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Invited Commentary

Prenatal Opioid Use Disorder Treatment— the Importance of Shared Decision-Making

Max Jordan Nguemeni Tiako, MD, MS; Kelly R. Knight, PhD; Davida M. Schiff, MD, MSc

In this issue of JAMA Internal Medicine, Suarez et al[1] studied a population-based cohort of publicly insured pregnant individuals receiving methadone or buprenorphine for opioid use disorder (OUD) in the US. Their study adds considerably to the sparse literature on rates of congenital malformations among newborns with in utero exposure to buprenorphine and methadone. The authors found a 1% absolute risk reduction of congenital malformations from buprenorphine exposure compared with methadone. First trimester exposure to methadone was associated with higher odds of cardiac malformations, oral clefts, and clubfoot than buprenorphine. In secondary analyses, they found that buprenorphine exposure was associated with higher odds of gastrointestinal-specific malformation, mostly pyloric stenosis.

The authors use robust statistical methods to address residual confounding concerns, including propensity score matching to account for a greater percentage of the methadone-exposed cohort being a race or ethnicity other than White, living in urban areas, and having lower county-level socioeconomic status.[1] They conducted multiple sensitivity analyses, including using individuals who underwent second trimester initiation of medications for opioid use disorder (MOUD) as a negative control group under the conventional assumption that most teratogenicity can be attributed to first trimester exposures.

Despite the cutting-edge statistical analyses, unmeasured environmental confounders may play a role in explaining the study findings.[1] However, additional research is needed to better understand potential mechanisms causing different effects of methadone and buprenorphine on organogenesis and congenital malformations. Prior work by Suarez's research group evaluating exposure to prescribed opioids using the same data source did not find a substantial increase in anomalies following first-trimester exposure to full μ-opioid receptor agonists.[2] Comparing the current study cohort with one of unexposed pregnancies would aid in the interpretation of the findings specific to methadone (a full μ-opioid receptor agonist) and buprenorphine (a partial μ-opioid receptor agonist). Similarly, the authors' new finding of an association between buprenorphine and pyloric stenosis is important.[1] However, it requires further investigation because pyloric stenosis is less clearly linked to first-trimester exposures than cardiac and neural tube anomalies.

For clinicians treating patients who are newly pregnant or contemplating pregnancy, it is essential to place the study's findings in the context of the current phase of the opioid overdose epidemic. First, the pregnant individuals included in this study comprise a relatively stable group of patients with OUD—more than three-quarters were taking MOUD before pregnancy, and the sample was restricted to individuals enrolled in Medicaid for 3 consecutive months before pregnancy,[1] thus excluding a substantial number of chronically underinsured and uninsured individuals. We urge caution when extrapolating these findings to newly pregnant individuals with untreated OUD. As fentanyl contaminates a growing proportion of the drug supply, patients with

OUD are experiencing more difficulty initiating and remaining stable on buprenorphine, and for those, methadone may be a more effective option.[3] As highlighted by Suarez et al,[1] for patients with more severe and untreated OUD and for whom methadone is most appropriate, it is safest for both the patient and the neonate to stabilize while receiving methadone given the risks conferred by the alternative: no opioid agonist therapy and the increased risk of return to drug use, associated severe infections and overdose, and neonatal opioid withdrawal syndrome.

The prevalence of OUD among individuals of reproductive age has continued to increase in the US over the past 2 decades, with postpartum overdose now a leading cause of pregnancy-associated deaths.[4] As highlighted by Suarez and colleagues,[1] the standard of care for OUD in pregnancy includes buprenorphine or methadone. Yet, rates of administration of MOUD and retention in treatment remain low. Most prenatal physicians and other professionals are not adequately trained to treat OUD.[5] At the same time, many addiction physicians and other professionals decline to treat patients with OUD if they are pregnant.[6] Other barriers to successful treatment and retention include states' punitive approaches to OUD in pregnancy, including the increased scrutiny through mandated child protective services reporting at delivery and the lack of flexibility from methadone programs (eg, required daily clinic attendance and frequent drug testing).[7] The confluence of state- and health care–sanctioned surveillance through Medicaid insurance, addiction treatment centers, and the child protective services system contributes to the stigma that pregnant and postpartum individuals with OUD experience. This stigma renders them particularly susceptible to disengaging from care because many fear family separation as punishment for being deemed "unfit" for parenthood.[7,8]

Racial discrimination has been well documented in both access to buprenorphine vs methadone and treatment decision-making.[9] It is crucial to discuss structural racism and racial discrimination as critical determinants that negatively shape pregnant people's access to and experience with MOUD. Black pregnant patients face greater scrutiny when seeking care and under the child protective service system, and they are more likely to experience family separation while facing larger barriers accessing MOUD. These structural factors likely contribute to unmeasured confounding in even the most methodological robust analyses using administrative data sets, including the findings by Suarez and colleagues.[1]

Rarely do clinicians sit down with a pregnant patient with OUD to discuss treatment options, risks, and benefits and find that they have not had prior positive or negative experiences with either buprenorphine or methadone. They usually know what the best treatment is for them. The findings from Suarez et al[1] are valuable data to share with patients. Still, the ultimate treatment decision must be the result of shared decision-making between a knowledgeable clinician and the patient, rather than promoting one medication over another. Such risks should be taken into consideration when counseling patients and weighed against the dangers of either discontinuing methadone in favor of buprenorphine or delaying initiating methadone in patients who have severe OUD refractory to buprenorphine.

Improving the quality of prenatal OUD care requires education for addiction, primary care, and prenatal physicians and other professionals to increase their respective comfort with providing OUD care to pregnant individuals. In terms of treatment advances, more research is needed to compare high-dose buprenorphine to methadone in patients with severe OUD refractory to

conventional buprenorphine dosing in the general population and in pregnant individuals. Different delivery models must also be tested, including medication formulation and care delivery setting (eg, telehealth, colocation with other services), to identify which best meets patients' needs and preserves their autonomy and dignity. Presently, the differences in delivery setting and associated restrictions for methadone vs buprenorphine impose greater burdens on patients who are receiving methadone and constitute barriers in care. Deregulating methadone by allowing office-based prescriptions and availability via pharmacies, thus establishing parity with buprenorphine, could be a meaningful advancement in the provision of MOUD in general, but especially for pregnant and postpartum individuals who are in particularly marginalized positions and are at risk of withdrawing from care. Indeed, the current most common approach requires daily methadone clinic attendance, which constitutes a barrier to postpartum patients who experience sleep deprivation. Policymakers should consider the effect of existing addiction treatment regulations on the success of treatment, engage with the affected communities, and enact recommendations from experts in redesigning the current treatment provision system.

ARTICLE INFORMATION

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