



# Behaviors Related to Medication Safety and Use During Pregnancy

Sara K. Head, PhD, MPH,<sup>1</sup> Laurén Doamekpor, PhD, MPH,<sup>1</sup> Erin M. South, PharmD,<sup>1</sup> Christina Louie, BS,<sup>2</sup> Stanislav Zakharkin, PhD,<sup>2</sup> Kaveeta Vasisht, MD, PharmD,<sup>1</sup> and Susan Bersoff-Matcha, MD<sup>1</sup>

## Abstract

**Introduction:** Most women take medication during pregnancy despite limited scientific evidence on safety. We investigated medication use, including changes in and reasons for changes in use during pregnancy, with attention to medication use in pregnant women with chronic conditions.

**Materials and Methods:** We conducted an online survey of pregnant women aged  $\geq 18$  years ( $n = 1,226$ ). We calculated descriptive statistics for aspects of medication use and performed multivariable logistic regression to examine associations between change in use and chronic conditions.

**Results:** Seventy-nine percent of women took at least one medication during pregnancy. Among those, 63.2% made at least one medication change: 42.0% started, 34.9% stopped, 30.0% missed dose(s), and 18.1% lowered dose(s) from that originally prescribed or recommended. More than a third (36.5%) of women who stopped, lowered, or missed medication did so independent of health care provider advice; 54.0% cited concern about birth or developmental defects as reasons for change. Odds of medication change were higher for women with chronic conditions: digestive conditions—starting (adjusted odds ratio [AOR]=1.8, 95% confidence interval [CI]=1.1–2.7), stopping (AOR=2.1, 95% CI=1.4–3.3), and lowering (AOR=2.4, 95% CI=1.7–3.3) medication; mental health conditions—starting (AOR=1.6, 95% CI=1.2–2.2), stopping (AOR=3.0, 95% CI=2.3–4.0), or missing (AOR=2.1, 95% CI=1.6–2.8) medication; pain conditions—stopping (AOR=2.9, 95% CI=2.0–4.2); and respiratory conditions—starting (AOR=2.0, 95% CI=1.3–3.1), stopping (AOR=1.7, 95% CI=1.1–2.6), and missing (AOR=2.2, 95% CI=1.4–3.4) medication.

**Conclusions:** Most pregnant women take medication and many, including those with chronic conditions, change their medication use during pregnancy. Medication change may occur independent of health care provider advice and due to women's safety concerns.

**Keywords:** pregnancy, medication safety, medication use, medication change, adherence

## Introduction

NINE OUT OF 10 pregnant women in the United States take a medication at some point in their pregnancy.<sup>1,2</sup> Medications might be taken inadvertently before a woman learns she is pregnant<sup>3</sup> or might be required to treat preexisting or pregnancy-induced health conditions.<sup>1,4,5</sup> Medication use during pregnancy has increased in recent decades<sup>1</sup> and may continue to do so given increases in both maternal age<sup>6</sup> and

the prevalence of chronic conditions requiring medication among women of reproductive age.<sup>7,8</sup>

There is limited scientific evidence, however, on the safe use of most medications during pregnancy<sup>3,9,10</sup> due to the history of exclusion of pregnant women from drug development research and clinical trials.<sup>5,11</sup> To address this need, the U.S. Food and Drug Administration (FDA) and its Office of Women's Health (OWH) have increased efforts to promote the inclusion of pregnant women in clinical research. FDA

<sup>1</sup>Office of Women's Health, U.S. Food and Drug Administration, Silver Spring, Maryland, USA.

<sup>2</sup>Market Research, WebMD, New York, New York, USA.

has been actively engaged in efforts to improve knowledge and research on safe and effective therapies for use during pregnancy and lactation, such as the Task Force on Research Specific to Pregnant Women and Lactating Women,<sup>12</sup> and the Agency has published guidance outlining-related scientific considerations.<sup>13–15</sup>

In addition, OWH has a long history of funding research<sup>16</sup> to expand the knowledge of medication use in pregnancy and provides a public listing of pregnancy exposure registries to raise awareness of opportunities for pregnant women to participate in research.<sup>17</sup> Despite this headway, there remains a dearth of data to inform drug safety in pregnant women, leaving pregnant women and their health care providers to navigate medication use without adequate information on most drugs' safety, efficacy, or optimal dosing regimen during pregnancy.<sup>5,11</sup>

For these reasons, it is important to study medication use in pregnancy. Studies have estimated overall prevalence of medication use in pregnancy,<sup>1,2,4,18</sup> but there is little research regarding patterns or changes in medication use, a critical component to understanding how pregnant women negotiate medication benefits versus risks to the health of themselves and their fetuses. Investigating changes in medication use may be particularly important for pregnant women with chronic health conditions, for which inadequate treatment might increase adverse pregnancy outcomes.<sup>19–23</sup> Further, pregnant women express fears about medication safety and the potential for its adverse effect on the health of their babies during pregnancy and beyond<sup>24,25</sup>; international research indicates that these fears influence pregnant women's medication nonuse and nonadherence.<sup>26–29</sup>

To better understand behaviors around medication use in pregnancy in the United States, we surveyed pregnant women about their medication use and how they assessed medication safety. This study investigated changes in and reasons for changes in their medication use during pregnancy with attention to women with chronic conditions.

## Materials and Methods

OWH contracted with WebMD Health Corp. (WebMD) to conduct an online survey of pregnant women who visited WebMD.com, a health website used to connect with the public, patients, and health professionals. WebMD.com has a large audience within the women's health landscape; in 2021, it reached 52 million adult women or 44% of the total number of U.S. adult women online.<sup>30</sup> From August 2019 to May 2020, visitors across WebMD.com and on select WebMD.com women's health topic webpages were randomly intercepted via an interstitial page and invited to take a survey with no identified topic. Potential respondents were screened for the following eligibility criteria: age of 18 years or older, U.S. residency, identifying as female, and current pregnancy.

Quota sampling was used to recruit respondents by self-reported race and ethnicity (non-Hispanic White, non-Hispanic Black/African American, Hispanic, non-Hispanic other racial and ethnic groups) in proportion to total U.S. 2016 births,<sup>31</sup> and poststratification weights were applied to reflect these population proportions.<sup>32</sup> Respondents were enrolled in a lottery to win 1 of 25 \$100 gift cards from WebMD if they completed the survey. WebMD.com visitors are subject to WebMD's privacy policy, and all respondents

were provided with a link to this information before taking the survey. The FDA's Institutional Review Board determined that this study was exempt from review.

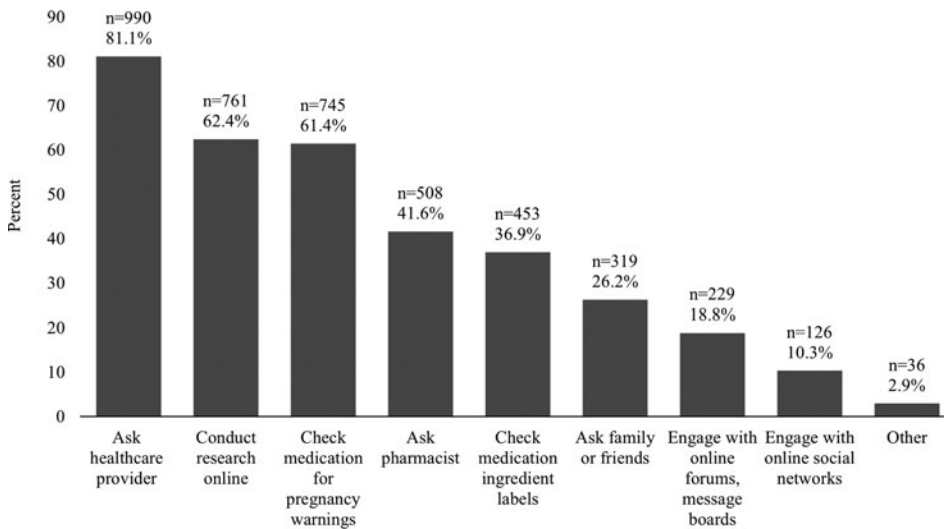
## Measures

Respondents' demographic characteristics included self-reported age in years (18–24, 25–29, 30–34, 35 and older), pregnancy trimester at the time of the survey, race and ethnicity (White, non-Hispanic; Black/African American, non-Hispanic; Hispanic or Latina; Asian, non-Hispanic; multiple or other race, non-Hispanic), education level (less than high school; high school, technical/vocational school; college education or degree; postgraduate education or degree), urban or rural residence, and region (northwest; midwest; south; west). We also estimated poverty level using federal poverty thresholds.<sup>33</sup> Household income was recorded in 10 categories ranging from less than \$10,000 to over \$200,000; we adjusted income to the categorical midpoint for family size 1–5 or more, and categorized women as at or below the federal poverty level or above the federal poverty level. Diagnosis of a chronic health condition was determined by asking respondents "Have you been diagnosed with any of the following chronic (long-lasting or persistent) conditions?"

Response options included any cancer, for example, skin, lung, or breast; any heart or cardiovascular disease, for example, coronary artery disease, atrial fibrillation, or irregular heart rhythm; type 1 or type 2 diabetes; any digestive condition, for example, gastroesophageal reflux disease (GERD) and irritable bowel syndrome; any mental health condition, for example, anxiety or attention-deficit hyperactivity disorder (ADHD); depression; any chronic pain, for example, back, migraine, rheumatoid arthritis, and sciatica; any chronic respiratory condition, for example, asthma, chronic obstructive pulmonary disease (COPD), and any other chronic condition not listed. Women who responded "other" were given a write-in option, and common responses were categorized, i.e., anemia, autoimmune disease, endometriosis, hepatitis C, hypercoagulable state, multiple sclerosis, polycystic ovary syndrome, and thyroid-related conditions, and included in descriptive analysis.

Medication use during pregnancy was assessed by asking women to indicate if they used the following medications during their pregnancy: acetaminophen (Tylenol), aspirin, ibuprofen (Advil, Motrin), antibiotics, antinausea medication, cold/cough/flu medication, allergy medication, antifungal medication, laxatives, anticonvulsant (antiseizure) medication, antidepressants, heart/cardiovascular medication, natural or dietary supplements, iron supplements, prenatal vitamins, and other vitamins (excluding prenatal). Iron supplements and prenatal and other vitamins were not considered to be medication for the purposes of this analysis. Women could choose to report "other types of medication not listed," and were asked to specify if each of the medications they had taken was prescribed or sold over-the-counter (OTC). They were also asked what actions they had taken to help decide which medications are safe to take while pregnant and were provided a list, from which they could select multiple responses (see response options in Fig. 1).

The survey assessed four measures of change in medication use by asking women if they had ever done any of the following while pregnant (response options were yes or no):



**FIG. 1.** Actions taken to help determine medication safety while pregnant ( $n = 1,226$ ).

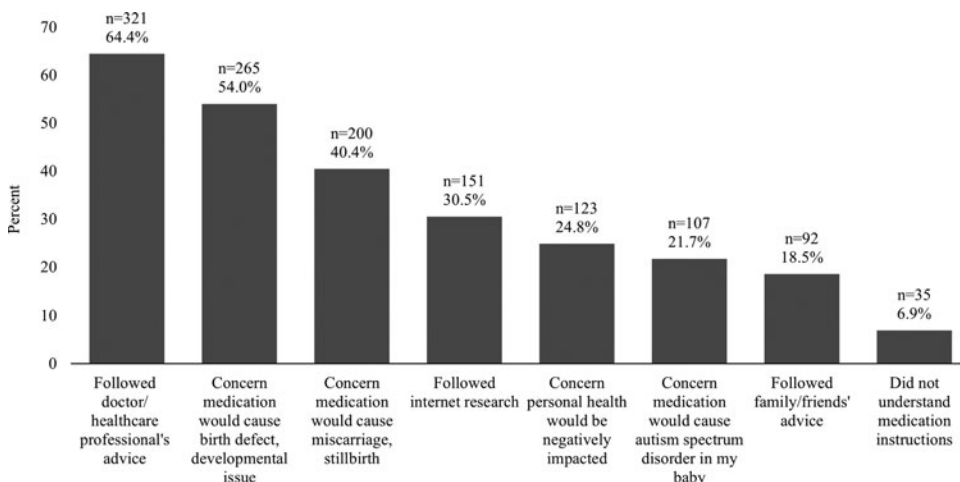
Notes: Sample n are unweighted; percents are weighted. Response categories are not mutually exclusive; women could have selected multiple responses to this question.

started a new prescribed or recommended medication; stopped taking a prescribed or recommended medication; took a lower dose of a medication than that originally prescribed or recommended; and missed a dose of a prescribed or recommended medication. Women who indicated that they had stopped, lowered, or missed medication during pregnancy were asked “Did you not take your medication(s) as prescribed or recommended while you were pregnant for any of the following reasons?” and were prompted with a list of eight possible reasons, from which they could select multiple responses (see response options in Fig. 2).

Responses to questions measuring health conditions, medication use, and changes in medication use were not mutually exclusive; women could select multiple responses. To minimize response bias, for each iteration of the survey, the display order of response options was randomized for questions in which the responses did not have a logical order or sequence.

*Data analysis*

Unweighted frequencies and weighted percentages were calculated for respondent characteristics, chronic health conditions, and aspects of medication use during pregnancy for the full study sample. Among women who took a medication during pregnancy, unadjusted logistic regression was used to test for associations between demographics, health conditions, type of medication use, and change in medication use. Also, among women who took a medication during pregnancy, a series of multivariable logistic regression models were estimated to identify associations between health conditions and changes in medication use. The multivariable models were mutually adjusted for age, trimester, race/ethnicity, education, estimated poverty status, and for having a chronic health condition and were only estimated for health conditions with sufficient observations given the number of covariates in the model (*i.e.*, digestive, mental



**FIG. 2.** Reasons for change in medication use among women who stopped, lowered, or missed medication during pregnancy ( $n = 468$ ).

Notes: Sample n are unweighted; percents are weighted. Response categories are not mutually exclusive; women could have selected multiple responses to this question.

TABLE 1. DESCRIPTIVE CHARACTERISTICS OF THE STUDY SAMPLE (N=1,226)

	n	%
Age, years		
18–24	223	18.3
25–29	302	24.9
30–34	355	28.8
≥35	346	27.9
Trimester		
First	604	49.2
Second	263	21.4
Third	281	23.2
Unsure	78	6.2
Race/ethnicity		
White, non-Hispanic	609	52.1
Black/African American, non-Hispanic	212	14.1
Hispanic or Latina <sup>a</sup>	247	23.3
Asian, non-Hispanic	58	3.9
Multiple or other, non-Hispanic	100	6.7
Education		
Less than high school	70	5.6
High school, technical/vocational school	334	27.4
College education or degree	636	52.0
Postgraduate education or degree	186	15.0
Poverty status <sup>b</sup>		
At or below poverty level	321	26.0
Above poverty level	751	61.5
Residence <sup>c</sup>		
Urban	1034	84.2
Rural	192	15.8
Region <sup>d</sup>		
Northwest	190	15.6
Midwest	261	21.2
South	483	38.7
West	291	24.4
Protectorate/territory	1	0.1
Diagnosed with chronic health condition <sup>e</sup>		
At least one health condition	579	47.7
More than one health condition	247	20.6
Cancer	8	0.7
Cardiovascular disease	50	4.0
Diabetes type 1 or type 2	40	3.2
Digestive condition	105	8.7
Mental health condition	385	32.0
Pain condition	161	13.3
Respiratory condition	101	8.4
Other	95	7.9
Anemia <sup>f</sup>	6	0.5
Autoimmune disease <sup>g</sup>	10	0.8
Endometriosis	4	0.4
Hepatitis C	2	0.2
Hypercoagulable state <sup>h</sup>	5	0.4
Multiple sclerosis	4	0.3
Polycystic ovary syndrome	12	1.0
Thyroid-related conditions <sup>i</sup>	20	1.7
No health condition	647	52.3
Medication use during pregnancy <sup>e,j</sup>		
At least one medication	965	79.0
At least one prescription	584	48.1
At least one OTC	855	70.0
Both prescription, OTC	474	39.1
Prescription only	110	9.0

(continued)

TABLE 1. (CONTINUED)

	n	%
OTC only	381	30.9
No medications	261	21.0

Sample *n* are unweighted; percents are weighted.<sup>a</sup>Hispanic or Latina includes any or multiple races.<sup>b</sup>Based on 2019 federal poverty guidelines.<sup>53</sup> Household income was adjusted to the categorical midpoint for family size 1–5+. Poverty could not be calculated for *n*=154 respondents who declined to provide household income.<sup>c</sup>Includes suburban and exurban.<sup>d</sup>Defined by U.S. Census Bureau.<sup>58</sup><sup>e</sup>Categories are not mutually exclusive; women may have selected more than one response.<sup>f</sup>Includes G6PD deficiency, pernicious anemia.<sup>g</sup>Includes Crohns' disease, Sjogren's syndrome, lupus, psoriasis, idiopathic thrombocytopenic purpura, ulcerative colitis, and pernicious anemia.<sup>h</sup>Includes antiphospholipid syndrome, protein C deficiency.<sup>i</sup>Includes hypothyroidism, hyperthyroidism, Hashimoto's disease, Grave's disease.<sup>j</sup>List of medications provided to respondents included: acetaminophen (Tylenol), aspirin, ibuprofen (Advil, Motrin), antibiotics, antinausea medication, cold/cough/flu medication, allergy medication, antifungal medication, laxatives, anticonvulsant (antiseizure) medication, antidepressants, heart/cardiovascular medication, natural or dietary supplements, and other types of medication.

OTC, over-the-counter.

health, pain, and respiratory conditions).<sup>34</sup> All regression models were weighted, and analyses were performed using SAS v9.4 (SAS Institute Inc., 2016).

## Results

Characteristics of the full study sample (*n*=1,226) are presented in Table 1. Each of the following age groups comprised a quarter or slightly more respondents: 25–29 years (24.9%), 30–34 years (28.8%), and ≥35 years (27.9%); 18.3% were between 18 and 24 years. Nearly half of women (49.2%) were in the first trimester of pregnancy. Most women were non-Hispanic White (52.1%), while 23.3% identified as Hispanic or Latina, 14.1% non-Hispanic Black/African American, 6.7% multiple or other racial or ethnic groups, and 3.9% non-Hispanic Asian.

The majority had college educations or degrees (52.0%); 27.4% had completed high school or technical/vocational school, 15.1% had completed postgraduate education, and 5.6% had less than a high school education. Most women were above the poverty level (61.5%) and were from urban areas (84.2%). By U.S. region, 38.7% of women lived in the South, 24.4% in the West, 21.1% in the Midwest, and 15.6% in the Northwest.

Slightly less than half of women reported being diagnosed with chronic health conditions (47.7%). Nearly a third (32.0%) reported a mental health condition, followed by 13.3% who reported having chronic pain. Approximately 8% reported a digestive condition (8.7%), chronic respiratory condition (8.4%), or other chronic condition (7.9%). Four percent of women reported being diagnosed with cardiovascular disease and 3.2% with diabetes. Fewer than 2% of women reported other health conditions such as thyroid-related conditions, polycystic ovary syndrome, or cancer.

Nearly 80% of women had taken a medication during pregnancy (79.0%) with 48.1% taking a prescription medication and 70.0% taking an OTC medication. Four in 10 women (39.1%) took both a prescription and an OTC medication during pregnancy; 30.9% took an OTC medication only and 9.0% took a prescription only. Iron supplements and prenatal and other vitamins were not considered to be medication.

Figure 1 shows actions that women in the full study sample took to determine medication safety during pregnancy. The majority (81.1%) asked a health care provider. Approximately 6 in 10 women conducted research online (62.4%) and checked medications for pregnancy warnings (61.4%). Roughly 4 in 10 (41.6%) asked a pharmacist and checked medication labels (36.9%), and 26.2% asked family or friends.

Among women who reported taking any medication during pregnancy, a majority ( $n = 609, 63.2\%$ ) made at least one change in their medication use during pregnancy, and 38.4% ( $n = 369$ ) made more than one change (data not shown). Table 2 shows that 42.0% started a new medication that was prescribed or recommended to them while slightly fewer stopped a medication (34.9%). Smaller but notable percentages of women reported missing a dose (30.0%) or lowering the prescribed or recommended dose (18.1%).

Among women taking a medication, age, race/ethnicity, and education were not associated with change in medication use. Pregnancy trimester was associated with starting medication (second trimester: odds ratios [OR] = 1.8, 95% confidence interval [CI] = 1.3–2.5; third trimester: OR = 2.3, 95% CI = 1.7–3.2) and with missing doses (third trimester:

TABLE 2. CHARACTERISTICS ASSOCIATED WITH CHANGE IN MEDICATION USE AMONG WOMEN TAKING MEDICATION DURING PREGNANCY (N=965)

	Started		Stopped		Lowered dose(s)		Missed dose(s)	
	%	OR (95% CI)	%	OR (95% CI)	%	OR (95% CI)	%	OR (95% CI)
Overall	42.0	—	34.9	—	18.1	—	30.0	—
Age group (years)								
18–24	42.9	1.0 (0.7–1.5)	35.8	1.1 (0.8–1.7)	13.9	0.8 (0.5–1.3)	33.7	1.3 (0.8–1.9)
25–29	40.1	0.9 (0.6–1.3)	36.2	1.2 (0.8–1.7)	16.2	0.9 (0.6–1.5)	30.5	1.1 (0.8–1.6)
30–34	43.0	1.0	32.9	1.0	17.2	1.0	28.5	1.0
≥35	41.9	1.0 (0.7–1.3)	35.2	1.1 (0.8–1.6)	23.2	1.5 (1.0–2.2)	28.9	1.0 (0.7–1.5)
Trimester								
First	34.4	1.0	34.9	1.0	21.0	1.0	26.9	1.0
Second	48.2	1.8 (1.3–2.5)	35.3	1.0 (0.7–1.4)	15.3	0.7 (0.4–1.0)	29.4	1.1 (0.8–1.6)
Third	54.9	2.3 (1.7–3.2)	35.1	1.0 (0.7–1.4)	17.3	0.8 (0.5–1.2)	37.6	1.6 (1.2–2.3)
Unsure	14.8	0.3 (0.2–0.7)	31.4	0.9 (0.5–1.5)	10.6	0.4 (0.2–1.1)	22.2	0.8 (0.4–1.5)
Race/ethnicity								
White, non-Hispanic	41.8	1.0	36.0	1.0	17.2	1.0	28.6	1.0
Black/African American, non-Hispanic	36.7	0.9 (0.4–1.9)	32.0	0.5 (0.2–1.1)	17.3	0.9 (0.3–2.4)	36.0	1.0 (0.5–2.3)
Hispanic or Latina <sup>a</sup>	46.1	0.8 (0.5–1.2)	34.4	0.8 (0.6–1.3)	21.7	1.0 (0.6–1.7)	30.0	1.4 (0.9–2.1)
Asian, non-Hispanic	39.5	1.2 (0.9–1.6)	21.1	0.9 (0.7–1.3)	15.8	1.3 (0.9–2.0)	28.9	1.1 (0.8–1.5)
Multiple or other, non-Hispanic	41.2	1.0 (0.6–1.6)	38.7	1.1 (0.7–1.9)	16.2	0.9 (0.5–1.9)	31.2	1.1 (0.7–2.0)
Education								
Less than high school	39.7	0.9 (0.6–1.2)	34.9	0.9 (0.7–1.3)	22.1	0.8 (0.5–1.2)	42.9	1.1 (0.8–1.6)
High school, technical/vocational school	40.9	0.8 (0.5–1.5)	35.0	0.9 (0.5–1.7)	15.6	1.2 (0.6–2.4)	31.3	1.9 (1.0–3.4)
College education or degree	44.0	1.0	36.5	1.0	19.3	1.0	28.7	1.0
Postgraduate education or degree	37.5	0.8 (0.5–1.1)	28.8	0.7 (0.5–1.0)	16.7	0.8 (0.5–1.4)	28.1	1.0 (0.6–1.5)
Poverty status <sup>b</sup>								
At or below poverty level	45.0	1.1 (0.8–1.5)	39.9	1.3 (1.0–1.8)	20.8	1.3 (0.9–1.8)	38.2	1.6 (1.2–2.2)
Above poverty level	41.8	1.0	33.6	1.0	17.3	1.0	27.7	1.0
Chronic health condition								
Diagnosed with chronic health condition	48.5	1.8 (1.4–2.3)	47.1	3.3 (2.5–4.4)	24.2	2.6 (1.8–3.6)	37.2	2.1 (1.6–2.8)
No health condition	34.5	1.0	21.0	1.0	11.1	1.0	21.9	1.0
Type of medication use								
Both prescription, OTC	59.3	5.8 (4.3–7.9)	46.3	3.0 (2.2–4.1)	23.3	2.5 (1.7–3.6)	41.3	2.5 (1.7–3.6)
Prescription only	41.8	2.9 (1.8–4.5)	28.2	1.4 (0.8–2.2)	19.3	1.9 (1.1–3.4)	30.7	2.4 (1.5–3.9)
OTC only	20.0	1.0	22.3	1.0	11.0	1.0	15.6	1.0

Percents are weighted. ORs are considered significant if 95% CIs do not include 1.0. Categories are not mutually exclusive; women may have made more than one change in medication use.

<sup>a</sup>Hispanic or Latina includes any or multiple races.

<sup>b</sup>Based on 2019 federal poverty guidelines.<sup>33</sup> Household income was adjusted to the categorical midpoint for family size 1 to 5+. Poverty status could not be calculated for  $n = 116$  respondents who declined to provide household income.

CI, confidence interval; OR, odds ratios; OTC, over-the-counter.

OR = 1.6, 95% CI = 1.2–2.3; Table 2). Being at or below poverty was associated with missing doses (OR = 1.6, 95% CI = 1.2–2.2) compared with being above the poverty level. There was a significant, positive association between diagnosis with a chronic health condition and each of the measures of change in medication use; ORs ranged from 1.8 (95% CI = 1.4–2.3) for starting medication use to 3.3 (95% CI = 2.5–4.4) for stopping.

The type of medication was also significantly associated with each of the changes in medication use. Compared to women taking OTC medication only, the odds of a change were greater for women taking both prescription and OTC medications and for women taking prescription medications only (Table 2). We tested for association between reported diagnosis with a health condition and type of medication and found a significant, positive association with prescription medication (OR = 2.9, 95% CI = 2.2–3.8) but no association with OTC medication (OR = 0.7, 95% CI = 0.4–1.0; data not shown).

Figure 2 presents reasons for change in medication use among women who reported stopping, lowering, or missing medication during pregnancy. The majority, 64.4%, reported following the advice of health care professionals while smaller percentages reported following advice based on internet research (30.5%) and from family and friends (18.5%). More than half (54.0%) cited concern about birth defects or other developmental issues as a reason for change in medication. Other concerns related to adverse health outcomes were also reported, including concern for miscarriage or stillbirth (40.4%), for personal health (24.8%), and that the baby would develop autism (21.7%).

Table 3 presents results from a series of multivariable logistic regression models testing for associations between select health conditions (*i.e.*, those with sufficient observations) and changes in medication use during pregnancy, controlling for demographic measures. Each of the health conditions examined had a significant association with at least one of the measures of medication change. Women who

reported digestive conditions had greater odds of starting (adjusted odds ratio [AOR] = 1.8, 95% CI = 1.1–2.7), stopping (AOR = 2.1, 95% CI = 1.4–3.3), and lowering (AOR = 2.4, 95% CI = 1.7–3.3) medication, while women with mental health diagnoses were more likely to start (AOR = 1.6, 95% CI = 1.2–2.2), stop (AOR = 3.0, 95% CI = 2.3–4.0), or miss (AOR = 2.1, 95% CI = 1.6–2.8) medication compared to women without these respective conditions.

For women who reported respiratory conditions, the odds of starting (AOR = 2.0, 95% CI = 1.3–3.1), stopping (AOR = 1.7, 95% CI = 1.1–2.6), and missing (AOR = 2.2, 95% CI = 1.4–3.4) medication were greater than for women who did not report respiratory conditions. Women who reported chronic pain conditions had 2.9 (95% CI = 2.0–4.2) greater odds of stopping a medication compared to women who did not report pain conditions.

## Discussion

In our study investigating pregnant women's behaviors related to medication safety and use during pregnancy, we found that nearly 80% of women surveyed reported taking a medication during pregnancy. These findings are in line with earlier estimates using population-based data<sup>1</sup> and with more recent cohort study data,<sup>18</sup> which report that the percentage of women in the United States using any medication during pregnancy ranges from 73% to 89%. Our estimates of prescription (48.1%) and OTC medication use (70.0%) were similar to those reported by other research in the United States,<sup>1,35–37</sup> and supply further evidence that medication use in pregnancy is common.

Women reported using several behaviors to help them decide which medications were safe to take while pregnant. Although most women in our study asked their health care providers (81.1%) or pharmacists (41.6%), more than 60% conducted their own research online (62.4%) or checked the medication for pregnancy warnings (61.4%). Use of the

TABLE 3. CHRONIC HEALTH CONDITIONS ASSOCIATED WITH CHANGE IN MEDICATION USE AMONG WOMEN TAKING MEDICATION DURING PREGNANCY (N=965)

Chronic health condition <sup>a</sup>	Started		Stopped		Lowered dose(s)		Missed dose(s)	
	%	AOR (95% CI)	%	AOR (95% CI)	%	AOR (95% CI)	%	AOR (95% CI)
Digestive condition (n=94)	51.8	1.8 (1.1–2.7)	51.1	2.1 (1.4–3.3)	21.9	2.4 (1.7–3.3)	37.2	1.6 (1.0–2.6)
No digestive condition (n=871)	40.9	1.0	33.1	1.0	17.7	1.0	29.3	1.0
Mental health condition (n=342)	47.8	1.6 (1.2–2.2)	51.0	3.0 (2.3–4.0)	26.0	1.3 (0.8–1.8)	38.8	2.1 (1.6–2.8)
No mental health condition (n=623)	38.7	1.0	25.8	1.0	13.6	1.0	25.1	1.0
Pain condition (n=144)	46.5	1.3 (0.9–1.9)	57.3	2.9 (2.0–4.2)	22.7	1.3 (0.8–2.0)	33.7	1.3 (0.8–1.8)
No pain condition (n=821)	41.1	1.0	30.9	1.0	17.3	1.0	29.4	1.0
Respiratory condition (n=89)	54.5	2.0 (1.3–3.1)	46.0	1.7 (1.1–2.6)	25.4	1.6 (1.0–2.7)	44.4	2.2 (1.4–3.4)
No respiratory condition (n=876)	40.7	1.0	33.7	1.0	17.3	1.0	28.5	1.0

Percents are weighted. AORs of the association between change in medication use and each of the health conditions were estimated using multivariable logistic regression. Each model adjusted for age (ref: 30–34 years), trimester (ref: first), race/ethnicity (ref: White, non-Hispanic), education (ref: college education or degree), poverty estimate (ref: above poverty level). AORs are considered significant if 95% CIs do not include 1.0.

<sup>a</sup>Categories are not mutually exclusive; women may have made more than one change in medication use or had more than one health condition.

AOR, adjusted odds ratios.

internet as a source of health information, including for medication safety,<sup>38–40</sup> is widespread among pregnant women.<sup>41</sup> There is limited evidence, however, as to the quality of the information accessed; a survey of pregnant women contacting a teratology information service, for example, found that 22% had retrieved incorrect information from the internet about their medication exposure.<sup>40</sup> Further, most women do not discuss the information they find with their health care provider.<sup>41</sup>

Medication labeling may also be an imperfect resource for products with insufficient data to inform risk on use during pregnancy. The FDA's Pregnancy and Lactation Labeling Rule (PLLR) requires that product labeling present benefit-risk information for pregnancy and lactation; information on pregnancy testing, contraception, and infertility is included, if applicable.<sup>42</sup> While the PLLR provides a cohesive and standard format, it is limited by the data or lack thereof.<sup>43</sup> A 2020 review of labeling for 290 medications found only 11% presented data derived from human studies and 90% relied on animal data.<sup>44</sup>

Among women who took a medication during pregnancy, we found that a majority (63.2%) reported making at least one change in medication use during their pregnancy. Forty-two percent started a prescribed or recommended medication while slightly fewer stopped medication (34.9%) or missed (30.0%) or lowered the prescribed or recommended dose (18.1%). Few U.S. studies have quantified changes in medication use during pregnancy.<sup>18,45</sup> Our findings suggest that there are additional unexplored patterns of use and adherence with potential to impact maternal and fetal health.

We also asked women who had stopped, lowered, or missed medication the reason for not taking a medication as prescribed or recommended. While a majority (64.4%) stated they followed the advice of a health care provider, more than one-third (35.6%) made a medication change independent of provider advice. Moreover, notable percentages of women reported stopping, lowering, or missing a dose due to concerns over medication safety, including that the medication would cause birth defects or developmental issues (54.0%), miscarriage or stillbirth (40.4%), negative impact on their own personal health (24.8%), and autism spectrum disorder in their baby (21.7%).

The finding that pregnant women changed their medications and dosing out of concern for safety and without consulting a health care provider is concerning for maternal and fetal health. Although the lack of scientific data prevents understanding the true risks for most medications in pregnancy, studies suggest that women overestimate the risks of taking medication<sup>26,46–48</sup> and decide against use when their own research yields conflicting information on safety.<sup>49</sup> Caution toward and avoidance of medication during pregnancy is further fed by social structures, which prioritize fetal health and judge the mother as responsible for and in control of fetal health.<sup>50</sup> These forces are evident in qualitative research, in which women report focusing most heavily on the safety of the fetus in their decisions about medication use<sup>24,25</sup> and may have influenced medication change among women in our study.

Our findings also indicated that women with chronic conditions were more likely to have taken a prescription medication during pregnancy and to have made a medication change than those without a chronic condition. We further examined the relationship between specific chronic conditions and medication change. Although our survey did not

track individual medications or their indications, we noted patterns in change specific to each health condition. Women with chronic digestive, mental health, or respiratory conditions had higher odds of starting and of stopping a medication compared to women without these respective conditions, and women with chronic pain were more likely to have stopped a medication than were those without pain.

Starting a medication may reflect treatment of a condition and, in combination with stopping a medication, may reflect a modification in treatment appropriate to standards of care during pregnancy, for example, switching from one medication to another with a more favorable safety profile. Starting and stopping a medication might also indicate treatment and resolution, respectively, of a temporary problem or the recurrence of a chronic condition exacerbated by pregnancy. In contrast, ours and other research also suggest that women stop medication used to treat chronic conditions independent of health care provider instruction due to concerns about medication safety<sup>25,28,29,51–53</sup> or due to unintentional nonadherence.<sup>54</sup>

Concerns about safety and nonadherence may be further reflected in our findings that women with these health conditions were more likely to lower (for digestive conditions) or miss (for mental health and for respiratory conditions) prescribed or recommended doses. Many chronic conditions worsen during pregnancy and when treated inadequately or inappropriately are linked to adverse pregnancy and birth outcomes.<sup>19–23</sup>

Our findings further suggest that patient–provider communication on medication use and safety is critical during pregnancy. Decisions on medication use and on treatment of chronic conditions during pregnancy are best made by the patient in concert with the provider to support the full evaluation of medication risk and benefit using the available data.<sup>23</sup> Research shows that evidence-based counseling on medication safety is successful at reducing anxiety and increasing adherence among pregnant women,<sup>46</sup> including those with chronic conditions.<sup>55</sup>

Our study is among the first in the United States to quantify actions pregnant women take to determine medication safety as well as changes in and reasons for changes in medication use during pregnancy. Further strengths include the representative nature of our sample, which used quotas to ensure racial and ethnic representation similar to that of the U.S. population, had a prevalence of chronic conditions and of medication use similar to that seen in other U.S.-based studies,<sup>1,7,18</sup> and was drawn from one of the most heavily accessed health-based websites in the United States.<sup>30</sup> Still, the sample may not be representative of individuals without access to or regular use of the internet and may be biased toward individuals more likely to use and to rely on the internet as a health information source.

In addition, we cannot calculate a response rate since survey administration did not capture refusal to participate and since there is no sampling frame for visitors to WebMD.com. Data were collected through self-report which may be subject to social desirability and recall biases although studies suggest that there is high concordance of pregnant women's self-reported medication use and pharmacy<sup>56</sup> or medical records.<sup>57</sup> Finally, we did not collect potential confounders to medication use such as parity, previous pregnancy outcome, or health insurance status, nor did we examine ways in which women's medication adherence may have improved as a result of pregnancy.

## Conclusions

A majority of pregnant women take at least one medication during pregnancy. Although most rely on health care provider advice both for evaluating medication safety and for making a medication change, a notable number take actions on safety or make medication changes independent of their health care provider. These findings are potentially problematic for maternal and fetal health as untreated health conditions may lead to adverse pregnancy outcomes, and providers cannot deliver adequate care if they are not informed of their patients' true medication use patterns.

An opportunity exists for patients and providers to discuss potential medication safety concerns and for providers to use evidence-based counseling, which has been shown to improve pregnant women's medication adherence and outcomes. Finally, additional research to inform safe medication use during pregnancy is necessary. FDA OWH remains committed to supporting this research, to providing education, and to advancing understanding of medication, use, safety, and effectiveness in pregnancy and lactation.

## Authors' Contributions

S.K.H.: Conceptualization, Methodology, Formal analysis, and Writing—Original Draft. L.D.: Conceptualization, Methodology, and Writing—Review and Editing. E.M.S. and C.L.: Conceptualization, Methodology, Writing—Review and Editing, Project administration. S.Z.: Conceptualization, Methodology, Formal analysis, Writing—Review and Editing, and Project administration. K.V.: Project administration, Funding acquisition, and Writing—Review and Editing. S.B.-M.: Conceptualization, Supervision, and Writing—Review and Editing.

## Acknowledgment

The authors thank the study participants for sharing their experience and Joanne Berger, FDA Library, for article editing assistance.

## Disclaimer

The contents of this publication reflect the thoughts of the authors and do not represent the official views of, nor an endorsement by, the FDA, Department of Health and Human Services, or U.S. Government.

## Author Disclosure Statement

No competing financial interests exist.

## Funding Information

This work was supported by a contract between FDA and WebMD Health Corp (Grant No. FDABAA-18-00123N).

## References

- Mitchell AA, Gilboa SM, Werler MM, et al. Medication use during pregnancy, with particular focus on prescription drugs: 1976-2008. *Am J Obstet Gynecol* 2011;205:51. e51-51. e58; doi: 10.1016/j.ajog.2011.02.029
- Palmsten K, Hernández-Díaz S, Chambers CD, et al. The most commonly dispensed prescription medications among pregnant women enrolled in the U.S. medicaid program. *Obstet Gynecol* 2015;126(3):465-473; doi: 10.1097/AOG.0000000000000982
- Thorpe PG, Gilboa SM, Hernandez-Diaz S, et al. Medications in the first trimester of pregnancy: Most common exposures and critical gaps in understanding fetal risk. *Pharmacoepidemiol Drug Saf.* 2013;22(9):1013-1018; doi: 10.1002/pds.3495
- Tinker SC, Broussard CS, Frey MT, et al. Prevalence of prescription medication use among non-pregnant women of childbearing age and pregnant women in the United States: NHANES, 1999-2006. *Matern Child Health* 2015;19(5): 1097-1106; doi: 10.1007/s10995-014-1611-z
- Sheffield JS, Siegel D, Mirochnick M, et al. Designing drug trials: Considerations for pregnant women. *Clin Infect Dis* 2014;59 (suppl 7):S437-S444; doi: 10.1093/cid/ciu709
- Mathews TJ, Hamilton BE. Mean age of mothers is on the rise: United States, 2000-2014. *NCHS Data Brief* 2016; 232:1-8.
- Hayes DK, Robbins CL, Ko JY. Trends in selected chronic conditions and related risk factors among women of reproductive age: Behavioral Risk Factor Surveillance System, 2011-2017. *J Womens Health (Larchmt)* 2020;29: 1576-1585; doi: 10.1089/jwh.2019.8275
- Hayes DK, Fan AZ, Smith RA, et al. Trends in selected chronic conditions and behavioral risk factors among women of reproductive age, Behavioral Risk Factor Surveillance System, 2001-2009. *Prev Chronic Dis.* 2011; 8(6): A120. [http://www.cdc.gov/pcd/issues/2011/nov/10\\_0083.htm](http://www.cdc.gov/pcd/issues/2011/nov/10_0083.htm)
- Adam MP, Polifka JE, Friedman J. Evolving knowledge of the teratogenicity of medications in human pregnancy. *Am J Med Gen C Semin Med Genet* 2011;157C(3):175-182; doi: 10.1002/ajmg.c.30313
- Lo W, Friedman J. Teratogenicity of recently introduced medications in human pregnancy. *Obstet Gynecol* 2002; 100(3):465-473; doi: 10.1016/s0029-7844(02)02122-1
- Caritis SN, Venkataramanan R. Obstetrical, fetal, and lactation pharmacology—a crisis that can no longer be ignored. *Am J Obstet Gynecol* 2021;225(1):10-20; doi: 10.1016/j.ajog.2021.02.002
- U.S. Department of Health and Human Services, National Institutes of Health: Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC); 2020. Available from: <https://www.nichd.nih.gov/about/advisory/PRGLAC> [Last accessed: May 5, 2022].
- U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER). Pregnant women: Scientific and ethical considerations for inclusion in clinical trials guidance for industry; 2018.
- U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER). Postapproval Pregnancy Safety Studies Guidance for Industry; 2019.
- U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER). Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry; 2020.



16. U.S. Food and Drug Administration: Women's Health Research; 2020. Available from: <https://www.fda.gov/science-research/science-and-research-special-topics/womens-health-research> [Last accessed: February 11, 2022].
17. U.S. Food and Drug Administration. Pregnancy registries; 2018. Available from: <https://www.fda.gov/science-research/womens-health-research/pregnancy-registries> [Last accessed: February 11, 2022].
18. Haas DM, Marsh DJ, Dang DT, et al. Prescription and other medication use in pregnancy. *Obstet Gynecol* 2018;131(5):789; doi: 10.1097/aog.0000000000002579
19. Yonkers KA, Wisner KL, Stewart DE, et al. The management of depression during pregnancy: A report from the American Psychiatric Association and the American College of Obstetricians and Gynecologists. *Gen Hospital Psychiatry* 2009;31(5):403–413; doi: 10.1016/j.genhospsych.2009.04.003
20. Stone S, Nelson-Piercy C. Respiratory disease in pregnancy. *Obstet Gynaecol Reprod Med* 2012;22:290–298; doi: 10.1016/j.bpobgyn.2015.04.005
21. Gomes CF, Sousa M, Lourenço I, et al. Gastrointestinal diseases during pregnancy: What does the gastroenterologist need to know? *Ann Gastroenterol* 2018;31(4):385–394; doi: 10.20524/aog.2018.0264
22. Ray-Griffith SL, Wendel MP, Stowe ZN, et al. Chronic pain during pregnancy: A review of the literature. *Int J Women's Health* 2018;10:153–164; doi: 10.2147/IJWH.S151845
23. Riley LE, Cahill AG, Beigi R, et al. Improving safe and effective use of drugs in pregnancy and lactation: Workshop summary. *Am J Perinatol* 2017;34(8):826–832; doi: 10.1055/s-0037-1598070
24. Lynch MM, Squiers LB, Kosa KM, et al. Making decisions about medication use during pregnancy: Implications for communication strategies. *Matern Child Health* 2018;22(1):92–100; doi: 10.1007/s10995-017-2358-0
25. Lynch MM, Amoozegar JB, McClure EM, et al. Improving safe use of medications during pregnancy: The roles of patients, physicians, and pharmacists. *Qual Health Res* 2017;27(13):2071–2080; doi: 10.1177/1049732317732027
26. Nordeng H, Ystrøm E, Einarson A. Perception of risk regarding the use of medications and other exposures during pregnancy. *Eur J Clin Pharmacol* 2010;66(2):207–214; doi: 10.1007/s00228-009-0744-2
27. Nielsen MJ, Nørgaard M, Holland-Fisher P, et al. Self-reported antenatal adherence to medical treatment among pregnant women with Crohn's disease. *Aliment Pharmacol Ther* 2010;32(1):49–58; doi: 10.1111/j.1365-2036.2010.04318.x
28. Julsgaard M, Nørgaard M, Hvas CL, et al. Self-reported adherence to medical treatment prior to and during pregnancy among women with ulcerative colitis. *Inflamm Bowel Dis* 2011;17(7):1573–1580. doi: 10.1002/ibd.21522
29. van Trigt AM, Waardenburg CM, Haaijer-Ruskamp FM, et al. Questions about drugs: How do pregnant women solve them? *Pharm World Sci* 1994;16:354–359.
30. comScore, Inc., Media Metrix® Multi-Platform U.S. Data. [Last accessed: November 2021].
31. Martin JA, Hamilton BE, Osterman MJ, et al. Births: Final Data for 2016. *Natl Vital Stat Rep* 2018;67(1):1–55.
32. Scheuren F. *Encyclopedia of Survey Research Methods*. Post-stratification. Thousand Oaks, California: Sage Publications, Inc.; 2008.
33. U.S. Department of Health and Human Services. 2019 Poverty Guidelines; 2020. Available from: <https://aspe.hhs.gov/topics/poverty-economic-mobility/poverty-guidelines/prior-hhs-poverty-guidelines-federal-register-references/2019-poverty-guidelines> [Last accessed: July 2021].
34. Harrell FE: *Regression Modeling Strategies: With Applications to Linear Models, Logistic Regression, and Survival Analysis*. Springer; 2001.
35. Werler MM, Mitchell AA, Hernandez-Diaz S, et al. Use of over-the-counter medications during pregnancy. *Am J Obstet Gynecol* 2005;193(3 Pt 1):771–777. doi: 10.1016/j.ajog.2005.02.100
36. Bercaw J, Maheshwari B, Sangi-Haghpeykar H. The use during pregnancy of prescription, over-the-counter, and alternative medications among Hispanic women. *Birth* 2010;37(3):211–218; doi: 10.1111/j.1523-536X.2010.00408.x
37. Refuerzo JS, Blackwell SC, Sokol RJ, et al. Use of over-the-counter medications and herbal remedies in pregnancy. *Am J Perinatol* 2005;22(6):321–324; doi: 10.1055/s-2005-873235
38. Bakhireva LN, Young BN, Dalen J, et al. Patient utilization of information sources about safety of medications during pregnancy. *J Reprod Med* 2011;56(7-8):339–343.
39. Kirubarajan A, Lam A, Yu A, et al. Knowledge, information sources, and institutional trust of patients regarding medication use in pregnancy: A systematic review. *J Family Reprod Health*. 2021;15(3):160–171; doi: 10.18502/jfrh.v15i3.7133
40. De Santis M, De Luca C, Quattrocchi T, et al. Use of the Internet by women seeking information about potentially teratogenic agents. *Eur J Obstet Gynecol Reprod Biol* 2010;151(2):154–157; doi: 10.1016/j.ejogrb.2010.04.018
41. Sayakhot P, Carolan-Olah M: Internet use by pregnant women seeking pregnancy-related information: A systematic review. *BMC Pregnancy Childbirth* 2016;16:1–10; doi: 10.1186/s12884-016-0856-5
42. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER). *Pregnancy, Lactation and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products—Content and Format Guidance for Industry*; 2020. Available from: <https://www.fda.gov/media/90160/download> [Last accessed: March 2022].
43. Wesley BD, Sewell CA, Chang CY, et al. Prescription medications for use in pregnancy—perspective from the US Food and Drug Administration. *Am J Obstet Gynecol* 2021;225(1):21–32; doi: 10.1016/j.ajog.2021.02.032
44. Byrne JJ, Saucedo AM, Spong CY. Evaluation of drug labels following the 2015 pregnancy and lactation labeling rule. *JAMA Netw Open* 2020;3(8):e2015094; doi: 10.1001/jamanetworkopen.2020.15094
45. Matsui D. Adherence with drug therapy in pregnancy. *Obstet Gynecol Int* 2012;2012(7419):1–5; doi: 10.1155/2012/796590
46. Hancock RL, Koren G, Einarson A, et al. The effectiveness of teratology information services (TIS). *Reprod Toxicol* 2007;23(2):125–132; doi: 10.1016/j.reprotox.2006.11.005
47. Petersen I, McCrea RL, Lupattelli A, et al. Women's perception of risks of adverse fetal pregnancy outcomes: A large-scale multinational survey. *BMJ Open* 2015;5(6):e007390; doi: 10.1136/bmjopen-2014-007390
48. Mulder B, Bijlsma MJ, Schuiling-Veninga CC, et al. Risks versus benefits of medication use during pregnancy: What do women perceive? *Patient Prefer Adher* 2017;12:1–8; doi: 10.2147/PPA.S146091

49. Hämeen-Anttila K, Nordeng H, Kokki E, et al. Multiple information sources and consequences of conflicting information about medicine use during pregnancy: A multinational Internet-based survey. *J Med Internet Res*. 2014;16:e2939; doi: 10.2196/jmir.2939
50. Lupton D. 'Precious cargo': Foetal subjects, risk and reproductive citizenship. *Crit Public Health* 2012;22:329–340; doi: 10.1080/09581596.2012.657612
51. Chambers K. Asthma education and outcomes for women of childbearing age. *Case Manager* 2003;14(6):58–61; doi: 10.1016/j.casemgr.2003.09.003
52. Nielsen MJ, Nørgaard M, Holland-Fisher P, et al. Self-reported antenatal adherence to medical treatment among pregnant women with Crohn's disease. *Aliment Pharmacol Therapeut* 2010;32(1):49–58; doi: 10.1111/j.1365-2036.2010.04318.x
53. Lupattelli A, Spigset O, Nordeng H. Adherence to medication for chronic disorders during pregnancy: Results from a multinational study. *Int J Clin Pharm* 2014;36(1):145–153; doi: 10.1007/s11096-013-9864-y
54. Sawicki E, Stewart K, Wong S, et al. Medication use for chronic health conditions by pregnant women attending an Australian maternity hospital. *Aust N Z J Obstet Gynaecol* 2011;51(4):333–338; doi: 10.1111/j.1479-828X.2011.01312.x
55. Einarson A, Selby P, Koren G. Abrupt discontinuation of psychotropic drugs during pregnancy: Fear of teratogenic risk and impact of counselling. *J Psychiatry Neurosci* 2001; 26:44.
56. Cheung K, El Marroun H, Elfrink M, et al. The concordance between self-reported medication use and pharmacy records in pregnant women. *Pharmacoepidemiol Drug Saf* 2017;26(9):1119–1125; doi: 10.1002/pds.4264
57. Sarangarm P, Young B, Rayburn W, et al. Agreement between self-report and prescription data in medical records for pregnant women. *Birth Defects Res Part A Clin Mol Teratol* 2012;94(3):153–161; doi: 10.1002/bdra.22888
58. U.S. Census Bureau. Census Regions and Divisions of the United States. Available from: [https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us\\_regdiv.pdf](https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf) [Last accessed: July 8, 2021].

Address correspondence to:  
*Sara K. Head, PhD, MPH*  
*Office of Women's Health*  
*U.S. Food and Drug Administration*  
*10903 New Hampshire Avenue*  
*Silver Spring, MD 20993*  
*USA*

*E-mail:* sara.head@fda.hhs.gov