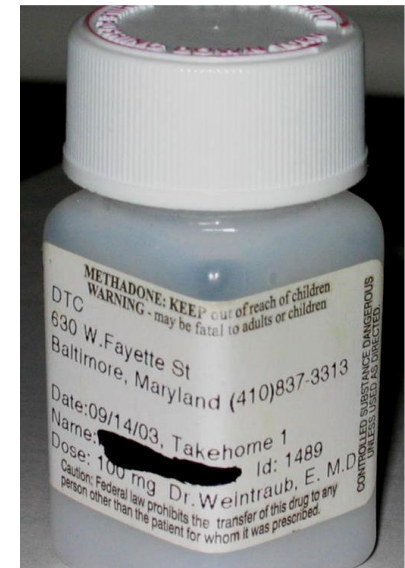


OPIOID USE DISORDERS & PREGNANCY



Christopher Welsh M.D.
Associate Professor





Disclosure

- I have no financial relationship with any companies related to this talk.



Confusing Terms

- **Addiction**
- **Dependence**
- **Use**
- **Misuse**
- **Abuse**
- **Risky/At-risk Use**
- **Problematic Use**
- **Non-medical Use**
- **Non-prescribed Use**
- **Illicit Use**
- **Illicit Use of a Licit Substance**
- **Experimentation**



Substance Use Disorder (DSM-5)

Mild=2*-3; Moderate=4-5; Severe=6 or more

A maladaptive pattern of substance use leading to clinically significant impairment or distress:

-Tolerance*

-Withdrawal*

-Often taken in larger amounts or over a longer period than intended

-Inability to cut down/control use

-Considerable time spent using/obtaining/recovering

-Important activities given up/reduced

-Use despite negative consequences

-Failure to fulfill role obligations

-Craving or strong desire to use

-Recurrent use in hazardous situations

-Recurrent use despite persistent, related social/interpersonal problems



Physical Dependence & Opioid Use Disorder

Physical Dependence

← OUD



Opioid Use “Scenarios”

- **Appropriate use of prescription opioids**
- **Inappropriate use of prescription opioids**
- **Use of illicit opioids**
- **Appropriate use of medications to treat opioid use disorder (MOUD)**
- **“Inappropriate” use of MOUD**

Born addicts, opioid babies in withdrawal from first breath



ADVANCE FOR USE SATURDAY, FEB. 18 - In this Aug. 7, 2017 photo, Logan Patel, 23, of Canton, holds her daughter, born Feb. 7, in the NICU unit at Holy Spirit-Garrettsville in East Pennsylvania Township, Pa. Patel was sobriety-addicted. [more >](#)

Search

The Vibe From Social

Politics: Jeff Flake Balls Dumps on Trump, Score Social

News: The NAACP Star American Airlines, Sod Piles On

Sports: Londo Ball Isn't Bailing Out, But...

MON

with 25 THE PUT OF THE

BY THE NUMBERS Taking a toll

Here's the human and financial impact of the opioid epidemic:

\$1.5 billion
yearly health care costs for babies with NAS

Fivefold
increase in NAS since 2000

Every 25 minutes
a baby is born with NAS

16.9 days
average LOS

\$66,700
average cost of hospital stay

78%
of health care costs are billed to state Medicaid programs

Sources: National Institute on Drug Abuse, Robert Wood Johnson Foundation

ADDICTED

AT BIRTH

Mom who gave her baby methadone 'to help her sleep' and killed her will serve up to 30 years in prison

- Courtney Nicole Howell, 27, of Layton, Utah cried in court on Wednesday as she was sentenced to 30 years behind bars for killing her child
- Howell gave her baby girl Jaslynn Mansfield, 17-months, methadone to help her sleep and the baby overdosed
- 'Trying to forgive myself is an endless battle I struggle with daily,' she said as she wiped away her tears

By ALEXANDRA KLAUSNER FOR DAILYMAIL.COM
PUBLISHED: 12:06 EDT, 27 August 2015 | UPDATED: 17:50 EDT, 27 August 2015

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A woman who killed her 17-month-old baby girl with a lethal dose of methadone last year was sentenced to up to 30 years behind bars on Wednesday.

Courtney Nicole Howell, 27, of Layton, Utah pleaded guilty in July to giving her baby girl Jaslynn Mansfield methadone to help her sleep. She thought the drug



Eight-month-old baby girl is likely to die after her 'mom rolled on top of her while high on heroin'

- Eight-month-old Olaia Marie Mejia is in her final days after her mom Lisa Scalia, 31, allegedly rolled on top of her
- Police say that they found 34 bags of heroin and 10 oxycodone pills mother Lisa Scalia's, 31, home on Sunday and arrested her
- An investigation discovered that Scalia was under the influence of drugs at the time of the incident

By ALEXANDRA KLAUSNER FOR DAILYMAIL.COM
PUBLISHED: 19:59 EDT, 8 January 2016 | UPDATED: 09:07 EDT, 9 January 2016

f Share t P g+ 635 shares View comments

A baby girl from New Jersey is likely to die after being accidentally smothered by her mother who was high on heroin at the time, say police.

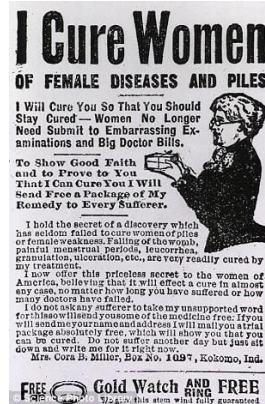
Eight-month-old Olaia Marie Mejia was hospitalized last week at AtlantiCare Regional Medical Center, City Campus, in Atlantic City, on Sunday, and later transferred to St. Christopher's Hospital





Factors Associated w/ Misuse of Prescription Drugs By Women

- Women have longer life expectancies relative to men
 - more likely to experience chronic pain or other health issues
- Women may be more sensitive to pain and report greater pain intensity than men
 - due to differences in sex hormones, genetics, or the cortical processing of pain
- Sex-specific differences in opioid receptors
 - slower onset and offset of morphine among women
 - need for greater doses to achieve similar effects
- Medications with potential for misuse are more often prescribed to women
- Therapeutic window for women may be smaller
 - may be more likely to experience dependency & withdrawal
 - differences in the absorption, metabolism, and elimination





Factors Associated w/ Misuse of Prescription Drugs By Women

- Gender-related factors (gender role beliefs, coping mechanisms, mood, and expectations of pain) may mediate the experience of pain and may shape women and men's use of prescription opioids
 - tendency for women to report more pain/more intense pain may be related
 - in part, reflects gender role socialization which teaches girls early on that it is more acceptable to express pain than boys
- Women make more frequent health care visits
- Women often targeted in pharmaceutical marketing
- Women misusing prescription drugs may also perceive these drugs to be safer & less stigmatized compared with illicit drugs
 - more likely to borrow/share medications
- Women are more likely to experience trauma



Trauma & Misuse of Prescription Drugs By Women

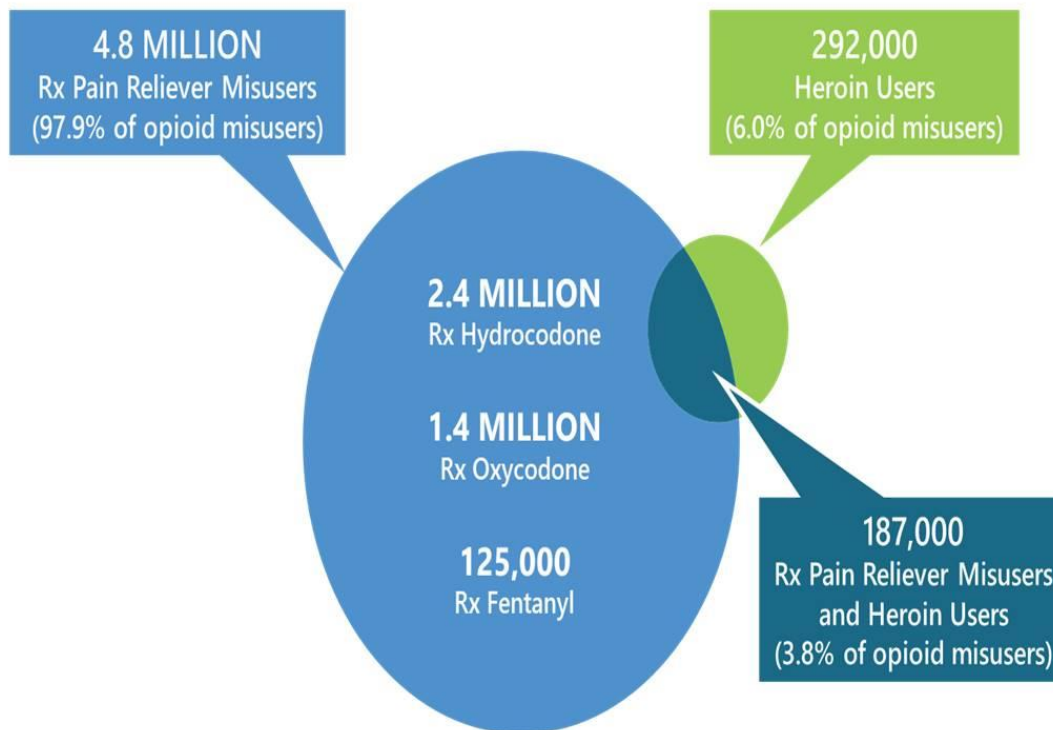
- Psychological effects of trauma may increase vulnerability to prescription opioid use and misuse
 - use of opioids to treat stress, anxiety, insomnia, PTSD, etc.
- Women who have experienced trauma are more likely to experience difficult to treat medical conditions such as fibromyalgia, irritable bowel syndrome, chronic fatigue syndrome, and premenstrual syndrome
- Women who have experienced trauma often have more acute and chronic injuries and chronic pain
 - even see if the trauma was only emotional/psychological



Prescription Pain Reliever Misuse Among Women

PAST YEAR, 2018 NSDUH, Women 12+

4.9 MILLION WOMEN WITH OPIOID MISUSE (3.5% OF TOTAL POPULATION)



Rx = prescription.

Opioid misuse is defined as heroin use or prescription pain reliever misuse.



Prescription Pain Reliever Misuse & Heroin Use Among Women

PAST YEAR, 2015-2018 NSDUH, Women 12+





Prescription Opioid Use In Pregnancy

- 14-22% of pregnant women receive a prescription for an opioid during pregnancy

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HEALTH
JAN 22 2015, 7:26 PM ET

Pill-Popping Mommas: 'Many' Pregnant Women Take Opioids, CDC Finds

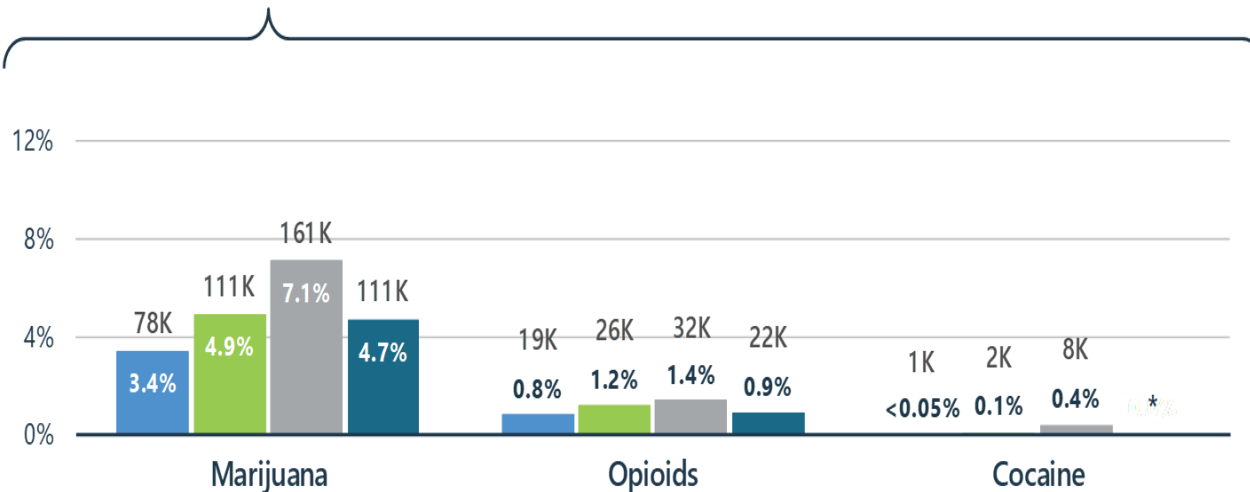
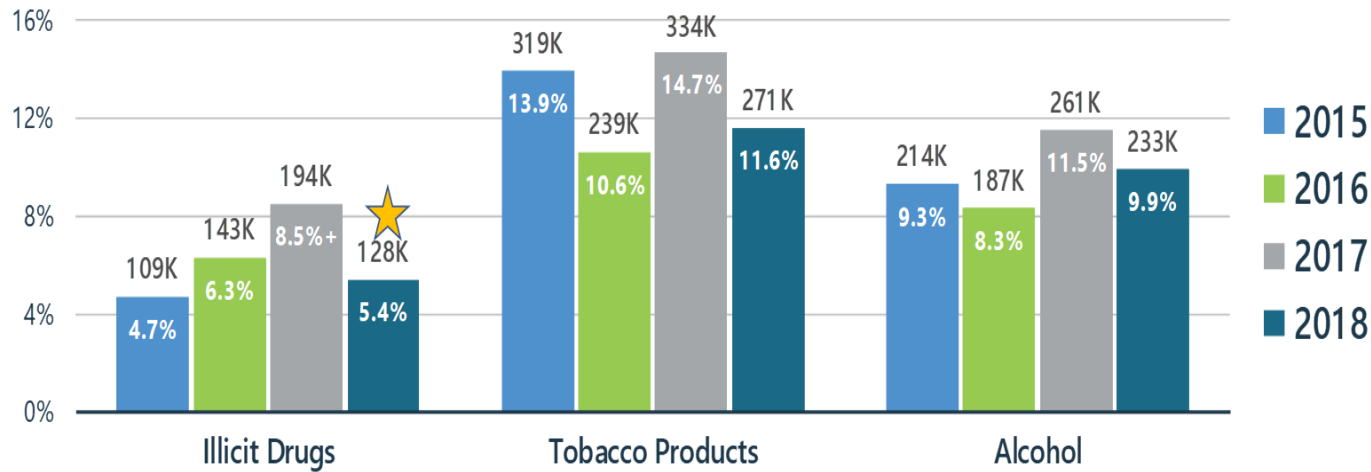
by BILL BRIGGS

A woman who suffers from fetal alcohol syndrome, smokes a cigarette while pregnant. She also admits to using many drugs while pregnant. © Jennifer Osborne / Redux Pictures file



Past Month Substance Use Among Pregnant Women

PAST MONTH, 2015-2018 NSDUH, 15-44





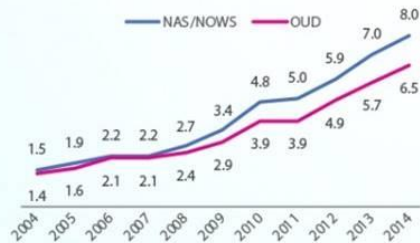
DRAMATIC INCREASES IN MATERNAL OPIOID USE DISORDER AND NEONATAL ABSTINENCE SYNDROME

Opioid use during pregnancy can result in a drug withdrawal syndrome in newborns called **neonatal abstinence syndrome**, or **neonatal opioid withdrawal syndrome** (NAS/NOWS), which causes **costly** hospital stays. A recent analysis showed that an estimated **32,000** babies were born with this syndrome in the United States in 2014, a more than **5-fold increase** since 2004.

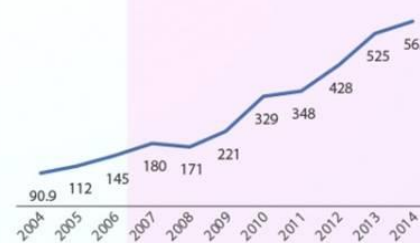


**EVERY ~ 15 MINUTES,
A BABY IS BORN SUFFERING
FROM OPIOID WITHDRAWAL.**

NAS/NOWS and Maternal Opioid Use Disorder on the Rise
Rates per 1,000 Hospital Births

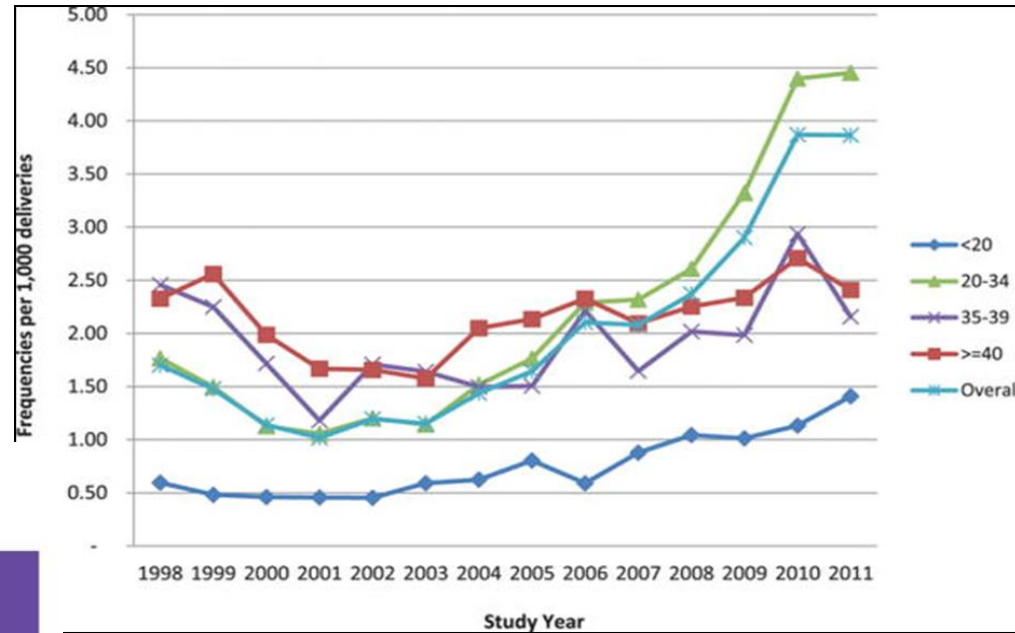
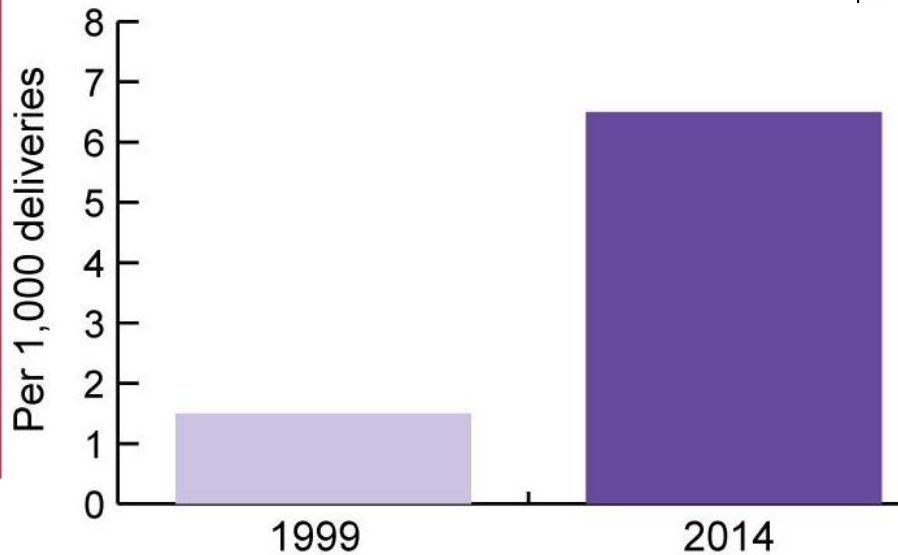


Growing Hospital Costs for Treatment of NAS/NOWS
Inflation-Adjusted U.S. Dollars (millions)





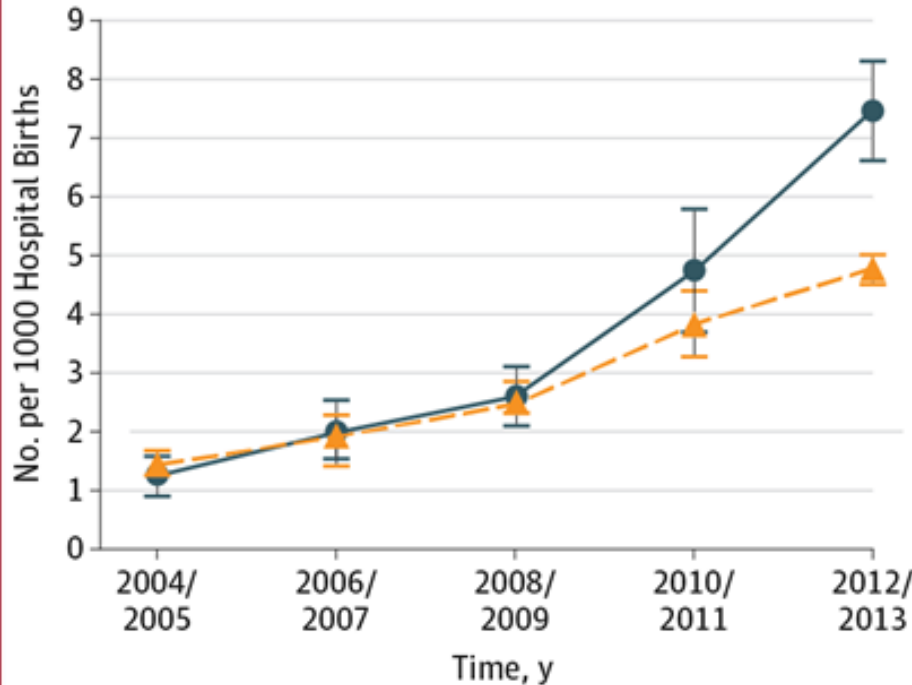
Opioid Use Disorders Per 1000 Deliveries –U.S.



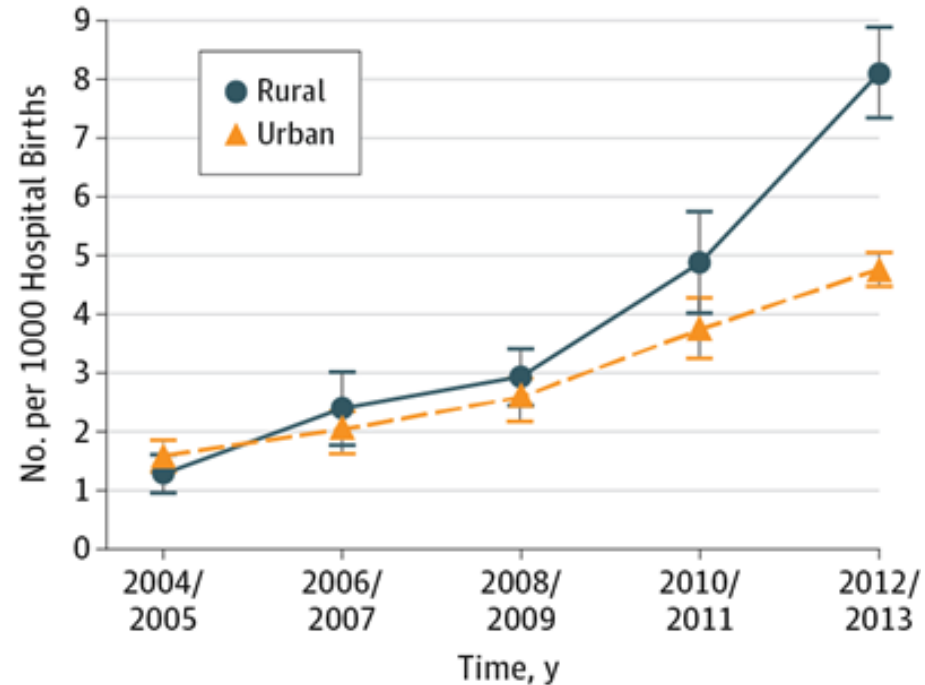


Urban vs Rural

A Neonatal abstinence syndrome



B Maternal opioid use





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HEROINYL or FENTONIN





Pregnancy is a time of
great potential for
positive change.

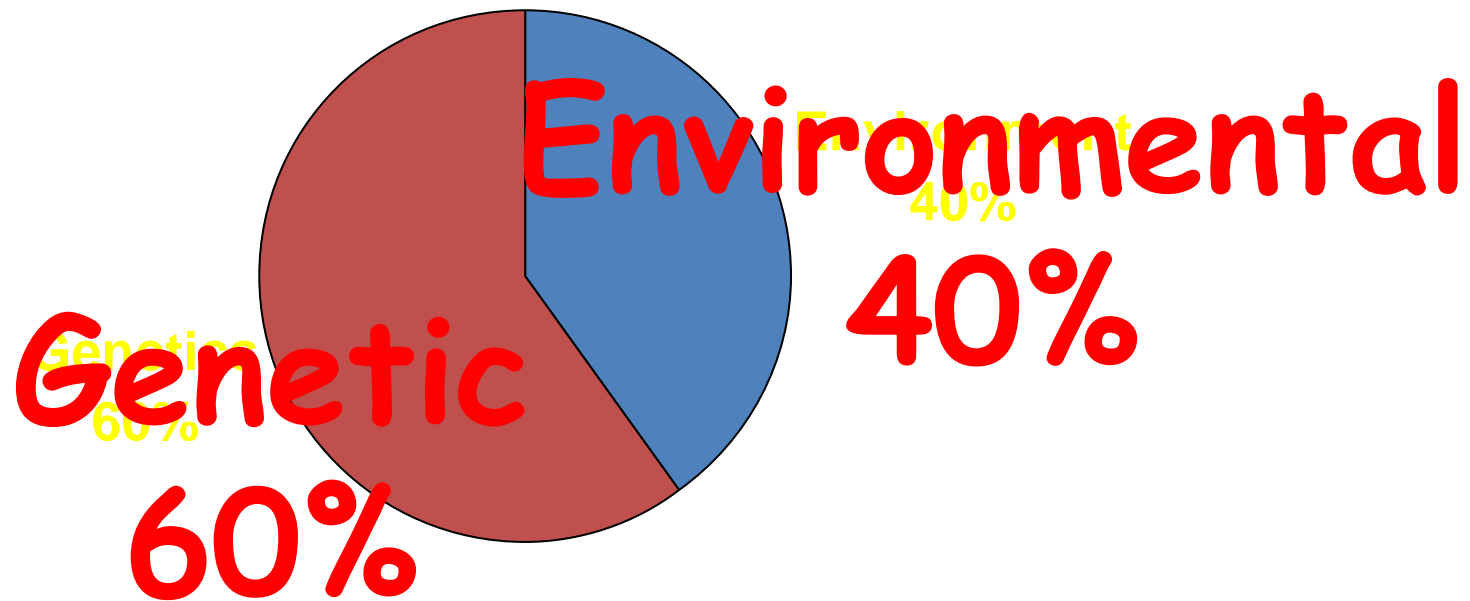


SUD Screening

- **NEEDS TO BE UNIVERSAL!!!**
- **4P's Plus/Integrated 5 P's**
 - Parents, Peers, Partner, Past, Present
- **Substance Use Risk Profile-Pregnancy (SURP-P)**
 - 1. Have you ever smoked marijuana?
 - 2. In the month before you knew you were pregnant, how many beers, how much wine, or how much liquor did you drink?*
 - 3. Have you ever felt the need to cut down on your drug or alcohol use?
- **CRAFFT**
 - Car, Relax, Alone, Forget, Family, Trouble
- **NIDA ASSIST**
- **Alcohol: T-ACE; AUDIT; TWEAK**



Nature vs Nurture





Toxicology Screening

- Prenatal vs at Delivery
- Mother vs Newborn
- Consent

- Remember:
 - Most standard assays don't test for most prescription opioids
 - Including methadone, buprenorphine
 - Most test for morphine which is a metabolite of heroin
 - None actually test for heroin
 - Many do not test for fentanyl and analogues





Legal Issues

- Varies by state
- 23 states consider substance use during pregnancy to be child abuse
 - Risk for incarceration
 - 3 states allow civil commitment
- Some states have mandatory reporting to CPS during pregnancy
 - Largely felt to dissuade women from seeking prenatal care
- Mandatory reporting at time of delivery
 - **CAPTA**

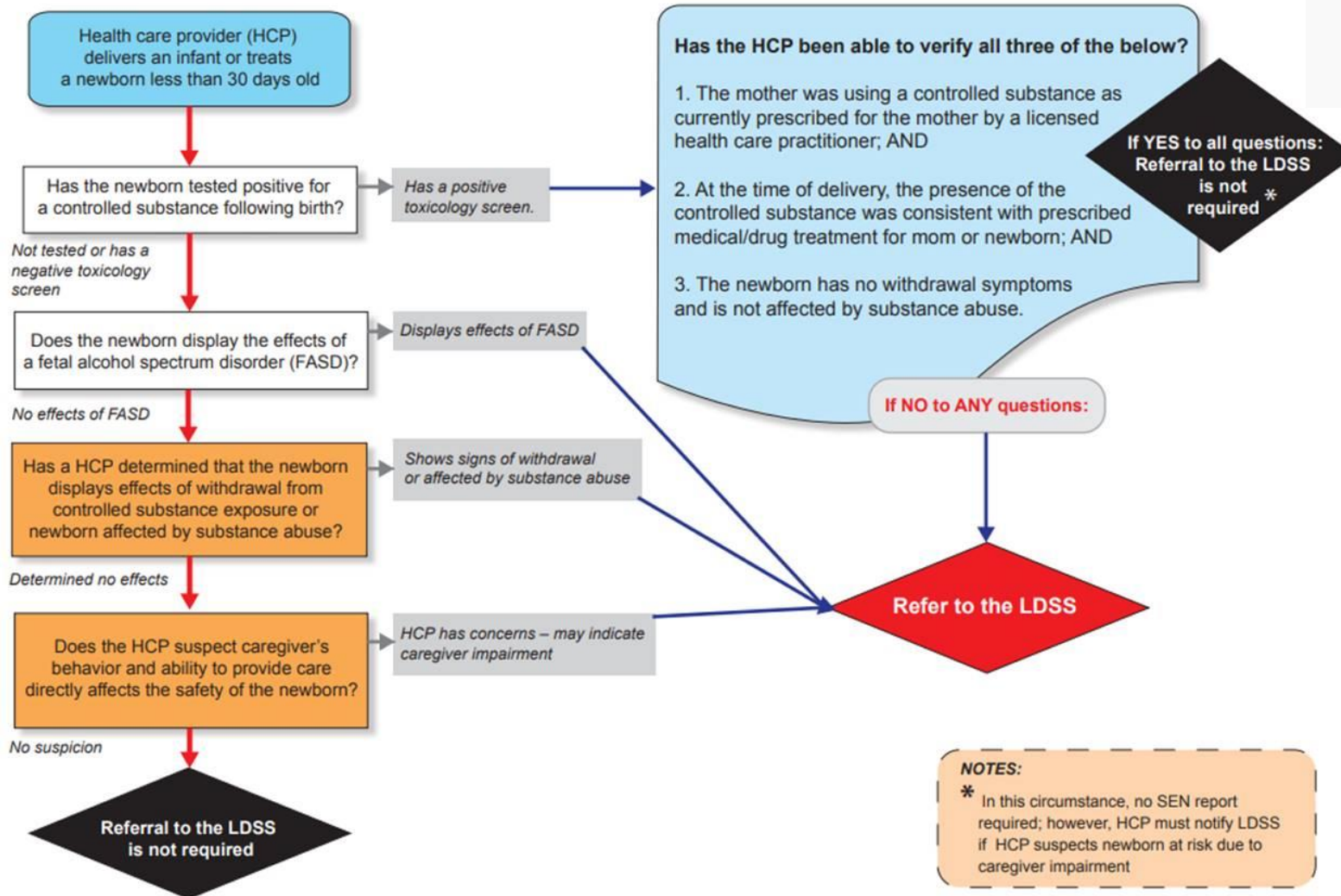


Reporting

- **CAPTA:** Child Abuse Prevention and Treatment Act
- Originally passed in 1974.
- Amended by the Comprehensive Addiction and Recovery Act (CARA) of 2016 & Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) in 2018.
- “State plan requirement for infants born and identified as being **affected by substance use or withdrawal** symptoms or **fetal alcohol spectrum disorders** by adding criteria to State plans to ensure the safety and well-being of infants following their release from the care of health-care providers, to address the health and substance use disorder treatment needs of the infant and affected family or caregiver, & to develop the **plans of safe care** for infants affected by all substance use.”
- Report to local DSS

Health Care Providers' Substance Exposed Newborn (SEN) Referral Guide v. 8.13.18

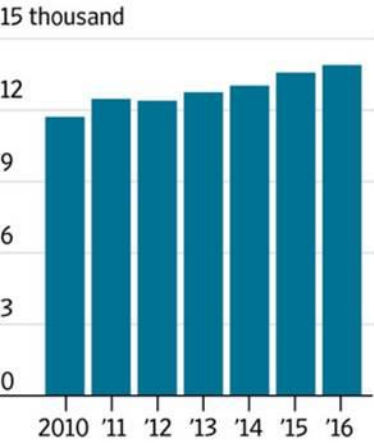
Substance Exposed Newborn



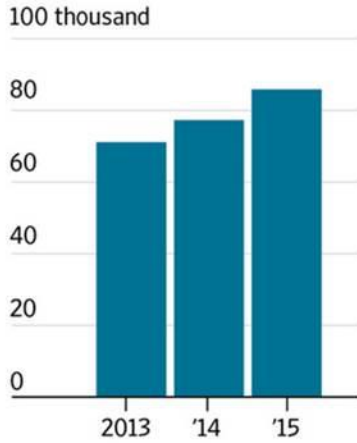
Young Victims

Ohio has seen a sharp increase in the number of minors removed from parental custody through the child-protection system since 2010. Nationwide, foster-care cases involving substance abuse are rising.

Ohio children placed with relatives or in foster care



First-time U.S. foster-care cases related to parental drug abuse



Sources: Public Children Services Association of Ohio; National Data Archive on Child Abuse and Neglect; Adoption and Foster Care Analysis and Reporting System
THE WALL STREET JOURNAL.



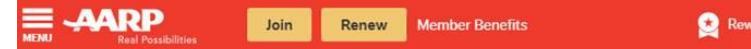
Couple fosters 13 children left by addicted parents

Story by Poppy Harlow, CNN
Article by Haley Draznin, CNN
Video by Jeff Simon and Zach Wasser, CNN
Updated 1:36 PM ET, Wed October 18, 2017



CBS NEWS August 7, 2017, 7:19 PM

Ohio foster care system flooded with children amid opioid epidemic



HEALTH / DRUGS & SUPPLEMENTS Special Report: The Opioid Epidemic

The Background · The New Dealers · The Caregivers · The Drugs · The Faces of Addiction · Take Action



The New Caregivers

Grandparents fill gaps in drug-ravaged families

by Michael Hedges, AARP Bulletin, June 2017

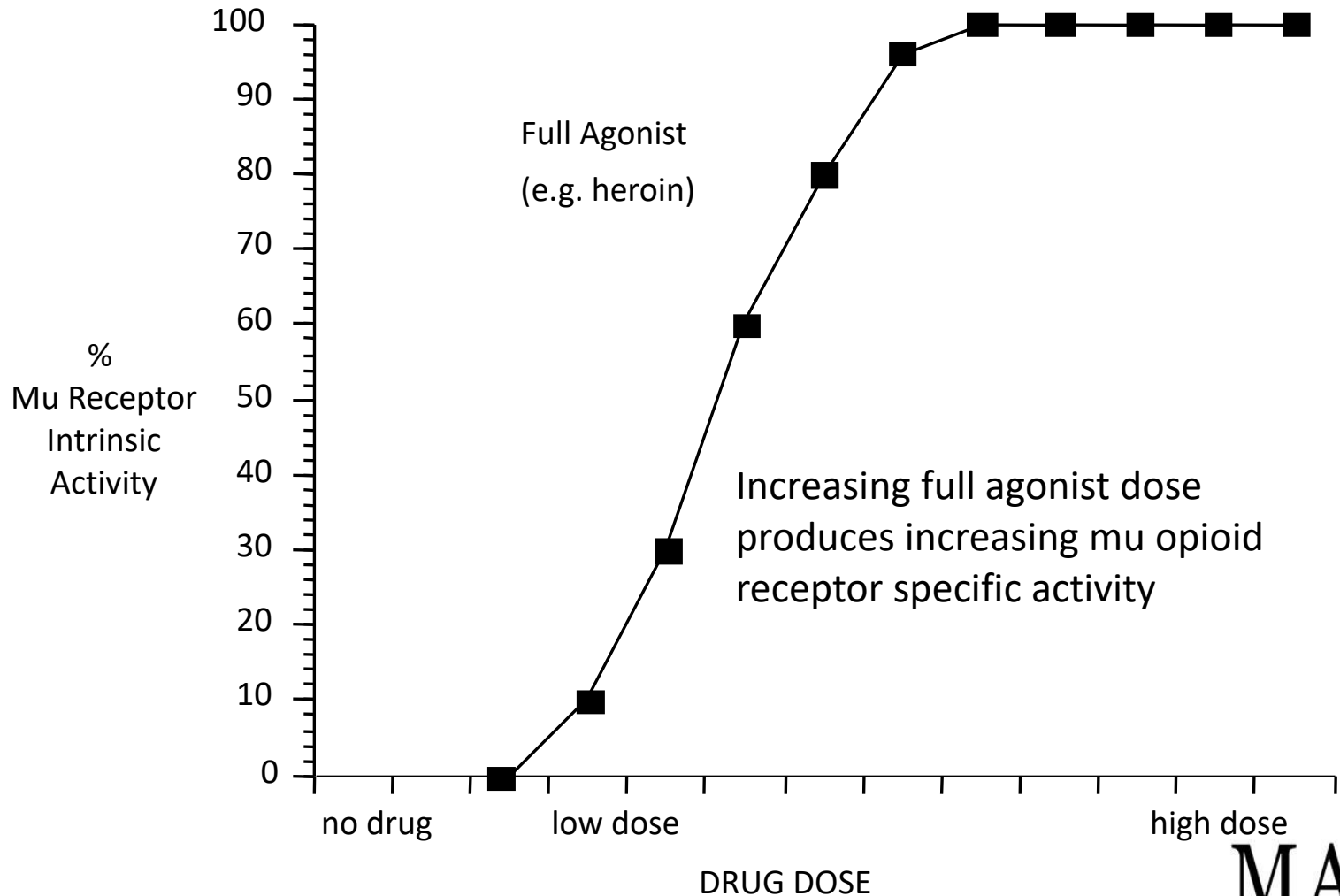


Maintenance Medications For OUD

- **FDA Approved**
 - **Methadone** (Methadose; Dolophine)
 - **Buprenorphine**(Suboxone; Suboxone Film; Subutex; Bunavail; Zubsolv; Sublocade)
 - **Naltrexone** (Trexan; Vivitrol)
- **Experimental/Not Approved**
 - Ibogaine
 - Heroin
 - Hydromorphone
 - Kratom
 - Cannabis
 - Psilocybin

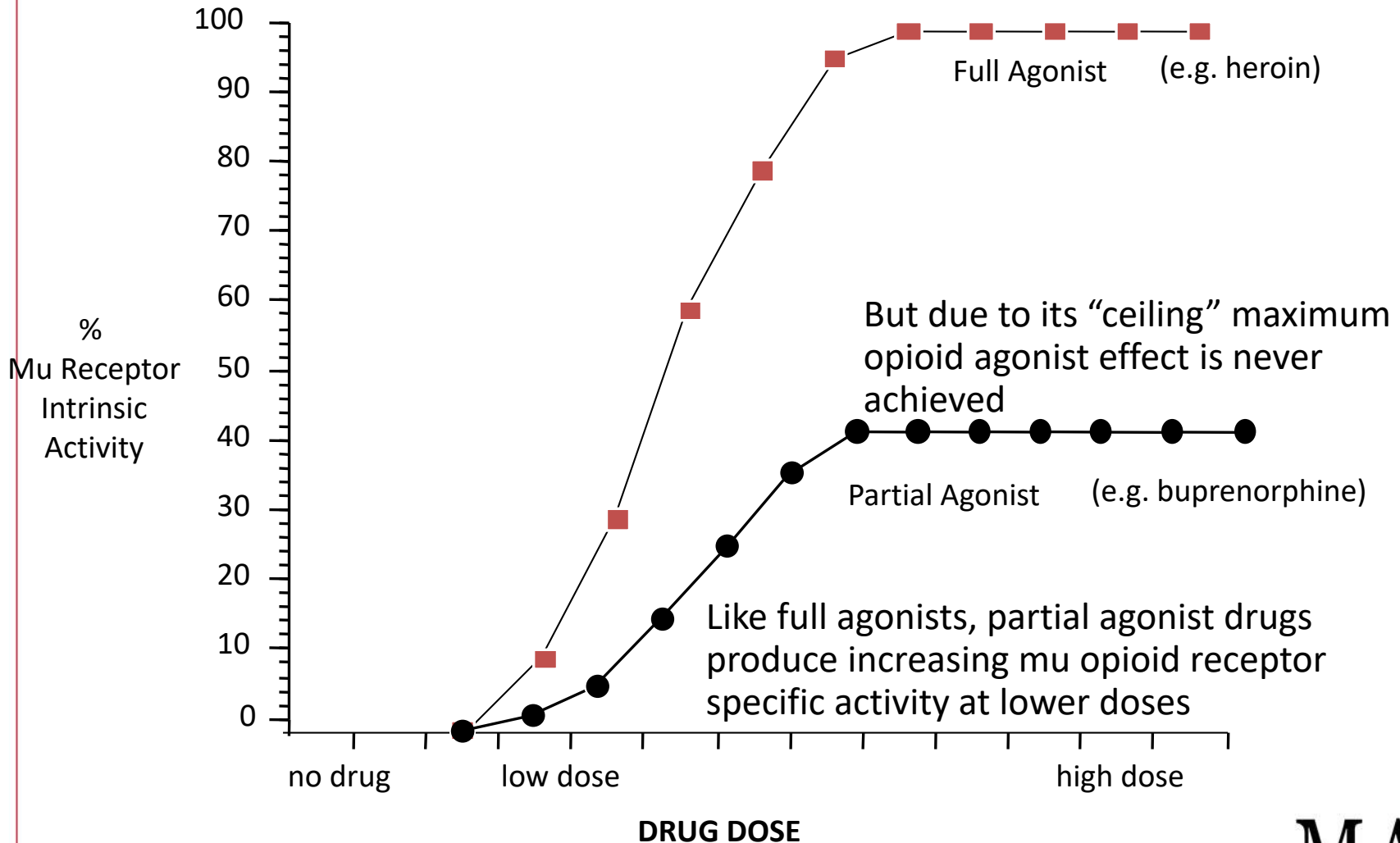


Full Agonist Activity Levels



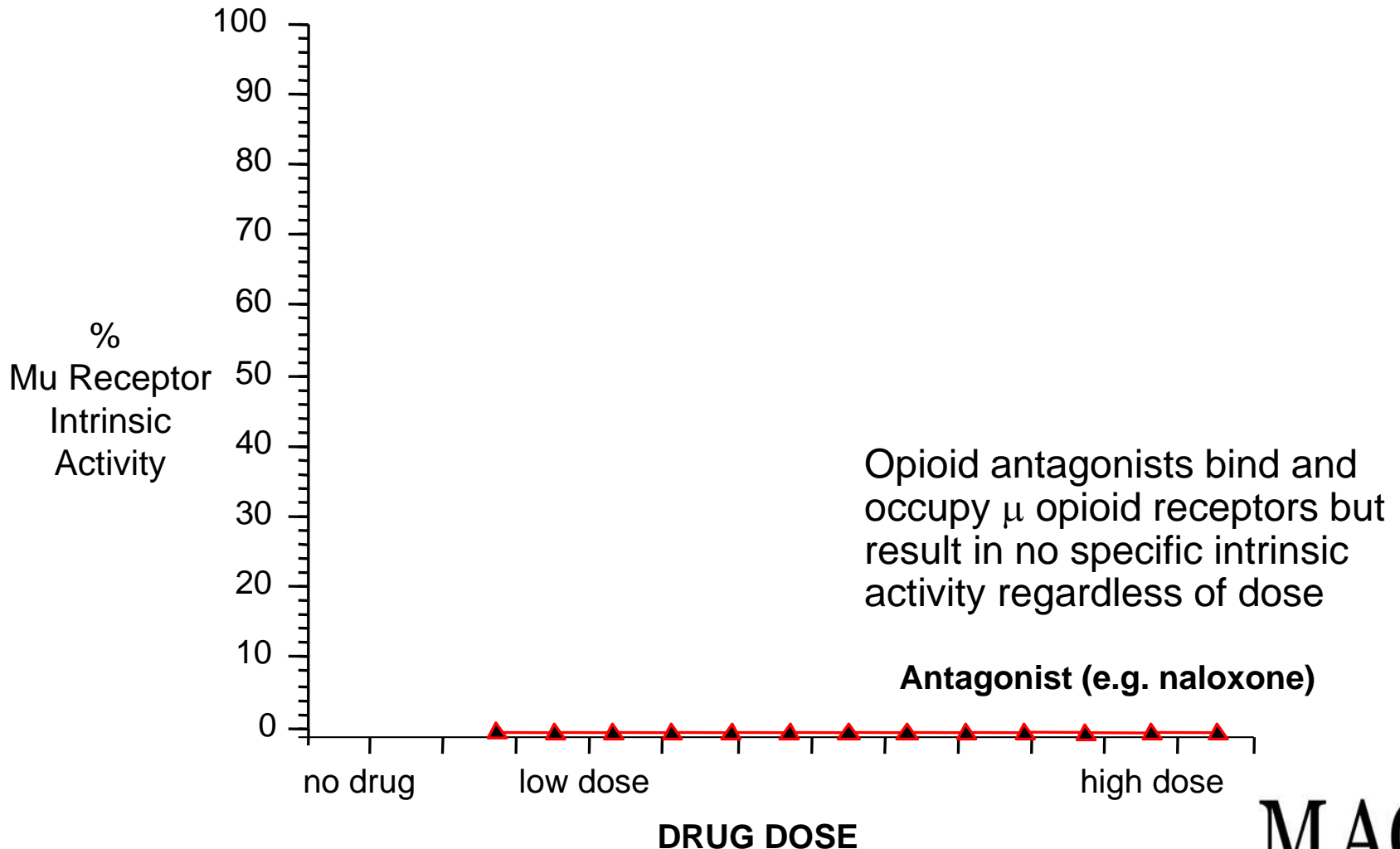


Partial Agonist Activity Levels



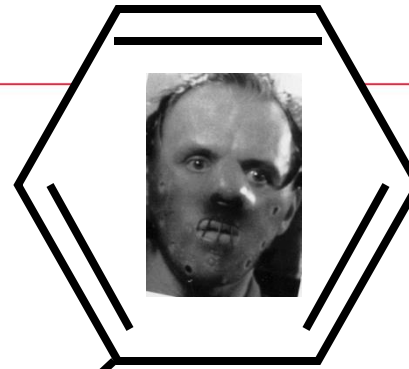
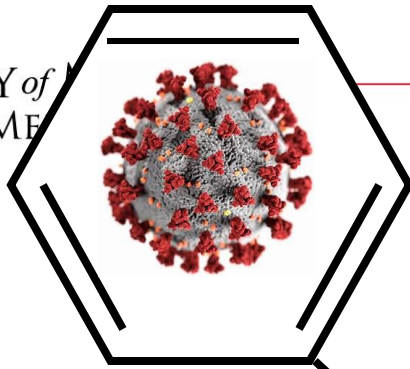


Antagonist Activity Levels



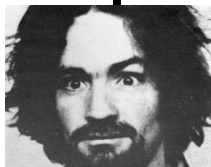


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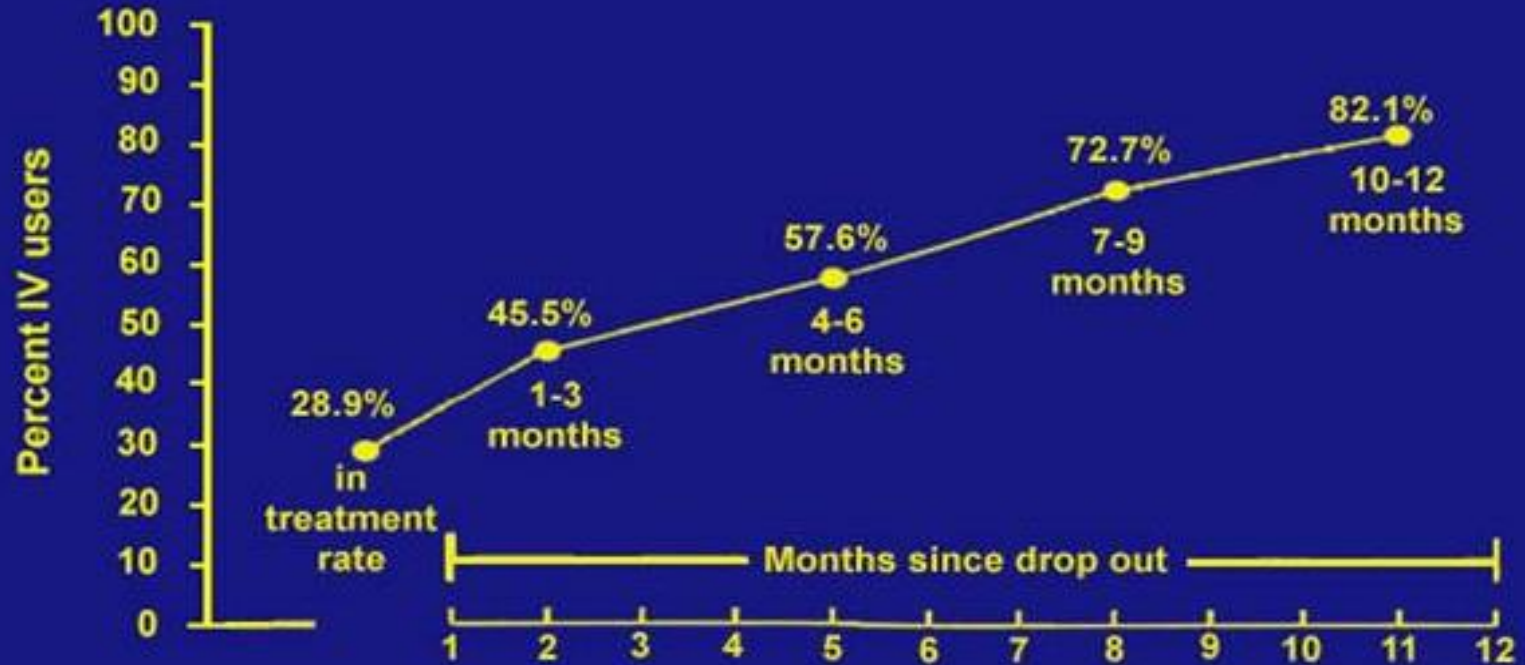
Advantages Of Methadone & Buprenorphine (compared to heroin)

- **Orally administered**
- **Gradual onset of action**
- **Long half-life**
- **Long duration of action**
- **Produces complete blockade of effects of heroin**
- **Minimal chronic problems**



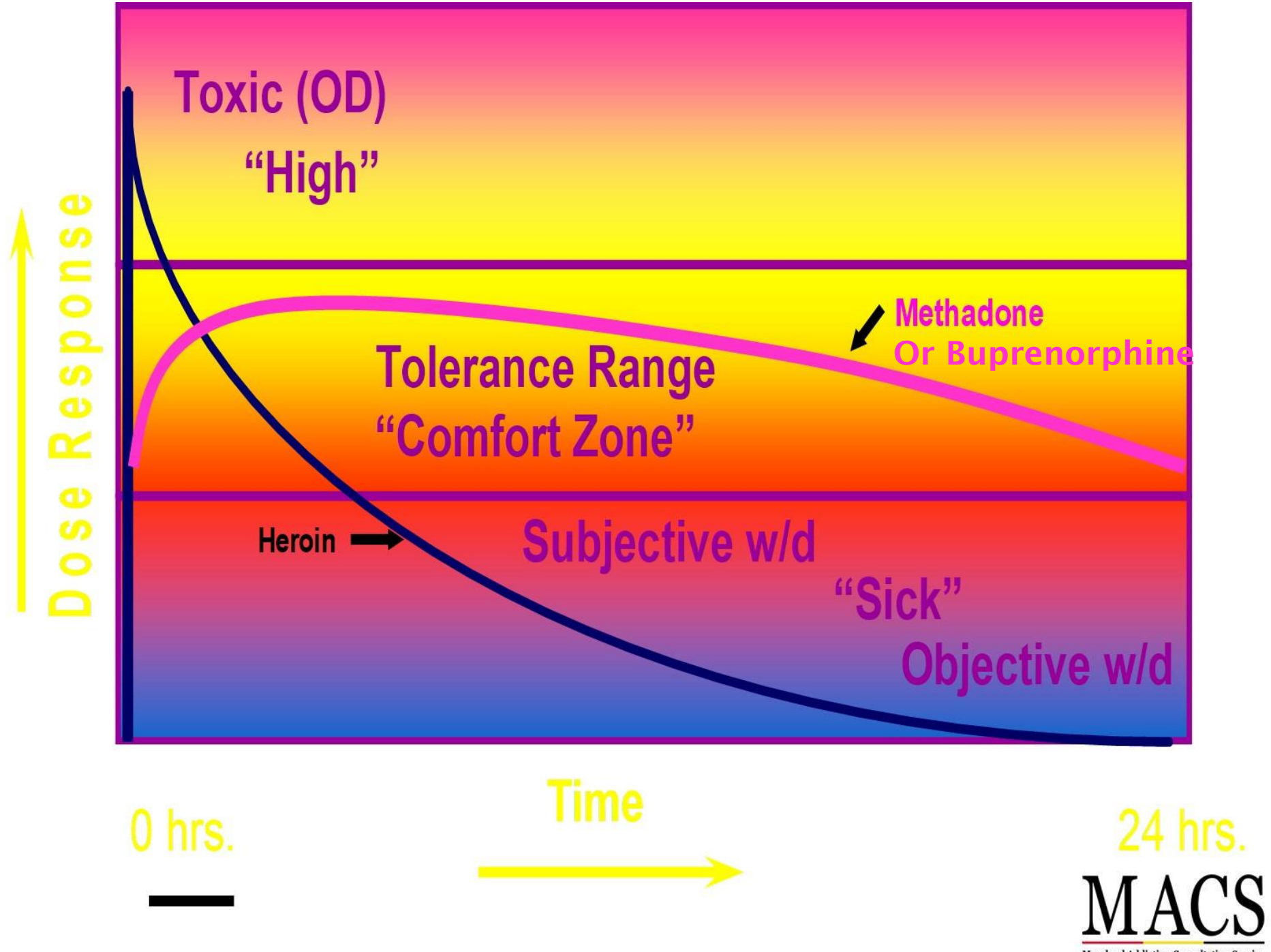
Benefits of Methadone & Buprenorphine Maintenance

- **Reduction in the use of illicit opioids**
- **Reduction in criminal activity**
- **Reduction in HIV and hepatitis infection rates & transmission**
- **Reduction in endocarditis, cellulitis, etc.**
- **Improvement in general health**
- **Improvement in productivity and “social health”**



Relapse to intravenous drug use after methadone maintenance treatment for 105 male patients who left treatment.

From the Effectiveness of Methadone Maintenance Treatment (p. 182), by J. C. Ball and A. Ross, 1991, New York
Copyright 1991 by Springer-Verlag New York, Inc. Reprinted with permission.





Methadone Maintenance Admission Criterion

- **Current physical dependence on an opioid**
- **One year history of opioid use disorder**
- **18 years or older**



Methadone Maintenance Admission Criteria Exemption

- **Patients from penal institutions**
 - if he/she met criterion prior to incarceration
- **Pregnant women**
- **Patients previously on maintenance**
 - for 2 years after last maintenance treatment
- **Patients under 18 years of age**
 - must have documentation of 2 failed outpatient treatments
 - must have parental consent



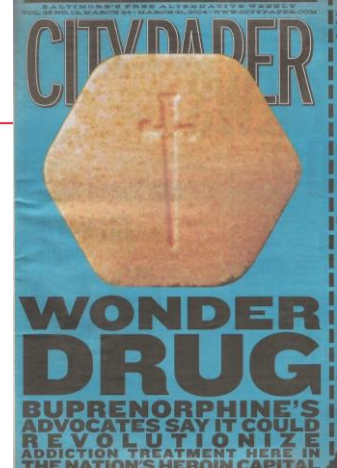
Methadone Induction

Induction is the most risky phase of methadone maintenance treatment.

- **START LOW** (10-30mg first dose)
- **GO SLOW**
- There is no optimal doses for all patients.
- Observe signs and symptoms over time.
- Understand the cumulative property of methadone.
- Communicate methadone's time-line to patients and family/significant others.



Maintenance Treatment Using Buprenorphine



- Numerous outpatient clinical trials comparing efficacy of daily buprenorphine to placebo, and to methadone
- Consistently find:
 - Buprenorphine more effective than placebo
 - Buprenorphine equally effective as moderate doses of methadone (e.g., 60 mg per day)
- Slightly worse retention than methadone in a few studies



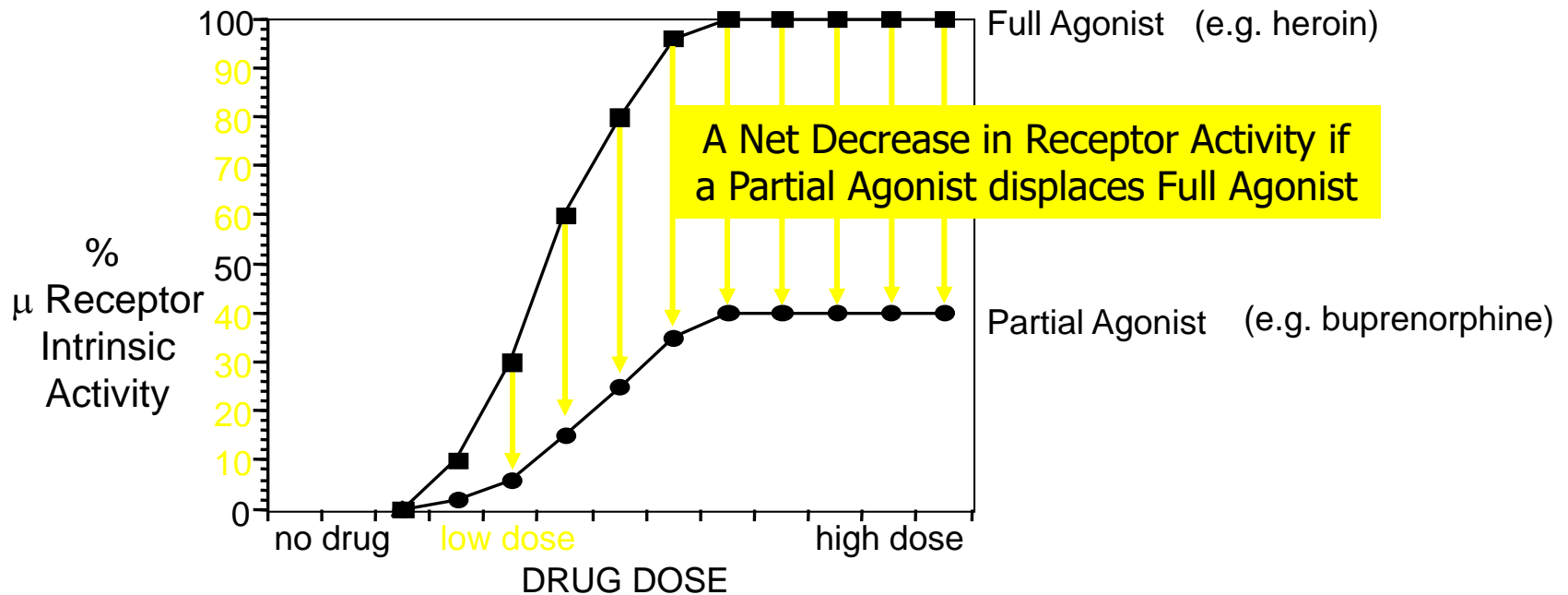
Buprenorphine Safety

- **Highly safe medication**
- **Primary side effects: like other mu agonist opioids but may be less severe**
- **No evidence of significant disruption in cognitive or psychomotor performance**
- **No evidence of organ damage with chronic dosing**
- **Possible mild increase in LFTs????**



Precipitated Withdrawal

- Displaces full agonist off μ receptors





Methadone Buprenorphine & Pregnancy

- Less risk to the fetus than heroin
- Less adverse pregnancy outcomes
- Less adverse birth outcomes
- Less chance that mother will contract STDs, endocarditis, cellulitis, etc.
- Less chance that mother will get shot, stabbed, beaten, arrested, etc.
- Neonatal abstinence syndrome is relatively easy to manage



Benefits

- Compared to infants born to mothers using heroin, infants from methadone/buprenorphine-treated mothers have:
 - Increased fetal growth
 - Increased head circumference
 - Reduced fetal mortality
 - Less preterm births
 - Decreased risk of HIV infection
 - Decreased risk of pre-eclampsia
 - Less fetal exposure to unpredictable cycles of heroin-induced highs and withdrawal
 - Increased likelihood of the infants being discharged to their parents



Methadone & Buprenorphine & Long-term Outcomes

- Overall, prenatal exposure to methadone & bup provided as a part of comprehensive treatment does not appear to be associated with developmental or cognitive impairments.
- One long term follow up study of 27 children who had been exposed to methadone in utero found no cognitive impairment in the preschool years.
- Less research with buprenorphine



Methadone & Buprenorphine

Dosing & Pregnancy

- If woman already on MOUD when gets pregnant, generally recommended to not switch
 - especially switching from methadone to bup
- Some women may need an increased dose
 - clearance is increased with increased progesterone
 - shifts in volume of distribution
 - especially in 3rd trimester
 - often needs to be “split”
 - Can get split “take-home” even if has not “earned” take-home
- Attempts to lower dose during pregnancy?



MOTHER: Measured Neonatal Outcomes

Primary Neonatal Outcomes

- Number of neonates requiring treatment for NAS
- Peak NAS score
- Total amount of morphine needed for treatment of NAS
- Length of Hospital Stay
- Head circumference

Secondary Neonatal Outcomes

- Number of days during which medication was given for NAS
- Weight and length at birth
- Preterm birth (< 37 weeks gestation)
- Gestational age at delivery
- 1 and 5 minute APGAR scores



MOTHER: Measured Maternal Outcomes

- Cesarean section
- Weight gain
- Abnormal fetal presentation during delivery
- Anesthesia during delivery
- Results of drug screening at delivery
- Medical complications at delivery
- Study discontinuation
- Amount of voucher money earned for drug-negative tests
- Number of prenatal obstetrical visits



MOTHER: Results

- A comparison of the 131 neonates whose mothers were followed to the end of pregnancy according to treatment group (with 58 exposed to buprenorphine and 73 exposed to methadone) showed buprenorphine group:
 - Required significantly less morphine (avg dose 1.1 mg vs. 10.4 mg)
 - Had a significantly shorter hospital stay (10.0 days vs. 17.5 days)
 - Had a significantly shorter duration of treatment for the NAS (4.1 days vs. 9.9 days)
- No significant differences between the groups in other outcomes or in the rates of maternal or neonatal adverse events (% needing NAS treatment, peak NAS score, head circumference,).

“Neonatal Abstinence Syndrome after Methadone or Buprenorphine Exposure”, Jones et. Al 2010, *NEJ M*.



MOTHER: Secondary Outcomes with significant differences:

- Neonates exposed to buprenorphine spent, on average, 58% less time in the hospital receiving medication for NAS than did those exposed to methadone (4.1 days vs. 9.9 days).
- There were no significant differences in any of the nine maternal outcomes.



Mono- vs Combo- Product

- “Subutex” - just buprenorphine
- “Suboxone” - buprenorphine + naloxone
- Subutex initially recommended for pregnant women because it was the only form studied when FDA approved in U.S. in 2002. Was also thought to have a lower risk for precipitated withdrawal.
- >10 studies now with Suboxone showing no negative outcomes
- 1 study with Suboxone showed significantly less NOWS than with Subutex





Naltrexone

- ***Revia (oral); Vivitrol (Long-acting injection)***
- ***mu* opioid receptor antagonist (blocker)**
- **Generally very well tolerated**
- **No abuse potential**
- **Several retrospective studies in Australia w + results**
- **1 prospective study in Tennessee**
 - **121 women on naltrexone; 109 on methadone or buprenorphine**
 - **No relapses during the 7 day period prior to starting naltrexone**
 - **34 stopped naltrexone (“didn’t think I needed it”; headache; nausea)**
 - **20 remained drug free; 11 switched back to bup/methadone; 3 using illicit opioids**
 - **No differences in birth outcomes compared to methadone/buprenorphine**
 - **No NOWS in neonates of 87 pts who remained on naltrexone**
 - **No fetal anomalies**



Choosing Which Treatment

- Medication
 - Methadone, Buprenorphine, Naltrexone
 - Formulation
- Treatment Setting
 - OTP, Non-OTP Outpatient, Primary Care, OB Provider, Residential
- Current Treatment Setting Limitations
 - ED, Acute Care Hospital, SNF, Correctional Facility



Choosing Which MOUD

- Patient preference- NEEDS TO BE DONE COLLABORATIVELY!
 - Medication (methadone, buprenorphine, naltrexone)
 - Setting (OTP, primary care, ASAM Level 1-4)
 - “Detox”- highly discouraged
- Patient treatment history
 - “Official”
 - “Self-treatment”
- Patient factors
 - Age; duration of OUD; current physical dependence (Fed. Regs.)
 - Age; QT; Sleep apnea; Liver failure; Concomitant pain; Other meds
- Practical factors
 - Availability of treatment(when & where); insurance; schedule
- Current comorbid conditions
 - Pain; infection; physical disability; other medications



Intrapartum Pain

- Often need more pain medication because of tolerance and hyperalgesia
- Avoid butorphanol and other mixed agonists
- ACOG position statement-
 - Women taking methadone or buprenorphine who are in labor should have their maintenance opioid agonist dose continued and should receive additional pain relief.
 - Epidural/spinal anesthesia; short-acting opioids
- May also consider stopping buprenorphine prior to planned C-section, using short-acting opioids for analgesia and switching back to buprenorphine as pain resolves.



Postpartum Management

- Variable
- Need to watch patient closely
- If methadone or buprenorphine dose was increased during pregnancy, may need to reduce quickly or may be gradual
- Need to explain to mother that this is variable and that she needs to alert OTP about over sedation.



Breast-Feeding

- Studies have found minimal transmission of methadone in breast milk, regardless of maternal dose.
 - Naloxone and naltrexone less studied.
 - Poor bioavailability lessens likelihood of transfer via milk
- Reduces duration and severity of NOWS
- Mothers maintained on methadone or buprenorphine can breast-feed if they are not:
 - HIV positive
 - using substances (Nicotine? Alcohol? Marijuana?)
 - do not have a disease or infection in which breast-feeding is contraindicated



Neonatal Opioid Withdrawal Syndrome (NOWS)

- Formerly known as NAS
- Does not seem to independently increase risk of future OUD
- Usually assessed with “standardized” scale
 - Shorter hospital stays
 - Finnegan; Modified Finnegan; Lipsitz; Neonatal Withdrawal Inventory
- Increased risk if:
 - tobacco, other substances (esp. benzos, SSRIs), premature
- 50-80% of newborns whose mother took methadone or bup
 - Severity less with buprenorphine; less medication needed
- Lessened with breastfeeding, rooming-in, swaddling, quiet environment, acupuncture
- Treated with morphine, methadone
 - Less common-buprenorphine, clonidine,



Educational Disabilities Among Children Born With Neonatal Abstinence Syndrome

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Abstract

Background: Neonatal abstinence syndrome (NAS) is a postnatal drug withdrawal syndrome that can occur after intrauterine opioid exposure. Adverse neurobehavioral outcomes have been documented in infants with NAS; however, educational outcomes have not been thoroughly examined. We analyzed Tennessee data to understand the need for special educational services among infants who are born with NAS.

Methods: By using Tennessee Medicaid and birth certificate data, infants who were born in Tennessee between 2008 and 2011 with a history of NAS were matched (1:3) to infants who were born during the same period without a history of NAS. Groups were matched on the basis of sex, race and/or ethnicity, age, birth region of residence, and Medicaid enrollment status. Data were linked to Tennessee Department of Education special education data during early childhood (3-8 years of age). Conditional multivariable logistic regression was used to assess associations between NAS and selected special education outcomes.

Results: A total of 1815 children with a history of NAS and 5441 children without NAS were assessed. Children with NAS were significantly more likely to be referred for a disability evaluation (351 of 1815 [19.3%] vs 745 of 5441 [13.7%]; $P < .0001$), to meet criteria for a disability (284 of 1815 [15.6%] vs 634 of 5441 [11.7%]; $P < .0001$), and to require classroom therapies or services (278 of 1815 [15.3%] vs 620 of 5441 [11.4%]; $P < .0001$). These findings were sustained in a multivariable analysis, with multiple models controlling for maternal tobacco use, maternal education status, birth weight, gestational age, and/or NICU admission.

Conclusions: Results of this novel analysis linking health and education data revealed that children with a history of NAS were significantly more likely to have a subsequent educational disability.

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