

Prevalence and Determinants of Prescribed Drug Use Among Pregnant Women at Public Health Center in Wolkite Town, Southern Ethiopia

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Abstract: *Background:* Incautious utilization of drugs by pregnant women for therapeutic reasons may result in severe functional and structural damages in the developing fetus. The objective of this study was to determine the prevalence and associated factors of prescribed drug use among pregnant women at public health center in Gurage Zone, Southern Ethiopia. *Methods:* Institution based cross sectional study was conducted on pregnant women. Data was collected from patient charts and interviewing pregnant women by using standard data collection tools. The data was analyzed using SPSS version 23.0 and multinomial logistic regression model was utilized estimate association across different study variables. *P-values* <0.05 were considered statistically significant. *Results:* Of a total of 418 pregnant women, about 91.1% were prescribed with at least one medication and there were an average 2.4 numbers of drugs per a prescription. Pregnant women with comorbidity were AOR = 19.66, 95% CI (8.747-44.218), who visited the health facility once were AOR = 2.787 95% CI (1.265-6.142) and twice were AOR = 2.704 (1.042-7.018), and with primigravida were AOR = 3.553 95% CI (1.644-7.680) times more likely to use prescribed drugs (except ferrous sulphate). *Conclusion:* Although majority of the drugs used was appropriate and safe medications according to FDA risk classification system, the prevalence of prescribed medication use during pregnancy is very high in public health center of Wolkite town. Presence of comorbidity, gravidity and time of first visits to health facilities were significantly associated with prescribed drug use during pregnancy.

Keywords: Pregnancy, WHO Core Prescribing Indicators, FDA Drug Category, Determinants of Drug Use

1. Introduction

Pregnancy is a unique physiological state where drug utilization presents a special concern for the health and life of mother and her unborn fetus. Although pregnancy is a physiological state, it still needs special care. Supplemental drug therapy, particularly with iron, folic acid, vitamins, minerals and calcium plays a vital role in the prevention of child and maternal mortality and morbidity [1-3].

Additionally, drugs may also be utilized for non-pregnancy related conditions such as infections of urinary tract, upper

respiratory and gastrointestinal tract. Pregnant women may also utilize prescribed drugs to treat pre-existing chronic conditions such as hypertension, diabetes or epilepsy or to treat pregnancy related conditions such as gestational diabetes and hypertension [4, 5].

However, Incautious utilization of drugs by pregnant women for therapeutic reasons may result in severe functional and structural damages in the developing fetus. The concern on use of medication during pregnancy has been

affected by historical incidents, comprising thalidomide crisis in the 1960s and the teratogenic effects discovered, connected to the use of diethylstilbestrol in 1971 [6, 7].

After these events, the FDA has started strict regulations regarding use of medications in pregnancy, drug labeling and requiring demonstrations on efficacy and safety of any drug before it became commercially available [1]. To protect against such events, the regulatory authority has also categorized use of drugs in pregnancy. Hence it would be realistic for clinicians to prescribe safe drugs during pregnancy [8].

FDA categorize drugs into the following major categories; A, B, C, D, X and non-FDA categorized drugs. For Category-A drugs sufficient clinical studies have revealed no risk to fetus in any trimester. In category-B drugs, animal studies have not shown adverse effect on the fetus and there is inadequate clinical study. In category-C drugs, animal studies have revealed adverse effects, no adequate clinical studies and it may be valuable in pregnancy in spite of potential risks. However in category-D drugs, there is proof of risk to human fetus, but potential benefits may be acceptable regardless of potential risks. In category-X drugs, animal/human studies show fetal abnormalities and risks involved clearly outweigh benefits. So category X drugs are absolutely contraindicated [9, 10].

The studies conducted in developed countries where drug-prescribing practices are thought to be superior, have identified need for interventional measures aimed at rational prescription during the prenatal period since about 8% of pregnant mothers need drug treatment due to numerous chronic illnesses and pregnancy related complications [11].

Highly utilization of prescribed medications by pregnant women has been widely reported in various health facilities of different countries including Ethiopia [6, 12]. In Gurage zone health facilities, there was no such study before for the safety and effectiveness of drug use during pregnancy. Hence, this study was carried out to evaluate the prevalence of drug use and its associated factors in women attending the ANC which will enable to provide recommendation to prescribers and the health centers so as to create awareness about irrational use of drugs. The findings of our study may be used as base-line information for conducting further study in the country.

2. Objectives

2.1. General Objective

To assess the prevalence and determinants of prescribed drug use among pregnant women at public health center in Wolkite town, Southern Ethiopia, 2019.

2.2. Specific Objectives

- 1) To determine the prevalence of prescribed drug use by pregnant women.
- 2) To assess appropriateness of prescribed drug use by pregnant women.

- 3) To determine factors associated with prescribed drug use by pregnant women.

3. Methods and Materials

Wolkite health center is found in Wolkite town, Gurage zone, Southern Nations and Nationalities Peoples Region State (SNNPRs). The services delivered by the health centers are organized into different units; these are out patients departments (under five and adult), emergency, TB-HIV, ART and Voluntary Counseling Testing (VCT), immunization, family planning, labor and delivery and antenatal care unite. Since there was no hospital in the town before the data collection period, the health center provided services for approximately 40,000 populations of Wolkite town and the surrounding. About 150 pregnant women per month were expected to be having ANC follow-up at the health center.

Institution based cross sectional study was conducted from January 1-June 15, 2019 among pregnant mothers who attended ANC of Wolkite health center. The study population was all pregnant women who came for ANC services to the health center during the study period. Any gestational age of pregnant women who were on ANC follow up at Wolkite health center were included in the study. However, pregnant women who were referred from other health care facilities were excluded from the study.

A single population proportion formula was used to calculate the sample size. Using the 44.5% prevalence of drug use among pregnant women in Fiche Hospital of Ethiopia [6], 5% margin of error at 95% confidence level and 10% inclusion of non-response rate, the calculated final sample size was 418. Systematic random sampling method was used to select the required number of pregnant mothers.

Data were collected by using both pretested semi-structured questionnaires and data abstraction format. Initially, the pregnant woman at waiting room was interviewed followed by her ANC chart was reviewed. Socio-demographic, obstetric and medical history of pregnant women data was collected by using semi-structured questionnaire. The data abstraction forms were utilized for collecting information on the total number of gestational age, ANC visits and drugs regimen prescribed during each trimester.

The data was collected by midwifery and nurse professionals who were working in ANC rooms in other health centers and who had data collection experience. Before conducting the actual study the questionnaire was piloted by 5% of the sample size (21 pregnant women) at other health center. Based on the pilot feedback, some questions were amended and the final questionnaire was used in the study. Completeness and consistency of data was checked by supervisor, data clerks and investigators before and after data entry.

Completeness of the collected data was checked manually. Then, the data was coded and analyzed using FDA pregnancy

drug category and WHO core prescribing indicators. The collected data was entered by Epi data version 3.1 and analyzed using SPSS version 23.0 statistical software package. The result was summarized by tables and was interpreted as per the objective of the study. Multivariable logistic regression was done and $p < 0.05$ was used to determine statistical significance.

4. Results

In this study a total number of 418 (response rate of 100%) pregnant women were studied.

4.1. Socio-Demographic Characteristics

The age of the study participants was in the range of 18-45 years and majority of them were within the age group of 18-35 years (98.2%) that denotes the usual reproductive age group. Majority of the pregnant women were Muslim (57.2%) and married (79.5%) (Table 1).

Table 1. Socio-demographic characteristics of pregnant women who were attending ANC in Wolkite Health centers, Ethiopia, 2019 (n=418).

Parameter		Frequency (n=418)	Percentage (%)
Age	18-35	410	98.2
	36-45	8	1.8
Marital Status	Married	332	79.5
	Not Married	86	20.5
Religion	Muslim	239	57.2
	Christian	179	42.8
Educational status	Illiterate	160	38.3%
	Literate	258	61.7%

4.2. Obstetrics and Medical Information

Relatively larger number (40.5%) of the pregnant women were multigravida and majority (78%) of them had less than three number of children before the current pregnancy. Almost half (53.8%) of the women visited the health centers for once in their entire pregnancy time. The time of their first visit for majority (73%) of the pregnant women was unknown (Table 2).

Table 2. Pregnancy-related characteristics of pregnant women who were attending ANC in Wolkite Health center, Ethiopia, 2019 (n=418).

Parameter		Frequency (n=418)	Percentage (%)
Gravidity	Primigravida	131	31.4
	Secundum gravida	118	28.2
	Multigravida	169	40.5
No of children before current pregnancy	0-2	326	78
	3-5	92	22
	one time	225	53.8
Number of visit to health facilities	Two times	74	17.6
	Three times	38	9.2
	Four times	81	19.4
	First trimester	79	18.9
Time of first visits of the health facilities	Second trimester	8	1.8
	Third trimester	26	6.3
	Unknown	305	73
Comorbid conditions	Yes	257	61.4
	No	161	38.6

4.3. Drug Use Characteristics

Of 418 pregnant women, 381 (91.15%) were prescribed with at least one medication. About 823 medications were prescribed to the pregnant women, from which a majority (91.6%) were tablet as a dosage form (Figure 1).

Among the total prescribed drugs for the pregnant mothers, FDA category A drugs (43.3%) were the most regularly prescribed drugs, after that category B & C which accounted for 25.4% and 24.9%, respectively. FDA category X (0.24%) were the least prescribed drugs. The most frequently (43.3%) prescribed individual drug was ferrous sulphate (Table 3).

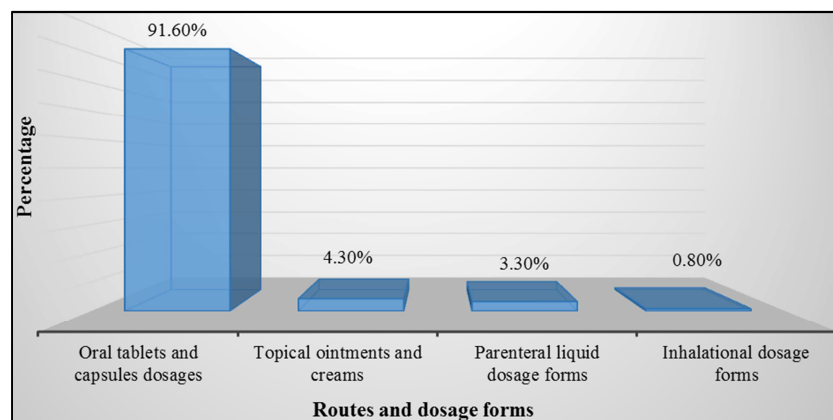


Figure 1. Distribution of routes of drug administered and their dosage forms.

Table 3. FDA category of drugs prescribed to pregnant women who attended ANC follow up in Wolkite Health center, Ethiopia, 2019 (n=418).

FDA drug category	Frequency (Percentage)	Representative drugs
Category A	356 (43.3%)	Ferrous sulphate
Category B	209 (25.4%)	Amoxicillin, Paracetamol, Cephalixin, Coartem, Metronidazole, Azithromycin, Cimetidine
Category C	205 (24.9%)	Mebendazole, Norfloxacin, Gentamycin, Diclofenac, Magnesium trisilicate/Aluminum hydroxide, Ibuprofen, Ciprofloxacin, Salbutamol, Dexamethasone, Ketoconazole, Doanil, Plasil
Category D	23 (2.8%)	Doxycycline, Phenytoin
Category X	2 (0.24%)	Misoprostol
Non-FDA categorized	28 (3.4%)	Chloroquine

Regarding WHO core drug prescribing indicators, Percentage of drugs prescribed from essential drug list merely matched with the WHO ideal value (100%). Average number of drugs per prescription (2.24), percentage of drugs

prescribed by generic name (95.7%), percentage of encounters with antibiotic prescribed (30.5%) and Percentage of encounters with an injection prescribed (5.8%), which were slightly deviated the WHO standard values (Table 4).

Table 4. WHO core drug prescribing indicators among pregnant women who attended ANC follow up in Wolkite Health center, Ethiopia, 2019 (n=418).

S. N	Indicators	Values	WHO ideal value
1	Average number of drugs per prescription	2.24	(1.6-1.8)
2	Percentage of drugs prescribed by generic name	95.7%	100%
3	Percentage of encounters with antibiotic prescribed	30.5%	(20.0-26.8%)
4	Percentage of encounters with an injection prescribed	5.8%	(13.4%-24.1%)
5	Percentage of drugs prescribed from essential drug list	100%	100%

4.4. Factors Associated with Drugs (Except Ferrous Sulphate) Use During Pregnancy

Multinomial logistic regression analysis result revealed that gravidity, the presence of comorbid condition and time of first visits to health facilities were significantly associated with drugs (except ferrous sulphate) use during pregnancy (Table 5). Pregnant women with comorbid conditions were AOR = 19.66, 95% CI (8.747-44.218) times more likely to use prescribed drug (except ferrous sulphate) than those without comorbidity. Pregnant women who visited the health facility once were AOR = 2.787 95% CI (1.265-6.142) and twice were AOR = 2.704 (1.042-7.018) times more likely to use prescribed drugs (except ferrous sulphate) compared with those who visited the health facility more than two times. Similarly, pregnant women with primigravida were AOR = 3.553 95% CI (1.644-7.680) times more likely got prescribed with drugs (except ferrous sulphate) compared with multigravida. However, women who with different marital and educational status had insignificant correlation with prescribed drug (except ferrous sulphate) use.

Table 5. Factors associated with prescribed drugs (except ferrous sulphate) use during pregnancy among pregnant women who attended ANC follow up in Wolkite Health center, Ethiopia, 2019 (n=418).

Variables	AOR (95% CI)	P-value
Comorbidity		
Yes	19.66 (8.747-44.218)	0.000
No	1	
Gravidity		
Primigravida	3.553 (1.644-7.680)	0.001267
Secundum gravida	1.153 (0.797-1.934)	0.288163
Multigravida	1	
Number visits to health facilities		
One time	2.787 (1.265-6.142)	0.011012
Two times	2.704 (1.042-7.018)	0.040870
More than two times	1	

Variables	AOR (95% CI)	P-value
Educational status		
Literate	0.836 (0.270-2.595)	0.757
Illiterate	1	
Marital status		
Married	0.512 (0.170-1.541)	0.234
Not married	1	

AOR: Adjusted odds ratio

5. Discussion

Recommending drugs for pregnant women is a great challenge for prescribers owing to the possibility of drugs side effects to the fetus. This would in turn be dependent on the amount and teratogenic nature of drugs used by pregnant women [1–3]. The prevalence of prescribed drug use during pregnancy in the current study was 91.15%. This value is relatively higher than the findings of other studies previously done in Ethiopia [13, 14]. This might be due to majority of the pregnant women in our study had received at least ferrous sulphate and there were high incidence of pregnancy related illnesses during the data collection period.

Almost half of the pregnant women visited the health center for ANC once throughout their entire pregnancy time and greater number of the pregnant women were multigravida. The findings are comparable with the previous study done in the Ethiopia [14], but it is somewhat different from another study done in the country at Fiche Hospital as the pregnant women came to the hospital 3-5 times for ANC visit and majority of the pregnant women were secundum gravida [6]. The observed different result may be attributed to the higher percentage of multigravida in the current study made the women to adapt pregnancy which may decreases the number of ANC visit. It may also be due to, pregnant women preferred hospitals and private clinics for other clinical cases.

The FDA category A drug prescribed for pregnant women was ferrous sulphate and it comprised 43.3% from total drugs prescribed. The study conducted in other health facilities of Ethiopia revealed that less number of category A drugs were prescribed [6]. The observed higher percentage of category A drug use in our setting may be due to prescriber routinely recommended minerals especially ferrous sulphate for pregnant women at their first ANC visits.

About 25% of drugs prescribed were FDA category B drugs. This finding is different from various study findings as it is relatively less compared to the observation made by various researches [1, 8, 14, 15], however, it is more than the finding of the study reported by other researcher [6, 11]. The majority of category B drugs were antibiotics includes amoxicillin, cephalixin, coartem, metronidazole and azithromycin, amoxicillin, cephalixin, coartem, metronidazole and azithromycin, mainly prescribed for infectious diseases.

Category C drugs prescribed in the health centers accounted 24.9%. Different kinds of drugs such as antibiotics, anti-pain, anti-ulcer, anti-emetics and anti-diabetic agents were prescribed from this category. Although similar trend was seen in the previous study done in Fiche Hospital, Ethiopia [6], it is somewhat higher than various studies done in Ethiopia and other parts of the world [8, 10, 11, 15]. Therefore, the prescribing pattern of potentially harmful drugs to pregnant women was comparatively high in the present study. This can be due to the wrong perception of category C drugs are safe during pregnancy.

About 3% of the drug used by pregnant women were category D drugs. Doxycycline and phenytoin were the two drugs used in this category. Various researchers reported comparatively less finding than the present study [1, 8, 10, 15]. On other hand it was reported that large numbers of category D drugs were prescribed in another study in Ethiopia [3, 6]. Use of drugs from this category is more risky than drugs from category C.

The use of doxycycline are inappropriate since it can cross the placenta and its use in second and third trimester causes permanent discoloration of teeth, enamel hyperplasia and impaired fetal skeletal growth. The second drug phenytoin also known to cause congenital malformations (including a pattern of malformations termed the “fetal hydantoin syndrome” or “fetal anticonvulsant syndrome”) in infants. Isolated cases of malignancies (including neuroblastoma) and coagulation defects in the neonate following delivery have also been reported [6, 8].

Only 0.24% the drug used in the health facilities were category X. FDA category X drug was prescribed only in first trimester of pregnancy and misoprostol was the only drug used by two pregnant women for abortion. Similar trend was seen in the previous study done in Ethiopia [6]. Misoprostol was used most extensively for first-trimester medical abortions. Another study in India reported that progesterone was used for threatened abortions, missed abortions and preterm labor in first and second trimesters [1]. However, various study in different part of the world

reported that no drugs were prescribed from category X [4, 8, 11, 14, 16]. The availability of prescription paper containing category D and X drugs in our setting may showed that the prescription habit in our set up was not quite safe.

WHO core prescribing indicators are useful parameters to assess the rationality of prescribing of medications. They are helpful in preventing polypharmacy, overuse of antibiotics, usage of costly forms of therapy, etc [16]. Average numbers of drugs per prescription was above the upper limit of the range in WHO core prescription [2, 4]. This might increase the chances of adverse reactions and/or drug-drug interactions in these women, which might be harmful for them as well as their baby. This value is also not in line with various study findings as it is higher compared to the study done in two health facilities in Ethiopia [6, 15], however, it is more than the finding of the study reported by other researchers [8, 1]). The higher value in our settings as compared to the result observed other health facilities (hospitals) of Ethiopia may be attributed to use of combination of antibiotics for empiric therapy as there is no culture testing method to identify the specific microorganism.

Majority of the drugs were prescribed by generic name although it doesn't meet the WHO standard value. Similar trend was seen in the previous study [6, 17]. However, in the other findings only less than 50% of the drug were prescribed generic name [8]. So the habit of prescribing by generic name in our settings is encouraging.

Percentage of encounters with antibiotics prescribed was higher than WHO core drug prescribing indicators and the previous study findings [8], which show over use antibiotics that may in turn increases antibiotics resistance in our settings. Percentage of encounters with an injection is less than the WHO standard and the previous study findings [6, 17]. The lower value in the current study may be attributed to the health centers may prefer referring the patients to the nearby hospitals than prescribing injectable drugs for critical cases.

Pregnant women with comorbid conditions were more likely to use prescribed drug than those without comorbidity. Similar findings were observed in the previous study done in different part of Ethiopia [13, 14]. This might be due to pregnancy increases acute or chronic illnesses that require medication therapy.

Primigravida pregnant women were more likely took prescribed drug as compared to Multigravida in the current study. This might be due to Primigravida pregnant women would not tolerated the common physiological changes and they promptly needed drug utilization. This finding is similar with a study conducted in Southern Tigray region [14] and in contrast to the study conducted in Bahir Dar city administration [13].

Pregnant women who had visited the health facility only one or two times were more likely to use prescribed drugs as compared to those who had more than two times visits. A similar trend of more drug prescription with decreased number of visits to the health facilities was observed in a study conducted in Southern Tigray region of Ethiopia and

Brazil [10, 14]. This may be attributed to the more frequent visits to the health facilities the patient will manage their health related problems non-pharmacologically as the health care providers have much time to counsel the pregnant patients. Contrast to the current study, there were more utilization of prescribed drugs by the pregnant woman with more frequent visits [18].

6. Conclusion

Although majority of the drugs used was safe and appropriate medications according to FDA risk classification system, the prevalence of prescribed medication use during pregnancy is very high in public health center of Wolkite town. Percentage of drugs (except ferrous sulphate) use during pregnancy is higher when the women were primigravida, when there were comorbid conditions and when pregnant women were unable to visit the health center more than twice. It is important to provide short term training for the health care givers on appropriateness of drug use during pregnancy and on institutional based prevention of comorbid conditions during pregnancy. Overuse antibiotics and polypharmacy in our setting should be given serious attention by prescribers as they may be the cause for increasing emergency of drug resistance, adverse drug reaction and drug-drug interaction.

7. Limitation of the Study

The main limitation of this study was only one institution based research even though the health center used as the main health care facility of the town for many years. We also did not examine non-prescribed medications and drugs dispensed by other health facilities like private clinics which might underestimate the prevalence of drug use by pregnant women.

List of Acronyms and Abbreviations

ANC: Antenatal Care
 FDA: Food and Drug Administration
 SNNPRS: Southern Nation Nationalities Region State
 US-FDA: United States Food and Drug Administration
 WHO: World Health Organization

Declarations

Ethics Approval and Consent to Participate

Before data collection ethical clearance was obtained from Wolkite University, college of medicine and health science, department of biomedical science. The letter was submitted to Wolkite Health center managerial office and ANC unite for permission.

Availability of Data and Materials

The data supporting the finding had attached to editorial

office if necessarily.

Author's Contribution

The authors contribute for this study is conducting and preparing the manuscript.

Competing Interests

Author declares that there is no competing of interest.

Consent to Publish

It is not applicable because the manuscript cannot contain individual person's data in any form (including individual's details images or videos).

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