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Antenatal drug consumption: the burden of self medication in a developing world setting

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Title

Antenatal drug consumption: the burden of self medication in a developing world setting

Short title

Antenatal self medication

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Abstract

This institutional-based cross sectional study examines the burden of self medication during pregnancy in a middle-income country setting and the impact on fetal wellbeing. Using a blend of open-ended and indication-oriented questionnaires, 346 pregnant women at term were interviewed about their pregnancy complaints and drug intake. Inferential statistical data analysis was employed with level of significance (α) set at 0.05. Excluding routine supplements and vaccinations, 251(72.5%) women used medicines out of whom 79(31.5%) had self-medicated. Consuming drugs without prescription was associated with increased US Food & Drug Administration (FDA) risk category ($\chi^2 = 8.375$; $p = 0.015$). There is therefore a need to scale-up efforts towards educating women about dangers of self-medication, whilst also introducing effective restrictive policies on over-the-counter drug sales.

Keywords: Pregnancy, medical complaints, self-medication

Introduction

Since the tragedy of thalidomide[1], the need for rational prescription and cautious consumption of drugs during pregnancy is well understood [2]. As a guide to prescribers, drugs used in pregnancy have been classified according to risk categories [3-5]. Nonetheless, inappropriate drug use by pregnant women in low- and middle income countries (LMICs) persists and self-medication is frequent [6,7]. There is a dearth of information as to what propels pregnant women to self-medicate, the pattern of drug use, the extent of self medication and its impact on fetal development.

Methods

Our study was conducted at the department of Obstetrics and Gynaecology, Ekiti State University Teaching Hospital (EKSUTH), Ado-Ekiti, Nigeria between April 1 and July 31, 2014. EKSUTH is a tertiary health facility located in the capital city of Ekiti State, southwest Nigeria and serves as the referral centre for high risk pregnancies and complicated labour. Its average annual pool of antenatal attendees is 3,600 and the hospital delivery rate is 2,500 per year.

Permission for the conduct of the study was sought and obtained from the Ethics Committee of EKSUTH. An estimation of sample size was calculated using a previous report of 71.3% prevalence of medication use among pregnant women[8]. With a 10% allowance for non-response, an acceptable error margin of 0.05, a standard normal deviate of 1.96 and 95% level of confidence, it was calculated that 346 participants would be needed to power the study adequately. All eligible pregnant women (gestational ages of 37-42 weeks) booked for antenatal appointments, who gave an informed written consent to participate in the survey, were sequentially recruited until the required sample size was reached.

An interviewer-administered, semi-structured questionnaire was used for data collection concerning drugs consumed by the women during their pregnancy. The questionnaire was developed from previous studies and was specifically conceptualized to fit the study setting. It had 3 sections - information on biodata of respondents, modified treatment indication-oriented questions (based on 24 common pregnancy disorders which included malaria because of its peculiarity to the study

setting) and, sets of open ended questions as recommended by the Collaborative Group on Drug Use in Pregnancy [9,10].

The developed questionnaire was pre-tested in the antenatal clinic for content validity and clarity prior to commencement of the study. Based on feedback from the pre-test, appropriate corrections were made to the questionnaire. Pregnant women used for the pre-test were however excluded from participating in the actual study to avoid data contamination. Interviewers were resident doctors purposely trained for the study. Since all antenatal attendees are routinely on iron and folic acid supplements owing to subsisting high prevalence of anaemia in pregnancy in the study region, haematinics and regular vaccinations were excluded from the drug consumption survey.

Drugs used by participants were categorized according to the FDA risk classification [3] [i]. Drugs consumed were also grouped as prescribed by a health practitioner or bought over-the-counter (OTC). Information about drug consumption was obtained at interview, but additional information was extracted from respective medical files. The number of times in which a drug was either purchased based on prescription or for self-medication was noted.

The collected data was entered into computer software, Statistical Package for Social Sciences (SPSS) version 17. The data was cleaned and analyzed using both univariate and multivariate statistical methods. Frequency tables were generated to reflect the socio-demographic characteristics of respondents, the common complaints during pregnancy and medicine used by the pregnant women based on FDA classification. Chi square (χ^2) was used to test for association between OTC drug purchase and increased FDA risk category. Logistic regression analysis was equally employed to identify socio-demographic factor(s) that predicts self-medication through OTC drug purchase. The level of significance (α) was set at 0.05.

Results

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FDA Risk category	*Description*
A	Adequate and well-controlled studies have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of risk in later trimesters)
B	Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women
C	Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks
D	There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks
X	Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits

As presented in Table 1, of the 346 women interviewed, 131 (37.9%) were nulliparous. Only 78 (22.5%) had the index pregnancy unplanned.

Table 2 displays the overall pattern of complaints by study participants; this prevalence was 272/346 (78.6%). Fever topped the list, occurring in 179 (51.7%) of respondents; next was the complaint of oedema by 69 (19.1%) followed by headache in 56 (16.2%). Vaginal discharge was reported among 49 (14.2%) and 30 (8.7%) complained of anorexia or vomiting. Whereas none of the participants had epilepsy, 2 (0.6%) were diabetic and 8 (2.3%) had hypertension in pregnancy.

Excluding routine haematinics (iron and folic acid supplements) and vaccinations, the prevalence of use of medications by respondents was 251/346 (72.5% of the total number of respondents, but 92.3% of those who had complaints). Of the medication consumed, 172 (68.5%) were based on prescription by health practitioners while 79 (31.5%) were by OTC purchase.

Details of drugs consumed according to risk category are shown in Tables 3 & 4. The consumption of drugs with increased FDA risk category was significantly greater for OTC medications ($\chi^2 = 8.375$; $p = 0.015$). No socio-demographic predictors were statistically significant.

Discussion

Our study shows that more than 75% of our respondents had medical and/or gynaecological complaints during their pregnancy, the commonest being fever as in available local reports[11,12]. Although endemicity of malaria in our region supports the recommendation of routine antenatal administration of intermittent preventive therapy (IPT) [13], it is worrisome that fever is assumed to be due to malaria, often with no testing, and OTC medication taken inappropriately.

Our study noted that four of the 41 different drugs consumed are classified as risk Category D. Most of these were purchased OTC. Although the one respondent who purchased Tinidazole stated that it was not used during the first trimester, this drug is tagged Category X if consumed then. Some of the Category D drugs used by study participants are recorded as being responsible for craniofacial abnormalities,

oligohydraminous, ototoxicity, nephrotoxicity, fetal withdrawal syndromes, in the fetus [14,15].

Self-medication by approximately a third of our respondents is quite alarming but not surprising in an environment with poor drug sales regulation. In fact, in Nigeria, virtually all drugs can be procured without prescription. This situation may not be peculiar to Nigeria alone, as a 28.8% prevalence of self-medication during pregnancy was reported in South Africa and 52.2% in Ethiopia [7,16].

Our study found that self-medication is associated with increased risk to the fetus. An earlier African study came to the same conclusion [7]. This suggests a need to tighten policy on OTC drugs while at the same time scaling up education of women concerning drug safety during pregnancy.

Without doubt, interview studies are characterized by inherent memory lapses and under-reporting; thus under-estimation of drug consumption is likely. Furthermore, many respondents were uncertain concerning the exact timing of consumption of OTC drugs, obviously important regarding first trimester category X drugs.

In conclusion, OTC drugs need strict controls and the sale of medication of category D and X to pregnant women should carry a legal penalty.

Ethical considerations

This study was carried out in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki)

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Conflict of interest: The authors report no conflict of interest.

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Table 1: Socio-demographic variables (n=346)

Variables	n (%)
Age	
≤20	5(1.4)
21-30	172(49.7)
31-40	167(48.3)
≥41	2(0.6)
Marital status	
Single	20(5.8)
Married	326(94.2)
Education status	
Primary	44(12.7)
Secondary	107(30.9)
Tertiary	195(56.4)
Parity	
0	131(37.9)
1-2	186(53.8)
3-4	27(7.8)
≥5	2(0.6)
Pregnancy planned?	
Yes	268(77.5)
No	78(22.5)

Mean age: 30.61±4.46

Table 2: Common complaints during pregnancy

[#]**Complaints**	**n (%)**
Asthma	3(0.9)
Anorexia/Vomiting	30(8.7)
Breathlessness	3(0.9)
Cold/Flu	16(4.6)
Cough	28(8.1)
Dermatological disorders	3(0.9)
Diabetes	2(0.6)
Diarrhoea	6(1.7)
Epilepsy	0(0)
Fatigue/Malaise	15(4.3)
Haemorrhoids	8(2.3)
Headache	56(16.2)
Heartburn	12(3.5)
Hypertension	8(2.3)
Imminent miscarriage	4(1.2)
Insomnia	6(1.7)
Malaria fever	179(51.7)
Nervousness	2(0.6)
Constipation	2(0.6)
Oedema	66(19.1)
Pains	13(3.8)
Urinary tract infections	11(3.2)
Vaginal infections	49(14.2)
Other infections	4(1.2)

[#]multiple complaints allowed

Table 3: US-FDA risk category of medicines consumed during pregnancy

Risk category	Medicines (Prescribed : OTC)	Total drug consumption, n=324	Type of medicine per risk category, n=41
A			
B	Methyldopa (3:1); Amoxicillin (6:2); Ampicillin/cloxacillin (0:2); Ampicillin/Clavulanic acid (2:2); Cimetidine (1:0); Erythromycin (3:0); Metronidazole (5:1); Nevirapine (3:0); vaginal Nystatin (3:0); Paracetamol (48:24); Azithromycin (0:1); Cefuroxime (1:1); Proguanil (1:0); Nitrofurantoin (1:0); Chlorpheniramine (4:2); Insulin (2:0); Hydroxyprogesterone (1:0)	120(37.0%)	17(41.5%)
C	Artesunate (30:10); Anusol suppository (1:0); Promethazine (4:1); Camoquine (1:0); Chloroquine (7:6); Ciprofloxacin (2:0); Clotrimazole pessary (6:4); *Cough mixture (10:3); [+]Sulphadoxine/pyrimethamine (76:9); Antacid (4:2); Lamivudine (3:0); Zidovudine (3:0); Hydrocortisone (1:0); Nifedipine (1:2); Quinine (1:1); Tramadol (2:0); Salbutamol (1:1); Prednisolone (1:0); Dexamethasone (3:0); ±Tinidazole (1:0)	197(60.8%)	20(48.8%)
D	Bromazepam (2:2); Acetylsalysalic acid (0:1); Doxycycline (1:0); Streptomycin (0:1);	7(2.2%)	4(9.8%)
X			
Uncertain			-

*Cough mixture contains chlopheniramine, pseudoephedrine, and dextromethophan or guaifenesin.

[+]Sulphadoxine/pyrimethamine risk increase from 'C' to 'D' when consumed close to term.

±Tinidazole risk increases from 'C" to 'X' if consumed in first trimester.

Table 4: Relationship between over-the-counter (OTC) drug purchase and increased FDA risk category

OTC drug purchase	FDA risk category			Total	Chi square	P value
	B	C	D			
Yes	36(45.6)	39(49.4)	4(5.1)	79(100)	8.375	0.015*
No	84(34.3)	158(64.5)	3(1.2)	245(100)		

Data presented as n(%); total prevalence of OTC purchase: 79/346(22.8%)
*statistically significant