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Opioid Use Disorder in Pregnancy: Health Policy and Practice in the Midst of an Epidemic

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Abstract

Opioid abuse among pregnant women has reached epidemic proportions and has influenced maternal and child health policy at the federal, state and local levels. As a result, we review the current state of opioid use in pregnancy and evaluate recent legislative and health policy initiatives designed to combat opioid addiction in pregnancy. We emphasize the importance of safe and responsible opioid prescribing practices, expanding the availability and accessibility of medication-assisted treatment and standardizing care for infants at risk of neonatal abstinence syndrome. Efforts to penalize pregnant women and negative consequences for disclosing substance use to providers are harmful and may prevent women from seeking prenatal care and other beneficial health care services during pregnancy. Instead, providers should advocate for health policy informed by scientific research and evidence-based practice to reduce the burden of prenatal opioid abuse and optimize outcomes for mothers and their infants.

Introduction

The prevalence of opioid use among women of childbearing age has reached epidemic proportions in the United States. Between 2008 and 2012, an average of 39.4% of Medicaid insured and 27.7% of privately insured women of reproductive age (15-44 years) filled an outpatient prescription for an opioid each year, with a greater number in the South and among non-Hispanic white women.¹ This escalation has led to a rise in opioid use in pregnancy. In an evaluation of over one million Medicaid enrollees, one out of five pregnant women (21.6%) filled a prescription for an opioid and 2.5% received a chronic opioid prescription for greater than 30 days.² Increases in prescription opioid use among pregnant women has led to a stark increase in the proportion of women needing treatment for abuse. From 1992 to 2012, the proportion of pregnant women admitted to substance abuse treatment facilities that reported a history of prescription opioid abuse increased from 2% to 28%.³

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Over the last two decades several factors have led to the rapid increase in the consumption of prescription opioids in the US. In the early 1990s, concern about undertreating pain led to increased emphasis on measuring and treating pain. In that decade, the American Pain Society introduced pain as “the fifth vital sign” and improved provider recognition of pain's importance in patient outcomes and experience.⁴ However, this emphasis on pain coupled with pharmaceutical company marketing practices downplaying the addictive potential of opioid pain relievers has led to overprescribing and a notable shift in indications for prescription opioids to include chronic, non-cancer pain.

An expanded, socioeconomically and demographically diverse population of patients has become addicted to opioids.⁵ In the 1960s, over 80% of patients entering treatment programs for opioid abuse were men, living in inner city, urban areas that used heroin.⁶ By 2010, the majority of patients entering treatment programs were women, often middle class, living in less urban or rural areas and over 90% were white.⁶ Today, the United States accounts for less than 5% of the world's population and over 80% of the world's consumption of opioid pain relievers.⁷ In 2012, there were 259 million prescriptions written for opioid pain relievers in the US – more than one for every American adult.⁸ Complications from opioid pain reliever use are evident throughout society, highlighted by the fact that opioid-related overdose deaths now outnumber deaths from auto accidents in the United States.⁹

Increases in prescription opioid abuse have also contributed to a rise in heroin use and overdose. Since 2010, heroin use and overdose deaths have more than tripled in the United States, in part due to an increase in heroin's availability and affordability.¹⁰ In 2007, over 98% of heroin in the United States was imported from South America in contrast to the 1980's when the majority of heroin was sourced from Southeast Asia.¹¹ Due to proximity and an established drug trafficking infrastructure from cocaine, heroin distribution from Columbia and Mexico led to a significant drop in the price of heroin and a rise in availability.¹¹ Between 1981 and 2012, the average price per pure gram of heroin dropped from \$3,260 to \$465.¹² As a result, many patients who begin abusing prescription opioids eventually switch to heroin because it is cheaper, more available and easier to use intravenously.⁶ Over two-thirds (66%) of pregnant women on medication-assisted treatment (MAT) report a history of heroin use and approximately 63% report a history of intravenous heroin use.¹³

The rising prevalence of opioid use in pregnancy has led to an increase in associated adverse neonatal outcomes such as neonatal abstinence syndrome (NAS). NAS is a drug withdrawal syndrome that opioid-exposed infants experience shortly after birth. From 2000 to 2012, the number of infants diagnosed with the syndrome grew nearly 5-fold.^{14,15} By 2012, one infant was born, on average, every 30 minutes in the United States having drug withdrawal, which accounts for an estimated \$1.5 billion in healthcare expenditures.¹⁵ States with the highest rates of opioid prescribing have the highest rates of NAS¹⁵ and in some communities NAS admissions represent nearly 50% of all neonatal intensive care unit hospital days.¹⁶ Compared to non-opioid-exposed infants, those with NAS are more likely to be Caucasian, have lower birth weights, respiratory complications, feeding difficulty and seizures.¹⁷

Health policy and opioid abuse

Escalating trends in opioid abuse during pregnancy and NAS have captured the attention of policymakers and elected officials at the federal, state and local levels. While the majority of recent public policy initiatives are designed to improve the accessibility and affordability of substance abuse treatment services for pregnant women, efforts to criminalize pregnant women who suffer from addiction have been on the rise.¹⁸ In 2014, Tennessee became the first state to prosecute women for assault for the illegal use of a narcotic while pregnant.¹⁹ While assault charges remain unique, a number of states have taken alternative policy approaches to penalize pregnant women suffering from addiction. For example, the Supreme Courts of Alabama and South Carolina expanded their interpretation of child-welfare statutes, originally intended to protect children from illicit drug production and distribution in homes, to allow for prosecution of pregnant women with substance use disorders.²⁰ In 18 states, substance abuse during pregnancy can now be classified as criminal child abuse and can result in the termination of parental rights.²⁰

Efforts to penalize pregnant women or negative consequences for disclosing substance use to providers may prevent women from seeking prenatal care and other preventive health care services, alienating vulnerable patients from their providers.¹⁸ Instead, providers should routinely screen all pregnant women for drug and alcohol use through a comprehensive history and physical evaluation and with validated screening tools such as the “4P’s.”²¹ After informed consent and assurance of patient confidentiality, urine drug testing can then be used to detect or confirm suspected substance use.

Addiction as a chronic disease

The National Institute on Drug Abuse (NIDA) defines addiction as a chronic disease that can be managed and treated successfully.²² Similar to other chronic disease processes (e.g. diabetes, hypertension), the successful treatment of substance use disorders depends on social support, patient-provider rapport and treatment availability. Approximately 40-60% of patients relapse and resume illicit drug use in the first year after discharge from substance abuse treatment programs which is similar to a 60% relapse rate for adults undergoing treatment for hypertension or asthma.²³ Barriers to treatment in pregnancy created by misguided policy approaches result from a fundamental misunderstanding of the chronicity of addiction and the need to provide ongoing treatment for addiction disorders with both medical and psychosocial interventions.

The standard of care for pregnant woman with opioid use disorder (OUD) is to initiate MAT with either methadone or buprenorphine (Box 1).²¹ OUD has replaced opioid abuse and opioid dependence psychiatric diagnoses in the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) and is defined as a problematic pattern of opioid use resulting in symptoms such as tolerance, withdrawal, craving or an inability to cut down or control opioid use.²⁴ Opioid detoxification or withdrawal in pregnancy is not recommended due to associations with decreased neonatal birth weight, illicit drug use relapse and resumption of high-risk behaviors such as intravenous drug use, prostitution and criminal activity.^{25,26} In contrast, stabilization on MAT during pregnancy minimizes opioid

withdrawal, reduces risk-taking behavior and decreases the acquisition and thus, the transmission of infectious diseases such as hepatitis C virus and HIV.^{27,28} MAT is most effective when used in combination with counseling or behavioral therapy. As a result, a coordinated team of clinicians including addiction medicine specialists, behavioral health providers, obstetricians and gynecologists and social services providers should supervise the initiation of MAT in pregnancy, which is required by 21 states for patients enrolled in MAT treatment programs.²⁹

The recommended MAT for pregnant women with OUD is methadone.³⁰ Approximately 1,300 federally licensed methadone treatment facilities across the United States offer MAT options to patients (Box 2).³¹ While protocols differ among treatment programs, methadone inductions often occur in inpatient settings because it is a full opioid receptor agonist and supratherapeutic doses carry the risks of respiratory depression and overdose.²⁷ Once dose stabilization is achieved, patients continue to receive medication at federally regulated outpatient methadone treatment facilities, which require patients to return each day for supervised dose administration. Due to federal requirements, many methadone treatment facilities have clinical staff formally trained in addiction medicine, offer on-site individual and group counseling and are equipped to provide case management and referral services, educational resources and job training to patients.

In 2002, the United States Food and Drug Administration approved buprenorphine, a partial opioid receptor agonist, for the treatment of OUD. Over 30,000 physicians, from a variety of clinical specialties, are licensed to prescribe buprenorphine in private, office-based settings.³² Due to a decreased risk of overdose, buprenorphine inductions can occur in office-based settings and patients self-administer their medication by filling an outpatient buprenorphine prescription.³³ Office-based administration liberates patients from the stigma associated with many methadone treatment facilities and increased flexibility may eliminate barriers for women with work or childcare responsibilities.³⁴ Moreover, emerging evidence demonstrates superior neonatal outcomes, including shorter treatment duration for NAS for infants exposed to buprenorphine compared to methadone.³⁵⁻³⁹ While clinical guidelines are still evolving, candidates for buprenorphine include patients who may have limited access to methadone, who demonstrate an ability to self-administer their medication without a concern for diversion and who have been successfully treated with buprenorphine prior to pregnancy.²¹ Pregnant patients enrolled in methadone treatment programs should not be transitioned to buprenorphine due to a risk of precipitated withdrawal. All pregnant patients treated with buprenorphine should be counseled that there is limited data regarding the impact of buprenorphine on infant and child outcomes beyond the neonatal period.²¹ Despite the growing availability and popularity of buprenorphine, the number of licensed providers who offer services to pregnant women remains unknown.

Improving medication-assisted treatment availability and accessibility

State legislative and judicial efforts to criminalize pregnant women who suffer from OUD have generally not been accompanied by efforts to expand the availability and accessibility of treatment programs for pregnant women. Only 19 states have substance abuse treatment programs specifically designed to treat women during pregnancy and only 12 give pregnant

women priority access to existing state-supported programs.²⁰ Limited treatment accessibility also exacerbates barriers in obtaining treatment for OUD among pregnant women. In 2013, 20 states did not include methadone on their Medicaid preferred drug lists in contrast to buprenorphine, which is covered by Medicaid in all 50 states.²⁹ A lack of Medicaid coverage for methadone is a missed opportunity to provide comprehensive drug treatment services for pregnant women. The vast majority of the research demonstrating the effectiveness of MAT to prevent adverse maternal and neonatal outcomes in pregnancy has focused on methadone. Moreover, methadone has also proven to be cost-effective. Over a lifetime, methadone treatment has been estimated to yield \$37.72 in benefits for every \$1 in cost.⁴⁰ Additional limits on Medicaid eligibility and benefits for MAT such as prior authorization, quantity limits and lifetime treatment limits imposed by states to control costs create additional barriers for patients. Eleven states have a lifetime treatment limit, which restricts the total length of time that an individual can receive a medication, for buprenorphine of 3 years or less, which creates significant challenges to treating the chronic nature of addiction.²⁹

It is imperative to ensure adequate access to both methadone and buprenorphine during pregnancy because the most effective treatment for OUD may differ for each woman.⁴¹ Opioid use history (prescription opioids vs. heroin), addiction severity, social support and resource availability vary widely among pregnant women and can differentially impact the ability of the two treatments to facilitate recovery. While buprenorphine's office-based availability may be more convenient for patients with work and childcare responsibilities, busy office-based providers may not be able to adequately address the complex needs of women including screening for intimate partner violence, co-occurring substance use disorders and psychiatric co-morbidities.⁴² Moreover, buprenorphine's partial agonist activity may not suppress illicit opioid use for many pregnant women. Buprenorphine's partial agonist activity may ineffectively alleviate cravings,⁴³ provide less euphoria⁴⁴ and may be less satisfying for patients with severe addiction compared to a full agonist such as methadone.^{45,46}

Improving care for neonatal abstinence syndrome

Infants with NAS are also exposed to treatment variability, resulting in inconsistent outcomes.⁴⁷ In 2012, the American Academy of Pediatrics released a policy statement calling for standardizing care for substance-exposed infants at risk of NAS.⁴⁸ Since that time, studies have shown that simple adherence to a single treatment protocol, even more than medication choice, is associated with improved outcomes.⁴⁹ Despite attempts to standardize NAS treatment, large gaps remain in our understanding of NAS and its optimal medical treatment.⁵⁰ Further, more work is needed to explore the potential positive impact of NAS care delivery models that minimize separation of the mother-infant dyad and that minimize adverse post-discharge outcomes such as readmission.⁵¹

Protecting our mothers and infants

The opioid epidemic has resulted in several funding and legislative initiatives designed to improve healthcare services for pregnant women and their infants. In 2011, the White House

Office of National Drug Control Policy released a national plan to curb the prescription opioid epidemic entitled *Epidemic: Responding to America's Drug Abuse Crisis*. The plan focuses on four main pillars to combat the epidemic: 1) education of providers, parents, children and the public at large, 2) improving tracking and monitoring of prescribers by bolstering prescription drug monitoring databases, 3) ensuring proper medication disposal and 4) enforcement targeting pill mills and doctor shopping.⁵² The Substance Abuse and Mental Health Services Administration (SAMHSA)'s National Center on Substance Abuse and Child Welfare (NCSACW) also pledged to provide in-depth technical assistance to six states (Connecticut, Kentucky, Minnesota, New Jersey, Virginia and West Virginia) to strengthen collaboration across child welfare, addiction treatment, medical providers, early child care and education systems to improve the health of pregnant and parenting women suffering from addiction and their infants.⁵³

In February 2015, the Government Accountability Office (GAO) released a report entitled *Prenatal Drug Use and Newborn Health* that highlighted gaps in research and federal programs that provide services to pregnant women with OUD and infants with NAS.⁵⁴ In response to the release of the GAO report, *The Protecting Our Infants Act of 2015* was introduced and passed with broad bipartisan support in the United States Senate and House of Representatives and was signed into law on November 25, 2015 by President Obama.⁵⁵ The law directs the Department of Health and Human Services to conduct a review of programs that coordinate services for pregnant women with OUD and infants with NAS, develop a strategy to address research gaps, study and develop guidelines to prevent OUD and NAS and provide technical assistance to states that are collecting data through existing surveillance mechanisms. Findings from *Protecting Our Infants* will provide much needed evidence-based recommendations and fill the gaps in research with respect to a) the most appropriate treatment for pregnant women with OUD, b) the most appropriate treatment and management for infants with NAS and c) the long-term effects of prenatal opioid exposure on children in the hopes of improving the efficiency and effectiveness of health care services for pregnant women suffering from opioid addiction and their children.⁵⁵

Conclusion

The American College of Obstetricians and Gynecologists, the American Academy of Pediatrics and the American Society of Addiction Medicine must collaborate and coordinate their professional guidelines, advocacy positions and research endeavors regarding prenatal substance use and NAS in order to provide clarity and guidance for policymakers on the national, state and local levels in the midst of this emotionally charged, national epidemic. By partnering in this manner, these professional organizations can play a vital role in supporting health policy efforts to reduce maternal opioid abuse and NAS and oppose punitive legislation against pregnant women and their children.^{18,21} Obstetricians, pediatricians, neonatologists and addiction medicine specialists should advocate for evidence-based practices in the management and treatment of addiction in pregnancy and create trusting and meaningful relationships with patients. Providers play a vital role as gatekeepers to health care services designed to effectively manage opioid addiction such as safe and responsible opioid prescribing practices, nonjudgmental screening of all pregnant patients for OUD, assistance with referral and enrollment in MAT programs and thoughtful

guidance and counseling regarding NAS. Through coordination and collaboration, stakeholders invested in the health and welfare of women and children can reduce the burden of prenatal opioid abuse.

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Box 1**American College of Obstetricians and Gynecologists' Resources**

Alcohol abuse and other substance use disorders: ethical issues in obstetric and gynecologic practice. Committee Opinion No. 633. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2015;125:1529-37.

Nonmedical use of prescription drugs. Committee Opinion No. 538. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2012;120:977-82.

Opioid abuse, dependence, and addiction in pregnancy. Committee Opinion No. 524. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2012;119:1070-6.

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Box 2**Additional Resources**

Substance Abuse and Mental Health Services Administration (SAMHSA). Substance abuse treatment facility locator. Available at <http://dpt2.samhsa.gov/treatment/directory.aspx>. Retrieved March 3, 2016.

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