Lessons Learned in a Nurse Care Manager Model Treating Patients with Buprenorphine

Karen Hannon
Colleen LaBelle
Marie Trenouth
Kristin Wensely
Boston University Medical Center
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DEA

Colleen LaBelle

Prescription Requirements

- In order to be legal, a prescription must:
  - Be issued by a registered practitioner
  - For legitimate medical purpose
  - In the usual course of professional practice 21 CFR 1306.04 (A)

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Prescription Requirements

- DEA does NOT define nor regulate medical practice standards
- There are no federal laws or regulations that put limits on the quantity of controlled substances that may be prescribed
- Some states or insurance providers may limit the quantities of controlled substances prescribed or dispensed

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DATA WAIVED Practitioners

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Patient Limits

- Practitioner must first apply via notification to Center for Substance Abuse Treatment (CSAT) prior to dispensing or prescribing controlled substances approved for drug treatment
- Initial patient limit: 30
- After one year may submit to CSAT with intent to increase to 100
- CSAT will forward request to DEA

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Prescription Requirements

- All prescriptions for controlled substances must be dated as of, and signed on, the day when issued and must have the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner
- 21 C.F.R 1306.05 (a)

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Prescription Requirements

- A prescription for a Scheduled III, IV, or V narcotic drug approved by FDA specifically for "detoxification treatment" or "maintenance treatment" must include the identification number issued by DEA
- 21 C.F.R. 1306.05 (a)

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Record Keeping Requirements

- All records required to be kept, must be available for inspection
- 21 U.S.C. 827 (b) and 21 C.F.R. 1304.03 (a)
- What needs to be kept?
  - Records of prescriptions issued
  - Dispensing Records

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Record Keeping Requirements

- A registered individual practitioner is not required to keep records of controlled substances in schedules II-V which are prescribed in the lawful course of professional practice, unless such substances are prescribed in the course of maintenance or detoxification treatment of an individual
- 21 C.F.R. 1304.03 ©

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Record Keeping Requirements

- What should the record look like?
  - The regulations only require that a record of the prescription be kept
  - It does not stipulate in what form the record must be
  - Suggestions:
    - Can be a copy of the prescription
    - Can be a log of prescriptions issued
    - Can be noted in patient chart (EMR useful)

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Record Keeping Requirements

- A registered individual practitioner is required to keep records of controlled substances in Schedules II-V which are dispensed
- 21 C.F.R 1304.03 (b)
- Need to account for stock ordered and dispensed. For example:
  - Inventories (Initial and Biennial)
  - Receiving and dispensing records
  - Theft or loss Reports

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Record Keeping Requirements

- All records required to be kept must be kept by the practitioner and be available for at least 2 years for inspection and copying by authorized employees of the Administration
- 21 C.F.R. 1304.04 (a)

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Storing Required Records

- Records that are required to be kept must be kept at the registered location
- If you registered at your residence because you have determined this to be your principle place of business, that is where the records have to be maintained
- It is also the location DEA will show up to inspect since the address on the DEA Registration is the registered location

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Storing Required Records

- One state with multiple practices:
  - Records of prescription for drug treatment must be maintained at the DEA Registered Location
- Multiple states:
  - Records of prescriptions for drug treatment must be maintained at the DEA Registered Location in each state from which the prescription was written

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The Inspection Process, what to Expect ..

- The investigation should be conducted by 2 DEA Diversion Investigators.
- The primary purpose is to ensure compliance with the recordkeeping
- Security requirements under CSA and DATA 2000.
- Verification of credentials including DEA registrations and state licensure

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The Inspection Process..What to Expect

- **The inspectors will verify the number of patients you are treating to ensure that they are in line with the limits in DATA 2000.**
- **You must keep any log of patients who are treated with buprenorphine, as well a record of the prescriptions for each patient, in the location listed on your DEA registration**

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Lessons Learned: DEA Inspection

- DEA is mandated to protect the public's safety
- DEA is required to ensure that DEA Registrants comply with the Controlled Substance Act and its implementing regulations
  – Inspections (Unannounced) Maintains the integrity of the inspection process
  – Issue a Notice of Inspection to inspect records required to be kept/Giving consent to inspect records
  – Audit of dispensing records to ensure accountability
  – Verify patient limit compliance

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Misuse, Abuse, Diversion

Karen Hannon

Managing Pain Issues in OBOT

- Acute pain- Dental, Injuries
- Procedures- Colonoscopy, Liver Biopsy
- Surgeries- Gallbladder, Joint Replacement
- New Cancer Diagnosis
- Chronic Pain- Arthritis, Back Pain, Hepatitis C

The New York Times

U.S.

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POLITICS EDUCATION BAY AREA CHICAGO TEXAS

When Children's Scribbles Hide a Prison Drug

Craig Dilger for The New York Times

Officer Paul Cabral at the Maine Correctional Center in Windham handing screened mail to an inmate. Suboxone smuggling has changed how mail is handled.

By ABBY GOODNOUGH and KATIE ZEZIMA

Published: May 26, 2011

Cape May County Sheriff's Department

Suboxone (hint: the fish) was hidden in this coloring book.

Enlarge This Image

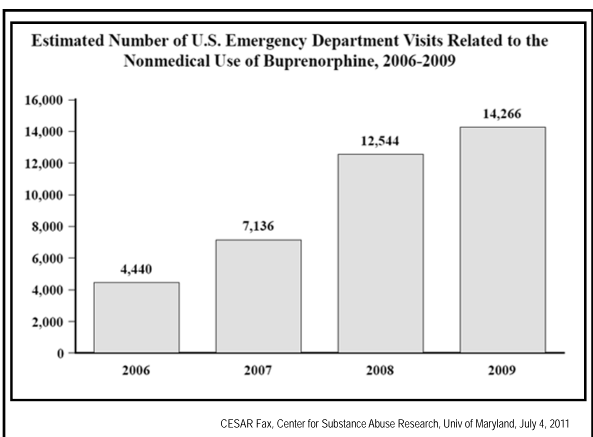
Craig Dilger for The New York Times

Officer Mike Barrett removes stamps from mail at the Maine Correctional Center; the drug is often hidden behind them.

Abuse Potential of Buprenorphine

- Euphoria in non-opioid dependent individuals
- Abuse potential less than full opioid agonists
- Abuse among opioid-dependent individuals is relatively low
- Blinded **opioid-dependent** research subjects rated IV combo product not as desirable and worth less (i.e., “street value”) compared to mono product*
- Opioid naïve individuals unable to distinguish between IV mono or combo preparations**
- IV use of combo product in patients maintained on buprenorphine does not precipitate withdrawal***
- Most illicit use is to prevent or treat withdrawal and cravings

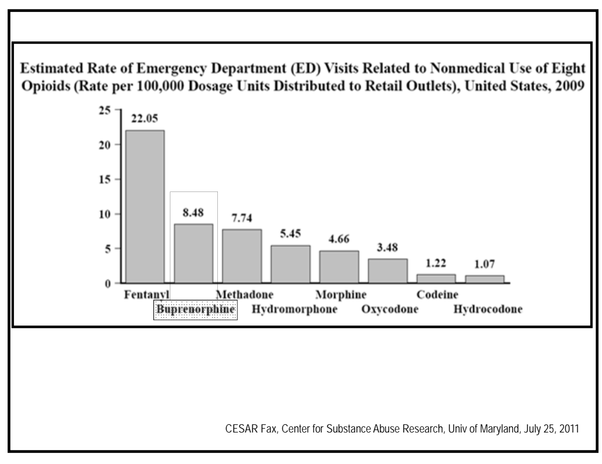
Yokell MA et al. Curr Drug Abuse Rev 2011
*Mendelson J et al. Psychopharm 1999. Alho H et al. Drug Alcohol Depend 2007
**Comer SE et al. J Pharmacol Exp Ther 2002
***Harris D et al. Drug Alcohol Depend 2000



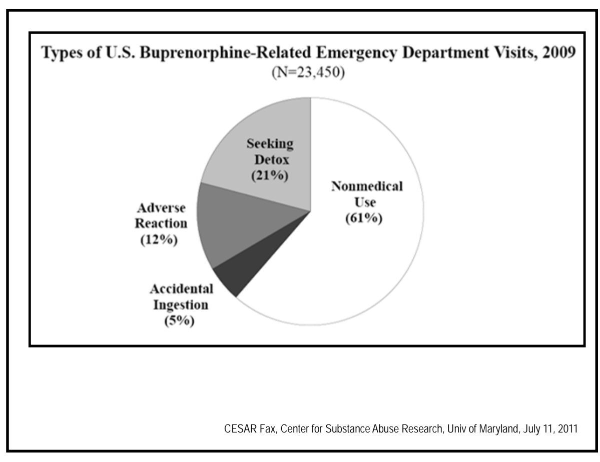
CESAR Fax, Center for Substance Abuse Research, Univ of Maryland, July 4, 2011

Buprenorphine as an Analgesic

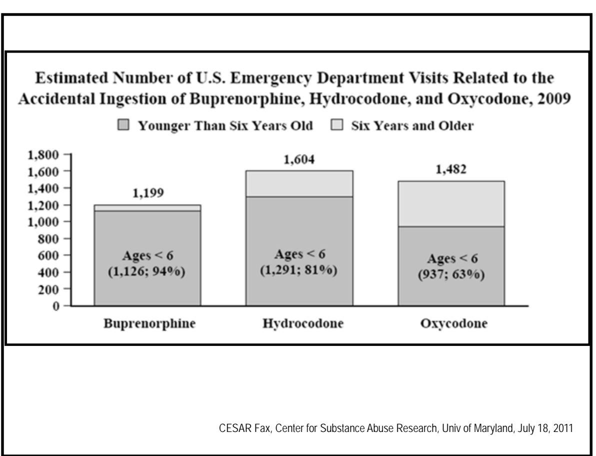
- In U.S., sublingual formulation not developed for analgesic purposes
- Small studies in Europe and Asia demonstrate analgesic efficacy of sublingual formulation (0.2-0.8 mg q 6-8 h) in post-operative pain
  - Ceiling analgesic dose ~ 1.5-5 mg
  - Onset of analgesia ~ 30 minutes
  - Peak analgesia ~ 3 hours
  - Duration of analgesia ~6-8 hours



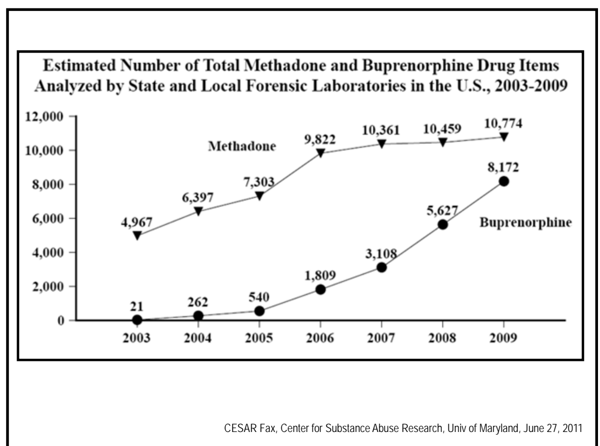
CESAR Fax, Center for Substance Abuse Research, Univ of Maryland, July 25, 2011



CESAR Fax, Center for Substance Abuse Research, Univ of Maryland, July 11, 2011



CESAR Fax, Center for Substance Abuse Research, Univ of Maryland, July 18, 2011



CESAR Fax, Center for Substance Abuse Research, Univ of Maryland, June 27, 2011

Source and Route of Misuse

	Buprenorphine (n=264)	Other Prescription Opioids (n=799)
Doctor source	57%	53%
Friend source	23%	64%
Dealer source	35%	74%
SL route	87%	14%
IV route	6%	37%
IN route	9%	45%

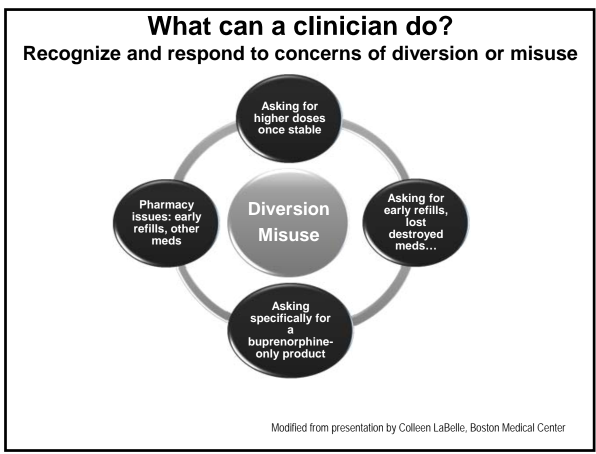
Cicero C et al. J Opioid Manag 2007

Understand Diversion and Misuse

Understand Diversion
- Help addicted friend
- Peer pressure
- Income

Understand Misuse
- Perceived under-dosing
- Relieve craving
- Relieve withdrawal
- Relieve other symptoms (e.g.

Modified from presentation by Michelle Lofwall, MD Univ of Kentucky



What can a physician (practice) do?

- Begin with clear expectations
- Open discussion about misuse, diversion, drug-drug interactions
- Therapeutic dosing (i.e., minimum effective dose) with combo product
- Frequent face-to-face visits until stable
- Encourage safe storage
- One pharmacy per patient
- Encourage concurrent non-pharmacological treatment
- Monitor and respond to aberrant behaviors and abnormal drug tests
- Collaborative care when possible
- If treatment is not working, refer to alternative treatments
- Utilize PCSS-B (buprenorphine)

Alford DP et al. Archives of Internal Medicine 2011

SAMHSA/CSAT sponsored
www.pcssb.org

PCSS-B Training
Physicians' Clinical Support System – Buprenorphine

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Upcoming Waiver Eligibility Trainings New!

Now Available
Advanced Case Studies for Prescribing Buprenorphine for Opioid Dependence

An Educational Resource for Those Treating Patients With Opioid Use Disorders

The American Academy of Addiction Psychiatry (AAAP), the American Osteopathic Academy of Addiction Medicine (AOAAM) and the American Psychiatric Association (APA) are pleased to announce that we have been awarded a three year grant by the Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment (CSAT) to operate the Physicians' Clinical Support System for Buprenorphine (PCSS-B).

Patient Education

Protecting Others and Protecting Treatment...

Acknowledgements:
This brochure was produced by STATE OBOT (State Technical Assistance Treatment Expansion Office Based Opioid Treatment of Buprenorphine), and BSAS Bureau Substance Abuse Services

Individual Sites Include:
Boston Health Care for the Homeless Program
Boston Medical Center
Baystate Brightwood Community Health Center
Cambridge Health Alliance
The Dimock Center
Duffy Health Center
Family Health Center Worcester
Greater Lawrence Family Health Center
Holyoke Health Center
Lowell Community Health Center
Lynn Community Health Center
MGH Chelsea HealthCare Center
MGH Revere HealthCare Center
South Boston Community Health Center
Stanley Street Treatment and Resources: SSTAR

Funded by:
Bureau of Substance Abuse Services
Massachusetts Department of Public Health

Pediatric/Child Exposure to Buprenorphine/Suboxone/Subutex

Protecting Others and Protecting Treatment

Poison Control 1-800-222-1222

Lessons Learned

- Treat responsibly
- Listen to your patients
- Take reports of diversion, abuse seriously: don't violate confidentiality
- Have a system in place to address
- Outline program expectations at start and intermittently
- Educate on safe storage, and prescription process

Pain and Surgery

Marie Trenouth

Epidemiology of Pain

- Up to 34 million Americans suffer from pain
- Causes more disability than cancer and heart disease combined
- Results in 4 billion work days lost per year
- Prevalence of chronic pain at any time is 17%
- Pain is the most common complaint for which individuals seek medical attention

Factors That Lower Pain Threshold

- History of addiction/substance dependence
- Anxiety and depression
- Insomnia and fatigue
- Fear and anger
- Loss of confidence in physician
- Past painful experience (memory)

Addiction Alters Pain Experience

- Both stimulant and opioid abusers have less pain tolerance than peers in remission or matched controls
- Former opioid abusers have decreased pain tolerance to pain compared with non-addict siblings
- HIV-infected patients w/ hx of substance abuse required higher doses of opioid analgesics than patients without a hx of substance abuse

Martin J (1965), Ho and Dole V (1979), Compton P (1994, 2001), Swica Y (2002)

Under-treatment of Pain

- Continued addiction
  - Self medicating pain with illicit drugs
- Unsuccessful detoxification
  - Pain worsens during withdrawal
- Relapse risk
  - Increased distress and anxiety

Opioid Agonist Treatment and Pain

The "Opioid Debt"

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

Doug Gourlay, MD College of Physicians and Surgeons of Ontario

Acute Pain Management
General Principles

- Reassure patients that their addiction will not be an obstacle to aggressive pain management
- Include the patient in the decision-making process to allay anxiety
- Remember buprenorphine (or methadone) maintenance will not treat acute pain
- Try non-opioid analgesics initially
- Offer addiction counseling

Peri-procedure management WITHOUT expected need for opioid analgesics: Recommendations

- Patient takes usual buprenorphine dose morning of procedure
- If patient unexpectedly requires post-procedure opioid analgesics follow guidelines
- If pain control is needed, we recommend use of tramadol and/or NSAIDS
- The buprenorphine provider should be contacted to assist in ongoing assessment, support, and post procedure pain management

Peri-procedure management WITH expected need for opioid analgesics: Recommendations

- Hold buprenorphine dose on day of surgery
- Start Opioids analgesics using standard dosing protocols with close monitoring due to decreased pain tolerance and cross-tolerance need higher opioid doses and shorter dosing intervals.
- Fentanyl high affinity at the opioid receptor should be the opioid of choice for analgesia during surgery and in PACU for these patients

Post-procedure INPATIENT analgesia with opioids: Recommendations

- Continue to hold buprenorphine
- All patients should be placed on a long acting morphine (e.g. 15 mg bid) for pain control
- If patient also requires parenteral analgesia for breakthrough pain control use PCA (fentanyl, dilaudid or morphine) with NO basal dose. Continue long acting morphine
- If patient does not require parenteral analgesia for breakthrough pain control use short acting opioids e.g.,oxycodone, morphine. Continue long acting morphine.

Post-procedure OUTPATIENT analgesia with opioids

Recommendations:

- Continue to hold buprenorphine
- All patients should be continued on long acting morphine
- Treat patient's breakthrough pain with short acting opioids e.g.,oxycodone, morphine.
- Schedule patient to seen by their buprenorphine provider to be restarted on buprenorphine maintenance when they no longer require opioids analgesics

Lessons Learned in Treating Pain in OBOT

- Patients experience acute anxiety and obsession over pain management.
- Fear of relapse
- Fear of being unertreated
- Need for close follow up pre-procedure/surgery and post
- Collaboration and communication with all providers
- Establishment of a plan with patient and providers
- Have a protocol and system in place for patient and providers

Pregnancy

Kristin Wensley

OBOT Patient Becomes Pregnant

- At every visit ask about possible pregnancy
- Urine "dip", if positive then blood HCG
- +HCG next step is discuss with pt and refer to High Risk OB at BMC
- Pt meets with High Risk OB – she will either continue on buprenorphine through Project Respect, now on mono-tab, or she may decide to have outside OB care and continue on mono-tab through OBOT program

Benefits of Opioid Agonist Tx in Pregnancy?

- Healthy mom & healthy, full-term infant
- Drug-free home environment for family
- Identify/treat psychiatric/ medical conditions
- Eliminate use, prevent relapse
  - Fetal stress from cycles of high/withdrawal
  - Risk of fetal & maternal death from overdose
  - Improve fetal weight, premature birth
  - Risk of violence, legal consequences
  - Risk of HCV, HIV, MRSA, STIs
  - Risk of non-attendance to prenatal care

Jones HE Am J Addictions 2008

OBOT Eligibility May Vary With Baseline Status

- Stable in bupe treatment and becomes pregnant
  - Safe and effective; continue to avoid disrupting care
- Not abusing opioids currently
  - Eligible if hx opioid addiction and seeking relapse prevention admit with careful informed consent
- Actively abusing opioids
  - Opportunity: Pregnancy often significant motivator
  - Risks: induction, ability to stabilize, insurance
- In Methadone treatment, looking to transition
  - Potentially risky transition; careful risk/benefit analysis
  - In trials, patients have been bridged with morphine

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Potential Benefits: Methadone vs. Buprenorphine

Methadone OTP
- Slightly more effective in meta-analysis
- Full agonist may better stabilize higher tolerance
- Highly structured, daily attendance
- No risk for induced withdrawal

Buprenorphine OBOT
- Lower duration of NAS symptoms
- Flexible dosing intervals
- Less need for dosing adjustments
- NOT daily attendance
- More discrete

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The MOTHER Study:
Bup vs. Methadone in Pregnancy

- 175 randomized to either bup or methadone
- Babies born to mothers taking bup had:
  - Lower rates of NAS treatment, 47% vs. 57%, but not statistically significant p = 0.26
  - Lower total morphine doses (mg) 1.1 vs. 10.4
  - Shorter hospital stays (days) 10.0 vs. 17.5
- Women taking bup had:
  - Higher rates of treatment drop out 33% vs. 18%
  - 77% of bup patients who voluntarily withdrew reporting "dissatisfaction with the medication"
    - compared to 10% with methadone

Jones HE NEJM 2010

FDA Drugs in Pregnancy Categories

A Controlled studies in humans show no risk

B Animal studies show no risk OR no controlled studies in animals or humans that show risk

C Studies in animals show some risk and there are no controlled studies in women OR there are no studies in women or animals. Medications given only if benefits outweigh risk

D Evidence of risk. Used only in life threatening situations or condition serious and no alternative

X Too much risk to be used in any circumstance

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Informed Consent

- Not “approved” for use in pregnancy
  - Methadone and Buprenorphine both Category C
- Physical dependence for both mother and infant
  - Mother may find tapering off med challenging
  - Infant will require monitoring for NAS
  - Infant may require treatment for NAS that could leave infant in hospital for weeks
- May limit opioid pain medication options
- Risk of induced withdrawal during induction
- Other treatment options available

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Monitoring During Pregnancy

Maternal monitoring

- Increase frequency office visits and toxicology
- Mono tablet
- Smaller prescriptions
- Coordination of care with OB providers
- Engagement in psycho-social supports
- Education and Support

Fetal monitoring

- No specific recommendations
  - All pregnancies on OAT “high risk”
  - Variable monitoring depending on clinical status of the mother ?

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Dose Adjustments

- With Methadone
  - Dose increases often needed in 2nd and 3rd trimester
  - Dose decreases often needed in the immediate post partum period
- With Buprenorphine
  - Dose adjustments may be indicated during pregnancy
  - Consider divided dosing if uncomfortable
  - Post partum sedation rare
- Elective tapers still discouraged due to risk of withdrawal and relapse
  - Dose decreases not likely to change need for NAS tx

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Preparing for Labor and Delivery

- Communication with OB providers
- Plan for pain control; consider anesthesia consult
- Anticipate social services involvement
- Anticipate need for assessment/treatment for neonatal withdrawal symptoms
  - Hospital should have experience with NAS
  - Consider consultation with nursery
- Empower patients to advocate and educate
- Be available to labor and delivery team

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Post Partum Pain Management

Uncomplicated Vaginal Deliveries

- Restart buprenorphine at previous dose ASAP
  - Use NSAIDS, other non-opioid analgesics
  - Some will offer short acting opioid agonists on top of regular buprenorphine doses

Complicated vaginal deliveries, surgical deliveries

- Treat pain with opioids as you would in any patient
- Treat for period of time expected for procedure
- Restart buprenorphine at previous or slightly higher dose when acute pain management completed

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Neonatal Abstinence Syndrome

- S/S: hyperactive, irritable, uncoordinated sucking & swallowing, fever, sweating, nasal stuffiness
- Estimated rates approximately 50%
- Dose at the time of delivery does not correlate with need for treatment or severity of symptoms
- Treatment can be prolonged 1-3 weeks
  - Within 12 to 48 hours, peaks 72 to 96, lasts 120-168 hours (some seen 6 to 10 weeks)

  NAS treatment course complicated by withdrawal from other substances
  - Tobacco/nicotine
  - Psychiatric medications
- Hospitals should have experience and protocols

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Breastfeeding

- 1:1 serum to breast milk ratio (that's high)
- Poor oral bioavailability
  - 1/5-1/10 of medication will be absorbed
  - Lower than other opiates
  - Not enough to suppress NAS
- Package insert says no
- Practice guidelines say "use your judgment"
- Experts say "yes"

Patients' Main Concerns

- "DCF" / Department of Family and Children
- Neonatal Abstinence Syndrome
- Disclosure
- HCV
- Outside stressors: partner, family, housing, finances

In Summary:

- Buprenorphine is safe in pregnancy
  - Minimal toxicity potential, no teratogenicity
- Lower duration NAS, shorter hospital stays
  - More flexible, discrete treatment
- OBOT with buprenorphine appropriate for some groups of pregnant women
  - Specific informed consent and high quality monitoring
  - Careful induction under controlled conditions
  - Coordination with obstetrics, anesthesia, pediatrics
  - Anticipation of pain management issues
  - Transition to other modalities if unable to stabilize

Methadone

Colleen LaBelle

Methadone to Buprenorphine Transfer

Methadone to Buprenorphine Transfer

Study - Salsitz et al. J Addict Med. 2010 Jun;4(2):88-92.

- 25/104 stable long-term MMT patients on doses of 5-80mg agreed to transfer – 100% completed
- Moderate correlation between meth and bup dose
- At 30 months FU – 22/25 remained on bup, 1 tapered off, 1 died of liver disease, 1 relapsed to cocaine

Methadone to Buprenorphine Transfer

Primary Goal: Continue control of cravings and withdrawal and minimize the risk of precipitated withdrawal

Step 1: Find bup provider willing to accept patient and educate patient

Step 2: Communicate plan between MMT and bup provider

Step 3: Taper methadone to 30mg/d (or lower) and hold for 1 week

Step 4: Stop methadone for 2-3 days or more, until COWS score > 12. Ensure the patient has adequate sober support and offer comfort meds

Step 5: Observe/Support induction as symptoms dictate

Step 6: Ensure patient can return to methadone if transfer is unsuccessful for the patient

Methadone to Buprenorphine Transfer

Considerations:

- Inadequate sober support: Consider inpatient transfer
- Patient does not tolerate taper: Consider switch to intermediate short-acting opioid as inpatient and then transfer to bup

"The key to a smooth transition is not the length of time since the last methadone dose, but rather how much objective withdrawal the patient is in when he/she comes for the first buprenorphine dose. Both the doctor and the patient may be surprised to learn that it may take much longer than 36 hours to begin methadone withdrawal."

Cassadonte. PCSS-B Guidance: Transfer from methadone to buprenorphine. 2006

Lessons Learned in Methadone to Buprenorphine Transfer

Communication is key:

- Patient needs to be aware: This may be hard, be Honest!
- Difficult transition
- Support structure needed: counselor, sponsor, partner, provider access
- Mental Stability and desire
- ***Long*** waits for admission
  - Need to experience withdrawal "ever missed a dose?"
  - May not feel well for a week or more
  - Can they take time off from work?
  - Can they go back to OTP?
  - Do they have take homes?
  - Will it jeopardize take home status?

Thank you for your attention!
Questions?

Karen.hannon@bmc.org
Colleen.labelle@bmc.org
Marie.trenouth@bmc.org
Kristin.wensley@bmc.org