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RESEARCH ARTICLE

OVER THE COUNTER MEDICATION USE, PERCEIVED SAFETY AND DECISION MAKING BEHAVIOUR IN PREGNANT WOMEN IN JOS, NIGERIA

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ABSTRACT

Many studies have described the prevalent use of over-the-counter (OTC) medications, including herbals and vitamins, in pregnancy. The main objective of this study was to assess OTC medication use, perceived safety and decision-making behaviour in pregnant women in Jos, Nigeria. The subjects included 150 pregnant women 18 years and older. Subjects were solicited using a stratified random sample in two tertiary hospitals that provide antenatal care in Jos. A pretested self-completed questionnaire was used to collect data which was coded into Statistical Program for Social Sciences (SPSS) version 20 to generate descriptive statistics that satisfied the study objectives. Of the 150 respondents, 98.7% had used an OTC medication, herbal, or vitamin during the pregnancy. The most common products included folic acid, ferrous sulphate, paracetamol, Coflin^(R) syrup, Gestid^(R) suspension, PregnaCare^(R) Capsule and Vitamin D plus Calcium. The majority of respondents regarded OTC medications, vitamins, and herbals as "safe, but would talk to a healthcare professional before using." The most utilized sources of drug information during pregnancy were physicians (66.7%), nurses (16.0%), and midwives (14.7%). Only a few number of respondents obtained general OTC information from pharmacists (12.7%). Almost all subjects had used an OTC medication during their pregnancy and the majority considered OTCs safe after first consulting a healthcare professional. Although a high percentage of subjects have obtained their information and recommendations from healthcare professionals, a very small proportion of subjects had utilized a pharmacist as a resource. These findings highlight the need for thorough medication history taking and proper medication education by clinicians during antenatal care.

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INTRODUCTION

Pregnancy is a special physiological state where medication intake presents a challenge and a concern due to altered drug pharmacokinetics and drug crossing the placenta possibly causing harm to the fetus (Banhiday *et al.*, 2005). Medication treatment in pregnancy cannot be totally avoided since some pregnant women may have chronic pathological conditions that require continuous or uninterrupted treatment (e.g. asthma, epilepsy, and hypertension). New medical conditions can also develop during pregnancy, and the existing ones may worsen (e.g. migraine, headache, hyperacidity, nausea and vomiting)

requiring drug therapy (Deborah *et al.*, 2005). So it becomes a major concern for pregnant women to take medication whether prescription, OTC, or herbal medication. Since the thalidomide era, there has been great awareness about harmful effects of medications on the unborn child (Kacew, 1994; Melton, 1995). It has been documented that congenital abnormalities caused by human teratogenic drugs account for less than 1% of total congenital abnormalities (Sachdeva *et al.*, 2009). Hence in 1979, Food and Drug Administration developed a system that determines the teratogenic risk of drugs by considering the quality of data from animal and human studies (Sachdeva *et al.*, 2009). It is common knowledge that most pregnant women use one medication or the other to manage or treat a minor ailment during pregnancy without prior consultation

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with a health care professional. Often pregnant women resolve to make decisions on OTC medication use alone.

Many people, pregnant mothers included, consider OTC medications safe simply because they are available without prescription. Another issue arises with dietary supplement and vitamin use, as these products are often considered “natural” and thus harmless. A few OTC drugs have proven safety profile for use during pregnancy, while others have unproven safety or are known to adversely affect the fetus (Tillet *et al.*, 2003). In addition, the safety of certain OTC products may change depending on the gestational age of the fetus. Thus, there is the need to assess the type of OTC medications pregnant women use and their perceived safety. This will help in instituting programs that will educate women on the rational use of OTC medications including herbals and vitamins during pregnancy. Although many studies have been done pertaining to self-medication during pregnancy in Nigeria, no study has been done covering OTC medication use, perceived safety and decision-making behaviours in pregnant women in Jos. OTC or non-prescription medications describe medications that are easily accessible to the consumer without a written prescription from a health care professional (FDA, 2005). They include such medications used for common ailments such as pain, cough and cold, sore throats, allergies, diarrhea, constipation, stomach upset, heartburn and a host of bacterial and fungal infections. OTC drugs also include vitamins and herbals commonly used as dietary supplements. Prescription only medicines (POM), describe medicines that require a written prescription from a health care professional before they can be dispensed (FDA, 2005).

Several studies are present in the literature exploring questions related to drug use during pregnancy. Many focus on prescription drug use, while others include OTC and herbal drugs (Glover *et al.*, 2003; Conover, 2002; Refuerzo *et al.*, 2005). A few studies also describe the prevalence of use and its relationship to maternal characteristics such as age, income, or educational status (Werler *et al.*, 2005; Buitendijk and Bracken, 1991; Rubin *et al.*, 1993). OTC medication use by pregnant women is very common as evidenced by several studies. Glover *et al.* (2003), examined prescription, OTC and herbal medicine use in a rural obstetric population and they found 92.6% self-medicated with at least one OTC product and 45.2% used herbals. In addition, the authors found that 20.8% took five or more OTC medications during pregnancy. They noted a trend of increased use as pregnancy progressed, especially with paracetamol, calcium carbonate, cough drops, and guaifenesin. Other common OTC medications used included ibuprofen, aspirin, prenatal vitamins, H₂-antagonists, and non-sedating antihistamines. Another primary study focused on the frequency of prescription, OTC, and herbal use, but questioned women immediately post partum (Refuerzo *et al.*, 2005). They found 96.9% had taken at least one medication while pregnant. After excluding prenatal vitamin and iron supplements, they found 62.8% used OTC medications and 4.1% used herbals. Additionally, 33.5% used two or more medications and 13.6% used four or more drugs during their most recent pregnancy. A study carried out by Tamuno *et al.* (2011) described the prevalence of use of herbal remedies together with OTC drugs in pregnant women. In a

large scale, retrospective study, OTC medication use was quantified for more than 10,000 pregnant women (Werler *et al.*, 2005). Data was collected from two case-control studies: the Slone Epidemiology Centre Birth Defects Study and the National Birth Defects Prevention Study. They found most pregnant women had taken an OTC product, most commonly paracetamol, pseudoephedrine, diphenhydramine and guaifenesin. Rates of analgesic and decongestant use were higher for white women, those with at least a high school education, and women who were 20 years and older.

Many studies are present in the literature that not only focused on medication use during pregnancy, but also studied the relationship of use to maternal characteristics. In one of such studies, 54.9% of pregnant subjects used at least one OTC medication, with the most common being analgesics, antacids, and cold/allergy products (Buitendijk and Bracken, 1991). The authors determined that women who used prescription medications were more likely to also use OTC medications. In addition, women who were older, white, married, college-educated, and concurrently used caffeine, alcohol, and/or marijuana, took OTC medications more frequently than other groups. Perceptions on safety about medication have been shown to be strongly associated with patients’ adherence to medication (Gatti *et al.*, 2009). In a survey, data collected on perceived safety of OTC medication showed that majority of women regarded OTC medications (62.3%), vitamins (67.2%), and herbals (54.1%) as “safe, but would talk to a healthcare professional before using.” No participant believed vitamins to be unsafe for use during pregnancy. In addition, no participant considered herbals as “very safe, don’t need to talk to a healthcare professional before using.” (Kline and West berg, 2011)

Few attempts were made to identify how the socio-demographic characteristics of pregnant women correlated with attitudes and beliefs, with respect to safety, regarding medications (Nordeng *et al.*, 2010a, b; Rizk *et al.*, 1993; Skouteris *et al.*, 2008). Among these parameters such as education, socioeconomic level, age, occupation, lifestyle, common beliefs as well as severity of illness were reported. A patient’s knowledge and capacity to get knowledge are important in the development of beliefs (DiMatteo *et al.*, 2007; Veazie and Cai, 2007). Although some pregnant women may have the sufficient knowledge about high-risk medication in pregnancy, there is a “general fear” from medications (Norden *et al.*, 2010b). The hesitation in medication use by pregnant women might result in serious consequences which include but are not limited to: termination of a wanted pregnancy (Einarson, 2007), reluctance to drug use for nausea and vomiting (Baggley *et al.*, 2004), preference of herbal medications (Glover *et al.*, 2003), non-compliance to prescriber’s medication (Ito *et al.*, 1993; Williams *et al.*, 2002) and inclination toward OTC drugs and other medication methods (Holst *et al.*, 2009). Medication use in pregnancy has been studied in different communities. Norwegian women demonstrated a positive attitude toward medication in general, but a more restrictive one during pregnancy (Nordeng *et al.*, 2010a). In Serbia, women had higher drug exposure during (34.7%) than before pregnancy (29.9%) and less self-medication with OTC (Odalovic *et al.*, 2012). In Tanzania,

most pregnant women (66.5%) reported that they hesitated to take medications without consulting their physicians, and few (31.5%) were aware of certain drugs that are contraindicated during pregnancy (Kamuhabwa and Jalal, 2011). Pregnant women regarding the use of OTC medications utilize many sources of information and recommendations. A study by Kline and Westberg (2011) showed that the most utilized source of information included physicians (68.9%) followed by midwives (55.7%). The next most referenced resource was the Internet with 44.3% use. Other referenced sources included books and magazines (32.8%), and friends and family (26.2%). One of the least drawn upon sources of information were pharmacists (26.2%); the same percent as friends and family.

Most women received recommendations from a nurse or midwife (52.5%) followed by a physician (44.3%). Of those using OTC medications during pregnancy, 14.8% reported choosing the product on their own. Even less received recommendations from a pharmacist (6.6%) (Kline and Westberg, 2011). In summary, few studies had been published examining the use and perceived safety of OTC medications during pregnancy and the decision-making process. Even fewer studies, if any, mention the impact of this topic on pharmacists. Pharmacists can provide valuable instruction on safe and unsafe OTC drugs during pregnancy. They can educate and inform patients that many drugs and herbals available over-the-counter lack evidence as to their safety and efficacy during pregnancy. Thus, the goal of this study was to gather information related to OTC use, decision-making behaviours, and beliefs in pregnant women and present it in a way that aids health care providers in providing the best patient care to this population.

MATERIALS AND METHODS

Setting: The study was carried out in the Antenatal Care Departments of two tertiary hospitals, Plateau State Specialist Hospital and Bingham University Teaching Hospital, both in Jos, Plateau State, Nigeria. Jos is the capital of Plateau State located in the North central region of Nigeria with a population of about 900,000 spread across three local government areas namely Jos-North, Jos-East and Jos-South (NPC, 2006). Plateau State Specialist Hospital is a 160-bed hospital owned by Plateau State Government and Bingham University Teaching Hospital is a 150-bed hospital owned by Evangelical Church Winning All (ECWA).

Study Design: A cross sectional study design was adopted in which an anonymous self-completed, pre-tested questionnaire was distributed to pregnant women attending antenatal clinics in two tertiary health care centres in Jos, Nigeria.

Inclusion and Exclusion Criteria: The inclusion criteria included pregnant women between the ages of eighteen (18) and forty (40) years and those that consented to take part in the study. The exclusion criteria included pregnant women less than eighteen (18) years of age or more than 40 years.

Sampling: A sample of pregnant women attending antenatal clinics in these hospitals was obtained by a stratified random

sampling. (Explain the demographic basis for stratification) – please delete this statement.

Sample Size: A sample size of one hundred and fifty pregnant women was adopted for the study based on a previous research carried out by Emmanuel *et al.* (2014).

Study Instrument: A self-completed pre-tested questionnaire was adopted and modified from a previous research carried out by Kline and Westberg (2011). The questionnaire was pretested and validated by the two community pharmacists, two academic pharmacists, two hospital pharmacists and two midwives.

The questionnaire comprised three sections:

- Section A contained questions pertaining to demographic data of respondents including the age, tribe, level of education, occupation, current annual household income, religion and trimester of current pregnancy.
- Section B contained questions relating to use of OTC medications including herbals and vitamins women commonly use during pregnancy.
- Section C contained questions relating to perceived safety of OTC medications including prenatal vitamins and herbals used in pregnancy.

Ethical Clearance: Ethical clearances were obtained from the Ethics and Research Committees of the two hospitals. Although no risk was involved in participating in the research, the confidentiality of the respondents was guaranteed. In addition, informed consents of the respondents were obtained before participation in the study.

Data Collection: Data was collected by means of a self-completed pretested questionnaire composed of three sections developed in English language. Pregnant women were asked to respond to the nineteen questions that assess their demographic characteristics, the types of OTC medications including prenatal vitamins and herbals they are using, the perceived safety of these medications and the decision-making behaviours they employ regarding medication use. Data was collected between October and December of 2014, during the clinic days.

Data Analysis: The data obtained from the research was coded and entered into the Statistical Package for Social Sciences (SPSS), version 20 software to generate descriptive statistics of percentages and frequency distributions that satisfied the study objectives.

RESULTS

One hundred and fifty completed questionnaires were obtained from Bingham University Teaching Hospital and Plateau State Specialist Hospital for 150 respondents, making it 100% response rate. This was achieved because it was researcher administered. Demographic data are presented in Table 1. The majority of respondents were between the ages of 20-30 (54.7%), Christians (90.7%) and in their second (22.7%) or third trimester (73.3%). The highest level of education was most commonly tertiary (62.0%). The most frequent household monthly income was between ₦10, 001 – ₦25, 000 (30.0%) per month.

Cumulative % < 100 for any subgroup was due to non-response

Figure 1 below depicts pictorially the distribution of self-medication drug classes among respondents. It shows at a glance that most of the respondents self-medicated on vitamins (98.7%), followed by analgesics(58.0%) and then anti hyperacidity medications(26.0%).The figure shows that 16.0% of respondents have self-medicated on supplements and herbals.

Table 1. Demography of respondents (N=150)

Variable	Frequency	Percentage
Age		
<20	15	10.0
20-30	82	54.7
31-40	50	33.3
> 40	3	2.0
Tribe		
Yoruba	15	10.0
Igbo	24	16.0
Hausa	20	13.3
Others	91	60.7
Level of education		
Primary	4	2.7
Secondary	52	34.7
Tertiary	93	62.0
Vocational training	1	0.7
No formal education		
Occupation		
Civil servant	38	25.3
Farming	19	12.7
Business	56	37.3
Others	37	24.7
Average monthly income (in ₦)		
< 10,000	35	23.3
10,000-25,000	45	30.0
26,000-50,000	41	27.3
51,000-100,000	21	14.0
>100,000	8	5.3
Religion		
Christianity	136	90.7
Islam	13	8.7
Others	1	0.7
Trimester of present pregnancy		
First	6	4.0
Second	34	22.7
Third	110	73.3

Table 2. Distribution of individual self-medication drugs among respondents

Variable	Frequency	Percentage
Analgesics(pain killers)		
Paracetamol®	85	56.67
Ibuprofen	2	1.33
Cataflam®	2	1.33
Cough medicines		
Coflin® syrup	16	10.67
Procold®	11	7.33
Logenges	8	5.33
Benilyn®	1	0.67
Actifed®	3	2.00
Mixagrip®	1	0.67
Heart burn medicines		
Gestid® suspension	33	22.00
Ranitidine tabs	1	0.67
Relcer® gel	2	1.33
Cimetidine tabs	5	3.33
Meprasil tabs	1	0.67
Constipation/diarrhoea/stomach upset		
Gestid® suspension	11	7.33
Buscopan®	1	0.67
Castor oil	1	0.67
Andrew liver salt®	2	1.33
Allergy medicines		
Loratidine	5	3.33
Chlorpheramine	8	5.33
Xylomepha® nasal spray	1	0.67
Vitamin medicines		
PregnaCare®	29	19.33
Folic acid	110	73.33
Ferrous sulphate	106	70.67
Daily multivites	5	3.33
Multivits	17	11.33
Vit-D/calcium	64	42.67
Prenatal vitamins	4	2.67
Women daily multivitamin	8	5.33
Herbs/herbal supplements		
Ginger	20	13.33
Moringa	21	14.00

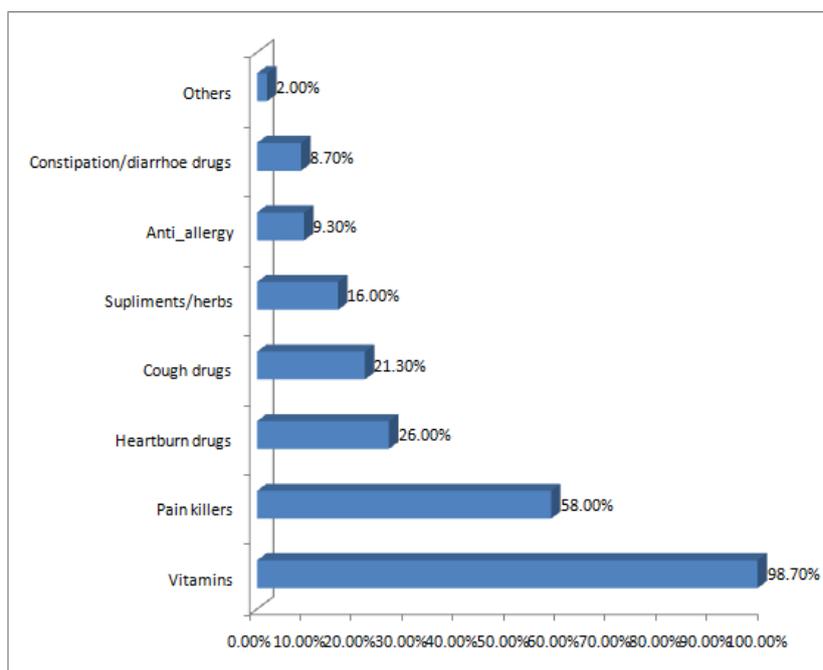


Fig.1. Distribution of self-medication drug classes among respondents

Table 2 lists all of the over-the-counter medications, herbals, and vitamins taken by respondents. Medications were grouped by indications with the corresponding percent use out of the total number of respondents. The most common OTC taken by subjects was folic acid (73.33%) and then ferrous sulphate (70.67%) both of which are vitamins frequently dispensed together during antenatal visits. Twenty two percent of pregnant women used Gestid® to help resolve heartburn symptoms. Histamin₂-blockers were also taken for acid reflux, mostly cimetidine (3.3%).

Perceived Safety of Medicines in Pregnancy

Data on the perceived safety of OTC medication, vitamin, and herbal use during pregnancy is presented in Table 3. The majority of women surveyed regarded OTC medications (61.3%), vitamins (58.0%), and herbals (20.0%) as “safe, but would talk to a healthcare professional before using.” Only a few respondents (2.7%) believed vitamins to be unsafe for use during pregnancy. Furthermore, 6.7% of respondents considered herbals as “very safe, don’t need to talk to a healthcare professional before using.”

Table 3. Respondents’ perceived safety of medicines in pregnancy

Variable	Drug		
	OTC n (%)	Vitamins n (%)	Herbs n (%)
Very safe, I don’t need to talk to a healthcare professional before using	8 (5.3)	55 (36.7)	10 (6.7)
Safe, but I would talk to healthcare professional before using	92 (61.3)	87 (58.0)	30 (20.0)
Safe, but I would check with resources, such as friends or internet before using	4 (2.7)	4 (2.7)	8 (5.3)
Unsafe, I would not use these during pregnancy	46 (30.7)	4 (2.7)	102 (68.0)

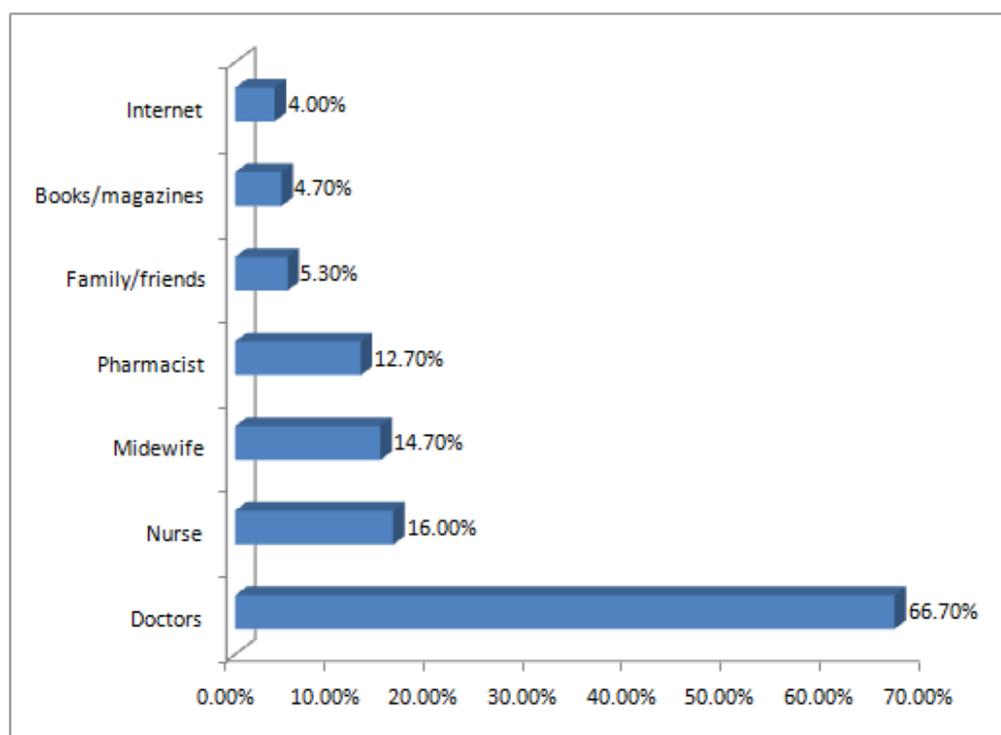


Fig.2. Distribution of respondents’ sources of drug information during pregnancy

To help manage other gastrointestinal conditions, Gestid® suspension was mostly used (7.33%). Other less frequently used OTC medications for these conditions included Buscopan®, castor oil and Andrew Liver Salt®. The most common OTC therapies to manage cough and cold symptoms were Coflin® syrup (13.1%), Procold® (7.33%), and lozenges (5.33%). Chlorpheniramine (5.33%) was more commonly chosen over the non-sedating antihistamine, loratidine (3.33%), to treat allergies. About 20% of respondents made use of PregnaCare® during their pregnancy. Many subjects claimed to use a variety of herbals, such as ginger (13.33%), known to help reduce symptoms of nausea, and moringa (14.00%) and in addition, 58.0% used analgesics. Over ninety-eight percent of pregnant women surveyed had taken an OTC product while pregnant.

Figure 2 presents data pertaining to pregnant women’s sources of information and recommendations regarding OTC use during pregnancy. As Figure 2 indicates, the most utilized source of information and recommendations for the use of OTC medicines during pregnancy by respondents was physicians (66.70%) followed by nurses (16.0%). One of the least drawn upon sources of information and recommendations on OTC medication use were pharmacists (12.7%).

DISCUSSION

Over the years, there has been an increase in the use of OTC medications, including herbals and vitamins, and a decline in the use of prescription medicines (Rubin *et al.*, 1993). Furthermore, the convenience associated with self-medication,

the perceived safety of OTCs, and the usually high cost of consulting a physician in his clinic, especially for the uninsured Nigerian, could all contribute to this increasing prevalence of self-care. This survey and many other studies have shown that OTC use during pregnancy is extremely common. In the studied population, 98.7 % of the respondents had used at least one OTC medication, vitamin, or herbal while pregnant. The most common medications used included, folic acid, ferrous sulphate, paracetamol, Gestid®, Coflin® syrup, vitamin D either alone or in combination with calcium. Even after excluding vitamins and herbals, 71.3% of women had used an OTC medication during their pregnancy. This to some extent is in tandem with the findings of Kline and Westberg (2011), in which of the 61 respondents studied, 96.7% had used an OTC medication, vitamin, or herbal while pregnant. This study also agreed with their findings that paracetamol was the most widely used OTC analgesic by pregnant women.

In a Research carried out by Kline and Westberg (2011), the subjects considered OTCs (62.3%), vitamins(67.2%) and herbals(54.1%) as safe but only after consulting a healthcare professional. No participant regarded vitamins as unsafe. Their findings, to some degree, correlates with the result of this study where 61.3% and 58.0% of the respondents respectively regarded OTCs and vitamins as safe but only after consulting a healthcare professional. However, 2.7% of the respondents of this research oddly regarded vitamins to be unsafe and would not use these during pregnancy. This is insignificant. Most patients, including during pregnancy, consider OTC medications safe, just because they are available without a prescription. Although rare, women may not realize the potential risk some OTC medications may pose to themselves or their developing fetuses. A particular example is the use of non-steroidal anti-inflammatory drugs such as ibuprofen and Cataflam® respectively by two respondents. These drugs should not be used in the first or third trimester as there is enough evidence that associate them with abortion, post-term pregnancy, gastroschisis and increased bleeding leading to blood loss (Tillett et al., 2003).

Although the majority of subjects claimed they would talk to a healthcare professional before using an OTC product, many had used potentially harmful medications during their current pregnancy. Cataflam® and ibuprofen are examples stated above. The percentage of subjects receiving information and recommendations from pharmacists regarding OTC use during pregnancy was quite low (12.70%) compared to doctors, nurses and midwives. This result could be compared with the result obtained in a similar survey conducted in the USA by Kline and Westberg (2011). In the survey, the most utilized source of information was physicians, followed by midwives. One of the least drawn upon source of information was pharmacists (26.2%). Based on the findings of this study, there is a need for more patient education concerning the safe and effective use of OTC medications, herbals, and vitamins during pregnancy especially during antenatal visits. Due to a relatively small sample size, the results may not accurately represent the obstetric population, although it can still give a general perspective of the topics under study. Another limitation is the choice of study locations, two tertiary hospitals providing antenatal care in the urban city of Jos.

These patient responses may differ from those of a rural or suburban population. The majority of subjects have had tertiary education; therefore, a more diverse participant group would be beneficial in a future study. Nonetheless, this the first study to investigate self-medication practices and perceived medicines safety among pregnant women in the local setting and results could serve as important baseline data for further study.

Conclusion

This research was designed to determine which OTC medications including supplements, herbals and vitamins pregnant women are using during pregnancy and to assess pregnant women perceived safety of these medications, alongside the decision-making process they adopt in OTC, herbal and vitamin use. Based on the result of this research, it can be concluded that nine out of every ten pregnant women used OTC medication including herbals and vitamins during their current pregnancy with folic acid, ferrous sulphate, paracetamol, Gestid® suspension, vitamin D plus calcium, coflin® syrup, Procold®, ginger, moringa and PregnaCare® being the most utilized medications. It can also be concluded that most women regarded OTCs and vitamins as safe during pregnancy but would talk to a healthcare professional before using.

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