ACOG
THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS

TOOLKIT on STATE LEGISLATION

Pregnant Women & Prescription Drug Abuse, Dependence and Addiction

Misuse and abuse of prescription drugs—namely opioids or "prescription painkillers"—has received a lot of public attention recently from many sectors: state and federal lawmakers, law enforcement, the FDA and other drug policy organizations. Numerous policy recommendations are being considered, some of which focus on pregnant women and the increase in opioid exposure during pregnancy.

ACOG agrees. This issue is deserving of wider attention. Obstetrician-gynecologists share concerns about prescription drug abuse and maternal-fetal exposure to opioids. Because ob-gyns prescribe drugs of potential abuse and treat women who abuse or are dependent on prescription drugs, ACOG has issued extensive policy and clinical guidance over several decades. We welcome the opportunity to work together with state lawmakers to respond appropriately to this important public health issue.

TALKING POINTS

I. Drug and alcohol abuse is a health issue that deserves greater attention and more public health resources. State lawmakers can help. For pregnant women who misuse and abuse drugs and alcohol including prescription opiate painkillers, our shared goal must be a healthy outcome for both mother and baby.

- Every leading medical and public health organization that has addressed this issue — the AMA, ACOG, ACNM, AAP, APHA, AAFP, ASAM and MoD — has concluded that the problem of drug and alcohol use during pregnancy is a health concern best addressed through education, prevention and community-based treatment, not through punitive drug laws or criminal prosecution.

- Research shows that whether or not a pregnant woman can stop her drug use, obtaining prenatal care, staying connected to the health care system, and being able to speak openly with a physician about drug problems helps to improve birth outcomes.

II. Safe prescribing during pregnancy includes opioid agonist therapy (OAT)

- Like all individuals who are drug or alcohol dependent, pregnant women who use or abuse prescription opiates require appropriate medical interventions to treat their disease of opioid addiction. Opioid-assisted therapy with methadone or buprenorphine is the medical standard of care for these women. Physician prescribed and supervised use of opioid-based medications, known as opioid agonist therapy (OAT), improves outcomes for both mom and baby when compared to no treatment or to medication-assisted withdrawal.

- Opioid medication is the appropriate and safest treatment for women experiencing moderate to severe pain during pregnancy and childbirth. Short term use of opioids during pregnancy for episodic pain has not resulted in symptoms of neonatal abstinence syndrome.

- For severe pain during pregnancy including labor and delivery, there are well-established, safe protocols for the use of opioid medications that have been developed by obstetrician-gynecologists and anesthesiologists.

Neonatal Abstinence Syndrome

Neonatal abstinence syndrome is an expected and treatable condition that follows prenatal exposure to opioids.

- Some newborns exposed prenatally to opiates – most commonly, heroin and oxycodone – experience an abstinence (withdrawal) syndrome at birth. In utero physiologic *dependence* on opiates (*not addiction*) – known as Neonatal Abstinence Syndrome (NAS) – is characterized primarily by hyperactivity of the central and autonomic nervous systems. NAS is an expected, readily diagnosed, and treatable condition.

- While NAS is understandably concerning, there is no evidence to indicate that, with effective modern treatment, NAS itself is life threatening or results in permanent harm. For infants with symptoms of NAS—whether from a mother's use of opioid agonist therapy (OAT) or misuse of other opioids—there are safe, effective, and evidence-based treatment protocols endorsed by the American Academy of Pediatrics being used today.

- Unlike neonatal exposure to maternal alcohol and tobacco use, there have been no reported long term effects of maternal opioid use on the developing child. Longitudinal studies over 5 to 10 years have shown that children who experienced NAS as infants do not exhibit signs of physical or cognitive impairment as they mature.

Distorted information and sensationalized rhetoric could drive ineffective responses.

- Despite the lack of evidence that NAS results in permanent harm, media coverage and even some health care communities have responded to this issue with inaccurate information and conclusions about NAS. Recent alarmist news reporting and ill-conceived policy proposals could spiral NAS into the next, now-debunked "crack baby" epidemic.

- Media reporting in the 1980s and early 1990s invented, promoted and perpetuated the non-scientific and highly stigmatizing term, "crack baby". Crack-using women were blamed for societal problems despite the fact that alcohol and tobacco use are more detrimental to the fetus. Unfortunately, this highly charged rhetoric fueled a criminal justice approach to the "crack epidemic" which prioritized simplistic, overly coercive and punitive measures, with negative consequences for women and families.

- Today, overwhelming scientific consensus based on over 20 years of child development research has not identified a recognizable long-term condition, syndrome or disorder that should be termed "crack baby." It is now understood that poverty, poor nutrition and inadequate health care can account for many of the effects popularly, but falsely attributed to cocaine.

Overtreatment for NAS does not achieve optimal outcomes and contributes to unnecessary spending.

- Treatment is not necessary for every infant exposed to opioids. Reports indicate that many infants with in utero opioid exposure are being treated with medical interventions that are not consistent with evidenced-based approaches.

- Many of these infants are unnecessarily given pharmacological treatment that transforms an infant's normal withdrawal and dependence on opioids to an addiction. This prolongs hospitals says and can interfere with maternal-infant attachment.

- Nearly all of these infants are placed in NICUs, despite evidence that NAS can and should be managed in a quiet, comforting, dimly-lit environment. NICUs, with their high wattage lighting and noisy medical machines and equipment, are hyper-stimulating and can aggravate a baby's symptoms.

- Extended NICU stays are associated with increased risk of medication errors and other adverse events, increased stress on families, and impaired parent-infant attachment.

- These modes of treatment cost an average of $50,000 per hospital stay.

Appropriate treatment for NAS improves infants' wellbeing while reducing costs for families and society.

Pediatric experts recommend:

- Guidelines issued in 2012 by the American Academy of Pediatrics based on decades of research indicate that treatment is not necessary for every infant exposed to opioids in utero.

- Neonates with known or expected exposure to maternal opioid use should be monitored in a low-stimulus environment for symptoms of NAS for up to 1 week, depending on the type of maternal opioid use and timing of last drug taken before birth.

- Infants with mild to moderate NAS symptoms should not be treated with opioid replacement drugs. The use of the Finnegan NAS scale will identify the appropriate treatment course for these infants.

- *Non*pharmacologic therapy should be used as a first-line intervention for infants with neonatal withdrawal including:
  - rooming-in (caring for the mother and newborn together in the same room immediately from birth) rather than NICU placement
  - comfort care (swaddling and skin-to-skin contact between mother and baby)
  - minimizing environmental stimuli
  - promoting rest and sleep
  - providing sufficient caloric nourishment for weight gain (high caloric formula or breast milk with supplement)
  - encouraging most mothers to breastfeed, regardless of current opioid use

- Neonates requiring greater intervention as determined by the Finnegan scale can be treated with a methadone or morphine dose.

III. What's NOT working: Interventions that may do more harm than good.

Any serious approach to the misuse and abuse of prescription opiates by pregnant women must start from a scientifically sound foundation and prioritize positive health outcomes. Yet much of the current rhetoric and many popular policy responses fail to achieve this goal. For example, punitive drug enforcement policies don't work. They deter women from seeking prenatal care actively putting women and their pregnancies at risk. State lawmakers instead should look to science-based guidelines and to decades of medical evidence to help guide us towards appropriate public health interventions that will optimize health outcomes for moms and babies.

The following proposals do not achieve healthy outcomes for moms and babies:

- **Criminal penalties for women and their doctors**
  - Experts agree: Incarceration and the threat of incarceration have been proven ***in***effective in reducing the incidence of drug and alcohol abuse. As with other chronic diseases, managing drug addiction requires targeted treatment.
  - Criminal penalties are more likely to deter women from seeking beneficial health care than they are to protect children, reduce the use of harmful substances, or further the States' policy of combating prescription drug abuse and diversion.

- The threat of criminal charges discourages pregnant women who *do* seek prenatal care from disclosing critical information about their drug use to their health care providers.

- Punitive laws may have the unintended effect of encouraging women to end wanted pregnancies. Women who do not think they can overcome a drug problem may seek to terminate a pregnancy to avoid arrest.

- Criminal penalties for health care providers drive a wedge into the physician-patient relationship, impinge on physicians' ability to achieve the best medical outcomes for their patients, and may have a chilling effect on appropriate treatment for pain or for substance addiction.

DOES NOT SUPPORT Healthy Outcomes for Mom & Baby	**SUPPORTS Healthy Outcomes for Mom & Baby**
Overtreatment of NAS in NICUs	Appropriate comfort care in low-stimuli environment and pharmacological therapy where indicated
Criminal penalties for women and doctors	Public health approaches focused on prevention and treatment
Mandatory urine testing	Screening dialogue/questionnaire with patient consent
Mandatory reporting to law enforcement or child protective services (CPS)	Statistical reporting to department of health or direct reporting to CPS only for actual indications of impaired parenting
Overreliance on fragmented PDMPs	Safe prescribing and initial check of PDMPs
Punitive drug treatment courts	Family-centered drug treatment programs
Restrictions on medication access and forced withdrawal	OAT with methadone or buprenorphine for women and protections for treating physicians
Misleading drug prescribing warnings	Evidence-based labeling of opioid medications
Anti-family, one-size-fits-all drug treatment programs	Family-centered, community-based, outpatient treatment
Coercive referrals for fertility control	Counseling on pregnancy planning, prevention and contraception
Losing sight of the real harms of alcohol and cigarette use during pregnancy	Continued focus on the greatest preventable health threats—alcohol and tobacco use during pregnancy

- **Mandatory urine drug testing**
  - Urine drug tests are not a substitute for verbal, interactive questioning and screening of patients about their drug and alcohol use.

  - ACOG policy states that urine drug tests should *only* be used with the patient's consent and to confirm suspected or reported drug use, including for women who present at **hospitals for labor and delivery**. Even with consent, urine testing should not be relied upon as the sole or valid indication of drug use. Positive urine screens must be followed with a definitive drug assay.

  - Routine urine drug testing is not highly sensitive for many prescription drugs and results in false positive and negative results that are misleading and potentially devastating for the patient,

including accusations of child abuse and neglect. Testing does not provide valid or reliable information about harm or risk of harm to children.

- Imposing mandatory urine testing within the **Medicaid program** disproportionately burdens low-income communities and communities of color and exacerbates the consequences of false positive results by jeopardizing women's access to health care.

- Recent legal decisions affirm that physicians have no right or obligation to perform prenatal testing for alcohol or drug use without a pregnant woman's consent. This includes consent to testing that could lead to reporting to legal authorities for purposes of criminal prosecution and to civil child welfare authorities.

➢ **Mandatory reporting to law enforcement**

- Prescription drug misuse does not by itself indicate child abuse or neglect nor prove inadequate parenting.

- Punitive laws that mandate testing and reporting to law enforcement or child protective services jeopardize the therapeutic relationship between the obstetrician-gynecologist and the patient.

- Reporting requirements actively put women and their pregnancies at risk by deterring women from seeking prenatal care. Women may not trust their health care providers to protect them from legal penalties or loss of custody of their children, and therefore are likely to avoid, delay, or emotionally disengage from needed prenatal care and drug treatment.

➢ **Punitive drug courts**

- Family drug courts often treat drug use as a behavior that needs to be corrected, rather than as a disease that needs to be treated. While these courts may be a helpful step for some, they are not a remedy for all women—especially pregnant women—who are reliant on substances.

- In some jurisdictions, to be seen at family drug treatment court, a woman must plead guilty to child neglect. Consequently, she relinquishes her right to a defense, is placed on the state list as a person who maltreats children, and suffers restricted housing and employment options as a result.

- Often, the only choice given to a woman with a positive drug test is inpatient treatment, which in terms of expense and access, is impractical and not feasible for women supporting their families.

- Training of drug court officials on the disease of substance abuse and addiction and the unique medical needs of pregnant women is inconsistent. For instance, many women are pressured to detox, which is not a safe or medically recommended approach for pregnant women and their fetuses.

- Other women are coercively mandated to receive contraception or punished for becoming pregnant subsequently.

- **Overreliance on fragmented PDMPs**
  - Prescription drug monitoring programs (PDMPs) are important tools when considering prescribing opioid medications and can help to identify potential abusers. However, mandating clinician use of PDMPs at every prenatal encounter—regardless of whether opioids are prescribed—is not appropriate and creates an environment of suspicion rather than fostering trust and open communication.

  - PDMPs are currently state based with little capacity for critical data sharing across states or in real time. Many are chronically underfunded and inadequately staffed.

  - PDMPS only detect individuals who get opioids through medical prescribing. They do *not* detect individuals who rely on illegal sources, diversion, or purchase the drugs online from international vendors.

- **Restrictions on medication access and forced withdrawal**
  - For women with severe pain, blanket restrictions on some opioids block access to appropriate medication.

  - For addicted women, the alternatives to opioid agonist treatment—heroin abuse or withdrawal during pregnancy—are much more dangerous.

  - Some court sanctioned policies have dictated that pregnant women who are dependent on prescription painkillers undergo withdrawal from these drugs. Withdrawal and detoxification can be extremely dangerous to the fetus causing preterm labor, fetal distress, and pregnancy loss. These outcomes can be prevented through medically approved opioid maintenance treatment.

  - Medically supervised withdrawal during pregnancy is also not recommended because of the high risk of relapse to illicit opioids such as intravenous heroin.

  - Lowering the dosage of maternal OAT has not proven effective in lessening the severity of NAS and results in an increased incidence of symptoms of maternal and fetal withdrawal and its concomitant harms such as induced fetal stress and maternal relapse to illicit drugs.

- **Misleading drug prescribing warnings**
  - Recent action by state law enforcement officials and the FDA on opioid prescribing for pregnant women do not reflect the weight of scientific evidence and should be reconsidered.

  - Current FDA-approved labeling for opioid analgesics *already* describes the effects on newborns of exposure to these drugs while in the mother's womb and warns against use by women during pregnancy and labor and while nursing.

  - The new FDA black box warning label requested by the National Association of State Attorneys General stating that *"prolonged use during pregnancy can result in life-threatening neonatal*

opioid withdrawal syndrome" is false and misleading. There is no rational connection between scientific and medical research on NAS and statements regarding its potential lethality.

- The black box warning makes no distinction between heroin, misuse of prescription opioids, and opioids prescribed by health care professionals for legitimate pain management or OAT in pregnant women.

- Inaccurate and imprecise labeling could have a chilling effect on prescribing by blocking appropriate medication and therapy for women who are addicted and for whom the alternatives—heroin abuse or withdrawal during pregnancy—are much more dangerous.

- Distorted labeling may have the unintended effect of dissuading women from continuing wanted pregnancies after opioid exposure. A woman who is wrongly led to believe that opioids will fatally harm her pregnancy may seek instead to terminate it.

➢ **Drug treatment programs that are not tailored to pregnant or parenting women**
- The few drug treatment facilities in the US accepting pregnant women rarely provide child care, do not account for the woman's family responsibilities, and do not provide treatment that is affordable.

- Very few treatment programs give priority access to pregnant women.

- A woman should not be separated from her family in order to receive appropriate treatment. Substance abuse treatment that supports the family as a unit has been proved to be effective for maintaining maternal sobriety and child well-being.

- Mothers receiving therapeutic opioid maintenance treatment prescribed by their physicians should not be pressured to detox by court-ordered drug treatment programs.

IV. What's needed?

The following public health-oriented approaches rely on evidence and have been documented to support the health of mothers and their babies:

➢ **Effective drug and alcohol screening**
- Screening is a conversation between the clinician and the patient, based on a mutual dialogue. Prenatal drug screening includes "the 4Ps": questions about "parents, partners, past and pregnancy."

- ACOG's current medical protocols call for all women – not just those at risk or with a history of drug use or past involvement with child protective services – to be screened annually for substance abuse, including prescription drug abuse. Screening is done in partnership with the woman using validated screening tools *and with her consent*. Health care providers routinely ask female patients about their use of alcohol and drugs including prescription opioids and other

medications used for nonmedical reasons before pregnancy, in early pregnancy and when there are symptoms of abuse.

- ACOG policy suggests that another way to identify drug use is urine testing, but advises this is best done as an adjunct to confirm suspected or reported drug use and only with the patient's consent.

➢ **Appropriate drug treatment programs for women**

- Drug addiction is a chronic disease and – as with diabetes and hypertension – often the goal of treatment is ongoing management, not cure. Appropriate drug treatment programs can yield significant benefits to women and cost savings to society.

- Infants with NAS should not be removed from mothers who are engaged in treatment. Women need the option of outpatient, community based treatment programs that are responsive to their complex responsibilities, often as the primary or sole caregivers for their families. Ideally, this could be delivered in an integrated setting with prenatal and postpartum care.

- The current medical standard of care for women who are dependent on opioids and who become pregnant is referral for opioid-assisted therapy with methadone or buprenorphine. Opioid agonist therapy (OAT) improves outcomes for both mom and baby when compared to no treatment or to medication-assisted withdrawal. The patient is prescribed these medications under the close medical supervision of physicians specially trained in the appropriate methods to safely withdraw medications or regulate maintenance therapy. Two drugs—methadone and buprenorphine—can be legally used for opioid withdrawal and maintenance treatment. Methadone is dispensed on a limited-dose basis within state-licensed opioid treatment programs. Specially trained and licensed physicians can dispense buprenorphine from their medical offices to appropriate patients, potentially increasing the availability of treatment while decreasing the stigma associated with methadone clinics.

- After pregnancy, women should continue in their treatment and addiction support. Women who were abstinent from drug use during pregnancy often resume drug use postpartum. These women are susceptible to overdose—if not involved in substance abuse treatment—because their physiologic drug requirement decreases as their blood volume and mass decreases.

- Some models are:
  - ***Early Start*** **-** a Kaiser Permanente program, provides nonjudgmental integrated prenatal care, education, and substance abuse treatment for pregnant women who misuse prescription drugs.

  - ***Healthy Mothers, Healthy Babies*** **-** a demonstration program in New York City pairing women at high risk for a substance exposed infant with peer advocates who help them navigate the health and social service system, identify resources and prepare them for what to expect following birth.

- **Safe prescribing for the treatment of pain and integrated, interstate, interoperable PDMPs**
  - ACOG policy advises that when prescribing medications that may be misused, physicians should educate their patients on proper use, storage, and disposal.

  - Other possible improvements include the development of national standards for the prescribing and dispensing of schedule 2 and schedule 3 drugs – limiting the prescription size and eliminating refill ability.

  - PDMPs could be improved through enhanced staffing, data sharing, and access, as well as reliable funding.

- **Counseling on pregnancy planning, prevention, and contraception**
  - Policy makers could address concerns about NAS more effectively not by coercive measures but by supporting health care and counseling including voluntary pregnancy prevention for those who cannot curb substance use and do not currently wish to have a child.

  - Some models are:
    - ***Project CHOICES*** *(**C**hanging **H**igh-Risk Alcohol Use and **I**ncreasing **C**ontraception **E**ffectiveness **S**tudy)*- Developed with CDC funding, this is a well-reviewed and replicable model that produced marked results in curbing alcohol abuse and empowering women to avoid alcohol-exposed pregnancies. Participants in pilot projects received information about risks associated with alcohol, counseling about contraceptive methods and efficacy rates, and if desired, contraceptive services and follow up.

    - ***Long Acting Reversible Contraception*****-** Helping women prevent unintended pregnancy improves newborn health, and spacing births improves maternal health and lowers the risk of low birth weight and preterm birth. Better access to highly reliable methods of contraception—including IUDs and implants—could improve health outcomes for women and babies across the board, but particularly for individuals who are reliant on substances and do not wish to become pregnant.

- **Increased focus on postpartum care visits:**
  - Research shows that a particular emphasis on postpartum visits has the potential to markedly improve contraceptive use and allows additional opportunities for continued care planning for mother and baby.

  - One promising model is:

    - **MPOP** (**M**aternal **P**ostpartum **O**utreach **P**rogram): Anthem Health, a major provider of Medicaid managed care, offers a **comprehensive postpartum program** including phone calls, transportation vouchers, and other incentives to ensure women complete a postpartum visit 21-56 days after delivery. These interventions have increased postpartum care rates from 51.82% in 2010 to 71.45% in 2013.

- **Increased focus on curbing alcohol and tobacco use during pregnancy – the greatest preventable threats to a healthy pregnancy**
  - Curbing the use of alcohol and tobacco before and during pregnancy will yield the greatest public health gains for maternal and child welfare and must remain our primary objective.
  - Tobacco and alcohol dependence during pregnancy may independently cause NAS in infants; however, the symptoms may be more subtle than with opioids.
  - Decades of evidence have shown that alcohol and cigarettes—unlike opioids—cause long-term serious health consequences for mothers and infants, including prematurity. Smoking is the number one risk factor for delivering a baby prematurely.
  - Polysubstance use is common among women who use drugs. Those who misuse prescription medication or take illegal drugs also tend to smoke and use alcohol. Concurrent use of alcohol and cigarettes can explain many harmful pregnancy outcomes often attributed to other illicit substances.

  <u>Alcohol:</u>
  - A serious consequence of alcohol use during pregnancy, fetal alcohol syndrome (FAS) is the most common preventable cause of mental retardation.
  - There is no safe level of alcohol consumption during pregnancy and no period during pregnancy is safe for alcohol consumption. Alcohol readily crosses the placenta and can cause life-long physical and neurobehavioral effects on the developing baby.
  - About 10% of women use alcohol during pregnancy, and about 5% report binge drinking.
  - Education and intervention counseling during pregnancy is effective for many pregnant women who drink.

  <u>Smoking:</u>
  - Despite the well-known health risks associated with smoking during pregnancy, about 11% of women smoke during pregnancy.
  - Smoking during pregnancy is associated with risks to the fetus and infant including: low birth weight, prematurity, abruptio placentae, sudden infant death syndrome, and an increase in childhood respiratory illnesses as well as possible cognitive effects. For the pregnant woman, smoking increases the risk of preterm delivery, preterm premature rupture of membranes, placental complications of pregnancy, ectopic pregnancy and spontaneous abortion.
  - Successful smoking cessation strategies supported by clinical evidence are available and should be integrated into routine prenatal care.

ACOG References

1. *Opioid Abuse, Dependence, and Addiction in Pregnancy* (Joint Committee Opinion #624 with the American Society of Addiction Medicine)
2. *Nonmedical Use of Prescription Drugs* (Committee on Health Care for Underserved Women Opinion #538)

3. *Maternal Decision Making, Ethics, and the Law* (Committee on Ethics Opinion #321)
4. *Substance Abuse Reporting and Pregnancy: The Role of the Obstetrician-Gynecologist* (Committee on Health Care for Underserved Women #473)
5. *Long-Acting Reversible Contraception: Implants and Intrauterine Devices* (Practice Bulletin #121)

Other Resources

1. American Academy of Pediatrics: http://pediatrics.aappublications.org/content/129/2/e540.full.pdf
2. *Early Start*, Kaiser: http://xnet.kp.org/earlystart/providers/index.html
3. *Healthy Mothers, Healthy Babies*, Bronx Defenders: http://www.bronxdefenders.org/programs/healthy-mothers-healthy-babies/
4. *Project Choices*, CDC: www.cdc.gov/ncbddd/fasd/research-preventing.html
5. Comprehensive postpartum follow up: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3071902/
6. Rooming-in study: http://link.springer.com/article/10.1007%2Fs00431-009-0994-0
7. Costs of NICU stays: http://jama.jamanetwork.com/article.aspx?articleid=1151530&resultClick=3#ref-joc120014-45