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ORIGINAL RESEARCH

# Medication Use and Associated Factors Among Indonesian Pregnant Women: A Cross-Sectional Study

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Purpose: Medication use during pregnancy should be considered carefully due to its potential harm to the fetus. Data on prescribed medication and self-medication among Indonesian pregnant women is lacking. This study aimed to assess the prevalence and factors related to medication use among pregnant women attending antenatal care services at community health posts in Soreang, a suburban area in Indonesia.

Patients and Methods: A cross-sectional community-based study was conducted. Data on medication use, excluding supplements, were collected. Medication was categorized using the former United States Food and Drug Administration (US FDA) pregnancy risk classification system. Proportions of pregnant women using prescribed medication and self-medication during pregnancy and associated factors were calculated.

**Results:** A total of 439 pregnant women were enrolled. There were 155 (35.5%) subjects who used at least one medication during pregnancy. These subjects had medical problems as the reasons for medication use. Among medication users, prescribed medication and self-medication were demonstrated in 138 (89.0%) and 17 (11.0%) pregnant women, respectively. There was a pregnant woman who was exposed to category D medication. Self-medication among pregnant women was less likely when health insurance was available (adjusted OR = 0.11, 95% CI: 0.027–0.413, P = 0.001).

**Conclusion:** The prevalence of medication use among Indonesian pregnant women is high. The presence of health insurance was protective against self-medication among pregnant women. Safe and effective practices in prescribing have to be ensured for pregnant women.

Keywords: medication, self-medication, pregnancy, prevalence

#### Introduction

Pregnancy is a physiological process with some changes for the mother and the fetus. Pregnant women may require medications to alleviate pregnancy-related symptoms or chronic medical conditions.<sup>1-3</sup> Some pregnant women may obtain health information regarding their medical problems and provide self-medications. These practices are prone to occur in many developing countries, where medications are not well-regulated.<sup>4</sup>

The first trimester is the organogenesis period and fetal development, including vital tissue.<sup>5</sup> Medication use during this period can reach the fetus by crossing the placenta and may cause harmful side effects.<sup>6,7</sup> According to the former United States Food and Drug Administration (US FDA) pregnancy risk classification of medications, category A is considered the safest category, followed by category B. Medications in US FDA category C may have potential risk to the fetus and those in categories D and X have evidence of human fetal risks.<sup>2,8</sup>

It has been reported that approximately 8% of pregnant women received pharmacological treatment due to various medical problems.<sup>3</sup> The previous study in Ethiopia found that 55.2% of pregnant women consumed at least one prescribed medication. About 7–17% of pregnant women took the US FDA categories D and X medications.<sup>9</sup>

Medication use among pregnant women should be considered a public health concern because of gaps in understanding about adverse consequences of medications on fetus.<sup>9,10</sup> Previous studies regarding medication use among pregnant women in Indonesia only assessed blood supplement tablets<sup>11</sup> or over-the-counter medicine,<sup>12</sup> as well as descriptive study about medication use pattern and knowledge among pregnant women in health center without analyzing the associated factors.<sup>13</sup> There were some studies regarding medication use during pregnancy in some countries.<sup>3,5,6,9,14</sup> However, little is known about medication use among Indonesian pregnant women and its associated factors. Additionally, most of the previous studies were hospital-based. Therefore, the objectives of this study were to assess the prevalence and factors related to medication use among Indonesian pregnant women in the suburban community, including prescribed medication and self-medication among medication users.

#### **Materials and Methods**

A community-based cross-sectional study was conducted in May-July, 2018 at community health posts in Soreang, a suburban area in Bandung, West Java, Indonesia. The community health posts can function as meeting points for women who seek antenatal care and health education. These posts were managed by voluntary health cadres and visited monthly by healthcare workers from the primary health centers.

At 95% confidence interval, using the formula  $n = (Z_{1-d/2})^2 * P(1-P)/d^2$  with P = 0.50 and d = 0.05, we obtained a minimum sample size of 384.<sup>15</sup> Non-probability convenience sampling was used to recruit the subjects because of its speed, cost-effectiveness, and ease of availability of the sample.<sup>16</sup> Pregnant women who were following the antenatal care service at the community health posts and were willing to participate were included in the study. The sources of medication among medication users were divided into two groups, namely prescribed medication and self-medication. A woman is said to have used prescribed medication if she reported using prescribed medication during her current pregnancy. Additionally, a woman is said to have used self-medication if she reported the act of using medications without medical supervision during her current pregnancy.<sup>8</sup>

After obtaining written informed consent, pregnant women were interviewed by study staff members. Data related to medication use, excluding supplements, were collected through interviews and reviews of maternity books to know medications prescribed previously. The data collected included socio-demographic characteristics, provisions of health insurance, amount of monthly income, obstetric history of pregnant women, and types of medication used during the current pregnancy. Maternal age was divided into three groups, <20, 20–35, and >35 years. The income was classified into two groups by the cut-off point based on the regional minimum wage of IDR 2.678 million (equals 178.53 USD) per month per family.

The types of medication were further classified based on the former US FDA pregnancy risk classification. Category A refers to drugs in which well-controlled studies have failed to demonstrate any risk to the fetus. Category B defines drugs in which animal studies have not shown any risks to the fetus and no studies in pregnant women. Category C medications harm the fetus in animal studies, but no studies on humans. Category D medications have shown fetal risk, but the benefits may outweigh the risks. Category X medications have demonstrated evidence of fetal risk, and risks outweigh any possible benefit.<sup>17</sup>

Data were analyzed using Statistical Package for Social Sciences (SPSS) for Windows version 24.0 (SPSS, Chicago, IL, USA). Frequencies and percentages for categorical variables are the main descriptive statistics reported. Univariate analysis and multivariable logistic regressions were used to determine the association between medication use and the characteristics of pregnant women. If the P-value was <0.10 in univariate analysis, the variable was regarded as a confounder and was included in the multivariable logistic regression analysis for adjustment. Results were expressed as crudes, adjusted odds ratio (OR), and 95% confidence interval (CI). All tests were two-tailed, and a P-value < 0.05 was used to determine statistical significance.

This study was undertaken with permission from the Institutional Health Research Ethics Committee of the Faculty of Medicine, Universitas Padjadjaran, Bandung (approval number: 345/UN6.KEP/EC/2018) and conformed to the principles outlined in the Declaration of Helsinki.

## Results

#### Characteristics of Study Participants

During the study period, 439 pregnant women completed the survey. The majority of pregnant women in this study (334 or 76.1%) were in the age group of 20–35 years. In terms of educational level, the largest proportion of pregnant women had educational levels up to junior high school (160 or 36.4%), while very few had attended university level (32 or 7.3%). Most pregnant women were housewives (381 or 86.8%) with family incomes below regional minimum wages (290 or 66.1%). More than half (223 or 50.8%) of pregnant women had health insurance. The subjects were mostly in the second pregnancy (176 or 40.1%) and with the gestational age mainly in the second trimester (191 or 43.5%), followed by 177 (40.3%) in the third trimester. The antenatal care facilities visited by the subjects were 392 (89.3%) provided by midwives and only 47 (10.7%) provided by physicians.

### Medication Use During Pregnancy

Out of 439 women, 155 (35.3%) reported medication use during their pregnancy. There were 52 (39.1%) women who consumed more than one medication, excluding supplements. The medications used were mainly non-steroidal antiinflammatory drugs (NSAIDs) and analgesics (39.9% in prescribed medication and 47.1% in self-medication groups), followed by antiemetics and antacids (32.6% in prescribed medication and 35.3% in self-medication groups). The most commonly used medications were from US FDA category B, followed by category C in those who did self-medication, as well as those who used prescribed medication, as shown in Figure 1. The frequently used drugs include metoclopramide from US FDA category A medications and paracetamol and antacids from US FDA category B medications. The proportion of pregnant women who used US FDA category D medications was only one subject (0.6%) that received piroxicam. Most prescribed medication group, 66.7% of pregnant women reported consumption in the first trimester, while 23.8% in the second trimester.

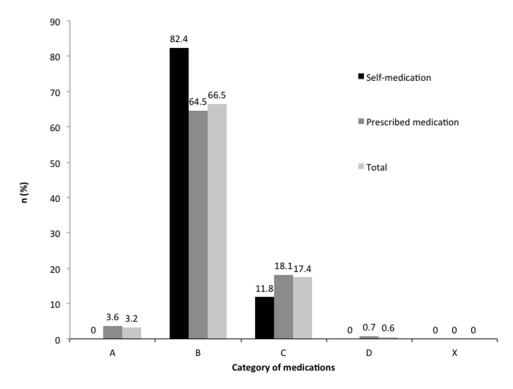


Figure I Percentage of pregnant women exposed to medications according to the former United States Food and Drugs Administration (US FDA) risk category.

Variables	Medication Use		Crude OR (95% CI)	P-value	Adjusted OR	P-value
	Yes (n = 155)	No (n = 284)			(95% CI)	
Age of women (years)					_	_
<20	15 (9.7)	30 (10.6)	1.31 (0.537–3.185)	0.555		
20–35	122 (78.7)	212 (74.6)	1.51 (0.768–2.967)	0.232		
>35	18 (11.6)	42 (14.8)	1.00			
Educational status					-	-
Elementary school	43 (27.7)	73 (25.7)	1.00			
Junior high school	55 (35.5)	105 (37.0)	0.89 (0.540-1.464)	0.644		
Senior high school	43 (27.7)	88 (31.0)	0.83 (0.491-1.401)	0.485		
University	14 (9.0)	18 (6.3)	1.32 (0.597–2.920)	0.492		
Parity					-	-
0	50 (32.3)	92 (32.4)	1.14 (0.684–1.910)	0.611		
I	66 (42.6)	110 (38.7)	1.26 (0.774–2.056)	0.351		
≥ 2	39 (25.2)	82 (28.9)	1.00			
Gestational age					-	-
First trimester	25 (16.1)	46 (16.2)	0.87 (0.491-1.546)	0.637		
Second trimester	62 (40.0)	129 (45.4)	0.77 (0.502-1.182)	0.233		
Third trimester	68 (43.9)	109 (38.4)	1.00			
Provider of antenatal care facility						
Midwife	128 (82.6)	255 (89.8)	1.00		1.00	
Physician	27 (17.4)	29 (10.2)	1.86 (1.054–3.265)	0.032	1.80 (1.022–3.183)	0.042
Health insurance	. ,					
Yes	88 (56.8)	135 (47.5)	1.45 (0.978–2.150)	0.065	1.42 (0.954–2.107)	0.084
No	67 (43.2)	149 (52.5)	1.00		1.00	

Table I Univariate and Multivariable Logistic Regression Analysis of Factors Associated with	Medication Use Among
Pregnant Women (n = 439)	

Abbreviations: OR, odds ratio; Cl, confidence interval.

#### Reasons for Medication Use

In this study, women who used medications during pregnancy had health problems as the reasons. Digestive conditions, including nausea, vomiting, diarrhea, and bloating, were the main reasons for medication use in 61 (44.2%) and 7 (41.1%) of pregnant women with prescribed medication and self-medication, respectively. Fever, cough, and cold were demonstrated in 30 (21.7%) pregnant women with prescribed medication, and 5 (29.4%) women with self-medication, respectively. Medications for some medical conditions, such as asthma, diabetes, and hypertension, were found only in the prescribed medication group in 19 (13.0%) cases.

#### Factors Associated with Medication Use During Pregnancy

The characteristics comparison of the pregnant women stratified by medication use are shown in Table 1. There were no differences in age range, educational status, parity, and gestational age between those who reported medication use during pregnancy and those who did not. Antenatal care facility provided by physicians was associated with medication use (adjusted OR = 1.80, 95% CI: 1.022-3.183, P = 0.042), as shown in Table 1.

Self-medication during pregnancy was admitted by 11% of pregnant women who used medications (Table 2). In univariate analysis, multiparity, age >35, and absence of health insurance were more likely associated with self-medication. These were included in the multivariable logistic regression for adjustment. Pregnant women who had health insurance were 0.11 times less likely to provide self-medication compared to those who had no health insurance (adjusted OR = 0.11, 95% CI: 0.027-0.413, P = 0.001), as shown in Table 2.

Variables	Medication Users		Crude OR	P-value	Adjusted OR	P-value
	Self- Medication (n = 17)	Prescribed Medication (n = 138)	(95% CI)		(95% CI)	
Age of women (years)						
<20	0 (0.0)	15 (10.9)	0.00	0.999	0.00	0.998
20–35	13 (75.5)	114 (82.6)	1.00		1.00	
>35	4 (23.5)	9 (6.5)	3.90 (1.051–14.446)	0.042	3.38 (0.601–18.996)	0.167
Educational status					-	-
Elementary school	6 (5.3)	37 (26.8)	1.00			
Junior high school	5 (29.4)	50 (36.2)	0.62 (0.175–2.175)	0.452		
Senior high school	5 (29.4)	38 (27.5)	0.81 (0.228-2.890)	0.747		
University	l (5.9)	13 (9.4)	0.47 (0.052-4.321)	0.508		
Parity						
0	5 (29.4)	45 (32.6)	0.43 (0.129–1.440)	0.171	0.85 (0.197–3.689)	0.832
L	4 (23.5)	62 (44.9)	0.25 (0.070-0.895)	0.033	0.30 (0.067–1.351)	0.117
≥ 2	8 (47.1)	31 (22.5)	1.00		1.00	
Gestational age					-	-
First trimester	4 (23.5)	21 (15.2)	1.43 (0.390-5.237)	0.590		
Second trimester	5 (29.4)	57 (41.3)	0.67 (0.203–2.130)	0.485		
Third trimester	8 (47.1)	60 (43.5)	1.00			
Provider of antenatal care facility					-	-
Midwife	14 (82.4)	115 (83.3)	1.00			
Physician	3 (17.6)	23 (16.7)	1.02 (0.271-3.819)	0.979		
Health insurance						
Yes	3 (17.6)	85 (61.6)	0.13 (0.037–0.487)	0.002	0.11 (0.027–0.413)	0.001
No	14 (82.4)	53 (38.4)	1.00		1.00	

Table 2 Univariate and Multivariable Logistic Regression	Analysis of Factors Associated with	th Self-Medication and Prescribed
Medication Among Medication Users (n = 155)		

Abbreviations: OR, odds ratio; Cl, confidence interval.

#### Discussion

In this study, 155 (35.5%) pregnant women reported medication use, excluding supplements. This finding was similar to a study in Belgium.<sup>14</sup> However, the prevalence in this study was smaller compared to other studies conducted in Bangladesh (100%)<sup>18</sup> and Egypt (96.3%).<sup>5</sup> The results of previous studies differed presumably because of the inclusion of supplements. In a study in Malaysia, 62% of women used medications during pregnancy, excluding supplements.<sup>19</sup> Similarly, prescription medications, excluding supplements during pregnancy, were high in Ethiopia.<sup>10</sup> The results of previous studies on medication use during pregnancy differed, presumably because of the inconsistency of the methodology and healthcare settings where studies were conducted.

Women who used medications during pregnancy in this study were mostly in the 20–35 years age group and had low educational levels. Most of them were housewives and came from families with total income under regional minimum wage. The parity of the pregnant women was distributed almost equally from null to higher parities (>2 previous children). These findings were similar to earlier results in India.<sup>2</sup> In terms of factors associated with medication use in pregnant women, our study showed that only antenatal care facility was significantly related to medication use during pregnancy. The study in Belgium, however, reported that medications during pregnancy were positively associated with age older than 35 years, Western origin, being born in Belgium, high education, and employment status.<sup>14</sup> Additionally, Mitchell reported that the average number of medications taken during any time in pregnancy and also in the first trimester were higher by increasing age and education level.<sup>20</sup>

This study showed that the main reasons for medication were digestive problems, fever, cough, and cold. The results were similar to the study in Malaysia.<sup>19</sup> However, there were discrepancies between the underlying medical conditions and the most frequently used medications, namely analgesics and NSAIDs. These possibly were caused by recall bias.

To guide safe medication use during pregnancy, the former US FDA classified medications into five major categories, with categories D and X indicating evidence of risk in pregnancy.<sup>21</sup> This study showed that US FDA category B medications were the most frequently prescribed drugs. The proportion of pregnant women prescribed category D medications was 0.6%. This proportion was lower than the findings in Ethiopia, Brazil, and Ireland.<sup>7,21,22</sup> The results in our study were comparable with a study conducted in Alexandria, Egypt, which showed that 0.5% of pregnant women were prescribed from category D.<sup>5</sup>

In terms of factors associated with medication use, our study showed that the provider of antenatal care facility was related to medication use during pregnancy. Pregnant women who visited physicians for antenatal care were 1.80 times more likely to receive prescription medications than those who consulted with midwives. Other studies reported that drug use during pregnancy was positively associated with older age and high education level.<sup>14,15</sup>

Our study indicated the existence of self-medication in 11.0% of pregnant women. A previous study showed that the prevalence of self-medication in Brazil was 18.8%,<sup>15</sup> while it was 15.5% in Ethiopia.<sup>4</sup> Self-medication has become a focus of interest because in most developing countries with inefficient health care systems, people may access medications easily, and there may be an increased risk of self-medication.<sup>8</sup> Continuous education for women should be encouraged.<sup>23</sup> Additionally, over-the-counter drug distributions have to be monitored.<sup>1</sup>

This study found that the absence of health insurance contributed to self-medication among Indonesian pregnant women. Indonesia launched a comprehensive health insurance program in 2014 to cover diverse health and social conditions. Additionally, there are some providers of private health insurance programs. The prescription proof is usually required to claim insurance. However, low self-enrollment exists.<sup>24</sup> This has been reported as a common occurrence among the illiterates and those in the lower economic class. Therefore, affordability of cost of care and ensuring availability of health insurance may be essential factors.<sup>1</sup>

Pregnancy is an essential phase of life, either for the mother or the fetus, so necessary precautions should be taken during pregnancy.<sup>25</sup> It is important to convince that the medications during pregnancy have no teratogenic or hazardous effects, especially on the fetus. It was clear from this study that in this suburban community the safety of medication use among pregnant women should warrant concern. Safe prescribing practices for pregnant women should be ensured through developing guidelines on the risk status of commonly used medications.<sup>10</sup>

Several limitations need to be considered in the interpretation of the study findings. This study was a cross-sectional study with a non-probability sampling technique and a small number of medication users among pregnant women. Moreover, the information regarding medication use was self-reported; therefore, there was a potency of recall bias. Selection bias was also a concern because pregnant women not attending the antenatal care facility were excluded. Lastly, since we interviewed the women, there was potential for social desirability bias.

#### Conclusion

The prevalence of medication use among pregnant women in this study was 35.3%. Antenatal care facility provided by the physician was the only determinant of medication use among pregnant women. Self-medication practices were admitted by 11.0% of pregnant women, especially those who did not have health insurance. Safe prescribing practices for pregnant women should be ensured when medication is needed.

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#### Disclosure

The authors report no conflicts of interest in this work.

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