Association of Criminal Statutes for Opioid Use Disorder With Prevalence and Treatment Among Pregnant Women With Commercial Insurance in the United States

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Abstract

IMPORTANCE Inadequate treatment of opioid use disorder (OUD) in pregnant women increases the risk of life-threatening consequences on maternal and fetal outcomes. Untreated OUD during pregnancy is associated with higher rates of adverse outcomes among newborns.

OBJECTIVE To examine the variation in the prevalence of OUD and the use of medication-assisted treatment among commercially insured pregnant women according to region and state legislature.

DESIGN, SETTING, AND PARTICIPANTS Cohort study in which the patient cohort used was derived from a 10% random sample of enrollees within the IQVIA PharMetrics Plus adjudicated claims and enrollment database from 2007 to 2015. The database consists of a 10% random sample of private health insurance recipients in the United States and contains claims and enrollment data that are representative of the commercially insured US population. The cohort comprised women (n = 110 285) between 18 and 45 years of age with a code indicating a delivery and continuous insurance enrollment 9 months before and 12 months after delivery. Data analysis was performed from December 2017 to May 2018.

EXPOSURES Based on their state of residence, the women were classified into 4 different regions: South, Midwest, West, and Northeast. Those residing in states with statutes that imposed civil or criminal penalties for OUD diagnosis during pregnancy were placed in a separate population from those residing in states without these statutes.

MAIN OUTCOMES AND MEASURES Diagnosis of OUD in the 9 months before delivery and the receipt of medication-assisted treatment in the 9 months before or 12 months after delivery.

RESULTS The 110 285 pregnant women included in the analysis had a mean (SD) age of 30.26 (5.59) years, with most (67 771 [61.5%]) falling within the 26- to 35-year age range. Of this cohort, 277 women (0.25%) had a diagnosis of OUD and 312 (0.28%) received treatment. Among the 277 women with OUD, 127 (45.9%) received treatment. The prevalence of an OUD diagnosis and receipt of treatment within regions was statistically significant (OUD diagnosis by region: Midwest, 0.05%; North, 0.09%; South, 0.06%; West, 0.06%; χ² = 45.148 [P < .001]; OUD treatment by region: Midwest, 0.05%; North, 0.08%; South, 0.10%; West, 0.05%; χ² = 26.5654 [P < .001]). The prevalence of OUD diagnosis was also statistically significant when comparing women residing in states with statutes with those in states without statutes (OUD diagnosis by criminal statutes: criminalization, 0.07%; no criminalization, 0.18%; χ² = 14.6456 [P < .001]; OUD treatment by criminal statutes: criminalization, 0.12%; no criminalization, 0.17%; χ² = 0.0895); the receipt of treatment was not statistically significant (P = .76).

(continued)
CONCLUSIONS AND RELEVANCE

These results appeared to show significant variations in the patterns of OUD diagnosis and receipt of medication-assisted treatment among pregnant women, suggesting the need to further explore the source of these variations.
OUD and the use of medication-assisted treatment among pregnant women have either involved solely the Medicaid population or have shown that most women are covered by Medicaid.4,8,19 No studies thus far have shown the variations in prevalence of OUD and the use of medication-assisted treatment among pregnant women within a commercially insured population.

The objective of this study was therefore to examine the variation in the prevalence of OUD and the receipt of medication-assisted treatment among commercially insured pregnant women according to region and state legislature. We hypothesized that the diagnosis of OUD and receipt of treatment would vary by region and state legislature. Evaluating the prevalence of OUD and the receipt of medication-assisted treatment is important to define the current practices among commercially insured individuals and to inform future research within this population in the context of policy on civil or criminal laws on substance use.

Methods

Study Design and Setting
This retrospective observational cohort study included pregnant women with commercial insurance across the United States. Pregnant women were assessed for the outcomes 9 months before and 12 months after their recorded delivery date. The data obtained were deidentified, and the study was determined exempt from review by the University of Maryland Institutional Review Board. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline.21

Study Data

The patient cohort used in this study was derived from a 10% random sample of enrollees within the IQVIA PharMetrics Plus adjudicated claims and enrollment database from 2007 to 2015. The 10% random sample consisted of 12,416,600 enrollees. The IQVIA PharMetrics Plus database comprises fully adjudicated health plan claims data and enrollment information for commercially insured individuals.

The database receives information from health plans and self-insured employer groups throughout the United States for more than 150 million unique enrollees since 2006. This anonymous, patient-centric database includes all medical and pharmacy claims data (costs and descriptive services). Claims represent payments to medical practitioners for services rendered to individuals with health plan coverage. Procedural and diagnoses data are obtained from the medical claims file using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes and Current Procedural Terminology, Fourth Revision (CPT-4) codes. The pharmacy claims information includes National Drug Codes, date of medication dispensed, quantity dispensed, and estimated days' supply. The database also includes patient-level enrollment, which is a record of demographic variables, such as eligibility status (year of birth, sex, US census region, and eligibility by month). The enrollee population in the database is generally representative of individuals younger than 65 years and commercially insured, with a subset of individuals with commercial Medicare and Medicaid categorized by both age and sex. The mean length of enrollment is 39 or more months, and more than 30 million patients have 3 or more years of continuous enrollment (medical and pharmacy coverage). Each contributing plan's data undergo a rigorous data quality review by IQVIA before their addition to the IQVIA PharMetrics Plus database.

Identification of Sample

The study period spanned from June 30, 2007, to June 30, 2015. Female patients younger than 18 years and women older than 45 years were excluded from the cohort. To identify pregnancy, we collected 2995 ICD-9-CM codes and 88 CPT-4 codes related to pregnancy. Codes were identified using published literature22-25 and the IQVIA PharMetrics Plus data dictionary. Based on the descriptions of the collected ICD-9-CM and CPT-4 codes, the codes were classified into 1 of 8...
categories by 3 researchers (including L.E.G. and S.S.) independently. Any disagreement in category classification of the code was discussed and resolved by the researchers. The 8 categories included pregnancy, complication of pregnancy, delivery, complication of delivery, miscarriage, complication of abortion, labor, and lactation. A code was classified as delivery if the description was indicative that a delivery occurred on the claim date. The date of the first claim indicating delivery was used as the index date. Women who only had a claim for a category other than delivery were excluded from the pregnancy cohort given that an index date could not be computed for them. Women were required to be continuously enrolled 9 months before the index date and 12 months after the index date to identify the outcomes.

The primary outcome was a diagnosis of OUD during the 9 months before the index date. From the published literature, we used 20 ICD-9-CM codes to identify an OUD.

Receipt of medication-assisted treatment was observed 9 months before the index date to reflect the mean duration of pregnancy and 12 months after the index date. The postdelivery time frame of 12 months was chosen to allow ample time after delivery to capture receipt of treatment. This time frame was primarily a concern for women who lived in states with statutes criminalizing OUD. Receipt of treatment was recorded if National Drug Codes for methadone, buprenorphine, or naltrexone hydrochloride were present during this duration.

On the basis of state of residence, women were classified into 4 different regions: South, Midwest, West, and Northeast and further categorized into 2 populations. The first population resided in any of the 18 states with statutes that imposed civil or criminal penalty on women with OUD during pregnancy. The 18 states were as follows: Arkansas, Colorado, Florida, Illinois, Indiana, Iowa, Louisiana, Minnesota, Nevada, Oklahoma, Rhode Island, South Carolina, South Dakota, Texas, Virginia, Wisconsin, Alabama, and Tennessee. The second population resided in states without these statutes.

**Statistical Analysis**

Data analysis was performed from December 2017 to May 2018. The prevalence of OUD diagnosis in the commercially insured US population was calculated using the unique number of pregnant women between 18 and 45 years of age with an OUD diagnosis during the 8-year study period as the numerator and the total number of pregnant women within the age restriction as the denominator. The prevalence of treatment was calculated in a similar manner. Prevalence calculations were stratified by region and by the presence of legislation that criminally or civilly prosecutes pregnant women with an OUD diagnosis. All states categorized as having such legislation had passed laws before 2012 and had cases convicting women before 2012. Cochran-Mantel-Haenszel ($\chi^2$) statistics were calculated to determine whether a substantial difference exists between the prevalence of OUD diagnoses and receipt of treatment by region and by presence of civil or criminal statutes. Statistical significance was determined at 2-sided $P = .05$ using a 2-sided Pearson $\chi^2$ test. All statistical analyses were performed in SAS, version 9.4 (SAS Institute Inc).

**Results**

Of a total 12 416 600 individuals in the commercially insured population, 2 683 387 (21.6%) were women between 18 and 45 years of age, of whom 295 837 (11.0%) had a code for a delivery date. The final cohort consisted of 110 285 pregnant women between 18 and 45 years of age who were continuously enrolled 9 months before the delivery date and 12 months after the delivery date (Figure 1). The women had a mean (SD) age of 30.26 (5.59) years, with most (67 771 [61.5%]) falling within the 26- to 35-year age range. The women were primarily commercially insured (68 356 [62.0%]) or self-insured or other/unknown (34 361 [31.2%]). Medicaid was the primary payer for 7568 pregnant women (6.9%) in the sample. Some categories are collapsed owing to the small sample sizes that could not be reported. Demographic data are summarized in Table 1.
Figure 1. Inclusion and Exclusion Criteria

Table 1. Demographics of the Sample

| Variable                  | No. (%) | Women With an Opioid Use Disorder Diagnosis | Women Receiving Medication-Assisted Treatment |
|---------------------------|---------|---------------------------------------------|----------------------------------------------|
|                           | All Women |                                           |                                              |
| Total                     | 110 285  | 277                                        | 312                                          |
| Age, mean (SD), y         | 30.26 (5.59) | 28.54 (6.37)    | 29.97 (6.68)                                 |
| Age category, y           |          |                                            |                                              |
| 18-25                     | 17 545 (15.9) | 94 (33.9)        | 81 (25.9)                                    |
| 26-35                     | 67 771 (61.5) | 133 (48.0)      | 157 (50.3)                                   |
| 36-45                     | 24 969 (22.6) | 50 (18.1)       | 74 (23.7)                                    |
| Insurance type            |          |                                            |                                              |
| Commercial                | 68 356 (62.0) | 135 (48.7)    | 171 (54.8)                                   |
| Medicaid                  | 7568 (6.9)   | 70 (25.3)       | 51 (16.4)                                    |
| Self-insured or other/unknown | 34 361 (31.2) | 72 (25.9)       | 90 (28.8)                                    |
| Region                    |          |                                            |                                              |
| Midwest                   | 32 228 (29.2) | 52 (18.8)       | 52 (16.7)                                    |
| Northeast                 | 23 066 (20.9) | 98 (35.4)       | 87 (27.9)                                    |
| South                     | 34 621 (31.4) | 66 (23.8)       | 113 (36.2)                                   |
| West                      | 20 370 (18.5) | 61 (22.0)       | 60 (19.2)                                    |
| Legislation present       |          |                                            |                                              |
| Yes                       | 44 683 (40.5) | 81 (29.2)       | 129 (41.4)                                   |
| No                        | 65 602 (59.5) | 196 (70.8)      | 183 (58.7)                                   |
| Received treatment        | 312 (0.28)  | 127 (45.9)      | 312 (100)                                    |
| Treatment type            |          |                                            |                                              |
| Buprenorphine hydrochloride | 215 (0.19)  | 105 (37.9)      | 215 (68.9)                                   |
| Methadone/naltrexone hydrochloride | 97 (0.09)  | 22 (7.9)        | 97 (31.1)                                    |
Among the 110,285 pregnant women, 277 (0.25%) had a recorded diagnosis of OUD and 312 (0.28%) received medication-assisted treatment. Women with a recorded diagnosis of OUD had a mean (SD) age of 28.54 (6.37) years and were primarily insured commercially (135 [48.7%]) or by Medicaid (70 [25.3%]). Buprenorphine was the primary medication dispensed among women with an OUD diagnosis. One hundred five women (37.9%) received buprenorphine, and 22 (7.9%) received methadone or naltrexone. Among 312 women who received treatment, the mean (SD) age was 29.97 (6.68) years. These women were primarily covered by commercial insurance (171 [54.8%]) or were self-insured or other/unknown (90 [28.8%]). Among the treated pregnant women, 215 (68.9%) received buprenorphine and 97 (31.1%) received methadone or naltrexone.

In the Midwest, 52 women (0.05%) had an OUD diagnosis and 52 (0.05%) received treatment, and these numbers represented the lowest prevalence of OUD diagnoses and receipt of treatment among all regions. In contrast, the Northeast had a higher prevalence of OUD diagnosis, representing 98 women (0.09%), and a higher prevalence of treatment, representing 87 women (0.08%). The South also had a higher rate of women receiving treatment, representing 113 women (0.10%), but had a lower prevalence of OUD diagnoses, representing 66 women (0.06%), which indicates that more women received treatment than received a diagnosis. In the West, 61 women (0.06%) had an OUD diagnosis and 60 women (0.05%) received treatment. The differences in prevalence of OUD diagnoses and receipt of treatment within regions were statistically significant (OUD diagnosis by region: Midwest, 0.05%; North, 0.09%; South, 0.06%; West, 0.06%; $\chi^2 = 45.1148$ [P < .001]; OUD treatment by region: Midwest, 0.05%; North, 0.08%; South, 0.10%; West, 0.05%; $\chi^2 = 26.5654$ [P < .001]) (Table 2).

Of the 44,683 women living in states in which women with OUD diagnoses were civilly or criminally prosecuted, 81 (0.07%) had a diagnosis code for OUD and 129 (0.12%) received treatment. The prevalence of diagnosed OUD and the prevalence of treatment were higher in states without these statutes. Of the 65,602 women living in states with no substance use criminalization statutes, 196 (0.18%) had an OUD diagnosis and 183 (0.17%) received treatment (Table 2). The prevalence of OUD diagnoses was statistically significant (OUD diagnosis by criminal statutes: criminalization, 0.07%; no criminalization, 0.18%; $\chi^2 = 14.6456$ [P < .001]; OUD treatment by criminal statutes: criminalization, 0.12%; no criminalization, 0.17%; $\chi^2 = 0.0895$), but the prevalence of treatment receipt was not statistically significant (P = .76) (Table 2). All prevalence rates are illustrated in Figure 2. In summary, in a cohort of 110,285 commercially insured pregnant women, 25 in every 10,000 women had a recorded OUD diagnosis and 28 in every 10,000 received treatment. Variations by region and by presence of criminal or civil statutes were observed in the diagnosis of OUD. Statistically significant regional variations were observed in the receipt of treatment. No statistically significant variations were observed in the receipt of treatment by presence of criminal or civil statutes. Of the 277 women with an OUD diagnosis, only 127 (45.9%) received medication-assisted treatment.

### Table 2. Prevalence of Opioid Use Disorder Diagnosis and Treatment of Pregnant Women by Region and Presence of Legislation

| Variable          | All Women | Women With an Opioid Use Disorder Diagnosis, No. (%) | P Value | Women Receiving Medication-Assisted Treatment, No. (%) | P Value |
|-------------------|-----------|------------------------------------------------------|---------|-------------------------------------------------------|---------|
| Region            |           |                                                      |         |                                                       |         |
| Midwest           | 32,228    | 52 (0.05)                                            | <.01    | 52 (0.05)                                             | <.01    |
| Northeast         | 23,066    | 98 (0.09)                                            |         | 87 (0.08)                                             |         |
| South             | 34,621    | 66 (0.06)                                            |         | 113 (0.10)                                            |         |
| West              | 20,370    | 61 (0.06)                                            |         | 60 (0.05)                                             |         |
| Legislation present |         |                                                      |         |                                                       |         |
| Yes               | 44,683    | 81 (0.07)                                            | <.01    | 129 (0.12)                                            | .76     |
| No                | 65,602    | 196 (0.18)                                           |         | 183 (0.17)                                            |         |
| All               | 110,285   | 277 (0.25)                                           |         | 312 (0.28)                                            |         |
Discussion

These results differ from findings in a similar study by Angelotta et al., who found that criminal or civil statutes did affect whether a pregnant woman would receive treatment. Note that the population in the Angelotta et al. study included a Medicaid population, in which OUD was more prevalent and treatment more likely to be covered than in commercially insured populations, such as this study population. Medicaid patients are twice as likely as patients with no insurance or private insurance to receive OUD treatment. Bateman et al. explored the Optum data and found results similar to those in the present study, showing a low prevalence of methadone and buprenorphine dispensing for commercially insured pregnant women. Bateman et al. found that buprenorphine was dispensed to 0.03% of women during pregnancy and methadone was dispensed to 0.02% of women in pregnancy. Among the women exposed to opioids during pregnancy, 0.5% had a diagnosis of opioid dependence and 0.02% had an OUD diagnosis.

A notable finding in the present study pertains to the analysis by region and by civil and criminal statutes. Regional variations may account for the limited availability of treatment centers or practitioners specializing in medication-assisted treatment within a region. This lack would indicate that even if practitioners who treat the commercially insured have good practices and want to provide treatment, they may not be able to send women to receive care. We found a lower prevalence of recorded OUD and lower prevalence of medication-assisted treatment in states with statutes civilly or criminally prosecuting women with an OUD diagnosis.

These results show a statistically significant association between the presence of these statutes and a lower prevalence of recorded OUD. The low prevalence of OUD in the states with statutes may be the result of fewer women seeking care for OUD, perhaps out of the fear of being criminally charged and losing custody of their newborn. In addition, the same fear compounded by stigma may lead some women to avoid receiving care from medical practitioners, even when they have insurance coverage. One study that interviewed pregnant women who were substance users reported that 73% feared being identified as substance users, and many often used tactics, such as skipping appointments or forgoing prenatal care altogether, to avoid any detection of their drug use.

Limitations and Strengths

Even as we note the importance of these findings, we also advise that they should be carefully considered because of the inherent limitations of claims data. First, practitioners may be hesitant to code for an OUD diagnosis for a number of reasons, including the concern that the patient may face consequences and may no longer seek prenatal care. Second, information in commercial claims databases is limited. The database does not contain information on the gestational age at birth. Given
that women with OUD are more likely to give birth preterm, the look-back period of 9 months from delivery may yield a conservative estimate and may be longer than some pregnancies. Furthermore, women may have received medication-assisted treatment from a separate facility specializing in substance use disorder, such as a freestanding methadone clinic. These facilities may not bill the insurance, and therefore treatment would not be captured in the database. Third, women may be less likely to seek care for their OUD and may not report the diagnosis or treatment to their insurance because the plan does not cover treatment. Even if a claim is entered, pharmacy claims measure whether the medication was dispensed and do not indicate whether the medication was actually taken by the patient. Moreover, pharmacy claims do not capture medications dispensed to patients during hospitalizations. A number of women with an OUD diagnosis may have been hospitalized and received treatment during an inpatient stay. This inpatient treatment would not have been captured in our analysis. All of these limitations may underestimate the prevalence of OUD and medication-assisted treatment. The results of this study are not generalizable to women covered by other forms of insurance.

However, despite the challenges of identifying pregnancy and treatment frequency in claims databases, several strengths of this study should be noted. This study is the first, to our knowledge, to attempt to identify the OUD prevalence and treatment during pregnancy within the IQVIA PharMetrics Plus database commercially insured population. We used a novel method of identifying pregnancy within claims and found a possible underdiagnosis and treatment of OUD among pregnant women.

The most striking finding and contribution from this study to an ongoing effort to address the opioid epidemic is that the criminality statute is the basis of geographic variations. The process leading to the unintended consequences of such statutes is very complex and should be examined very carefully lest it produces the opposite of its intended purpose. The geographic variations indicate that differential factors within regions may play a role in the diagnosis of OUD among pregnant women.

Conclusions

The prevalence of OUD in commercially insured pregnant women and receipt of treatment within the United States appeared to vary by region. The diagnosis of OUD also significantly varied by the presence of criminal or civil statutes within the state of residence, whereas the receipt of treatment did not. The proportion of women with OUD and receiving treatment within this insured population was relatively low compared with women in other populations. These findings indicate a discrepancy in the diagnosis and treatment of OUD both on a regional and a legal basis. This study demonstrates the need for further studies into policies that reduce stigma and discrimination and that encourage the proper identification of OUD during pregnancy as part of a national quest to address the opioid epidemic among society’s most vulnerable women.
Author Contributions: Ms Gressler and Dr Shaya had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: All authors.

Acquisition, analysis, or interpretation of data: All authors.

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