- Do not smoke before, during, immediately after
First Dose of Buprenorphine

- Patient in clinical opioid withdrawal
- Objective signs are key to making diagnosis (can be challenging)
- COWS > 8-12
- Start with 2-4 mg sl
- Assess: 40-60 minutes after dosing
- Ask: better, worse, or the same?
Induction

- Continue to titrate until symptoms resolve
- Re-assess patient 40-60 minutes after first dose
- Dose with 2-4 mg sl
- Reassess over the next few hours
- Stabilize day one around 8 mg or per your protocol and clinical assessment
Induction days 2-3

- Assess symptoms

- Adjust dose accordingly:
  - withdrawal symptoms
  - decrease over-medicated

- Continue adjusting by 2 - 4 mg increments
  - target dose of 12 - 16 mg

- Resolution of craving and withdrawal
Determining the Best Dose

- Remember goals of treatment
  - Relieve withdrawal symptoms
  - Reduce craving
  - Opioid blockade

- Achieving these should result in improved function
Methadone to Buprenorphine

- Challenging transition
- Objective withdrawal: most important
- May take much longer than 36 hours
- Support, communication, support
- Back up plan: can they return to methadone?
Methadone to Buprenorphine

- Agonist
- Agonist & Antagonist
- Partial Agonist

Log [Dose]
Methadone to Buprenorphine

• Primary Goal: Minimize risk of precipitated withdrawal, manage withdrawal
  - Knowledgeable provider
  - Communication: MMT and BUP provider
  - Taper methadone 30 mg/d or <, hold for 1-2 weeks (ideal)
  - Stop methadone for 2-3 days, COWS score > 12
  - Ensure patient supports, comfort meds, emergency numbers
  - Day 3 off methadone, observed induction with bup/nlx 2/0.5 mg, up to 8 mg on day as symptoms dictate. Treat symptoms
  - Seamless return to methadone if needed
  - Utilize inpatient detox if possible, allows added supports
What is the Optimal Dose?

• Like most medications, the optimal dose is the lowest dose that maximizes function and minimizes side effect
  ❖ Most patients stabilize on 8-24 mg/day
  ❖ Narcotic blockade
  ❖ Rarely 32 mg with the highly tolerant patient
Buprenorphine Induction: Procedure

• Patients not physically dependent on opioids
  ❖ For example: high risk for relapse i.e., released from prison
  ❖ First dose: Start **low**, go **slow** (2 mg buprenorphine)
  ❖ Monitor and reassess
  ❖ Gradually increase dose over days/weeks
  ❖ Support
Buprenorphine Induction: Goals

• Dose of buprenorphine at which the patient:
  ❖ Has no opioid withdrawal symptoms
  ❖ Discontinues use of opioids
  ❖ No cravings
  ❖ Has narcotic blockade
  ❖ Has minimal or no side effects
Induction: Not Physically Dependent on Opioids

• Examples:
  ❖ High risk for relapse to opioid use:
    ➢ Pre/post incarceration
    ➢ Environmental
    ➢ Life stressor
    ➢ Cravings
Induction: Not Physically Dependent on Opioids

- First dose: 2 mg SL buprenorphine
- Monitor after first dose
- Gradually increase dose ( +2 mg/day) over several days/week as needed
- Stabilize dose that eliminates craving; dose range 2 mg to 16 mg
- Go slow and low. Avoid relapse.
Induction Summary

- Put systems in place prior to starting
- Provide ongoing education and support
- Do not assume anything: ask questions
- Good clinical assessment: trust your gut
  - No harm in waiting it out
- Objective assessment vs subjective reports
- Go slow and low
- Ask for help
- Use mentors

AHRQ, Gunderson
Facilitators of Engaging RNs, NPs, PAs into Treatment of Patients with SUD/OUD

• Increased public awareness about the opioid epidemic and treatment need

• Increase awareness about costs associated with inadequate treatment

• The collaborative approach is cost effective and sustainable in some states in the FQHC model (CMS Modeling)

• Collaborative approach proven to expand access to care in significant numbers quickly

• Boots on the Ground…
NIDA Developing On Line Modules

• 24 One hour modules
• Multidisciplinary
• Case based/vignettes
• One CE per module
• Free
• Released 2017
  • Harvard global health Opioid Use Disorder
SAMHSA Opioid Initiatives

- Strategic Prevention Framework for Prescription Drugs (SPF-RX)
- Grants to Prevent Prescription Drug/Opioid Overdose-Related Deaths (PDO)
- Targeted Capacity Expansion: Medication Assisted Treatment-Prescription Drug and Opioid Addiction (MAT-PDOA)
- Screening, Brief Intervention and Referral to Treatment (SBIRT) [www.integration.samhsa.gov/clinical-practice/sbirt]
- Physician Clinical Support System for Opioids [www.pcss-o.org]
- Physician Clinical Support System for Buprenorphine [www.pcssb.org]

SAMHSA Technical Assistance Centers

- Opioid Treatment Technical Assistance Program (OTTAP)
- Addiction Technology Transfer Center (ATTC)
- Center for the Application of Prevention Technologies (CAPT)
- Center for Integrated Health Solutions (CIHS)
Resources for Treating Pregnant Women

A Collaborative Approach to the Treatment of Pregnant Women with Opioid Use Disorders  http://store.samhsa.gov/

Advancing the Care of Pregnant and Parenting Women with Opioid Use Disorder and Their Infants: A Foundation for Clinical Guidance

https://www.regulations.gov/document?D=SAMHSA-2016-0002-0001
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 treatment, addictions, and clinical education.

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

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

For more information on requesting or becoming a mentor visit: pcssmat.org/mentoring
Providers’ Clinical Support System
For Medication Assisted Treatment

What We Do
We are a national training and mentoring project developed in response to the prescription opioid misuse epidemic and the availability of pharmacotherapies to address opioid use disorder. 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, substance use disorder treatment, and pain management settings.

View Modules
The foundation for provider education on topics related to medication-assisted treatment for opioid use disorder.

Find a Mentor
The mentor program provides individualized support and mentoring for providers treating opioid use disorder.

Watch Webinars
Webinars provide expanded education targeted at clinicians engaged in the treatment of opioid-dependent patients.

Start Training
Connect Now
Watch Now
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