Addiction and Pregnancy 2019

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November 1, 2017
Disclaimers

- No Financial Relationships
- Consultant, DEA/DOJ
- Consultant, BCBS Mich
- Methadone provider, Wayne State SOM
- Medical Director, Dawn Farm, Ann Arbor, MI
- Buprenorphine and naltrexone provider, A2
Medications will be referred to in the generic whenever possible; will discuss FDA specific formulations.

We will be discussing off-label use of buprenorphine and methadone; neither of these are approved by the FDA for use of opioid dependence in pregnancy.
James Wardell, MD
WHY TALK ABOUT THIS?

**FIGURE 1. Rate* of unintentional drug overdose deaths — United States, 1970–2007**

*Rate per 100,000 population.

Overdose Deaths U.S. 1999-2016

Drugs Involved in U.S. Overdose Deaths, 2000 to 2016

- Synthetic Opioids other than Methadone, 20,145
- Heroin, 15,446
- Natural and semi-synthetic opioids, 14,427
- Cocaine, 10,619
- Methamphetamine, 7,663
- Methadone, 3,314

Pills
Overdose Deaths U.S. 1999-2016

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Heroin and Fentanyl

Overdose Deaths throughout the years from 1999 to 2016.
CDC, 2018: opioid sales 2006 – 2017: Going DOWN
CDC, 2018: opioid sales 2006 – 2017: Going DOWN

OPIOID DEATHS ARE STILL INCREASING DESPITE A DECREASE IN PILLS PRESCRIBED.
WHY TALK ABOUT THIS?

THE OPIOID CRISIS

Drug overdose is now the leading cause of death for Americans under 50

An analysis by The New York Times shows we’re overdosing more and more.
WHY TALK ABOUT THIS?
NAS in Michigan
Steep Rise in Rural Infants Born With Opioid Withdrawal
What is Addiction?  
Why would a pregnant patient/mom hurt her baby?

**Couple overdoses on heroin while driving with kids in car, prosecutor says**

*Posted Jun 21, 2018*

Brandy Lynn Tubbs and Stephen A. Vliet

**Pregnant woman and unborn child die after heroin overdose**

*Posted Oct 17, 2015*

By Ben Freed | benfreed@mlive.com

Police are investigating after a pregnant 22-year-old Michigan woman died of heroin overdose that also killed her unborn child.
Physiologic Dependence: Tolerance and Withdrawal

- **Tolerance:** requiring increasing amounts of drug to get the same effect
- **Withdrawal:** the opposite effect of the drug when it is removed
- **NEITHER** of these imply chemical dependency (addiction)
What is the problem?

- Addiction is not a problem of drug WITHDRAWAL.....
- It is a problem of:
  - CRAVING
  - LOSS OF CONTROL
  - COMPULSIVE USE
  - USE DESPITE CONSEQUENCES
  - (the “4 Cs”)

"the 4 Cs"

Lack of Willpower?
An “amoral” condition?
Brain disease?
The Nucleus Accumbens: the Pleasure Center.
Dopamine: the Pleasure DRUG
VTA: the “gas tank”: supplies dopamine to the Nucleus Accumbens
Frontal Cortex: inhibits the Pleasure Center (maybe)
Why Can’t Addicts Stop??????

- The relapse rate after undergoing detox approaches 100%
- The relapse rate when coming off meds (buprenorphine, methadone) is 90%
- But: their withdrawal is gone.
- SO: why do they relapse??????

Physiology of Addiction
Normal Volunteers
Red: good blood flow

- Non users
- Cocaine users, 10 days sober
- Cocaine Users, 100 days sober

High blood flow
Low blood flow
Blood Flow Recovery: 10 days off cocaine

Non users

Cocaine users, 10 days sober

Cocaine Users, 100 days sober
Blood Flow Recovery: 100 days

Non users

Cocaine users, 10 days sober

Cocaine Users, 100 days sober
Treatment of Opioid Dependence (without) Pregnancy
Medication Assisted Therapy (MAT):
Methadone
Medication Assisted Therapy (MAT)
Medication Assisted Therapy (M.A.T.): naltrexone
BOTTOM LINE: (non-pregnant)

- In both controlled and retrospective studies, the success rate for most medications is between 40 and 60% (one to two years). (may be as low as 15% for heroin dependent IV patients)
- When patients come off the medication, they relapse.
- Relapse may be associated with an increased chance of overdose and death.
Benefits of Methadone
Salsitz, ASAM, 2012

- Reduction in death rates (Grondblah, 1990)
- Reduction in IVDU (Ball & Ross, 1991)
- Reduction in # of crime days (Ball & Ross)
- Reduced HIV seroconversion / HCV conversion
- IMPROVED OUTCOME AFTER INCARCERATION
Ball, 1988: IVDU in methadone clinics

- Occurred during the HIV epidemic before HAART (Highly Active Anti Retroviral Therapy)
- Over 5 years in methadone clinics, IVDU decreased by 70%. BUT:
- When those same patients left the clinic, 80 were injecting within one year.
Problems with methadone

- Requires initial daily dosing first 90 days.
- Must be “clean” for 2 years before you can increase take homes!
- Methadone clinics may be a source of “wet faces and wet places”
- Stigma
- Judges will often try and force moms off methadone—now forbidden by the feds.
Buprenorphine

- A partial opiate agonist (less potent)
  - Less analgesic effect
  - Less respiratory depression
  - <100 documented deaths in the U.S; 4000+ PER YEAR WITH METHADONE
  - Treats both pain and opiate dependency
    - Different formulations are approved

Soyka M. Pharmacopsychiatry 2006; 39(3): 85-87
Buprenorphine +/− Naloxone: for addiction

- Available in 3 branded forms:
  - Generic buprenorphine (Subutex®): sublingual OFF MARKET: Medicaid may not cover generic due to concerns about diversion.
  - Bunavail®: sublingual buprenorphine + naloxone (Narcan®): prevents IV use*
  - Suboxone®: sublingual buprenorphine + naloxone (Narcan®): prevents IV use*
  - Zubsolv®: ditto

- ANY of these will precipitate sudden withdrawal: only give when patient is going INTO withdrawal!

* not FDA approved for pain
U.S. joins lawsuits against Indivior, Reckitt over drug Suboxone

(Reuters) - The U.S. Justice Department has joined several whistleblower lawsuits against Indivior Plc and Reckitt Benckiser Group PLC, alleging that the drugmakers improperly marketed the opioid addiction treatment Suboxone.

FILE PHOTO: A pharmacist fills a Suboxone prescription at Boston Healthcare for the Homeless Program in Boston, Massachusetts January 14, 2013. REUTERS/Brian Snyder/File Photo
What Formulation Should You Use?

- Generic buprenorphine (*Subutex*) avoids naloxone.
- It is more susceptible to diversion than *Suboxone/Zubsolv*.
- Use whatever their insurance will pay for!!
- Can’t use *Butrans* or *Belbuca* for addiction.
Buprenorphine long-term follow up: Fiellin, 2008
Concerns about buprenorphine

- It can be abused (mostly for withdrawal)
- It is unsafe when combined with sedatives & alcohol.
- It is sold and smuggled into prisons.
- It is an opioid.
- **Relapse rates after detox exceed 90%**. (Weiss, 2011)
Vivitrol® (injectable naltrexone) for opioid dependence

This medication is not currently used during pregnancy; but may be used following delivery.
Addiction Tx in Russia

Kupitsky et al; Lancet 2011; 377: 1506-13
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3160743/
Vivitrol: abstinence (>50%)
No Vivitrol, Control Treatment (40%)
No Vivitrol; No Treatment (0%)
Why the handcuffs?
Vivitrol: concerns

- As with methadone and buprenorphine, when the medication is stopped, relapse may lead to death due to lack of tolerance.
- It would be very difficult to treat acute pain while on Vivitrol: suggestion is “20x normal dose”.
- It (usually) cannot be started as an outpatient due to required withdrawal off opioids; most patients come from inpatient programs or incarceration.
Vivitrol to Prevent Relapse in Criminal Justice Offenders
Vivitrol to Prevent Relapse in Criminal Justice Offenders
Vivitrol to prevent relapse after incarceration.

- Bad News: when the injections were stopped, the differences “disappeared”.
- Good news: no OD deaths when the medication was stopped.
Doc, when can I get off this sh*t medication?
Can you detox off MAT?
Luty 2003

- 101 women underwent detox during pregnancy
- 40 successfully detoxed.
- No adverse fetal effects documented
- BUT:

  - Luty et al, J Sub Abuse Treat 24 (2003); 363 - 367
101 women underwent detox during pregnancy
40 successfully detoxed.
No adverse fetal effects documented
BUT: only 1 of 101 abstinent at delivery!

Luty et al, J Sub Abuse Treat 24 (2003); 363 - 367
Maintenance vs. Detox? Kakko et al 2003

- 40 heroin addicts were started on buprenorphine/naloxone.
- 20 were “detoxed” off and offered counseling.
- 20 were kept on buprenorphine/naloxone and offered counseling.
- A year later.......
Medical Withdrawal vs Maintenance

- N=20
- Both groups received counseling
- High mortality rate in detox group (20%, n=4)

Kakko et al., Lancet; 361:662-668, Feb 22 2003
Medical Withdrawal vs Maintenance

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Graph showing Remaining in treatment (nr) vs Treatment duration (days)

Kakko et al., Lancet; 361:662-668, Feb 22 2003
Can you taper off buprenorphine without relapse?

Adjunctive Counseling During Brief and Extended Buprenorphine-Naloxone Treatment for Prescription Opioid Dependence

A 2-Phase Randomized Controlled Trial

Roger D. Weiss, MD; Jennifer Sharpe Potter, PhD; David A. Fiellin, MD; Marilyn Byrne, MSW; Hilary S. Connery, MD, PhD; William Dickinson, DO; John Gardin, PhD; Margaret L. Griffin, PhD; Marc N. Gourevitch, MD, MPH; Deborah L. Hailer, PhD; Albert L. Hasson, MSW; Zhen Huang, MS; Petra Jacobs, MD; Andrzej S. Kosinski, PhD; Robert Lindblad, MD; Elinore F. McCance-Katz, MD; Scott E. Provost, MSW; Jeffrey Selzer, MD; Eugene C. Somoza, MD, PhD; Susan C. Sonne, PharmD; Walter Ling, MD

Buprenorphine in opioid dependence

- 654 patients enroll on buprenorphine for 2 weeks.
- 50% stay abstinent.
- They are tapered off and over 90% relapse.
- 360 remain, they go back on buprenorphine for 12 weeks,
- 50% stay abstinent (again).
- They taper off and 90+% relapse (again).
- Moral of the story: medications work as long as you take them.
Conclusions

- “MAT” is effective at decreasing opioid use. (50% abstinence from opioids)
- Stopping MAT will usually (?) result in relapse & increased chance of death.
  - Why would you expect otherwise?
- Methadone is better at keeping you in treatment. Buprenorphine has a superior safety profile.
- Vivitrol® (injectable naltrexone) is effective at reducing opioid use.
“Your Baby Will Die If You Detox”: Opioid Detox During Pregnancy

- Based on anecdotal cases of IUFD
- Incidence is probably no greater
- Risk of “intrauterine withdrawal” is unknown

Bell et al, AJOG 2016; 215: 374.e1-6
Dr. Craig Towers completed a five-year research study in which he detoxified more than 300 women.
“Your Baby Will Die If You Detox”: Opioid Detox During Pregnancy

- Fetal death during pregnancy is rare.
- Patients can be successfully and safely detoxed.
- The lowest neonatal abstinence rates are seen with incarcerated patients (19%). (Bell)

Follow up after delivery with detox is extremely limited and needs further investigation. (Terplan)

Bell et al, AJOG 2016; 215: 374.e1-6
https://www.ajog.org/article/S0002-9378(18)31184-0/fulltext
Treatment of Opioid Dependence During Pregnancy
METHADONE
“the gold standard”

- Was only approved for use for addiction in 1965; Dr. James Wardell started in Detroit in 1969.
- TIP 40: methadone was the preferred treatment in pregnancy
- Buprenorphine was considered experimental.
- Improvement in neonatal outcomes documented by Ed Johnson and Hendree Jones.
Maternal Opioid Treatment: 
Human Experimental 
Research

(MOTHER)
Neonatal Abstinence Syndrome after Methadone or Buprenorphine Exposure

Hendrée E. Jones, Ph.D., Karol Kaltenbach, Ph.D., Sarah H. Heil, Ph.D., Susan M. Stine, M.D., Ph.D., Mara G. Coyle, M.D., Amelia M. Arria, Ph.D., Kevin E. O’Grady, Ph.D., Peter Selby, M.B., B.S., Peter R. Martin, M.D., and Gabriele Fischer, M.D.

NEJM 2010; 363: 2320-31
MOTHER STUDY

- Double blinded, RCT
- Methadone vs. buprenorphine
- Contingency management (financial incentives $$$$$)
- CBT (cognitive behavioral tx)
- Transportation, etc.
- NO polysubstance dependence x tobacco!
MOTHER STUDY

- Patients already on methadone are admitted to research unit for detox
- 6 mg MS/mg methadone (4 divided doses)
- Rescue doses prn
- Kept until stabilized
- **THIS IS NOT FEASIBLE IN CLINICAL PRACTICE!!!!!!!**
- Randomized to study meds on L & D
Sites

- Johns Hopkins, Baltimore MD
- T. Jefferson Univ., Philadelphia, PA
- Women & Infants, Providence RI
- Vanderbilt UMC, Nashville, TN
- St. Joseph’s Hlth Ctr. Toronto, Canada
- Wayne State Univ., Detroit, Michigan
- University of VT, Burlington, VT
- Addiction Clinic Vienna, Austria
**Methadone vs. Buprenorphine: the MOTHER study**

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Addiction and Pregnancy
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Addiction and Pregnancy  79
MOTHER study....

“Buprenorphine exposed neonates...exhibited fewer stress-abstinence signs, were less excitable...less hypertonia...better self-regulation and required less handling...than methadone-exposed neonates.

Jones Finnegan & Kaltenbach Drugs 2012
What about treating the baby with buprenorphine???
Buprenorphine vs. Morphine in the Treatment of Neonatal Abx Syndrome

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Kraft et al. NEJM 2017; 376:2341-8
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Kraft et al NEJM 2017; 376:2341-8
Who should NOT go on buprenorphine? Patients who are:

- Already on methadone (>35 mg)
- Active hepatitis C (high LFTs)
- Unable to engage in treatment
- Taking benzos*
- Plan on mixing bupx with their opiates*
- Are diverting*
- Can’t get insurance coverage*
How do you start buprenorphine?

- LFT, UDS, informed consent
- If GA > 24 weeks: monitor on L&D
- Short acting opioids: 8 to 12 hrs abstinence or moderate withdrawal sx
- Start buprenorphine (2mg dose initially)
- DC on 8 to 16 mg bupx sublingual
- YOU NEED TO GET PREAUTHORIZATION
Buprenorphine --> Methadone?

- NOT necessary!
- Can continue buprenorphine
- Risk of NAS is decreased (severity and duration) with buprenorphine as compared to methadone!
- Again, neither of these is APPROVED for treatment of opioid dependence during pregnancy.
Buprenorphine --> Methadone?

- EXCEPTIONS:
  - If a patient is still using on buprenorphine, they run the risk of overdose, HIV, HCV and loss of custody.
  - Methadone treatment is a higher Level of Care (LOC) due to daily visits, counseling, and groups which are mandatory.
  - Patients who continue to use anything x MJ should be referred to a higher LOC!
Methadone → Buprenorphine?

- Methadone:
  - Has a LONG half life
  - MOTHER study dropouts were partially due to attempts to convert high dose methadone to buprenorphine
  - Current “expert opinion” is to limit to patients on 25 – 50 mg.
  - Safest course may be to remain on methadone.
Current Management: St Joseph Mercy, A2 MI

- Patients who present on SHORT acting opioids: buprenorphine
- Patients who present on long acting opioids or methadone: methadone
- Benzodiazepine use must stop immediately or they will be referred for methadone.
Questions?
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