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Use of Pharmacotherapies for Smoking Cessation:

Analysis of Pregnant and Postpartum Medicaid Enrollees

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Abstract

Background—The Affordable Care Act requires state Medicaid programs to cover pharmacotherapies for smoking cessation without cost sharing for pregnant women. Little is known about use of these pharmacotherapies among Medicaid-enrolled women.

Purpose—To describe the prevalence of prescription fills for smoking-cessation pharmacotherapies during pregnancy and postpartum among Medicaid-enrolled women, and to examine whether certain pregnancy complications or copayments are associated with prescription fills.

Methods—Insurance claims data for women enrolled in a Medicaid managed care plan in Maryland and who used tobacco during pregnancy from 2003–2010 were obtained (N=4,709) and analyzed in 2014. Descriptive statistics were used to calculate the prevalence of smoking-cessation pharmacotherapy use during pregnancy and postpartum. Generalized estimating equations were employed to examine the relationship of pregnancy complications and copayments with prescription fills of smoking-cessation pharmacotherapies during pregnancy and postpartum.

Results—Few women filled any prescription for a smoking-cessation pharmacotherapy during pregnancy or postpartum (2.6% and 2.0%, respectively). Having any smoking-related pregnancy complication was positively associated with filling a smoking-cessation pharmacotherapy prescription during pregnancy (OR=1.69, 95% CI=1.08, 2.65) but not postpartum. Copayments were associated with significantly decreased odds of filling any prescription for smoking-cessation pharmacotherapies in the postpartum period (OR=0.38, 95% CI=0.22, 0.66).

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Conclusions—Smoking-related pregnancy complications and substance use are predictive of filling a prescription for pharmacotherapies for smoking cessation during pregnancy. Low use of pharmacotherapies during pregnancy is consistent with clinical guidelines; however, low use postpartum suggests an unmet need for cessation aids in Medicaid populations.

Introduction

Cigarette smoking during pregnancy is a well-documented cause of adverse pregnancy and birth outcomes.^{1,2} Despite considerable public health efforts to eliminate tobacco use during pregnancy, nearly 18% of women enrolled in Medicaid during pregnancy smoke cigarettes, a prevalence that is nearly twice that of the overall population of pregnant women and more than three times that of women with private insurance during pregnancy.³ Effective as of 2010, the Affordable Care Act (ACA) requires that all state Medicaid programs cover both pharmacotherapies and counseling for smoking cessation among pregnant women with no cost sharing.⁴ Prior to this requirement, 43 states, including Maryland, had already chosen to cover pharmacotherapies for smoking cessation for pregnant women.⁵

Little is known about the utilization of pharmacotherapies for smoking cessation during pregnancy or postpartum among women enrolled in Medicaid. Only two previous epidemiologic studies have explored the use of pharmacotherapies for smoking cessation in pregnancy,^{6,7} and no published studies have examined their use specifically among Medicaid-enrolled women or women in the postpartum period. Although pharmacotherapies are effective for cessation in non-pregnant adults,⁸ considerable clinical uncertainty exists about the efficacy of pharmacotherapies for cessation among pregnant women.⁹⁻¹³ The American College of Obstetricians and Gynecologists (ACOG) recommends that pharmacotherapies for smoking cessation be used in pregnancy under close supervision and only among women who cannot quit smoking unaided or with counseling.¹⁴ Women enrolled in Medicaid have a disproportionately high share of prenatal smoking, pregnancy complications, and chronic conditions during pregnancy,^{3,15} suggesting a need to explore both overall patterns of pharmacotherapy use and patterns among women with high-risk pregnancies. Because lower-income women may have difficulty accessing over-the-counter cessation aids, the ACA policy to eliminate cost sharing for cessation pharmacotherapies during pregnancy in Medicaid might increase prescription fills.

The objective of this study is to describe the prevalence and predictors of filling a prescription for smoking-cessation pharmacotherapies during pregnancy and postpartum among women who used tobacco and were enrolled in a Maryland Medicaid managed care plan. Maryland's Medicaid program has required coverage of pharmacotherapies since 1996, and started requiring coverage of counseling in 2006.¹⁶ This study also explores the relationship of certain pregnancy complications (both smoking-related and other complications) and prescription copayments with the odds of filling prescriptions for smoking-cessation pharmacotherapies during pregnancy and postpartum. This descriptive study adds to the knowledge about use of pharmacotherapies for smoking cessation in pregnancy, and provides a snapshot of baseline use of pharmacotherapies that may inform efforts to maximize the effects of the tobacco-cessation coverage requirements in Medicaid under the ACA.

Methods

Data

Data were obtained including outpatient, inpatient, and pharmacy claims for 27,329 women who were enrolled in a Medicaid managed care plan in Maryland for at least one pregnancy between July 1, 2003 and December 31, 2010. In order to be able to analyze women for a sufficient time during and after pregnancy, inclusion criteria required pregnancy enrollment 100 days and 42 days after delivery. ICD-9 codes for tobacco use or tobacco use complicating pregnancy were used to identify women who smoked during pregnancy (17% of all women in the data set). Although these codes might indicate other tobacco use during pregnancy, they provide a reasonable definition of cigarette smoking because <1% of Maryland women use smokeless tobacco.¹⁷ The final analytic sample included 4,709 women (including 6,533 live births and stillbirths) who were coded as tobacco users during any pregnancy. To obtain neighborhood-level variables measuring neighborhood poverty and education, women in the insurance claims data were linked by ZIP code with aggregate data from the 2000 American Community Survey.

This data set met the Health Insurance Portability and Accountability Act's definition of a limited data set. The study was approved by the Johns Hopkins School of Medicine IRB.

Measures

The outcome was a binary measure of whether a women ever filled a prescription for any pharmacotherapy for smoking cessation, either during pregnancy or postpartum, during the study time period. Prescription fills were considered to be during pregnancy if they were up to 280 days (i.e., a 40-week gestation) prior to the date of delivery, and postpartum prescription fills were defined as those made in the 12 months following the date of delivery. The study focused on those pharmacotherapies indicated only for smoking cessation: nicotine replacement therapy (NRT) or varenicline. Because bupropion is indicated for smoking cessation and depression treatment, the present data did not provide adequate information to determine whether bupropion was prescribed for smoking cessation or depression, especially given that psychiatric disorders and smoking during pregnancy are correlated.¹⁸ For these reasons, the outcome was limited to those medications that are **only** indicated for smoking cessation.

The main independent variables of interest included the presence of pregnancy complications associated with smoking or health conditions that might influence a woman's motivation to quit smoking during pregnancy or postpartum. ICD-9 codes were used to identify these complications (see Appendix Table 1 for a complete list of ICD-9 codes and definitions). The presence of these complications was expected to alter the risk–benefit ratio in favor of prescribing pharmacotherapies for smoking cessation during pregnancy or postpartum, and therefore be positively associated with prescription fills for pharmacotherapies. First, an indicator variable for any of the following smoking-related pregnancy complications was defined, including intrauterine growth restriction, preterm labor/delivery, placental problems (placental abruption or placenta previa), or stillbirth. Next, a variable indicating any other substance use disorder or alcohol use in pregnancy was

defined. Third, a variable indicating the presence of depression or another mental illness during pregnancy was defined. Fourth, given that smoking is a risk factor for cardiovascular disease, a variable indicating pregnancy complications associated with increased maternal risk of future cardiovascular disease was created, including gestational diabetes mellitus, gestational hypertension, and obesity.

The other independent variable of interest was whether or not a woman had a copayment for prescription fills in the postpartum period. Prior to January 1, 2010, the managed care plan did not charge a copayment for any medication, regardless of income or pregnancy status. After January 1, 2010, Medicaid beneficiaries were required to pay \$1 for each generic medication fill and \$3 for each brand name medication fill. Women aged <21 years or those who were identified by the plan as pregnant were exempt from this requirement, however. The pharmacy claims data identified the copayment associated with each prescription fill, which was used to create an indicator variable for whether or not a woman had to pay any copayment for prescription fills.

Analyses were additionally adjusted for covariates including maternal age, maternal race/ethnicity, and ZIP code–level poverty and educational attainment. ZIP code–level variables included the proportion of residents in a ZIP code with household incomes below the federal poverty threshold and the proportion of residents aged ≥25 years without a high school diploma.

Data Analysis

Descriptive statistics were used to calculate characteristics of the study sample. The proportion of women who filled any prescription for a pharmacotherapy for smoking cessation at any time in the study time period was separately assessed during pregnancy and postpartum (i.e., 1 year after delivery). Data included many observations of women across one or more pregnancies, including in some cases multiple diagnoses of pregnancy complications and multiple prescription fills. The adjusted associations between independent variables and prescription fills of pharmacotherapies for smoking cessation were modeled using generalized estimating equations (GEE) to account for correlated residuals due to repeated observations of study subjects over time.¹⁹ Five separate GEE models were fit to estimate the association between the outcome of any prescription fill and each of the independent variables of interest: presence of smoking-related pregnancy complications, substance use, other psychiatric disorders in pregnancy, presence of cardiovascular risk factors, and having a prescription copayment (in the postpartum period only). All five GEE models controlled for maternal age, maternal race/ethnicity, and ZIP code–level proportion of residents with incomes below the federal poverty threshold, and proportion of residents aged ≥25 years without a high school education. Analyses were conducted in spring 2014.

Results

Table 1 shows the sociodemographic characteristics and pregnancy complications of women who used tobacco during pregnancy and were enrolled in the Medicaid managed care plan between 2003 and 2009. The majority of women (86.8%) were aged 18–34 years; the majority identified as non-Hispanic white (54.0%), with 37.2% of women identifying as

non-Hispanic black and 8.8% identifying as another race or ethnicity. Most women (94.6%) were observed for one pregnancy during the study time period. Pregnancy complications appeared prevalent in the study population, with 13.1% of women experiencing a smoking-related pregnancy complication in any pregnancy and 16.2% had substance use or alcohol use in any pregnancy. Nearly half of women (49.0%) had another psychiatric disorder in pregnancy, which included depression. In addition, 27.4% were diagnosed with a pregnancy complication associated with a future increased maternal cardiovascular risk.

Overall, few prescription fills occurred for NRT (245 fills) or varenicline (11 fills) among women during pregnancy or postpartum. Very low proportions of women enrolled in the Medicaid plan filled any prescription for smoking-cessation pharmacotherapies during pregnancy (2.4%) or in the 12 months postpartum (2.0%) (Table 2). The majority of prescription fills were for NRT, with <1% of women filling a prescription for varenicline in the postpartum period. Among those women who filled a prescription for smoking cessation in the postpartum period and were required to pay a copayment, the mean copayment paid was \$1.13 (Table 2).

Figures 1 and 2 show results from GEE of the association between certain pregnancy complications and the odds of filling any prescription for pharmacotherapies for smoking cessation during pregnancy and in the 12 months postpartum, respectively. Compared to women without a smoking-related pregnancy complication, women with a smoking-related pregnancy complication had increased odds of filling a prescription for smoking-cessation pharmacotherapy during pregnancy (OR=1.68, 95% CI=1.06, 2.65, $p<0.05$) (Figure 1), but not postpartum (Figure 2). Women with substance use (either drug or alcohol use) in pregnancy had increased odds of filling a prescription for smoking-cessation pharmacotherapies both during pregnancy (OR=2.97, 95% CI=1.98, 4.45, $p<0.01$) (Figure 1) and postpartum (OR=1.65, 95% CI=1.01, 2.76, $p<0.05$) (Figure 2), compared to women who smoked but did not have other substance use. Neither diagnoses for a psychiatric disorder, including depression, nor having a risk factor for future cardiovascular disease during a given pregnancy was associated with prescription fills for pharmacotherapies for smoking cessation.

Compared with women without prescription copayments, women with copayments had significantly lower odds of filling a prescription for smoking-cessation pharmacotherapies during the postpartum period (OR=0.38, 95% CI=0.21, 0.63, $p<0.01$) (Figure 2).

Discussion

Among women enrolled in a Medicaid managed care plan who smoked during pregnancy, the prevalence of prescription fills for pharmacotherapies for smoking cessation was quite low (<3%) during pregnancy and postpartum. This is the first study, to the knowledge of the authors, to describe use of pharmacotherapies for smoking cessation in a Medicaid population using claims data. The very low prevalence of NRT use is consistent with current uncertainty with respect to the efficacy, and potential harms, of its use for smoking cessation during pregnancy,²⁰⁻²² and with survey research showing low confidence prescribing NRT among obstetricians.²³ The finding that varenicline was almost never prescribed and filled

might reflect current debate about its safety, particularly in patients with psychiatric disorders or other substance use.^{24,25} The present results are also consistent with our and others' previous work showing state Medicaid policies with more generous coverage of smoking-cessation services did not increase in smoking cessation during pregnancy.^{26,27} Since Maryland's Medicaid program began covering individual counseling for cessation and Maryland's tobacco quitline started in 2006,¹⁶ it is possible that women who smoked were referred to counseling interventions rather than prescribed NRT. It is also possible that providers and patients were unaware that Medicaid covered these drugs in pregnant women.²⁸ Previous studies have documented low adherence to NRT when prescribed during pregnancy,^{20,21,29} and research exploring the reasons for such low adherence is needed, particularly in the Medicaid population.

The finding of few prescription fills of pharmacotherapies for smoking cessation in the postpartum period is notably lower than the estimated one third of U.S. smokers who use medication to attempt to quit smoking.³⁰ Although the few prescription fills during postpartum in this study population are suggestive of an unmet need, these results should be interpreted with caution, as about half of women were eligible for Medicaid because of their pregnancy and may have lost coverage 60 days after delivery, and in general, women's utilization of healthcare services is low in the postpartum period.³¹ To address the issue of loss to follow-up in the data postpartum, a sensitivity analysis was conducted in which the postpartum period was defined as 60 days after delivery (during which time Medicaid pregnancy coverage would still be effective), and results were unchanged.

Increased odds of filling a prescription during pregnancy for those women with a smoking-related pregnancy complication suggests that patients and clinicians perceive the risks of complications to outweigh potential risks of pharmacotherapies. This process may be facilitated by patients and clinicians spending more time together, increasing the opportunity for shared decision making related to smoking-cessation aids. In addition, women with current or history of smoking-related pregnancy complications may be more motivated to quit smoking to decrease future risks and improve fetal outcomes. For example, in the present data, among women with smoking-related complications, nearly all (95%) of prescription fills for NRT occurred after the complication was diagnosed. However, we did not find increased rates of prescription fills postpartum among women with recent smoking-related pregnancy complications, indicating a need for postpartum care providers to make the link between the recent pregnancy and smoking cessation for longer term sustained smoking cessation. A diagnosis of concurrent substance or alcohol use was associated with greater odds of filling a prescription for a smoking-cessation drug. This finding is notable because pharmacotherapies for smoking cessation are recommended only among those women who cannot quit smoking with counseling and when the potential benefits of quitting smoking outweigh the potential risks of pharmacotherapies.³² The current results might suggest clinicians' heightened recognition that women with other substance use find it more difficult to stop smoking with counseling alone, or might reflect that women with other substance use are receiving closer physician supervision during pregnancy and postpartum.³³

Eliminating copayments for smoking-cessation drugs during pregnancy, as required under the ACA, would be expected to increase prescription fills for these drugs from a low baseline.³⁴ Interestingly, similar proportions of women filled a prescription for smoking-cessation pharmacotherapies during pregnancy (when a copayment was not required) and during the postpartum period (when copayments were required). However, having a copayment, which the plan required starting in 2010, was associated with decreased odds of prescription fills in the postpartum period relative to women who did not have a copayment (i.e., prior to 2010). This finding might suggest that lower-income women are price sensitive after the birth of a child. More research is needed to explore the effects of copayments on receipt of smoking-cessation services in Medicaid-enrolled women in the postpartum period, particularly because states have the option to eliminate copayments for smoking-cessation drugs for non-pregnant adults. Given the uncertainty about use of pharmacotherapies for smoking cessation in pregnancy, policies eliminating copayments for these drugs before or after pregnancy could be a more effective way to reduce smoking prevalence before and during pregnancy.

This study has several key limitations that should be noted. First, the definition of smoking during pregnancy was based on coding available in insurance claims data. This may underestimate tobacco use prevalence owing to suboptimal rates of screening for tobacco use, under-reporting of tobacco use status by women, or under-coding. However, approximately 17% of women in the present study were coded for tobacco use during pregnancy, which is highly consistent with the estimated 18% of Medicaid-enrolled women who self-reported smoking during pregnancy in recent data from a multistate, representative survey.³ Secondly, the data did not capture the intensity of smoking and whether women who had greater smoking also had greater odds of filling prescriptions for cessation pharmacotherapies. Third, findings with respect to the postpartum period should be interpreted in light of the limitations of the data set. For instance, it is not possible to assess whether the low number prescription fills was due to women quitting smoking during pregnancy versus low use of healthcare services in the postpartum period. Fourth, data include members of a Medicaid managed care plan in Maryland and may not be generalizable to Medicaid plans in other states. Fifth, the study was unable to assess differences in prescription fills by the type of provider who prescribed the medication. Finally, this study was exploratory in nature, and the relationships observed between certain pregnancy complications and prescription fills should not be interpreted as causal in nature.

Conclusions

In the context of the ACA policy requiring that all states cover pharmacotherapies for smoking cessation for pregnant women, this study provides baseline information about the use of pharmacotherapies for smoking cessation during pregnancy and postpartum, in a state that provided comprehensive smoking-cessation benefits prior to the ACA requirement. The very low prevalence of prescription fills for smoking-cessation drugs during pregnancy is consistent current practice guidelines, which recommend counseling as the preferred cessation aid during pregnancy.¹⁴ The low number of prescription fills postpartum suggests further research is needed to understand the perceived risks and benefits about these drugs among both patients and providers. In particular, it will be important to study how the

presence of smoking-related pregnancy complications and other substance use disorders might motivate greater use of pharmacotherapies for tobacco use cessation in pregnancy and whether pharmacotherapies are efficacious in those circumstances.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.

Predictors of prescription fills for smoking cessation pharmacotherapies during pregnancy, among Medicaid-enrolled women who smoked during pregnancy

Note: Claims data from a Medicaid managed-care plan, 2003-2010. Smoking during pregnancy defined as those women who had any ICD-9 code for tobacco use during any pregnancy. Smoking-related complications include placenta previa, placental abruption, intrauterine growth restriction, preterm labor/delivery, and stillbirth. CVD (cardiovascular) risk factors include pre-eclampsia/eclampsia, gestational diabetes mellitus, gestational hypertension, and obesity.

Figure 2.

Predictors of prescription fills for smoking cessation pharmacotherapies postpartum, among Medicaid-enrolled women who smoked during pregnancy

Note: Claims data from a Medicaid managed-care plan, 2003-2010. Smoking during pregnancy defined as those women who had any ICD-9 code for tobacco use during any pregnancy. Smoking-related complications include placenta previa, placental abruption, intrauterine growth restriction, preterm labor/delivery, and stillbirth. CVD (cardiovascular) risk factors include pre-eclampsia/eclampsia, gestational diabetes mellitus, gestational hypertension, and obesity. All estimates are adjusted for maternal age, maternal race/ethnicity, and ZIP-code level poverty and educational attainment.

Table 1

Sociodemographic and pregnancy complications among Medicaid-enrolled women who smoked during pregnancy

	n (%)
Sociodemographics	
Age, years ^a	
<18	310 (6.6)
18-34	4,089 (86.8)
35	310 (6.6)
Race/ethnicity	
White	2,542 (54.0)
Black	1,753 (37.2)
Other race/ethnicity	414 (8.8)
No. of deliveries ^b	
1	4462 (94.6)
2	247 (4.4)
ZIP-code level sociodemographics	
Mean poverty ^c	-- (10.7)
Mean low educational attainment ^d	-- (23.5)
Pregnancy complications	
Smoking-related complication ^e	619 (13.1)
Substance use/alcohol use	761 (16.2)
Psychiatric disorder	2,309 (49.0)
CVD risk factor ^f	1,117 (23.7)
Total	4,709 (100.0)

Note: Claims data from a Medicaid managed-care plan, 2003-2010. Smoking during pregnancy defined as those women who had any ICD-9 code for tobacco use during any pregnancy.

^aDenotes age at first delivery in the dataset

^bDenotes deliveries observed while enrolled in the Medicaid plan from 2003-2010

^cObtained from Census data. Mean proportion of residents in ZIP code with income<federal poverty threshold.

^dObtained from Census data. Mean proportion of residents in ZIP code ages 25 and older with less than a high school diploma.

^eIncludes placenta previa, placental abruption, intrauterine growth restriction, preterm labor/delivery, and stillbirth

^fIncludes pre-eclampsia/eclampsia, gestational diabetes mellitus, gestational hypertension, and obesity

Table 2

Prescription fills for pharmacotherapies for smoking cessation during pregnancy and postpartum among Medicaid-enrolled women

	Pregnancy	Postpartum ^a
Any tobacco use cessation drug, n (%)	112 (2.4)	92 (1.0)
Nicotine replacement therapy	112 (2.4)	90 (1.0)
Varenicline	0 (0.0)	5 (0.1)
Copayment amount ^b (dollars; M (SD))	N/A	1.13 (0.31)

Note: Claims data from a Medicaid managed-care plan, 2003-2010, among women who smoked during pregnancy. Smoking during pregnancy defined as those women who had any ICD-9 code for tobacco use during any pregnancy.

^aPostpartum defined as the 12 months post-delivery

^bPrescription copayment required only among non-pregnant women ages ≥21