Medications use among pregnant women in Ethiopia: A cross sectional study

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ABSTRACT

Despite lack of scientific evidence about the safety of some medications, the reported use of medications during pregnancies has increased. This may lead to adverse reproductive outcomes, due to potential risk to the mother and the fetus. In contexts of most developing countries including Ethiopia, it is difficult to elucidate medications use prevalence during pregnancy and their relative contributions to birth defects for several reasons. Institution-based cross sectional study was conducted in Tertiary care hospital Ethiopia. Current medication use data were collected by reviewing patients' charts in the antenatal care follow up clinic, chronic care (internal medicine) as well as psychiatry clinic and by interviewing pregnant women using semi-structured questionnaire. Medications were classified using the United States Food and Drug Administration pregnancy risk classification system. A total of 339 women were included in the study; of which 187 (55.2%) had used at least one prescription and 162(52.2%) had used over the counter medications during pregnancy. The majority of the medications were antibiotics (42.5%) and analgesics (40.1%). 57(16.8%) and 24(7.1%) of medications were prescribed from category D and X respectively. Out of 187 (55.2%) prescription medications used, 51 (15.0%) were obtained without prescribers order. Majority (70.8%) of the women did not have awareness regarding risks associated with self medication. Prescription medications use was 0.08 times less among women with a co-morbidities (AOR 0.08(.05, 0.13), p=0.001) and 2.5 times higher among women from rural areas (AOR 2.53 (1.15, 5.56); P=0.02). Compared to employed women, over the counter medications use were 1.9 times more among house wife women (AOR1.87 (1.12, 3.09), p= 0.02) and about thrice higher among merchant women (AOR 2.88(1.10, 7.55), p= 0.03). Likewise, presence of medical problems was found to have 60% protective against OTC medications use (AOR 0.40 (.26, 0.64), p=0.01). The overall medications use during pregnancy was found to be high. Medications use without prescribers order was common and potentially harmful medications (category-D and X) use appeared to be higher in all trimesters. The findings of this study argue in favor of prescribing some potentially harmful medications which could have been avoided during pregnancy. Majority of the women lacked awareness about the potential risks associated with medications use in pregnancy without prescribers order.

INTRODUCTION

Medications use during pregnancy has always created a challenge in antenatal care due to the potential foetal risk associated with the use (Kacew, 1994). Drug utilization studies reveal that most women use medications during pregnancy with estimations varying from 44% to 99% (Bakker *et al,* 2006). In relation to pregnancy complaints inappropriate use of medications by women has been widely reported in many developing countries (Bamgboye *et al,* 2006; Koren *et al,* 1998). and self-medication reported to be common among pregnant women due

to varieties of pregnancy related ailments such as back pain, headache, heartburn, nausea, vomiting, and hemorrhoids (Gibson *et al,* 2001; Pangle *et al,* 2006). But little is known about the types of medications prescribed and extent of prescribing during pregnancy in many countries (Haramburu *et al,* 2000; Andrade *et al,* 2004) and most studies did not distinguish the different reasons for which medications are prescribed and it is not clear what extent of medications use among pregnant women is due to chronic, occasional or pregnancy-related illnesses. use of some medications during pregnancy may result in serious structural as well as functional adverse effects in the developing child (Kasew, 1994; Adhikari *et al,* 2011) and in any case the fetus is most vulnerable to

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the negative consequences of irrational use of medicines during pregnancy (Gibson *et al*, 2001). In addition to malformations, medications may also influence fetal well being at other times. For instance, NSAIDs may impair fertility by interfering with ovulation, fertilization, and implantation (Norman, 2001) and their use during the last trimester has been associated with increased fetal risk (Balasubramaniam, 2000) such as premature closure of the ductus arteriosus (UpToDate 19.2, 2011). Frequent maternal use of paracetamol during pregnancy may be associated with wheezing and asthma in early childhood and an increase in fetal death or spontaneous abortion (UpToDate 19.2, 2011) may be seen following maternal overdose of paracetamol if treatment is delayed. The use of ACEI during pregnancy may cause prolonged fetal hypotension, renal tubular dysplasia, growth retardation, and death when used in the second and third trimesters of pregnancy (Saji *et al*, 2001). Little is known about drugs with central nervous system activity and their possible long-term effects on the developing brain (Mantovani *et al*, 2001). The potential long-term consequences of intrauterine exposure to some medications such as diethylstilboestrol emphasize the importance of studying medications exposure during pregnancy (De Jong-van den Berg et al ,1991). On the other hand, presence of chronic illnesses such as hypertension, Diabetes or other medical conditions lead to exposure to potentially harmful medication due a failure to balance the risk of not treating pregnant women with chronic conditions against exposing the foetus to unknown harm (Fakeye *et al*, 2009). As result, studies conducted in developed countries where drug-prescribing practices are considered to be better have identified need for interventional measures aimed at rational prescribing during the prenatal period (C.G.D.U.P, 1992; Yusuff *et al*, 2011). Thus, medications use by pregnant women should be viewed as a public health issue due to numerous gaps in knowledge about deleterious consequences of medications on the fetus (Beyens *et al*, 2003). This study is designed in view of the inconsistency and non-conclusive data available on medications and herbal medicines use during pregnancy in Ethiopia. We believe it will help health care professionals, pregnant women and policy makers by providing the magnitude of medications, and herbal medicine use during pregnancy in the hospital.

Aim of the study

The aim of this study was to evaluate the pattern of medications use in a tertiary hospital Ethiopia.

METHODS AND PARTICIPANTS

Study setting

Institution-based cross sectional study was conducted by reviewing the antenatal care follow up, chronic care (internal medicine) as well as psychiatry clinic patient charts and by interviewing pregnant women using semi-structured questionnaire. The Hospital has a bed capacity of 450 and it provides services for approximately 9,000 inpatient and 80,000 outpatient attendances a year from the catchment population of about 15,000 million. The

hospital has five departments that offer clinical residency (internal medicine, surgery, pediatrics, OBGY and ophthalmology) and other departments without residency program like psychiatry and dermatology departments. The ANC clinic gives service for about 2595 clients annually and has one nursing staff (diploma) and few medical interns and residents. The study population was pregnant woman attending the antenatal clinic, psychiatry clinic, ambulatory clinics and internal medicine ward (female medical wards) during the study period fulfilling the inclusion criteria (age 18 years and above; new Women who came for ANC and those who were already enrolled in routine ANC program; women who were treated for co-morbidities at psychiatry and chronic illness clinics and female medical ward and women who gave their consent to participate in the study). The sample size for this study was estimated based on the previous study done in similar setting with a prevalence of medication use during pregnancy to be 71.3%. As a result, the number of sample size required for this study with 5% non-response rate was calculated to be 339. Although all women who were on ANC follow up at the time of study was known, the exact number of pregnant women being treated at psychiatric clinic and internal medicine wards and ambulatory clinics was unknown. For this reason, all pregnant women who came during the study period were included until the sample size of 339 was reached

Data collection

A semi-structured Questionnaire was designed based on previously done studies and contextualized to fit for the setting. It included basic demographic details, number of drugs written in each order sheet, prescriptions and over the counter medications, supplements, relevant medical history, co-morbidities and common ailment, educational status, pre-conception and current substance use status and other factors associated with medications and supplements use during pregnancy. A face-to-face interview was conducted along with simultaneous review of medical charts. All the information about prescriptions, OTC medicines was collected from pregnant woman via interview and additional information was extracted from women's medical charts. The questionnaire was pre-tested to assess the clarity, sensitivity, reaction, interview time to the study instrument and logistic materials. Content and face validity of the questionnaire was checked by 2 clinical pharmacists and one gynecology resident using a structured response sheet covering item relevance, clarity and format. Correction was made based on their comments. The questionnaire was pre tested on 5% pregnant women to see the soundness of the questionnaire and to make necessary corrections prior to starting the study. Pregnant women included in the pre-test procedure were excluded from participating in the study to avoid information contamination. The data collection took place from Feb13- Mar 13, 2012.

Statistical analyses

The collected data was clearly categorized, entered in to computer, edited, cleaned, and analyzed using Statistical Package

for Social Sciences (SPSS) for Windows version 16. statistical tests such as chi-square tests, and Binary and multivariate logestic regression analysis was conducted to observe the association between the independent variables and each outcome variables (Prescription medications, Over the counter medications) and 95% confidence intervals (CI) was estimated and variables whose levels were statistically significant (P <0.05) on bivariate analysis were selected and entered jointly into a multivariate logistical regression model to identify the independent predictors of each outcome variables. Statistical significance was determined by back ward Wald test. Finally variables with significance P-value <0.05 were considered for the final model as an independent predictor.

Table. 1: Socio-demographic description of the pregnant women (n=339) Jimma University Specialized Hospital, Ethiopia February - March 2012

	Characteristics	Frequency (%)
Age	15-20	69(20.4%)
	21-30	224(66.1%)
	31-40	45(13.3%)
	41-50	1(0.3%)
Religion	Muslim	149(44.0%)
	Orthodox	135(39.8%)
	Protestant	49(14.5%)
	Catholic	6(1.8%)
Ethnic background	Oromo	196(57.8%)
	Amhara	57(16.8%)
	Gurage/silte	27(8.0%)
	Yem	16(4.7%)
	Tigre	20(5.9%)
	Others	23(6.8%)
marital status	Married	299 (88.2%)
	Single	21(6.2%)
	Widow	10(2.9%)
	Divorced	9(2.7%)
Educational level	Illiterate	107(31.6%)
	Elementary	140(41.3%)
	Secondary	50(14.7%)
	Higher institution	42(12.4%)
Occupation	Employed	94(27.7%)
	House wife	207(61.1%)
	Merchant	23(6.8%)
	Student	15(4.4%)
Place of residence	Urban	289(85.3%)
	Rural	50(14.7%)
Income level	<1000	163(48.1%)
	1000-1500	105(31.0%)
	>1500	43(12.7%)
	Unknown	28(8.3%)

RESULTS

Socio-demographic results

A total of 339 pregnant women included in the study and all of them consented and completed the interview. Majority 224 (66.1%) of the women were in the age group of 21–30 years with the mean age of 25.28±4.9 years. Two hundred ninety nine (88.2%) of the respondents were married and 207 (61.1%) were found to be housewives. Hundred forty-nine (44.0%) of the women were Muslims followed by orthodox Christians135 (39.8%). Majority 196(57.8%) of the respondents were Oromo, followed by Amhara 57 (16.8%) and the remaining were from other Ethnic background. Two hundred ninety eight (85.3%) of the respondents live in urban areas and nearly half 163(48.1%) had an

income level of <1000ETB per month. Nearly one third 107(31.6%) of the women were illiterate while only 42 (12.4%) had higher institution education (Table1).

Pregnancy related information

Out of 339 total women, 50.1% were nullipara and the remaining 49.9% had 2.44 ±1.22 previous pregnancies and 2 children (1.6±0.71) on average. Out of all current pregnancies, 69(20.4%) of it was teenage pregnancies occurred in women age between 15 and 20 years and more than half 195(57.5%) of pregnancies was also found to be unplanned.

Nearly half 164(48.4%) of the women did not notice their pregnancy within 8 weeks after their LMP and 76(22.4%) of the women did not use any family planning methods but of the women who used family planning methods, larger proportion 131(38.6%) used implants followed by birth control pills 71(20.9%). Of total women interviewed, over half 183(54.0%) were in their third trimester of pregnancy. Of total women, 47(13.9%) had a history of previous adverse pregnancy outcome, of which cleft palate 30(63.8%) was the commonest among others. Out of 339 women, 31.3% drink alcohol and 4.7% were found to be smokers. (Table2).

Table. 2: Pregnancy Related Information of Pregnant Women (n=339) Jimma University Specialized Hospital, Ethiopia February - March 2012.

Pregnancy information		Frequency (%)
Pregnancy stage	First trimester	56(16.5%)
	Second trimester	89(26.3%)
	Third trimester	194 (57.2%)
Parity	Nuli-para	170(50.1%)
	1-3 children	124(36.6%)
	more than 3 children	45(13.3%)
Current pregnancy planning status	Planned	144(42.5%)
	Unplanned	195(57.5%)
Family planning methods used	Condoms	25(7.4%)
	birth control pills	71(20.9%)
	depo provera/implant	131 (38.6%)
	other methods	16(4.8%)
	Mixed	20(5.9%)
Cigarette smoking status during pregnancy	Yes	16(4.7%)
	No	323(95.3%)
Alcohol drink status during pregnancy	Yes	106(31.3%)
	No	233(68.7%)
History of adverse pregnancy outcome	Yes	47(13.9%)
	No	292(86.1%)
Types of adverse pregnancy outcome	down syndrome	4(1.2%)
	cleft lip/ palate	30(8.8%)
	neural tube defect	6(1.8%)
	cardiac defect	6(1.8%)
	more than one/ mixed	1(0.3%)

Medications use pattern during pregnancy

Excluding supplements and vaccination, 187 (55.2%) and 162(52.2%) of the pregnant women had used at least one POM and OTC medications respectively during the current pregnancy.

The average number of medications consumed was 1.5 ± 0.5 for OTC and 1.6± 0.5 for POM per pregnant women. Out of 187 (55.2%) prescription medications used, 51 (15.0%) were obtained without prescribers order. Higher proportion 238(70.2%)

of pregnant women used POM in the 2-4 weeks pre pregnancy period than 187(55.2%) during pregnancy. Increase in POM use across trimester was observed from 36(19.2%) in the first trimester to 50(26.7%) in the second and 101(54.0%) third trimester of pregnancy. Nearly two-third 218(64.3%) of pregnant women had used OTC medications in the 2-4 weeks pre pregnancy period and almost half 162(47.8%) had used OTC medications during pregnancy. the highest 98(60.5%) OTC medications use during pregnancy was observed in the third trimester of pregnancy than other trimesters. Majority 240 (70.8%) of the women did not have awareness regarding risks associated with self medication. Prescription and over the counter medications use during pregnancy did not show significant association with pregnancy stage (Table 3).

US-FDA pregnancy risk classification of drugs

Majority 191(56.3%) of medications used were from category-C followed by category-B 165(48.7%) and category-A (35.4%). Of the total medications used during pregnancy 57(16.8%) and 24(7.1%) were from category D and X respectively whilst 49(14.5%) of medications did not have a category as per the USFDA risk classification system. Out of all categories only category-A showed significant association with pregnancy stage of the women and thus, women in their second trimester of pregnancy used over thrice times more category-A medications compared to those in their third trimesters (Table 4).

The most commonly used medications were antibiotics (42.5%) and analgesics (40.1%), antacids (14.5%), asthma medications (12.1%). antihelmetics (9.7%), and antimalaria drugs (9.4%).The commonly used pregnancy risk category-D medications include 12(3.5%) Atenolol, 39(11.5%) flouroquinolones, 35(4.4%) tetracycline, 9(2.7%) Efavernez, and 3(0.9%) AEDs combinations (valporoic acid, phenobarbitone, phenytoin, carbamazepine). Category-X medications 19(5.6%) statins and warfarin; were also the most common among others

Bivariate Logistic regression analysis was conducted to explore women who were more likely to have used Prescription as well as over the counter medications of any type during pregnancy. Demographic factors (age, marital status, education, income, occupation, residency and pregnancy related factors (parity, History of adverse pregnancy outcome, presence of co-morbidities as well as current pregnancy planning status and previous abortion history) were each tested against the outcome variables (POM and OTC medications) use during pregnancy. Most of the variables did not show significant association with

POM use except place of residence (COR 1.89(0.99, 3.57); p=0.05), history of adverse pregnancy outcome (COR 0.33(0.17, 0.63); p=0.001) and presence of co-morbid conditions (COR 0.08(.045, .13) p=0.001). On the other hand, among all variables only occupation (p=0.01) and presence of co-morbid conditions (COR 0.42 (.27, 0.65); p=0.001) was found to have association with OTC medications use during pregnancy (Table 5).

Although age of the women did not show association with POM use, the variation across the age group showed that, women who were slightly younger (15-20 years of age) took about 1.5 times more POM compared to those in the age group between 31-50 years of age. In contrast to POM, the utilization of OTC medication was slightly higher in the age group between 21-30 years of age. Women in the second trimester of their current pregnancy were about 1.7 and 1.6 times higher to use POM and OTC medications compared those who were in their third trimester of pregnancy respectively. The utilization of both POM and OTC was found to be 1.45 and1.51 times higher among women in their secondary educational level compared to those in the tertiary level. Compared to nulli para women, those who have had more than 3 children were found to be slightly more prescription but less OTC medications users (Table 5).

Multivariate logistic regression was performed for variables that showed significant association during bivariate analysis with Prescription and over the counter medications use. The variables that were included in the final analysis for POM were place of residency (urban or rural), history of adverse pregnancy outcome and presence of medical problems. Results of this analysis showed that prescription medication use was about 0.08 times less among women with a co-morbidities (AOR 0.08(.05, 0.13), p=0.001) and women from rural areas were about 2.5 times higher to use POM (AOR 2.53 (1.15, 5.56); P=0.02).

Similarly, occupation and presence of medical problems were the final variables included in the analysis for OTC medications use and thus, the results showed that house wife women were about 1.9 times more in using OTC medications (AOR1.87 (1.12, 3.09), p= 0.02) compared to employed women and merchant women were about thrice more to take OTC medications (AOR 2.88(1.10, 7.55), p= 0.03) compared to employed women.

Likewise, presence of medical problems in the pregnant women was found to have 60% protective against OTC medications use (AOR 0.40 (.26, 0.64), p=0.01). No other variables were found to be independently associated with OTC, or prescription medications use in the multivariate analysis (Table 7).

Table. 3: Prescription and over the counter medications used by pregnant women Jimma University Specialized Hospital, Ethiopia February - March 2012.

Medications and herbs used	2-4 weeks pre pregnancy (N=339)	Pregnancy stages			
		First trimester	Second trimester	Third trimester	P-value
POM (n*=187)	238(70.2%)	36(19.2%)	50 (26.7%)	101 (54.0%)	0.26
OTC (n*=162)	218(64.3%)	29(17.9%)	35(21.6%)	98(60.5%)	0.18

n*= number of women who took POM, OTC, Supplements and Herbal Medicine during pregnancy. Pearson X^2 P-value

Table. 4: US-FDA pregnancy risk class of medications vs pregnancy stage of the women.

Pregnancy stage	FDA Category								
	A			B			C		
	n(%)	COR* 95% CI	P-Value	n(%)	COR 95%CI	P-Value	n(%)	COR95%CI	P-Value
1st Trimester	11(19.6%)	1.96(1.14,3.36)	0.02#	23(41.1%)	1.36 (0.82,2.25)	0.23	32(57.1%)	1.3(0.79,2.16)	0.30
2nd Trimester	25(28.1%)	3.12(1.52,6.40)	0.01#	40(44.9%)	1.59 (0.87,2.91)	0.13	46(51.7%)	1.05(0.57,1.91)	0.88
3rd Trimester	84(43.3%)	1		102(52.6%)	1		113(58.2%)	1	

Table. 4: Continued…..

	D			X			Unclassified		
	n(%)	COR* 95% CI	P-Value	n(%)	COR* 95%CI	P-Value	n(%)	COR* 95%CI	P-Value
1st Trimester	9(16.1%)	1.46 (0.72,2.97)	0.29	4(7.1%)	1.08 (.39,2.89)	0.89	9(16.1%)	.96(.46, 1.93)	0.88
2nd Trimester	12(13.5%)	1.19(.54, 2.65)	0.67	6(6.7%)	1.01 (.312,3.20)	0.99	13(14.6%)	.84 (.37,1.92)	0.69
3rd Trimester	9(16.1%)	1		14(7.2%)	1		27(13.9%)	1	

*COR=Cruds odds ratio; # statistically significant values.

Table 5: Binary logistic regression for Prescription and Over the Counter medications use during Pregnancy vs women's characteristics Jimma University Specialized Hospital, Ethiopia February - March 2012.

Women's characteristic	POM			OTC		
	N(%)	COR* (95%CI)	P-Value	N(%)	COR* (95%CI)	P-Value
Age						
15-20	36(52.2%)	1.48(.78, 2.79)	0.226	32(46.4%)	0.99(.52, 1.86)	0.96
21-30	129(57.6%)	1.19 (.56,2.51)	0.648	108(48.2%)	1.06 (0.50, 2.24)	0.88
>30	22(48.9%)	1		22(47.8%)	1	
Educational						
Illitrate	64(59.8%)	1.38 (0.61,3.15)	0.443	46(43.0%)	1.42 (0.62, 3.24)	0.40
Elementary	73(52.1%)	1.09 (.55,2.17)	0.807	70(50.0%)	1.21 (.61, 2.42)	0.59
Secondary	29(58.0%)	1.49(0.73,3.05)	0.278	23(46.0%)	1.61 (.78 ,3.29)	0.19
Tertiary	21(50.0%)	1		23(54.8%)	1	
Marital						
divorced	5(55.6%)	1		4(44.4%)	1	
Widow	4(40.0%)	0.99 (.26, 3.79)	0.99	5(50.0%)	.89(.23, 3.36)	0.86
Single	12(57.1%)	1.07(.22, 5.15)	0.94	11(52.4%)	.73(.15, 3.49)	0.69
Married	166(55.5%)	.53 (.09, 3.31)	0.50#	142 (47.5%)	.80 (.13, 4.87)	0.81
Occupation						
Employed	49(52.1%)	1		56(59.6%)	1	
House wife	117(56.5%)	1.19 (.73, 1.95)	0.478	91(44.0%)	1.88 (1.15, 3.08)	0.01
Merchant	11(47.8%)	0.84 (.34, 2.09)	0.712	9(39.1%)	2.29 (.90, 5.83)	0.08
Student	10(66.7%)	1.84(.58, 5.79)	0.299	6(40.0%)	2.21 (.73, 6.72)	0.16

*COR=cruds odds ratio; #statistically significant value.

Table. 5: Continued….

Characteristics	N(%)	COR* (95%CI)	P-value	N (%)	COR*(95%CI)	P-value
Residency						
Urban	153(52.9%)	1		139(48.1%)	1	
Rural	34(68.0%)	1.89(.99, 3.57)	0.051	23(46.0%)	1.09 (.59,1.99)	0.78
Income/month						
<1000	90(55.2%)	1		69(42.3%)	1	
1000-1500	59(56.2%)	0.58 (.25,1.37)	0.22	56(53.3%)	1.04 (.64, 1.71)	0.88
>1500	19(44.2%)	0.61(.25, 1.47)	0.27	28(65.1%)	0.64 (.33, 1.26)	0.19
Unknown	19(67.9%)	0.38(.14, 1.02)	0.06	9(32.1%)	1.71 (.73, 4.01)	0.22
Pregnancy stage						
1st trimester	36(64.3%)	1.18 (.71,1.96)	0.52	29(51.8%)	0.95 (.52,1.72)	0.08
2nd trimester	50(56.2%)	1.66(.896, 3.07)	0.11	35(39.3%)	1.58(.95,2.62)	0.87
3rd trimester	101(52.1%)	1		98(50.5%)	1	
Parity						
Nulli-para	99(58.2%)	1		77(45.3%)	1	
1-3 children	63(50.8%)	0.74 (.465, 1.18)	0.21	62(50.0%)	0.52 (1.32,.83)	0.83
>3 children	25(55.6%)	0.89 (.46, 1.74)	0.75	23(51.1%)	0.41(1.529,.79)	0.79
Comorbidity						
Yes	33(22.8%)	0.08(.045,.129)	0.001	87(60.0%)	0.42 (.27, .65)	0.001
No	154(79.4%)	1		75(38.7%)	1	
Adverse Pregnancy outcome						
Yes	15(31.9%)	0.33(.17,.63)	0.001	24(51.1%)	0.86(.46, 1.59)	0.63
No	172(58.9%)	1		138(47.3%)	1	
Pregnancy planning						
Yes	77(53.5%)	1		75(52.1%)	1	
No	110(56.4%)	1.13(.73,1.74)	0.59	87(44.6%)	1.35(.88, 2.08)	0.17
Abortion History						
Yes	43(50.6%)	0.78 (.48,1.28)	0.33	40(47.1%)	1.04 (.64, 1.70)	0.88
No	144(56.7%)	1		122(48.0%)	1	

Table. 6: Independent predictors for Prescription and Over the Counter medications use during pregnancy Jimma University Specialized Hospital, Ethiopia February - March 2012.

	Variables	COR* (95% CI)	P-Value	AOR**(95% CI)	P-Value
POM	**Co-morbidities**				
	Yes	0.08 (.05,.13)	0.001	0.08 (.05,.13)	0.001[#]
	No	1		1	
	Residency				
	Urban	1		1	
	Rural	1.89(.99, 3.57)	0.05	2.53 (1.15,5.56)	0.02[#]
OTC	**Co-morbidities**				
	Yes	0.42 (.27, .65)	0.001	.406(.26,.64)	0.01[#---]
	No(Ref)	1		1	
	Occupation				
	Employed	1		1	
	House wife	1.88 (1.15, 3.08)	0.01	1.87(1.12,3.098)	0.02[#]
	Merchant	2.29 (.90, 5.83)	0.08	2.88(1.10,7.55)	0.03[#]
	Student	2.21 (.73, 6.72)	0.16	1.94(.62,6.04)	0.25

*COR=Cruds Odds ratio; **AOR= Adjusted Odds ratio; # statistically significant values.

DISCUSSION

In our study, interviews were held before pregnancy outcome is known, so as to minimize recall bias. Several studies have showed that women commonly use medications during pregnancy though there are concerns regarding the potential effects of any medications taken during pregnancy (Headley *et al*, 2004; Bonati *et al*, 1990). Hence**,** information regarding the safety of medications use in pregnancy has always been a concern for healthcare providers. It is apparent from several studies conducted on medications use during pregnancy that there is a variation in medications use between countries, inconsistency of the methodologies (prescription collection, interview, chart review) and health care settings where these studies conducted and variations in prescribing practices between developed and developing countries (Rohra et al ,2008; Al-Humayyd *et al*, 2006; CGDUP, 1992). Moreover, the analysis of medications used in most studies has been done based on various risk classification systems. This all variations make comparison of our results with other studies difficult.

Our findings showed that out of 339 total pregnant women, 55.2% and 52.2% had at least one POM and OTC medications during pregnancy with the average number of 1.6±0.5 POM and 1.5±0.5 OTC medications respectively. Majority 194(57.2%) of the women who received these medications were in their third trimester of pregnancy. The prevalence and average number of medications used in the present study is comparable with the results of the study done in South Africa (59.3%), Pakistan, Palestine(56%), Egypt(86%) and USA(Sawalha, 2007; Rohra *et al*, 2008; Rubin *et al*, 1993; Rizk *et al*, 1993; Aviv *et al*, 1993). Our study demonstrated that the number of women taking POM increased across the trimesters and thus an increased trend of POM use across trimester was observed from first19.2% (n=187), to 26.7 %(n=187), and 54.0% (n=187) second and third trimesters respectively. Similarly, an increased in OTC medications use across trimester was observed from 17.9% (n=162), to 21.6% (n=162) and 60.5% (n=162) in the second and third trimesters of pregnancy. The increased use of both POM and OTC across trimesters could possibly be due to the fact that over half

194(57.2%) and one fourth 89(26.3%) of respondents in our study were in their third and second trimester of pregnancy respectively. The increase in trend of medications use across trimesters of pregnancy was also reported by studies done in Ethiopia and Pakistan (Kebede *et al*, 2009; Rohra *et al*, 2008).. Higher proportion of category-D medications use was observed in the third (18.6%) and first (16.1%) trimesters compared second (13.5%) trimester of pregnancy. Similarly, category-X medications use was higher in the third (7.2%) and first (7.1%) trimesters than second (6.7%) trimester of pregnancy. In the present study the proportion of category-D, X as well as unclassified medications use was found to be higher. Medications without risk class could be due to the fact that some medications are either not approved by the FDA or they have not been given a category yet, this is because some medications that are marketed and approved in any other place outside the USA may not have an American approval or classification. There are reports of potentially harmful medications use during pregnancy (category D drugs-1.5% to 4.8% and category X drugs 0.2 to 4.6%) both from developed and developing countries. compared to our findings these studies reported a lower prevalence of both category D and X medications use during pregnancy (Andrade *et al*, 2004; Sawalha, 2007; Rubin *et al*, 1993; Rizk *et al*, 1993; Aviv *et al*, 1993; Al-Riyami *et al*, 2011; Kebede *et al*, 2009; Linda *et al*, 2010; Riley *et al*, 2005). This inconsistency in the results could be due to methodological differences, types of medications analyzed, differences in the health-care settings, and variation in awareness level of pregnant women as well as educational level of prescribers. But similar to our finding, a study in Bratislava and Nitra (Tisonova *et al*, 2006) reported higher prevalence of category-C class medications during pregnancy than other classes and a comparable result of unclassified medications use prevalence in pregnancy was also reported by Linda et al (2010). Most of category-D and some Category-X medications identified in the present study might put a women and or her fetus at a higher risk. For instance, several studies revealed that anticonvulsants use during pregnancy are proven to cause cranial and cardiac defects, fatal hemorrhage, cleft palate and neuronal tube defects; exposure to warfarin may result

in embryopathy (nasal dysplasia, limb hypoplasia) in the first trimester, fetal hemorrhage, and CNS abnormalities (ventral midline dysplasia, dorsal midline dysplasia) in the second and third trimesters of pregnancy. On the other hand, ACEI may bring about oligohydraminos (deficiency on amniotic fluid), acute renal failure(pre-renal azotemia), fetal limb contractures, craniofacial deformation, and hypoplastic lung development (Cunningham *et al,* 2005; Briggs *et al,* 2005; McElhatton, 2003). Exposure to diazepam in the first trimester may result in congenital abnormalities in the fetus while third trimester exposure may result in neonatal withdrawal syndrome (Linda *et al,* 2010; Briggs *et al,* 2005). Though the use of many of the category D and X medications identified in our study seem to put pregnant women or her fetus at higher risk, some medications like anticonvulsants and PTU can be prescribed with careful considerations if the benefits of use in mother outweigh the potential risk to fetus (UpToDate 19.2, 2011). But other medications like ciprofloxacilline, tetracyclines and warfarine could have been replaced by safer medications in pregnancy such as penicillins, cephalosporins and heparins. In the present study, antibiotics (42.5%) and analgesics 40.1% (of which 35.9% paracetamol, 4.1% opioids and 2.1% Aspirin), antacids (14.5%) and asthma medications (12.1%) were the commonest among others. The higher prevalence of antibiotics identified in the present study imply the presence of higher prevalence of infectious diseases than others. In line with our result, Riley et al reported that antibiotics(62%), analgesics (18%), and asthma medications (18%) were among the most commonly used medications during pregnancy (Riley *et al,* 2005). Similarly, a study done in South Africa (analgesics 37%,) and Egypt (analgesic 41.8%) have showed comparable results with the present study (Rizk *et al,* 1993; Aviv *et al,* 1993).   On the other hand, on the top of their easily accessibility, lack of appropriate medications counseling by health care providers may create the impression that OTC medications are safely used during pregnancy without medical supervision like any other times. However, some OTC medications may result in potential adverse pregnancy outcomes if used at certain stages of pregnancy. For instance, NSAIDs like Aspirin especially in the last trimester may result in premature closure of the ductus arteriosus. Frequent maternal use of paracetamol during pregnancy may be associated with wheezing and asthma in early childhood and an increase in fetal death or spontaneous abortion may be seen following maternal overdose of paracetamol if treatment is delayed. Moreover, paracetamol use close to delivery may result in prenatal constriction of the ductus arteriosus (UpToDate 19.2, 2011). So, health care providers should always be aware that pregnant women may be at a potential risk of practicing self medication with OTC even POM medications, and need to regularly asses about their safe use and counsel against any medications use during pregnancy without medical supervision and discontinue some   OTC medications like Aspirin and paracetamol prior to delivery if any. Unlike to most other studies, while only less than one third (29.2%) of the women have claimed awareness about medications, it is worrying that out of all

medications used in the present study about 2.4% of tetracycline, 3.5% of floroquinolones, 13.6% of amoxicillin, 1.2% of metronidazole, 5% of chloroquine, 3.2% of quartem, 31.% of paracetamole and 8% of NSAIDs were obtained by women without prescribers order. On the other hand, only 15% and 18.3% of the women have received advice about medications from clinics and pharmacies respectively. Similar to our finding, Rizk MA et al (1993) reported majority (86%) of the participants had used medications during pregnancy without seeing doctors . likewise Adhikari A et al (2011) reported that 71% of the pregnant women used medications without prescribers order. In this study, it was found that presence of medical conditions and place of residence were found to be the independent predictors for POM use and thus the risk of POM use in women with co-morbid conditions and those from rural areas were 0.08 and 2.5 respectively. No any study was found in the similar settings to compare this results with but opposed to our finding a study done by Bercaw J et al (2010) revealed that POM use was over twice as high among women with co-morbid conditions. This inconsistency is may be due to the fact that, unlike the women in our study who presented with single co-morbidity and co-morbidity for which drug treatment was not required during our study period, the presence of multiple co-morbid conditions might have put the women to higher POM use in Bercaw J et al (2010) study. From our finding, it seems that women in rural areas were more exposed to POM which could be due to poor counseling by health care providers, weak control of POM in rural areas or easily accessibility of POM outside pharmacies/drug venders in those areas.   Similarly merchant and house wife women were about twice and thrice risk of practicing self medication with OTC drugs compared to employed women. The higher risk of OTC use observed in merchant women may be related to their job nature where they carry OTC medications such as anti pain, medications for dyspepsia etc because they may not see prescribers as they are frequently on trip. But the higher risk of OTC use in house wife women may be related to either awareness level or lack of resources for proper medical care. On the other hand, presence of co-morbid conditions was found to have a 60% protective effect against self medications with OTC drugs. This may be due to frequent counseling against OTC medications use by health care givers when the women come for regular follow up of co-morbid conditions checkups or refills.

CONCLUSION

Researches on medications use pattern especially in pregnancy is a neglected topic although it is of immense importance. The use of overall medications in this study was found to be high during perinatal as well as antenatal period. In this study POM and OTC medications use without prescribers order was common and potentially harmful medications (category-D and X) used appeared to be higher across all trimesters. The findings of this study argue in favor of prescribing some potentially harmful medications which could have been avoided during pregnancy.

Majority of the women lacked awareness about the potential risks associated with self selection of medications during pregnancy. It is essential for healthcare providers to acquire the latest evidence regarding the potential benefits or harm associated with medications use during pregnancy to recommend or prescribe any medications only after carefully considering evidences supporting the use during pregnancy. Further researches need to be done to further clarify the safety of medications.

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