Substance Use in Pregnancy

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Disclaimer

I have no relevant conflicts of interest to declare.
Aim of this presentation?

- Review of Addictions and Epidemiology of addictions in women

- **Alcohol Use Disorders** in Pregnancy:
  - Understands fetal malformation risks
  - Describe MAT options
  - Risks of alcohol withdrawal and risks of benzodiazepines in pregnancy

- **Opioid Use Disorders** in Pregnancy:
  - Maternal and fetal risks
  - Screening tools
  - Describe MAT options and risks: fetal/maternal/breastfeeding

- **Amphetamine Use Disorders** in Pregnancy:
From: “This Tennessee Law About Pregnant Addicts Won’t Make Them Stop Using Drugs” Mommyish, Mon July 14th 2014; Available on:
http://www.mommyish.com/2014/07/14/pregnancy-law-criminalizes-drug-use/
What is Addiction?

• **Addiction** is a chronic, progressive **behavioral** disorder whose central feature is **compulsive drug use** despite adverse consequences

• Not the same as physiologic dependence (tolerance and withdrawal)

• “Addiction” = Substance Use Disorder
Epidemiology of Addiction in Reproductive Age Women

- Gender Differences in Substance Use Disorders decreasing (Keyes 2008)
- Telescoping (Randall 1999)
- When present for treatment, report greater impairment relative to men in employment, social, psychiatric, and medical domains (Hernandez-Avila et al 2004)
- More likely to use substances than men to manage negative affects (Saladin et al 2012)
- Less than 20% of those women who need treatment receive it yearly (Terplan et al 2012)
- Women less likely to engage in treatment than men (Back et al 2010)
- Among pregnant women, perception of risk is important predictor of use (Blume et al 2007)
Epidemiology of Addiction in Pregnant Women

Prevalence of Illicit Substance, Cigarette, and Alcohol Use in Pregnant Women


Guidelines for the Management of Pregnant Women With Substance Use Disorders
Psychosomatics, Volume 57, Issue 2, 2016, 115–130
http://dx.doi.org/10.1016/j.psym.2015.12.001
Epidemiology of Addiction in Pregnant Women

• Women generally decrease use during pregnancy
  • Danish study: 90% of women reduced intake of EtOH upon learning of pregnancy (Kesmodel et al 2003)
  • NSDUH 2010:

<table>
<thead>
<tr>
<th></th>
<th>Pregnant (%)</th>
<th>Not Pregnant (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current EtOH Use</td>
<td>10.8</td>
<td>54.7</td>
</tr>
<tr>
<td>Binge Drinking</td>
<td>3.7</td>
<td>24.6</td>
</tr>
<tr>
<td>Heavy Drinking</td>
<td>1</td>
<td>5.4</td>
</tr>
</tbody>
</table>
Alcohol Use Disorders and Pregnancy
Hogarth’s Gin Lane (1751)

http://www.telegraph.co.uk/health/healthadvice/maxpemberton/9769425/William-Hogarths-Gin-Lane-has-a-lesson-for-binge-drinking-Britain.html
http://www.telegraph.co.uk/health/healthadvice/maxpemberton/9769425/William-Hogarths-Gin-Lane-has-a-lesson-for-binge-drinking-Britain.html
...more historical notes

- Paul Lemoine 1967: characterized alcohol as a teratogen

- Kenneth Lyon Jones 1973 (dysmorphologist): coined term *fetal alcohol syndrome* (typically 14 or more drinks daily)
What we know:
Risk of alcohol

• Not controversial: excessive alcohol use (>2 units per day, or >4 units per sitting) → **DOSE RESPONSE**
  
  
  
  – Dose response effect on **FAS** (Rehm 2010)
  
  – **Withdrawal** in infant
What we know: Risk of alcohol

• Controversial:
  – Mixed evidence that low-levels of drinking pose risk to fetus or mother (NICE March 2008), but no consensus on what “low level” is
  – Several countries have wrestled with how to advise pregnant women on alcohol use: Australia, Denmark.
American Academy of Pediatrics: November 2015

- During pregnancy:
  - no amount of alcohol intake should be considered safe;
  - there is no safe trimester to drink alcohol;
  - all forms of alcohol, such as beer, wine, and liquor, pose similar risk; and
  - binge drinking poses dose-related risk to the developing fetus.

(Williams, et al. 2015)
MAT for AUD in Pregnancy

- Disulfiram (Antabuse)
- Naltrexone (Revia, Vivitrol)
- Acamprosate (Campral)
What about alcohol withdrawal?

• Extrapolate from physiology, but no consensus on risk of withdrawal, specifically.
  – Risks to mother?
  – Intrauterine Seizures? (Seizure risk elevated in FAS/FASD children)
  – Hypertension/autonomic instability risks?
  – Cortisol
  – Delirium Tremens → could harm self/fetus
What we know: Risk of BZs

- Two camps:
  1. Benzos cause malformations

  - Dolovich 1998: meta-analysis of cohort and case control studies: CCS showed OR of MM 3.01 and oral cleft 1.79

  - Iqbal 2002: systematic review, looked at individual meds, not just class. Klonopin and xanax some risk but no pattern. Ativan linked to anal atresia.
What we know: Risk of BZs

• Problems with this data:
  
  – Did **NOT** consistently define:

    » the gestational age at exposure
    » concurrent substances used
    » dose of exposure
    » clear psychiatric indication provided
    » Data were not collected on MM in fetuses spontaneously aborted after BZD overdose (up to 28%).

  – Since compelling data for association came from case-control studies, bringing into question recall biases.
What we know: Risk of BZs

2. Benzos don’t cause malformations

- Reis 2013: Swedish National Health Registries (survey): 3000+ infants born to mothers exposed to BZs alone → no increased risk of MM
- Bellantuono 2013: Critical review → first trimester exposure & MM. Ativan risk of anal atresia 3/10,000 to 20/10,000
What we know: Risk of BZs

– Late third trimester: risk of floppy infant syndrome (McElhatton 1994):
  • Mild sedation
  • Hypotonia
  • Apneic spells
  • cyanosis
Changing Gears...
Opioid Use Disorders and Pregnancy

Provider’s Clinical Support System—Medication Assisted Treatment (PCSS-MAT)
DeVido J, Greenfield S. *Opioid Dependence in Pregnancy: Clinical Challenges*
First Published: July 14, 2014

OUD—Maternal Risks

• Infectious Diseases:
  – HIV
  – Hepatitis B and C
  – Other infections related to use: cellulitis, endocarditis

• Overdose

• Pain management: before, during, and after delivery

• Psychosocial challenges often co-occurring with opioid use disorders: prostitution, theft, violence to support habit(s), domestic violence, incarceration and other legal problems, poor engagement in prenatal care

• Psychiatric comorbidities: depression and anxiety along with opioid use disorders lead to worse treatment outcomes (Benningfield 2012)
OUD—Fetal Risks

- **Low birth weight** (Hulse 1997)
- **Birth defects** (congenital heart defects associated with first trimester codeine exposure) (Zierler 1985; Bracken 1986)
- Fetal growth restriction
- Abruptio placentae, fetal death, preterm labor, and intrauterine passage of meconium
- **Postulated to be related to withdrawal/intoxication cycles of mother**
  - (Center for Substance Abuse Treatment. Medication-assisted treatment for opioid addiction during pregnancy 2008)
Opioid Use Disorders & Pregnancy: IMPORTANT NOTE

• Heroin: (untreated) a 6-fold increase in risk of obstetrical complications and a 74-fold increase in risk of sudden infant death syndrome (Dattel 1990; Fajemirokun 2006; Ludlow 2004)

• While both buprenorphine and methadone carry risks, these risks are felt to be minor relative to ongoing untreated heroin or other non-medical opioid use
  – Both methadone and buprenorphine allow for more steady blood levels of opioids (Jarvis 1994, Rayburn 2004, respectively) that prevents exposure to repeated fetal/maternal withdrawal events.
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Opioid Use Disorders & Pregnancy: Screening Tools—CRAFFT

- CRAFFT (Chang 2011)—validated in pregnant women, in addition to adolescents
  - Have you ever ridden in a car with someone (including yourself) who was “high” or had been using alcohol or drugs?
  - Do you ever use alcohol or drugs to relax, feel better about yourself, or fit in?
  - Do you ever use alcohol or drugs while you are by yourself, alone?
  - Do you ever forget things you did while using alcohol or drugs?
  - Do your family or friends ever tell you that you should cut down on your drinking or drug use?
  - Have you ever gotten into trouble while you were using alcohol or drugs?
  - Advantage: Open-source
Opioid Use Disorders & Pregnancy: Screening Tools—Other

- **TWEAK:**
  - Tolerance, Worried, Eye-Opener, Amnesia, K/Cut Down
  - Validated screen for peri-conceptual risky *drinking* (Russell 1994)

- **T-ACE:**
  - Tolerance, Annoyance, Cut Down, Eye-Opener
  - Validated screen for peri-conceptual risky *drinking* (Russell 1994; Sokol 1989)
  - Vs. **CRAFFT** (Chang 2011)—CRAFFT better at detecting past 6 month usage of drugs or alcohol, T-ACE better at picking up lifetime alcohol use
Opioid Detoxification in pregnancy?

• Zuspan 1975: fetal distress during methadone detox

• Rementeria 1973: 5-fold increase in stillbirth incidence following opioid withdrawal

• Second trimester detoxification may be safer than 1st or 3rd
  – Luty 2003: retrospective case series of 101 pregnant women who underwent 21 day inpatient methadone withdrawal \(\rightarrow\) 1/5 miscarriage in 1st trimester, 0/54 in 2nd, no difference relative to general population in 3rd.

• **Maintenance therapy in pregnancy has been shown to increase retention in prenatal care, addiction recovery and in-hospital deliveries**  (Jones et al. 2008.)

• As with outcome measures in non-pregnant individuals, use of MAT (buprenorphine or methadone) as part of a comprehensive care approach to pregnant woman improves maternal and neonatal outcomes (Jones 2011; Winklbauer 2008; Kaltenbach 1998)
Opioid Detoxification in pregnancy?

• Fetal distress during detox

• Increase in stillbirth incidence following opioid withdrawal

• Second trimester detoxification may be safer than 1st or 3rd

• Maintenance therapy: increase retention in prenatal care, addiction recovery and in-hospital deliveries, improved neonatal and maternal outcomes.
Opioid Use Disorders & Pregnancy: Medication Assisted Treatment (MAT)

There are three general categories of MAT:

- Mu opioid antagonism with naltrexone
- Mu opioid agonism/partial agonism with either:
  - Methadone
  - Buprenorphine
Opioid Use Disorders & Pregnancy: Naltrexone

- Pure opioid antagonist at mu, kappa, and delta opioid receptors (highest affinity for mu)
- Available in oral and long-acting injectable forms
- Food and Drug Administration (FDA) safety category in pregnancy: C
  - Meaning: either studies in animals have revealed adverse effects on the fetus (teratogenic or embryocidal effects or other) and there are no controlled studies in women, or studies in women and animals are not available. Drugs should be given only if the potential benefits justify the potential risk to the fetus.

DeVido J, Greenfield S. Opioid Dependence in Pregnancy: Clinical Challenges. PCSS-MAT
Opioid Use Disorders & Pregnancy: Naltrexone

- Not currently approved or recommended in pregnancy
- Benefits:
  - no risk of NAS
  - NOT a controlled substance (does not require special licensure)
- Risks:
  - Long-term effects on fetal development due to blockade of opioid (mu, kappa, delta) receptors is not well known. Animal studies have shown developmental and behavioral changes in adult rats exposed to naltrexone in utero, but humans studies on developmental and behavioral sequelae are lacking (Farid 2012; White 2013).
  - Requires detoxification from opioids
  - High rates of relapse/dropout from treatment (Waal 2013)
  - Possible complications for pain management during and post-delivery
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DeVido J, Greenfield S. *Opioid Dependence in Pregnancy: Clinical Challenges. PCSS-MAT*
Management of Patient: Newly Pregnant

• For women already stable on buprenorphine/naloxone who become pregnant:
  – Current standard of care is to switch to buprenorphine monotherapy at the same dose

• For women already stable on methadone,
  – Current standard of care is to remain on methadone
    • Patient may need dose increase or split dosing
Opioid Use Disorders & Pregnancy: Methadone

Opioid Use Disorders & Pregnancy: Methadone

• Synthetic Mu opioid receptor agonist and N-methyl-D-aspartate (NMDA) receptor antagonist

• FDA safety category in pregnancy: C
  – Considered standard of care for MAT in pregnant women in US, although NOT FDA approved for this indication

• Crosses placenta

DeVido J, Greenfield S. Opioid Dependence in Pregnancy: Clinical Challenges. PCSS-MAT
Opioid Use Disorders & Pregnancy: Methadone

• Requires engagement in federally sanctioned methadone treatment programs/clinics (42 Code of Federal Regulations (CFR) Section 8.12)

• Benefits:
  – Pregnant women in MTPs have improved fetal outcomes compared to pregnant women using illicit drugs (ACOG 2012)
  – Structured clinic setting with additional substance use disorder treatment programming
Risks of Methadone Use in Pregnancy

• Risks:
  – Fetal growth, birth weight, length, and/or head circumference may be decreased but these effects do not appear to persist (ACOG 2012)
  – Decreased psychometric and behavioral tests has been found to persist into childhood (ACOG 2012)
  – NAS up to 2-4 weeks after delivery
  – Increased clearance and decreased half-life in pregnant women (2nd and 3rd trimesters) requiring increased dosing amounts and frequencies, and decrease after delivery (ACOG 2012)
  – Many drug-drug interactions
  – QTc prolongation, constipation, diaphoresis
  – May complicate pain management acutely, owing to blockade of mu receptors

DeVido J, Greenfield S. Opioid Dependence in Pregnancy: Clinical Challenges. PCSS-MAT
Opioid Use Disorders & Pregnancy: Buprenorphine

![Buprenorphine](https://upload.wikimedia.org/wikipedia/commons/thumb/b/b0/Buprenorphine.svg/2000px-Buprenorphine.svg.png)
Opioid Use Disorders & Pregnancy: Buprenorphine

- High-affinity Mu opioid receptor partial agonist and kappa opioid receptor antagonist
- FDA safety category in pregnancy: C
- Crosses placenta
- Available in diversion-deterrent formulation combined with naloxone
- Recommendation in pregnancy is to use buprenorphine alone, due to potential risks posed by naloxone

DeVido J, Greenfield S. Opioid Dependence in Pregnancy: Clinical Challenges. PCSS-MAT
Opioid Use Disorders & Pregnancy: Buprenorphine

• **Benefits:**
  - Office based: does not require clinic, although some buprenorphine clinics available for daily dosing
  - Ceiling effect for respiratory suppression (although this is eliminated when using benzodiazepines concurrently)
  - Maintain in treatment

• **Risks:**
  - NAS
  - Constipation, diaphoresis
  - Possible complications for acute pain management due to high affinity blockade of mu opioid receptors
  - Lower head circumference and birth weights (Hytinanti 2008)
  - Need for safeguarding medication

DeVido J, Greenfield S. *Opioid Dependence in Pregnancy: Clinical Challenges. PCSS-MAT*
Opioid Use Disorders & Pregnancy: Buprenorphine vs. Methadone

- Multi-site randomized controlled trial (Jones et al, 2010)
- **Buprenorphine:**
  - Fewer dose adjustments
  - Fewer drug-drug interactions
  - Ceiling effect
  - Office-based
  - More drop-out relative to methadone (33% vs. 18%, respectively) (Jones, et al, NEJM, 2010)
- **Methadone:**
  - More available data on long-term developmental and behavioral outcomes
  - Structure provided by clinic setting
  - Potentially easier acute pain management relative to buprenorphine
  - More familiarity amongst hospital staff and other providers

DeVido J, Greenfield S. *Opioid Dependence in Pregnancy: Clinical Challenges. PCSS-MAT*
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DeVido J, Greenfield S. *Opioid Dependence in Pregnancy: Clinical Challenges. PCSS-MAT*
Mu Receptor Intrinsic Activity

Full Agonist (methadone)

Partial Agonist (buprenorphine)

Full Antagonist (e.g. naloxone)

DRUG DOSE

no drug  low dose  high dose

Slide from The ASAM Buprenorphine Course—Stock set
Opioid Use Disorders & Pregnancy: Buprenorphine vs. Methadone

• “The current trend is moving toward considering a patient as a potential candidate for buprenorphine if she prefers buprenorphine to methadone, gives informed consent after a thorough discussion of relative risks and benefits, and is capable of adherence and safe self-administration of the medication. If the pregnant woman is receiving methadone therapy, she should not consider transitioning to buprenorphine because of the significant risk of precipitated withdrawal. The potential risk of unrecognized adverse long-term outcomes, which is inherent with widespread use of relatively new medications during pregnancy, should always be taken into consideration.” (ACOG 2012)
Maintenance Therapy in Pregnancy: Neonatal Abstinence Syndrome (NAS)

- Meta-analysis of 12 studies from 1996-2012: showed buprenorphine exposed neonates (515) compared to methadone exposed (855) had
  - Shorter mean length of hospital stay (-7.23 days, 95% CI: -10.64, -3.83)
- In treated neonates, buprenorphine exposed
  - Shorter NAS treatment duration (-8.46 days, 95% CI: -14.48, -2.44)
  - Lower morphine dose (-3.60 mg, 95% CI: -7.26, 0.07)

Brogly et al. 2014.

Slide from The ASAM Buprenorphine Course—Stock set
Maternal Dose and NAS Severity

- No correlation between maternal opioid maintenance therapy dose and the duration or severity of NAS (Berghella 2003)
Breastfeeding is beneficial to infant and mother

- Mother-infant bonding (Tharner 2012)
- Infant benefits: Decreased incidence of otitis media, gastroenteritis, severe lower respiratory tract infections, childhood leukemia, type 1 & 2 diabetes, obesity, asthma, sudden infant death syndrome, and necrotizing enterocolitis (Ip 2007)
- Mother benefits: Decreased incidence of type 2 diabetes, breast/ovarian cancer, and post partum depression (Ip 2007)

DeVido J, Greenfield S. *Opioid Dependence in Pregnancy: Clinical Challenges. PCSS-MAT*
Opioid Use Disorders & Pregnancy: MAT and Lactation/Breastfeeding

- Naltrexone
  - Enters breast milk (manufacturer does not recommend breastfeeding while on this medication)
  - Little data on its safety for use in breastfeeding (animal data demonstrates some potential tumorigenicity—product information, Vivitrol 2010)

DeVido J, Greenfield S. Opioid Dependence in Pregnancy: Clinical Challenges. PCSS-MAT
Opioid Use Disorders & Pregnancy: MAT and Lactation/Breastfeeding

- Buprenorphine
  - Excreted in breast milk
    - Manufacturer does not recommend breastfeeding while on this medication
    - However, most guidelines do not contraindicate usage while breastfeeding (ACOG 2012; CSAT 2004; Montgomery 2012)
    - Little is bioavailable to infant, owing in part to the need for sublingual absorption [Samples from single mother-infant pair demonstrated daily infant ingestion of 3.28mcg from a lactating mother receiving 4mg daily (Marquet 1997)]
Opioid Use Disorders & Pregnancy: Mandatory reporting considerations

- 18 states consider maternal substance use “child abuse” (1 state considers it “criminal”)
  - 3 states consider it grounds for civil commitments (MN, SD, WI)
- 18 states require health care providers to report suspected prenatal substance abuse
  - 4 states require them to test if they suspect it
- 19 states have targeted programs for pregnant women
- 13 states provide pregnant women with priority access to state substance abuse programs
- For more information refer to:
Opioid Use Disorders & Pregnancy: MAT and Lactation/Breastfeeding

• Methadone
  – Excreted in breast milk
    • Dose to a nursing infant is 2-3% of maternal dose (10-80mg maternal methadone daily dosing)
  – Manufacturer does not recommend breastfeeding while on this medication
  – However, most guidelines do not contraindicate usage while breastfeeding (ACOG 2012)
  – If illicit drugs are being used while mother is taking methadone, it is recommended that breast milk is pumped and discarded until sobriety is achieved (ACOG 2012; Dow 2012)

DeVido J, Greenfield S. Opioid Dependence in Pregnancy: Clinical Challenges. PCSS-MAT
Opioid Use Disorders & Pregnancy: Mandatory reporting considerations

• California:

  – Positive urine toxicology screen in infant born to mother either in or not in MAT does not mandate reporting. It is at the discretion of the provider to assess the need for reporting to county welfare department, police, or probation department.

Altered Pain Experience

- Patients with opioid use disorder (actively using) have lower pain tolerance than those in remission or matched controls.
- Patients on opioid maintenance treatment (i.e. methadone, buprenorphine) have less pain tolerance than matched controls.
- “Opioid Debt”
Acute Pain
Buprenorphine Maintenance Treatment

- Buprenorphine is good analgesic (without analgesic ceiling)

- Can combine buprenorphine with short acting opioids and will have synergistic effect.
Changing Gears...
Amphetamines

• Prescribed
  • Almost completely unstudied

• Illicit
Amphetamines

• Illicit
  • Comorbidities:
    • 78% active tobacco smokers
    • 14% regular alcohol users
    • 24% regularly tested positive for multiple substances (Uziel-Miller 2002)
  
• Risks
  • No evidence that they are teratogenic
  • Small-for-gestational age (Plessinger 1998)
  • Neonatal and childhood behavioral abnormalities (Plessinger 1998, ACOG 2011)
Amphetamines

• Illicit

• Risks, cont.
  • Intrauterine growth restriction (anorexia?) (Smith et al 2006)
  • decreased arousal, increased stress, and poor movement in newborns
    (Della Grotta S et al 2010)
  • Maternal/fetal hypertension (poorly studied) (ACOG 2011)
  • Infants: trouble feeding, sleep disruption, and abnormalities of muscle
    tone
    • resolve spontaneously within several weeks
  • Inhibits prolactin
  • Serum:milk of 1:1 to 1:7.5
  • Stopping cold turkey → depression, paranoia, fatigue, anergia
  • Placental abruption (due to vasoconstriction) → actually see LARGER
    placenta (thought to be related to chronic hypoxia, like at altitude)
    (Carter et al 2016)
Amphetamines

- Illicit
  - Treatment
    - No MAT
    - CBT, Contingency Management (Rawson et al 2004; Roll et al 2006)
Conclusions

• While the numbers of women with SUD in pregnancy are lower than in the general population, they still present significant risks

• Alcohol is known teratogen, but dose exposure uncertain

• Decisions regarding MAT in pregnancy need to be carefully weighed in risk-benefit discussion

• Alcohol withdrawal could pose particular risk to mother and infant

• Data suggest: treatment of withdrawal with benzodiazepines unlikely to have deleterious effects

• No amount of alcohol is considered “safe” during pregnancy
Conclusions

• Opioid detoxification during pregnancy is risky, and maintenance treatment with either buprenorphine or methadone is preferred.
• Buprenorphine and methadone each present unique pros and cons.
• Despite some cons, MAT is preferred over continued use.
• Generally speaking, women are encouraged to breastfeed while on MAT.
• Check with your state regarding mandatory reporting laws.
• We have no medication treatments for amphetamine use disorders, and amphetamine use carries unique maternal/fetal risks.
Resources

• AAAP
  • www.aaap.org

• ASAM/CSAM
  • www.asam.org
  • www.csam-asam.org

• PCSS-O
  • www.pcss-o.org

• PCSS-MAT
  • www.pcssmat.org
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