Addiction and Pregnancy 2019

Carl Christensen, MD, PhD, D-FASAM
Clinical Assoc Prof, Psychiatry and OB/Gyn,
Wayne State Univ School of Med, Detroit Mi
Medical Director, Mich Health Professional Recovery Program
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
Treatment of Addiction 2007

“He’s Very Depressing”
2011:

“"I left tonight entirely without hope""
2019:

"Maybe a more compelling lecturer would make the occasion less dreary"
James Wardell, MD
WHY TALK ABOUT THIS?


* 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
CDC, 2018: opioid sales 2006 – 2017: Going DOWN

Trends in Opioid Prescribing

**FIGURE 1A**
Annual opioid prescribing rates overall and for high-dosage prescriptions ≥ 90 MME/day in the United States, 2006–2017

Source: IQVIA™ Transactional Data Warehouse.

High-dosage prescriptions were defined as opioid prescriptions resulting in a daily dosage of ≥ 90 morphine milligram equivalents.

Temporal trends from 2006 to 2017 were evaluated by applying jointpoint regression methodology. This modeling approach simultaneously identified statistically significant trends as well as shifts in trends that occurred within a time series. A maximum of two joinpoints was allowed, and the permutation method was used for model selection. Different line dashes correspond to year groupings as determined by joinpoint regression.
CDC, 2018: opioid sales 2006 – 2017: Going DOWN

OPIOID DEATHS ARE STILL INCREASING DESPITE A DECREASE IN PILLS PRESCRIBED.

**Figure 1A**

*Annual opioid prescribing rates overall and for high-dosage prescriptions ≥ 90 MME/day* - United States, 2006–2017

- **Prescribing rate per 100 persons**
- **Year** (2006-2017)
- **Overall**
- **High Dosage**

Source: IQVIA™ Transactional Data Warehouse.

*High-dosage prescriptions were defined as opioid prescriptions resulting in a daily dosage of ≥ 90 morphine milligram equivalents.*

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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
Figure. Changes in Opioid-Related Diagnoses Among Infants and Mothers by Urban/Rural Status

A. Neonatal abstinence syndrome
B. Maternal opioid use

NAS

OPIOID USE

rural

Urban
Treatment of Opioid Dependence (without) Pregnancy
Medication Assisted Therapy (MAT): Methadone
Medication Assisted Therapy (MAT)
buprenorphine
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: reduction in IVDU

FIGURE 1. Effect of Methadone Maintenance Treatment on IV Use for 388 Male Methadone Patients

- 100% at admission
- 81.4% at last addiction period
- 63.3% at admission
- 41.7% at 2nd year
- 28.9% at 4th year

Mean time in treatment: 45 months
Ball 1988: reduction in IVDU

FIGURE 1. Effect of Methadone Maintenance Treatment on IV Use for 388 Male Methadone Patients in Six Programs

PERCENT IV USERS

100%

IN-TREATMENT PERIOD

LAST ADDICTION PERIOD

ADMISSION

63.3%

41.7%

28.9%

MEAN TIME IN TREATMENT 45 MONTHS

1st YEAR 2nd YEAR 3rd YEAR 4th YEAR

PRE-ADMISSION PERIOD
Ball 1988: resumption of IVDU!
Ball 1988: resumption of IVDU!
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. (Soyka); 4000+ PER YEAR WITH METHADONE
  - Treats both pain and opiate dependency
    - Different formulations are approved
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
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%)

Due to Vivitrol (naltrexone)

Due to treatment (placebo effect?)
Why the handcuffs?
CRAVING
Vivitrol: craving in control group
Vivitrol: craving decreased 50%!
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

Figure 2. Kaplan–Meier Curves for Relapse-free Survival.
Vivitrol to Prevent Relapse in Criminal Justice Offenders: the bad news

“On the basis of self-reports and a single urine sample at week 52 and week 78, months after extended-release naltrexone-one therapy had ended, the relapse-prevention effects had waned.”

Translation: it stops working when you stop taking it.
Vivitrol to Prevent Relapse in Criminal Justice Offenders: the good news

“All recorded overdose events, fatal or non-fatal, occurred among participants assigned to usual treatment (0 events in the extended-release naltrexone group vs. 5 in the usual-treatment group from week 0 to 25, P = 0.10; 0 vs. 7 events from week 0 to 78, P = 0.02); no overdoses occurred in the extended-release naltrexone group after discontinuation of the agent.”
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
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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Kakko et al., Lancet; 361:662-668, Feb 22 2003
Can you taper off buprenorphine without relapse?

**Online First**

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. Hauler, 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.
- 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

Bell et al, AJOG 2016; 215: 374.e1-6
Treatment, not Detox

- The obstetrical and neonatal impact of maternal opioid detoxification in pregnancy

Inpatient Methadone Detox During Pregnancy (UT Dallas)

- 53/95 (56%) women were successful.
- Slow methadone taper was used.
- Average duration inpatient stay was 25 days for successful patients.
- Only 10% required tx for NAS; vs 80% of patients with positive UDS at del.
- By comparison: Success rates of MTD in pregnancy: 60 to 80%; over 50% have withdrawal at birth!
- BUT: no hospital in Michigan will admit a patient for 30 days for detox during pregnancy.
“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%).
- Follow up after delivery with detox is extremely limited and needs further investigation (added)

Bell et al, AJOG 2016; 215: 374.e1-6
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.
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!
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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* indicates statistical significance.
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Addiction and Pregnancy
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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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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
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: Eleonore Hutzel Recovery Center/ Tolan Clinic, Detroit Mich (now: Academic OB Gyn Clinic, SJMH)

- 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.
What About Opioid Use without Addiction?

- A patient is referred to you "for Suboxone" at 16 weeks gestation.
- She has a history of lumbar stenosis and history of lumbar fusion.
- She is on 5 mg of methadone QID PRN pain (MED = 60).
- Her addiction evaluation is negative other than tobacco dependence.
- Plan?
What About Opioid Use without Addiction?

- Patients who are ADDICTED to opioids may require MAT either before or during pregnancy.
- Patients who are considering pregnancy and are on opioids for pain can successfully taper.
- However, patients who are pregnant on opioids can be successfully managed with low risk of NAS:
  - James Nocum, U of Indiana (up to 120 mg Morphine Equivalent Dose)
- Patients may be better managed on standard opioids than buprenorphine or methadone.