A SURVEY OF DRUG USE IN PREGNANCY AT THE KENYATTA NATIONAL HOSPITAL

A DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTER OF PHARMACY IN CLINICAL PHARMACY OF THE UNIVERSITY OF NAIROBI

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DECLARATION

This dissertation is my original work and has not been presented for a degree or any other award in any other University.

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LIST OF ABBREVIATIONS

KNH- Kenyatta National Hospital

ANC - Ante Natal Clinic

OTC -Over The counter

ACE- Angiotensin Converting Enzyme

FDA- Food and Drug Administration

NSAIDs- Non Steroidal Anti Inflammatory Drugs

U.o.N- University of Nairobi

ERC- Ethics and Research Committee

ABSTRACT

Background: The study set out to establish the appropriateness of drug use practices among mothers and prescribers at the Obstetrics and Gynaecology department of Kenyatta National Hospital. Since it is very difficult to determine the effects on the foetus before marketing new drugs due to ethical reasons, most drugs are not recommended to be used during pregnancy. The dilemma is that while avoidance of most drugs is recommended, especially in the first trimester, pregnancy itself is often a cause of need for drug use. A careful balance between the risks of medications to the foetus and the benefits to the mother is therefore necessary. This requires good prescribing and good drug use practices among pregnant women to achieve

Objectives: The objectives of the study were to establish the factors influencing the level of knowledge of mothers concerning safe use of drugs in pregnancy and their self medication practices during pregnancy, to determine which drugs are used by mothers during pregnancy for self medication and to determine which drugs are prescribed to mothers during pregnancy and the peri-natal period.

Setting: The study was carried out at the Obstetrics and Gynaecology wards of Kenyatta National Hospital, a Tertiary National Referral and Teaching Hospital in Kenya. This site was appropriate for the study because, being a National Referral Hospital, patients at the Hospital were a better representation of the situation of drug use in pregnancy in the whole Country.

Design: The study was conducted as a cross sectional survey.

Data collection: Data was collected by the investigator alone for the purposes of uniformity. The questionnaires were administered in English or Kiswahili depending the respondents' preferences. Research authorisation was obtained from the Kenyatta National Hospital Ethics and Research Committee and informed consent was obtained from every respondent before the interview.

Data analysis: Data was analysed using Statistical Package for Social Scientists (SPSS) version 11.5 and STATA 11 computer softwares. Knowledge was measured by a knowledge score generated by combining ten variables indicating knowledge into a single variable. Thirty per cent of the respondents had used self medication during pregnancy.

Results: Paracetamol was the drug used by most of the respondents (30%) for self medication during pregnancy while antibiotics were the most prescribed class of drugs with Augmentin® being the drug most prescribed. Most drugs prescribed (43.6%) belonged to FDA category B.

When examined alone (univariably) there was significant relationship between level of knowledge and age greater than 35 years, employment whether in the formal or informal sector compared to not being employed or self employed and level of education. However, in the multivariable analysis which adjusted for other factors only level of education was significant for having knowledge of drug use in pregnancy.

Conclusion and recommendations: The level of education and hence the level of knowledge of drug use in pregnancy of a woman is the single most important factor that significantly influences their self medication practices while pregnant. This implies that a lot of effort should be put toward improving level of education of women as this will improve their reproductive health outcomes.

CHAPTER ONE

INTRODUCTION AND LITERATURE REVIEW

1.1. Introduction

The prevalence of congenital malformation requiring medical intervention or affecting the quality of life of the infants is approximately 65 per 1000 births (1). Accounting for about one third of all deaths in the first year of life, they represent the single most frequent cause of infant mortality (2). Studies show that using all possible prevention methods such as genetic counselling, pre and post conceptional care of diabetic mothers, folic acid supplementation, and avoidance of alcohol and prevention of rubella virus can considerably reduce the prevalence of certain congenital malformations (1, 3). About 20% of these malformations are genetical, 10% are caused by environmental factors such as maternal conditions, infections, chemicals and drugs but in the majority of cases (65-75%), causes are unknown(4). The thalidomide tragedy has proved that drugs can have teratogenic effects in humans and that a systematic and comprehensive assessment of drug utilization in pregnancy and its effects on the unborn child is of major importance.

Use of drugs during pregnancy and lactation constitute a potential risk for both the mother and the foetus. The benefits of drug therapy to the mother must thus be weighed against risks for the foetus (5, 6). Although authorities have argued for therapeutic restraint during pregnancy (5, 7), most studies have shown an almost unchanged pattern of drug use among pregnant women over the last three decades (8, 9). Different studies have shown that 40-90% of pregnant women take at least one drug during pregnancy (7, 9, and 10) and that many women are exposed to several drugs (11). For example, in the Pegasus project (12), 85% of women recorded a drug intake during pregnancy. The average number of drugs taken was four. Of all drugs taken, 58.7% were prescribed drugs while 14.2% were self administered. Minerals, Iron and Iodine were the most commonly prescribed. Prescribed drugs were varied whereas self medications were mainly minerals, gastrointestinal drugs, respiratory drugs, vitamins and homeopathies. In four cases, drugs with known high risk potential were taken during a critical period or in a critical dosage; ethinyl estradiol in two cases, propylthiouracil and triamterene in one case each.

Apart from teratogenicity, drugs and other chemicals may affect the foetus at other times during pregnancy. For example, use of Angiotensin Converting Enzyme (ACE) inhibitors

may cause prolonged foetal hypertension, renal tubular dysplasia, growth retardation and death when used during second and third trimesters of pregnancy (13, 14). Furthermore, toxic manifestations of intrauterine exposure to drugs may not be detected clinically until several years after birth (15).

In many, but not all, situations, the benefits for the mother may well outweigh the risks for the foetus (5, 6). In a recently published Meta analysis (15), Dolovich et al found that foetal exposure to Benzodiazepines is associated with an increased risk of major malformations.

1.2. Birth defects

Birth defects are observed among 3.5% to 5% of infants examined at birth or during neonatal period (23) but prevalence of birth defects may be as high as 8% according to a survey of a universal disease registry from British Columbia (40). As many as 1% of congenital abnormalities are caused by drugs, chemicals and other exogenous agents implying that approximately 1 in every 400 infants has a birth defect with a teratogenic aetiology(4). However the magnitude of the problem of medication use during pregnancy may be somewhat worse because 65-70% of birth defects have unknown aetiology, including unreported medically prescribed medication with teratogenic potential, and or use of alcohol and drugs of abuse (9). It is important to note that the uniqueness of congenital abnormalities and other pregnancy complications due to drugs and chemicals exposure is that they are potentially preventable causes of damage to the unborn child and other morbidity and mortality. Knowledge of the effects of pre-natal exposure and the opportunity for intervention are the key functions in evaluation and prevention of morbidity and mortality due to clinical exposure during pregnancy (7).

1.3. Use of Prescription drugs in Pregnancy

The approach of the medical community to the use of medications during pregnancy has changed dramatically since the early 1970s, largely because of the problems with thalidomide and diethylstilboestrol. Since 1975, the U. S. Food and Drug Administration (FDA) has assigned pregnancy risk factors to all drugs used in the United States (24).Unfortunately, many drugs may not have been adequately researched during pregnancy because of ethical considerations (29).

According to a study done in Pakistan in 2008 (16), all the pregnant women attending ante natal clinics received a prescription of at least one drug. 55.4% of the prescriptions were

issued in the first trimester, 33.6% in the second and 11.0% in the third trimester. Anti anaemic drugs including iron and vitamin supplements were the most frequently prescribed drugs (79.4%) followed by analgesics (6.2%) and antibiotics (2.2%). 19.6% of the women received prescriptions containing drugs other than vitamins or mineral supplements. 2.3% of prescribed drugs were known to be teratogenic. Misiprostol was the most frequently prescribed among the teratogenic drugs followed by carbimazole and methotrexate.

In a similar study in Ethiopia (17), 71.3% of women interviewed were prescribed at least one drug during pregnancy. The majority of the drugs prescribed were, iron and mineral supplements followed by anti infectives. Nearly 4% of the pregnant women were prescribed drugs from category D or X of the FDA risk classification (47).

In Denmark, a study of 16001 primaparous women reported that 44.2% of Danish women received prescriptions for at least one drug. Users received 2.6 prescriptions in average. The majority of the prescriptions were for antibiotics (28.7%), gynaecological drugs (13.3%) and anti asthmatic drugs (7.6%) (18).

A study conducted in Yale University Medical school reported an overall decrease in the number dispensed drug used (excluding vitamins) during pregnancy; however, there was still substantial exposure to drugs including drugs that are contraindicated during pregnancy. During the gestational period, study mothers received an average of 3.1 prescriptions for non-vitamin drugs. (52).

A survey on drug intake during pregnancy was carried out in a sample of 3268 women who delivered live-born infants in 11 hospitals located throughout Italy. An overall mean consumption of 2.17 drugs per woman was reported. Apart from dietary supplements, the most used drugs were tocolytics, analgesics, and antibiotics. The proportion of women who did not use any drug was 17.3%. Geographic and socio-economic factors were seen to increase drug intake up to 44%, while the presence of anxiety provoked a 60%) higher consumption of drugs other than dietary supplements. Other factors influencing drug use during pregnancy were rural vs. urban residence and smoking habits (53).

According to a survey performed at a teaching Hospital in the United States of America, the medications most commonly used during pregnancy were vitamins, analgesics, calcium and iron preparations, and antibiotics. The mean numbers of medications consumed during the second and third trimesters (3.32 +/- 1.87 and 4.13 +/- 2.46) were significantly higher than the

mean number taken before pregnancy (2.65 +/- 1.95). Over-the-counter medications accounted for 54% of the total products taken during pregnancy. Percentages of women using caffeine, tobacco, alcohol, and illicit drugs decreased during pregnancy. (54)

In a study carried out in Tennessee, U.S.A, of the 2,528 gravidas interviewed, 62 per cent received systemic drugs (excluding dietary supplements) during their pregnancies. White women and women 30 years of age and older were most likely to receive these medications. Systemic anti-infectives were the most frequently prescribed category of drugs (excluding dietary supplements). One fourth of the women received a narcotic-containing drug and 13 percent of the women received psychotropic drugs, most frequently diazepam. Barbiturates and narcotic-containing drugs were often "hidden" in a fixed combination medication. In general, prescribing did not decrease as a result of pregnancy (7)

A cohort study conducted to determine the correlates of prescription drug use during pregnancy reported that a majority of these pregnant women were prescribed a prescription drug (56%), and 4% of women were prescribed a category D or X drug. The most common classes of medications prescribed were antibiotics (62%), analgesics (18%), asthma medications (18%), and antiemetics (17%). After adjustment for sociodemographic and clinical characteristics, African American women were more likely to use a prescription drug than white women. Lower levels of educational attainment were also associated with greater use of prescription drugs compared with women who had graduated from college. Women with a chronic health condition, gestational diabetes, a prenatal hospitalization, a history of infertility, or symptoms of acid reflux were also more likely to use a prescription drug than women without these conditions. Nulliparous women and women who were married or living with a partner were less likely to use category D or X drugs during pregnancy than women without these characteristics. Women with a history of infertility and those with a chronic health condition were more likely to use a category D or X drugs during pregnancy than those without these conditions (55)

1.4. Self Medication in Pregnancy

A common concern about the care of pregnant women involves the use of over the counter (OTC) medications. Non-prescription drugs account for about 70% of medications used worldwide and more than 80% of pregnant women take OTC or prescription drugs during pregnancy. Of the OTC drugs marketed between 1975 and 1994, 30 percent were previously prescription medications (21, 22). It is estimated that up to 60% of patients consult a healthcare professional when selecting an OTC product (21). Many physicians are cautious in their OTC recommendations because of concern about possible adverse effects on the developing foetus. At least 105 of birth defects are thought to result from maternal drug exposures (23). The issue is complicated by the fact that the safety and efficacy profile of a given medicine often changes during the course of a normal pregnancy (22).

Figure1.1 FDA Classification of Drug Safety in Pregnancy (24)

Category A	Controlled studies in women fail to demonstrate a risk to the foetus in the first trimester (and there is no evidence of risk in later trimesters), and the possibility of foetal harm appears remote.
Category B	Either animal reproduction studies have not demonstrated a foetal risk but there are no controlled studies in pregnant women, or animal reproduction studies have shown an adverse effect (other than a decrease in fertility) and there is no evidence of risk in later trimesters.
Category C	Either, studies in animals have revealed adverse effects on the foetus and there are no controlled studies in women, or studies in women and animals are not available.
Category D	There is positive evidence of human foetal risk but the benefits from the use in pregnant women may be acceptable despite the risk (for example if the drug is needed in a life threatening situation or for a serious disease in which safer drugs cannot be used or are ineffective).
Category X	Studies in animals or humans have demonstrated foetal abnormalities or there is evidence of foetal risk based on human experience and the risk of the use of the drugs in pregnant women clearly outweighs any possible benefits. The drug is contraindicated in women who are or may become pregnant.

1.4.1. Pain Medications in pregnancy

The safety of pain medications during pregnancy varies (25, 26). Acetaminophen is the most widely used analgesic in pregnancy. Although there is no known association with teratogenicity, there is little evidence to support the lack of association (25). Salicylates have been associated with increased perinatal mortality, neonatal haemorrhage, decreased birth weight, prolonged gestation and labour as well as possible birth defects (25). Other Non-steroidal anti inflammatory drugs (NSAIDS) such as ibuprofen have not been properly studied during pregnancy. However, an analysis of overdosed pregnant mothers showed no evidence of foetal abnormalities at birth (28).

1.4.2. Decongestants, Expectorants and Antihistamines

Diphenhydramine has been shown to have oxytocin like effects, especially in high doses. (29). Dextromethorphan has been associated with birth defects in animal studies (30). When used during the first trimester in the presence of a febrile illness, Guaifenesin has been associated with an increased risk of neural tube defects (31).

1.4.3. Antidiarrhoeal Agents in pregnancy

The most commonly used antidiarrhoeal medications include Kaolin and Pectin preparations, bismuth- subsalicylate, loperamide and atropine/diphenoxylate (24) Kaolin containing preparations have been associated with iron deficiency anaemia while Loperamide and Atropine/Diphenoxylate have been found to be teratogenic in animals (32).

1.4.4. Antacid preparations in pregnancy

Antacids commonly contain Alaginic acid, Aluminium, Magnesium and Calcium. High Aluminium containing antacids have been shown to cause foetal maldevelopment with prolonged use in pregnancy (34). H_2-receptor blockers readily cross the placenta thus likely to cause teratogenicity to the foetus (35). However, Cimetidine and Ranitidine have not been associated with significant adverse effects to the foetus both in human and animal studies (35). Magnesium compounds containing Magnesium Sulphate are known tocolytic agents while Nizatidine has been associated with increased risk of foetal death, spontaneous abortion and decreased foetal weight in animal studies (42).

1.4.5. Antifungal drugs in pregnancy

A study of 226 women exposed to Fluconazole during the first trimester of pregnancy did not show any association with miscarriage (36). However, Ketoconazole, Flucytosin and Griseofulvin may be teratogenic or embryotoxic in animals (37). Because imidazole agents are likely to be safe when used during pregnancy and may be more effective than Nystatin, they should be considered as first line therapy in pregnant patients. (38)

1.4.6. Smoking deterrents in pregnancy

Nicotine and its metabolic product, Cotinine cause intrauterine growth retardation, pre mature birth, spontaneous abortion, foetal pulmonary defects and increased risk of sudden infant death syndrome (39).FDA therefore categorises it as category D drug. Unfortunately, the safety of nicotine replacement products in pregnancy has not been adequately studied (40). However, smoking is likely to be more harmful to the foetus than nicotine replacement therapy (40).

1.5. Self Medication in Pregnancy in Sub-Saharan Africa

From a study conducted in a Hospital in Durban, South Africa (44), it was reported that 86.3% of the 577 women who participated in the study knew about herbs taken during pregnancy for cleansing and 43.7% were taking the medicinal herbs at the time of the study. Parents and relatives (69.8%) and traditional birth attendants /herbalists (22.6%) were the most common source of knowledge about the medications. These herbs were taken to improve foetal conditions (45.2%) or make labour easier (68.7%). Conditions such as childhood malnutrition, congenital malformations, tumours and acute renal failure have been linked to toxic or carcinogenic constituents present in herbal medicines taken during pregnancy (43, 44). A similar study conducted in Cape Town at Ante Natal clinics of two Tertiary hospitals showed that majority of Xhosa speaking women (76.3%) followed indigenous healing practices for both themselves and their babies because of the need to "strengthen" their wombs against sorcery, prevent childhood sicknesses and to treat symptoms they perceive that biomedical services would not be able to treat. Self medication was common practice among Afrikaan speaking women (45). A case control study of self medication during pregnancy at a maternity hospital in Ibadan, Nigeria reported that 65.7% of the women had ever used the drugs without prescription and 54.7% were on such medications at the time of the study: 28.3% for prophylaxis and the rest for therapy (46).

CHAPTER TWO

RATIONALE, JUSTIFICATION AND OBJECTIVES OF THE STUDY

2.1. Rationale of the study

Since it is very difficult to determine the effects on the foetus before marketing new drugs due to ethical reasons, most drugs are not recommended to be used during pregnancy (19). For this reason, there are a number of gaps in the knowledge about the deleterious consequences of these drugs on the foetus. Prescription and over the counter (OTC) drug use by pregnant women should therefore be viewed as a public health issue (20). The dilemma is that while avoidance of most drugs is recommended, especially in the first trimester (1), pregnancy itself is often a cause of need for drug use (19). For example, Indomethacin is commonly prescribed in pregnancy for the treatment of pain or as a tocolytic agent. Its use in pregnancy may cause oligohydramnios, premature closure of foetal ductus arteriosus with subsequent persistent pulmonary hypertension of the new born, foetal nephrotoxicity and periventricular haemorrhage (26). A careful balance between the risks of medications to the foetus and the benefits to the mother is therefore necessary (27). This study aimed at assessing how well this balance was applied among mothers at the department of Obstetrics and Gynaecology of Kenyatta National Hospital (KNH).

2.2. Significance of the study

Drug use in pregnancy, the world over, is rampant despite recommendations discouraging the same (22). Absolute avoidance of drugs in pregnancy is not realistic. However, judicious use of prescription and OTC drugs in pregnancy is paramount and more practical (24). This study sets out to determine the overall safety profile of drug use practices among the mothers admitted to the Obstetrics and Gynaecology department of Kenyatta National Hospital. The findings of this study will be used to improve policies that govern drug prescribing and use in pregnancy. They will also be used to inform the general public about the need to be cautious with drug use in pregnancy. Private pharmacies will also be supplied with the findings, with the aim of making drug use in pregnancy safer in Kenya by prevention of harmful effects of drugs on foetuses.

2.3. Purpose of the Study

The purpose of this study was to establish the level of safety of drug use practices among mothers and prescribers at the Obstetrics and Gynaecology department of Kenyatta National Hospital.

2.4. Objectives of the Study

The objectives of the study were as follows.

1. To establish the factors influencing the level of knowledge of mothers on safe use of drugs in pregnancy and their self medication practices during pregnancy.
2. To determine which drugs are used by mothers during pregnancy for self medication.
3. To determine which drugs are prescribed to mothers during pregnancy and the peri-natal period.

2.5. Research questions

1. What is the level of knowledge of mothers concerning the safe use of drugs in pregnancy and does it influence their self medication practices?
2. What drugs are commonly used by the mothers for self medication in pregnancy and what is their safety profile as per the FDA classification of drug safety in pregnancy?
3. What prescription drugs are commonly prescribed to the mothers during pregnancy and what is their safety profile as per the FDA classification of drug safety in pregnancy?

CHAPTER THREE

RESEARCH METHODOLOGY

3.1. Introduction

This chapter details the methods of data collection, analysis and presentation that were used in this study. It focuses on the methodology and steps taken to enhance the validity and reliability of the data that was obtained from the study.

3.2. Study Site

The study was carried out at the Obstetrics and Gynaecology wards of Kenyatta National Hospital, a Tertiary National Referral and Teaching Hospital in Kenya. This site was appropriate for the study because, being a National Referral Hospital, patients at the Hospital were a better representation of the situation of drug use in pregnancy in the whole Country. The Hospital also hosts some of the country's most experienced clinical consultants. These consultants are therefore expected to practice the best level of evidence based Pharmacotherapy in the region including during pregnancy.

3.3. Target population

The study population comprised mothers who were admitted to the Obstetrics and Gynaecology wards with medical or obstetric conditions during the period of the study.

3.4. Study Design.

The study was conducted as a cross sectional survey. This design was found appropriate because it was able to give an overview of the objectives with a view to inform policy makers to conduct larger studies for corrective or adoptive purposes

3.5. Patient selection

Inclusion criteria

Only consenting conscious and clinically stable patients present in the wards at time of the survey were recruited to participate in the survey.

Exclusion criteria

Patients who were unable to communicate effectively due to labour pains or other medical complications during pregnancy were excluded from the study.

3.6. Sample size determination

The minimum sample size (**n**) required for determining the prevalence of unsafe drug use in pregnancy was calculated using the formula.

$$n=Z^2Pq/e^2$$

Where,

Z= The value of the standard variate at a given confidence level, in this case, 95%=1.96

q=The proportion of the population that use drugs irrationally during pregnancy =20% (21)

p=1-p

e = The level of error allowable =0.05

Therefore, $\mathbf{n} = (1.96)^2 \times 0.2 \times 0.8/ (0.05)^2 = 245.86$ (246)

For this study 250 patients was taken as sufficient sample size that fairly represents the total population.

3.7. Sampling method

Sampling was done by simple random sampling method. This was considered appropriate in order to minimize sampling error. The sampling frame used was the list of mothers present in the wards at the time of sampling. Randomization was attained by the coin method where a coin was tossed and whoever got the head would be interviewed whereas those with the tail would not be interviewed. This was done for every mother in the ward who fitted the inclusion criteria.

3.8. Recruitment and consenting procedures

Only consenting respondents were incorporated into the study. To ensure there was informed consent all prospective participants were clearly informed about the study with respect to the title, background, objectives, risks and benefits, their right to participation, what kind of data was to be collected and how long the data was to be stored. They were also given the contacts of the investigator, supervisors and the KNH/U.o.N Ethics and Research Committee.

3.9. Data collection procedures and instruments

Data was collected by the investigator over a period of four weeks. Firstly, consent form was administered upon which the required data was obtained from the respondents by the use of investigator filled questionnaires (see appendices 1, 2 and 3). Information regarding the use of prescribed drugs by the respondents was obtained by review of respondent medical records.

3.10. Study Variables

Independent Variables

1. Socio-demographic attributes of the respondents such as age, parity, level of education, place of residence and marital status.
2. Level of knowledge on safe use of drugs in pregnancy.

Dependent variables

1. Number and classes of drugs used for self medication by the mother during pregnancy.
2. Number and classes of prescription drugs used by the mother during pregnancy.

3.11. Quality assurances procedures

Care was taken not to lose the confidence of the respondents by being neither too intrusive nor judgemental. Doubt about the answers was also not expressed by the investigator during the interview. Interpreters were sought to assist in cases of language barriers in order to assure data validity. Triangulation was used to enhance data validity. This means some questions were asked in different ways to test consistency of the responses

3.12. Ethical Considerations

Research authorisation was obtained from the KNH/U.o.N-Ethics and Research Committee. Informed consent of the participants was obtained before recruitment into the study. (Appendix 3).Confidentiality was ascertained by using codes to represent patients instead of names.

3.13. Data management and statistical analysis

Data security

All filled questionnaires were kept under lock and key by the investigator.

The personal computer on which data was kept was accessed only through a private password. Backups in form of compact discs, flash discs and hard copies of summarised results were kept under lock and key by the investigator.

Data Analysis

All qualitative responses were coded before data entry. The data was then entered into the computer and stratified by the socio-demographic attributes such as sex, age, and parity, level of education, occupation, marital status and place of residence. After analysis, data was summarised and presented in form of frequency tables, percentages, pie charts and bar graphs. Chi square measure of association was used to assess distribution among patient characteristics

while both univariate and multivariate analyses were used to test for association between the various socio-demographic and obstetric characteristics of the respondents and self medication during pregnancy. Analyses were done using SPSS version 11.5 and STATA 10 at a significant level of $p = 0.05$ and p values less than or equal to 0.05 were considered statistically significant.

3.14. Study limitations and how they were minimized.

The limitations experienced during the study include the following:

Most of the respondents could neither understand nor speak fluent English. This language barrier was overcome by reading out the Swahili translation of the questionnaire to the patients who could only understand Swahili.

Fear by the patient of victimisation based on the provided information leading to untrue or half true information. This was minimised by explaining that participation in the study would not lead to a change in the quality and attitude of service provided to the patient and that all information would be confidential and would not be traced to the person of the respondent.

CHAPTER FOUR

DATA ANALYSIS, PRESENTATION AND INTEPRETATION

4.1. Introduction

This Chapter focuses on the findings of this research. The data is summarised into tables of frequencies and percentages based on the analytical print outs obtained by Statistical Program for Social Scientists (SPSS) computer software version 11.5 and STATA 10. The results are organized based on the themes of the study, that is, sociodemographic variables, level of knowledge on drug use in pregnancy, drugs used for self medication and prescription medications used during pregnancy and are presented using tables and Pie charts.

4.2. Baseline Socio-demographic and Obstetric characteristics of the respondents

In this section, the sociodemographic and obstetric characteristics of the respondents are summarised and an analysis of how they influence self medication during pregnancy is done. These findings were as summarised in the table below.

Table 4.1 - Baseline characteristics of the respondents

Characteristic	N = 250	(%)	p value
Age			
<15	2	(0.8)	
15-24	90	(36.)	0.047
25-34	133	(53.2)	
35 and above	25	(10.0)	
Reason for admission			
Normal delivery	126	(50.4)	
Emergency delivery	56	(22.4)	0.269
Medical condition in pregnancy	32	(12.8)	
Obstetric complication in pregnancy	36	(14.4)	
Trimester of pregnancy			
1st trimester	8	(3.2)	
2nd trimester	27	(10.8)	0.497
3rd trimester	215	(86.0)	
Occupation			
Formal employment	3	(1.2)	
Informal employment	34	(13.6)	0.006
House wife	114	(45.6)	
Self employment	99	(39.6)	
Level of education			
None	16	(6.4)	
Primary	86	(34.4)	<0.001
Secondary	80	(32.0)	
College/university	68	(27.2)	
Residence			
Slum	158	(63.2)	
Middle class	64	(25.6)	0.876
Rural	28	(11.2)	
Previous pregnancies			
0	71	(28.4)	
1	62	(24.8)	
2	63	(25.2)	0.366
3	36	(14.4)	
4	13	(5.2)	
≥ 5	5	(2.0)	

4.2.1. Age Distribution

Majority of the respondents (53.2%) were aged between 25 and 34 years with only 2(0.8%) being less than 15 years.

4.2.2. Level of education

Most of the respondents had either primary level education 86(34.4%) or secondary level education 80 (32%). Those with College or University level education were 68 (27.2%) and 16 (6.4%) had no formal education at all.

4.2.3. Occupation

Most of the respondents were either housewives 114 (45%) or self employed 99(39.6%). Only 1.2% of the patients interviewed were in formal employment whereas 34 (13.6%) were in informal employment.

4.2.4. Place of Residence

Up to158 (63.2%) of the respondents lived in slums within Nairobi, 59(23.6%) in middle class estates in Nairobi, 28 (11.2%) in their rural homes and only 5 (2%) lived in up market estates.

4.2.5. Reason for admission

Majority of the respondents, 126 (50.4%) were admitted for normal (SVD) delivery. The rest were admitted either for emergency delivery 56 (22.4%), with an obstetric complication in pregnancy 36 (14.4%) or with a medical condition in pregnancy 32 (12.8%).

4.2.6. Trimester of pregnancy

Almost all 215 (86%) of the patients interviewed were in their third trimester of pregnancy with only 27(10.8%) and 8 (3.2%) in their second and first trimester respectively. Majority of the respondents, 71(28.4%) were primigravida. Sixty two (24.8%) had one previous pregnancy, 63(25.2%) had two, 36(14.4%) had three, 13(5.2%) had four and 5 (2%) had more than four previous pregnancies.

4.3. Level of knowledge on drug use in pregnancy among the respondents

In this section, information on level of knowledge on drug use in pregnancy and how the knowledge level influences self medication practices of the respondents is analysed.

A knowledge score was generated by combining 10 variables into a single variable. An individual's knowledge was reported as a score out of ten. The variables used were knowledge of pregnancy, knowledge of danger of drugs to the foetus, knowledge on the effects of drugs on foetus, knowledge on the trimester where drugs can have greatest effects on the foetus, (5) whether counselled or not on drug use in pregnancy, if they self prescribed drugs during pregnancy, knowledge of effects of tobacco and alcohol on the foetus, knowledge specific drugs likely to affect pregnancy, source of information on drug use in pregnancy and knowledge of malformed organs. All variables included for generating the score contributed equally to the score.

Knowledge was then grouped using the mean knowledge score (6.7) to generate variable for women who had or who did not have knowledge. The new knowledge score was then modelled with demographic characteristics.

Table 4.2 – *Knowledge characteristics of the respondents*

Characteristic	N = 250	(%)	p value
Knowledge of pregnancy status			
By Missing periods	170	(68.0)	
By Pregnancy testing	17	(6.8)	0.013
By Feeling symptoms (malaria like)	63	(25.2)	
Knowledge of dangerous drugs in pregnancy			
No	24	(9.6)	0.574
Yes	226	(90.4)	
Source of knowledge			
Pharmacist	41	(16.4)	
Gynaecologist	58	(23.2)	
Nurse	58	(23.2)	0.227
Media	30	(12.)	
Friend/relative	40	(16.)	
Not relevant	23	(9.2)	
Knowledge of effects of drugs on pregnancy			
Miscarriage	145	(58.)	
Deformation to the foetus	61	(24.4)	0.434
Not sure	44	(17.6)	
Knowledge of trimester with high likelihood of teratogenicity			
1st trimester	155	(62.0)	
2nd trimester	14	(5.6)	0.931
3rd trimester	27	(10.8)	
Not sure	54	(21.6)	
Knowledge of dangerous drugs in pregnancy			
Antimalarials in general	59	(23.6)	
Antibiotics in general	13	(5.2)	
Quinine	15	(6.0)	
Chloroquine	5	(2.0)	0.201
Aspirin	9	(3.6)	
Tetracycline	3	(1.2)	
Contraceptives	11	(4.4)	
Not sure	135	(54.0)	
Self medicated			
No	75	(30.)	
Yes	175	(70.)	
Aware of risks of tobacco and alcohol on pregnancy			
No	136	(54.4)	
Yes	114	(45.6)	
Knowledge Score mean (SD)	6.7	(2.1)	

Thirty per cent of the respondents had used self medication during pregnancy. Most (68%) of the respondents knew that they were pregnant only after missing their monthly periods. Sixty three of them (25.2%) knew of their pregnancy by feeling what they described as malaria like symptoms and 17 (6.8%) of them got to know when they were pregnant by taking a laboratory test. Only 23 (9.2%) of the patients interviewed were not aware that certain drugs are more dangerous to the foetus if used during pregnancy than others whereas 227(90.8%) of them were aware. A Gynaecologist (23%) and a Nurse (23%) were the most memorable sources of information on drug use in pregnancy for the respondents.

Miscarriage was cited by the majority, 145(58%) of the respondents as the adverse effect of drug use during pregnancy. Sixty one (24.4%) of the patients cited foetal deformation whereas 44 (17.6%) were not sure of a specific adverse effect of drugs on pregnancy and its outcomes

Most of the respondents (62%) were aware that the first trimester of pregnancy is most amenable to the teratogenic effects of drugs. Up 54% of the respondents were not sure of any specific drug as being the most dangerous to use during pregnancy. The rest of the respondents cited Antimalarials (23.6%), Quinine (6%), Antibiotics (5.2%), Contraceptives (4.4%), Aspirin (3.6%), Chloroquin (2%) and Tetracycline (1.2%) as the most dangerous drug in pregnancy.

More than a half (54.4%) of the respondents was not aware that drugs of addiction can cause harm to the foetus if used by the mother during pregnancy.

Table 4.3 Logistic regression for the odds of above average knowledge on self medication in pregnancy

Characteristic	Univariable analysis				Multivariable analysis			
	OR	[95% CI]		P>z	OR	[95% CI]		P>z
Age				0.047				
> 35	1.000				1.000			
≥ 35 years	2.626	1.011	6.822		2.412	0.803	7.245	0.117
Reason for Admission				0.269				
Normal delivery	1.000				1.000			
Emergency delivery	1.828	0.950	3.516		1.891	0.927	3.856	0.080
Medical condition	1.207	0.553	2.635		2.100	0.727	6.066	0.170
Obstetric complication	1.475	0.693	3.140		1.845	0.743	4.583	0.187
Trimester of Pregnancy				0.497				
1st trimester	1.000				1.000			
2nd trimester	2.424	0.478	12.302		2.446	0.397	15.087	0.335
3rd trimester	2.228	0.519	9.562		2.965	0.501	17.558	0.231
Occupation				0.006				
Employed (formal/informal)	1.000				1.000			
Self employment / house wife	0.312	0.136	0.713		0.500	0.196	1.274	0.147
Level of Education				< 0.001				
None / primary	1.000				1.000			
Secondary / college / university	2.772	1.646	4.668		2.238	1.222	4.100	0.009
Place of Residence				0.876				
Slum	1.000				1.000			
Middle class	2.034	1.093	3.784		1.333	0.658	2.701	0.425
Rural	0.644	0.286	1.450		0.650	0.270	1.564	0.336
Number of Previous Pregnancies				0.366				
0	1.000				1.000			
1	2.418	1.191	4.908		2.596	1.222	5.515	0.013
2	1.350	0.684	2.666		1.445	0.692	3.020	0.327
3	2.037	0.893	4.647		1.600	0.648	3.952	0.309
4	1.842	0.549	6.183		1.724	0.426	6.971	0.445
≥ 5	0.768	0.121	4.877		0.930	0.121	7.124	0.944

When examined alone (univariably) there was significant relationship between knowledge and age greater than 35 years, employment whether in the formal or informal sector compared to not being employed or self employed and level of education. The odd for having knowledge are 260 % higher when the women were older than 35 years. The odds for having knowledge were 70 % less for those self employed or not employed compared to those employed in the formal or in the informal sectors. The odds for having knowledge were 270 % higher if the woman had secondary, college or university education compared to those with no education or only primary education.

However, in the multivariable analysis which adjusts for other factors only education was significant for having knowledge. The odds of knowledge were 220 % higher for those with secondary, college or university education compared to those with primary education or no education.

4.4 Self medication in pregnancy

In this section, self medication practices as well as drugs used for self medication are presented

Table 4.4 Self Medication practices during pregnancy

Characteristic	N = 250	(%)	p value
Person consulted on drug use in pregnancy			
Pharmacist	100	(40.0)	
Gynaecologist	98	(39.2)	
Nurse	47	(18.8)	0.925
Herbalist	1	(0.4)	
Friend	4	(1.6)	
Counselled on drug use in pregnancy			
No	116	(46.4)	0.150
Yes	134	(53.6)	
Person who counselled			
Pharmacist	30	(12.)	
Gynaecologist	36	(14.4)	
Nurse	65	(26.)	0.345
Friend	3	(1.2)	
None	116	(46.4)	
Source of drugs used in pregnancy			
Chemist	95	(38.)	
Shop	78	(31.2)	0.000
None	77	(30.8)	
Ever experienced problem with pregnancy			
No	111	(44.4)	0.113
Yes	139	(55.6)	
Nature of problem experienced			
Deformation of foetus	27	(10.8)	
Premature rapture of the membranes	12	(4.8)	
Low birth weight	18	(7.2)	
Miscarriage	33	(13.2)	0.009
Preterm birth	29	(11.6)	
Still birth	22	(8.8)	
None	109	(43.6)	
Organs malformed			
Head	4	(1.6)	
Gonads	5	(2.)	
Lips/palate	9	(3.6)	0.110
Limbs	5	(2.0)	
None	225	(90.0)	
Heart	2	(0.8)	

For consultations on drug use during pregnancy, respondents preferred a Pharmacist (40%) almost equally with a Gynaecologist (39.2%) with a Nurse being preferred by 18.8 % of the respondents. Only four of the respondents (1.6%) stated that they would prefer to consult a friend whereas a Herbalist was mentioned by only one respondent (0.4%)

Out of the 250 respondents, 65 (26%) had been counselled by a Nurse, 36(14.4%) by a Gynaecologist, 30 (12%) by a Pharmacist and 3 (1.2%) by a friend while 116 (46.4%) had not been counselled on drug use during pregnancy.

More than half (56.4%) of the patients interviewed had experienced an obstetric problem either with the present or previous pregnancies; 13.2% had had a miscarriage, 11.6% a preterm birth, 10.8% a deformation of the foetus, 8.8% a still birth 7.2% a low birth weight and 4.8% a premature rapture of the membranes. However, 43.6% of the patients reported having experienced no remarkable problem during their pregnancies.

Respondents who used drugs for self medication during pregnancy obtained the drugs from a chemist (38%), from a shop (31.2%) or from a friend (8%). Twenty eight per cent of the respondents reported having used no drug at all for self medication during pregnancy.

Of the 25 respondents who reported having had a birth with a deformation, nine reported a deformation of the lips/ palate. Gonads and limbs were reported to have been deformed in five patients each with four of them reporting head deformations. Two patients reported deformations of the heart structures while 225 respondents reported having observed no deformations

Table 4.5- Drugs used for Self medication in pregnancy

Drug	Frequency	Percentage
Amoxicillin	32	12.8
Paracetamol	75	30.0
Antimalarials	22	8.8
Aspirin	14	5.6
Chlorpheniramine	9	3.6
Antacids	26	10.4
None	72	28.8

Paracetamol was the drug used by most of the respondents (30%) for self medication during pregnancy. Amoxicillin was used by 12.8%, Antacids, 10.4%, Antimalarials, 8.8% Aspirin 5.6% and Chlorpheniramine 3.6%. Up to 28.8% of the respondents reported using no drug during pregnancy.

4.5. Prescription drugs in pregnancy

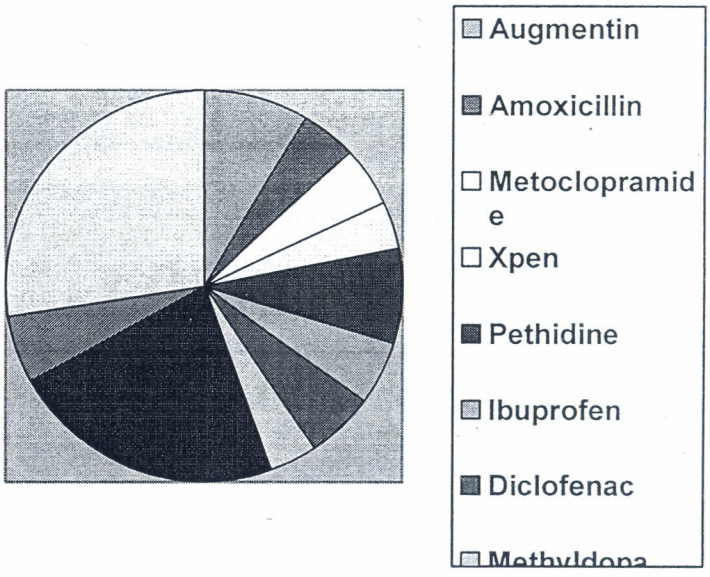
In this section, data on the drugs that were prescribed to the patients while in the wards is presented and analysed. The Names of the drugs, their Pharmacological classes, and FDA categories formed the basis of the analysis.

Table 4.6 – Use of Prescription Drugs during pregnancy

Characteristic	N = 250	(%)	p value
FDA categories of drugs prescribed			
Not applicable	64	(25.6)	
B	109	(43.6)	
C	65	(26.)	0.109
D	11	(4.4)	
X	1	(.4)	
Number of the drugs Prescribed			
Zero	64	25.6	
One	31	12.4	
Two	37	14.8	
Three	39	15.6	0.673
Four	22	8.8	
Five	26	10.4	
> Five	31	12.4	

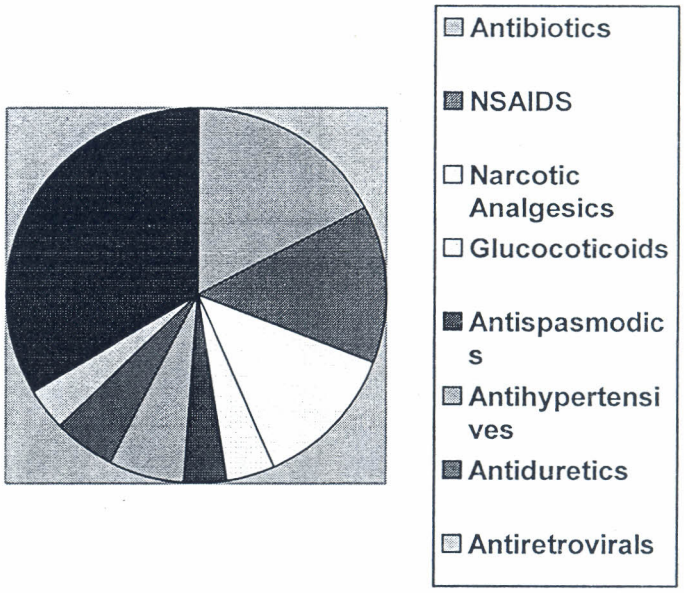
On average, each respondent was prescribed for 2.72 drugs. Most of prescriptions (15.6%) had three drugs. Augmentin (Co-amoxiclav) was the single most prescribed drug having been prescribed to 8% of the respondents. Also widely prescribed were Pethidine (7.2%), Tramadol (5.2%), Diclofenac (5.2%), Metoclopramide (4.8%) and Ibuprofen (4.8%). Quinine was prescribed to one patient only just like Hydralazine, Ampiclox and Paracetamol.

Figure 4.1- **Drugs prescribed in pregnancy**



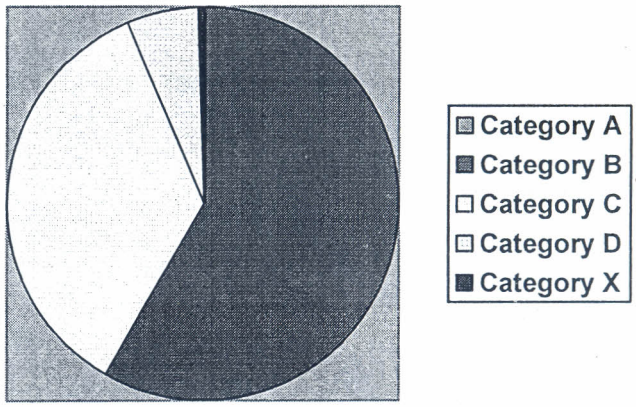
Antibiotics were the most prescribed class of drugs (17.2%). Equally widely prescribed were NSAIDS (13.6%), Narcotic analgesics (12.4%) and antihypertensives (6.4%). Anticonvulsants (0.8%) and antifungals (0.8%) were the least prescribed classes. Up to 25.6% of the patients interviewed were discharged without prescribing any drug to them.

Figure 4.2- Pharmacological Classes of drugs prescribed in pregnancy



Most drugs prescribed (43.6%) belonged to the category B of the FDA risk of drugs in pregnancy. No drug from category A was prescribed to any of the respondents whereas 4.4% of the respondents got a prescription with a drug of category D. A category X drug was prescribed to one patient only and 25.6% of the respondents were attended to and discharged without the use of any prescription drug

Figure 4.3- FDA Categories of drugs Prescribed in pregnancy



DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1. Introduction

In this chapter, study findings are discussed and conclusions drawn from the findings. Recommendations based on the study findings and the conclusions are also made.

5.2. Discussion

5.2.1. Level of Knowledge of respondents on drug use in pregnancy

Research has shown that the level of knowledge of a woman has an important bearing on their ability to understand their treatment and thus seek to improve its outcomes (31). It was therefore a key objective of this study to find out what factors influence the level of knowledge of the respondents on drug use in pregnancy and then relate the level of knowledge to the appropriateness of their use of medications while pregnant. Appropriate use of medicines in pregnancy was defined as not self prescribing while pregnant whereas inappropriate use was self medication in pregnancy.

A knowledge score was generated by combining 10 variables into a single variable. An individual's knowledge was reported as a score out of ten. All variables included for generating the score contributed equally to the score. Knowledge was then grouped using the mean knowledge score (6.7) to generate variable for women who had or who did not have knowledge. The new knowledge score was then modelled with demographic characteristics and the outcome indicated that on univariable analysis, age ($p=0.047$), occupation ($p=0.006$) and level of education ($p=0.001$) all significantly regressed on the level of knowledge. After adjusting for all the other variables by a logistic regression model, it was evident that only level of education ($p=0.09$) was significantly influencing the level of knowledge of the women and hence their drug use practices during pregnancy. This finding is in contrast with the findings of a study carried out in Italy which reported that older women, better educated women and those who reported health problems were at a higher risk of using drugs for self medication (56).

5.2.2. Self medication during pregnancy

Drugs mostly used for self medication during pregnancy were Paracetamol (30%), Amoxicillin (12.8%), Antacids (10.4%), Antimalarials (8.8%), Aspirin (5.6%) and Chlorpheniramine (3.6%). Just like it was evident from this study, paracetamol is the most widely used analgesic in pregnancy. Although there is no known association with teratogenicity, there is little evidence to support the lack of association (25).

In Kenya, amoxicillin is classified as a prescription only medicine. Despite such classification, the respondents who reported to have used the drug for self medication stated that they obtained it from chemists without a prescription. However, a population based study of maternal use of amoxicillin and pregnancy outcome in Denmark (50), did not find any increased risk of adverse pregnancy outcome associated with amoxicillin exposure during pregnancy.

Antimalarials were often not specified, leaving the risk of having used teratogenic ones like quinine in the third trimester. However, despite fear of potential toxicity limiting antimalarial drug use in pregnancy, there is no evidence to suggest that at standard doses, any of the antimalarial drugs is teratogenic (49).

Twenty eight per cent of the respondents reported having used no drug at all for self medication during pregnancy. Different studies have shown that 40-90% of pregnant women take at least one drug during pregnancy (7, 9, 10) and that many women are exposed to several drugs (11)
A case control study to determine the effects of self medication with Chloroquin and pyrimethamine during pregnancy (46) at a maternity hospital in Ibadan, Nigeria found out that 65.7% of the women had ever used the drugs without prescription and 54.7% were on such medications at the time of the study: 28.3% for prophylaxis and the rest for therapy.

5.2.3. Use of Prescription medicines in pregnancy

On average, each respondent was prescribed for 2.72 drugs. Most of prescriptions (15.6%) had three drugs. According to a study done in Pakistan in 2008, all the pregnant women attending the ante natal clinics received a prescription containing at least one drug. 55.4% of the prescriptions were issued in the third trimester, 33.6% in the second and 11.0% in the third trimester (16). A similar study in Ethiopia, 71.3% of women interviewed were prescribed at least one drug during pregnancy. The majority of the drugs prescribed were iron and supplements followed by anti infectives. Nearly 4% of the pregnant women were prescribed drugs from category D or X of the FDA risk classification (17).

Augmentin (Co-amoxiclav) was the single most prescribed drug having been prescribed to 8% of the respondents. Also widely prescribed were Pethidine (7.2%), Tramadol (5.2%), Diclofenac (5.2%), Metoclopramide (4.8%) and Ibuprofen (4.8%). Quinine was prescribed to one patient only just like Hydralazine, Ampiclox and Paracetamol.

Antibiotics were the most prescribed class of drugs (17.2%). Equally widely prescribed were NSAIDS (13.6%), Narcotic analgesics (12.4%) and antihypertensives (6.4%). Anticonvulsants (0.8%) and antifungals (0.8%) were the least prescribed classes. Up to 25.6% of the patients interviewed were discharged without prescribing any drug to them.

Most drugs prescribed (43.6%) belonged to the category B of the FDA risk of drugs in pregnancy. Category B drugs are those in which either animal reproduction studies have not demonstrated a foetal risk but there are no controlled studies in pregnant women, or animal reproduction studies have shown an adverse effect (other than a decrease in fertility) and there is no evidence of risk in later trimesters.(6). No drug from category A was prescribed to any of the respondents whereas 4.4% of the respondents got a prescription with a drug of category D. A category X drug was prescribed to one patient only and 25.6% of the respondents were attended to and discharged without the use of any prescription drug. These finding are similar to the reports from a cohort study conducted to determine the correlates of prescription drug use during pregnancy which reported that a majority of pregnant women were prescribed a prescription drug (56%), and 4% of women were prescribed a category D or X drug. The most common classes of medications prescribed were antibiotics (62%), analgesics (18%), asthma medications (18%), and antiemetics (17%) (55).

In a similar study in Ethiopia (17), 71.3% of women interviewed were prescribed at least one drug during pregnancy. The majority of the drugs prescribed were, iron and mineral supplements followed by anti infective drugs. Nearly 4% of the pregnant women were prescribed drugs from category D or X of the FDA risk classification (47).

5.4. Conclusions

The level of education and hence the level of knowledge of drug use in pregnancy of a woman is the single most important factor that significantly influences their self medication practices while pregnant. Improving the level of education of a woman therefore improves not only their health but also those of their offspring by lowering the chances of their in utero-exposure to potentially teratogenic drugs.

Prescribers at the K.N.H Obstetrics and Gynaecology Department adhere to safe prescription practices but given the low level of education of most of their patients, there is still a high risk of inappropriate medicines use among them.

5.5. Recommendations

1. There is need for further research to find out factors influencing the safety of drug use practices among pregnant women attending Kenya and the wider Eastern African region from which literature on drug use in pregnancy was very scanty.

2. A cohort study with focus on pregnancy outcomes secondary to use of different drugs in pregnancy is warranted.

3. There is need for a national campaign against inappropriate medicines use in pregnancy as this would improve the safety of motherhood. Pharmacovigilance efforts also need to be increased with a focus on drug use in pregnancy.

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APPENDICES

Appendix 1: Questionnaire on drug use during pregnancy

To be read in a language that the respondent is fluent

Questionnaire number.....

A. SOCIODEMOGRAPHIC CHARACTERISTICS OF THE RESPONDENT

1. Reason for admission
   - □ Normal delivery
   - □ Emergency delivery
   - □ Medical condition in pregnancy
   - □ Obstetric Complication in pregnancy
2. Age (in completed years)
   - □ >15 □ 15-24 □ 25-34 □ 35 and above
3. Trimester of pregnancy
   - □ 1st □ 2nd □ 3rd
4. Occupation
   - □ Formal employment
   - □ Informal employment
   - □ Self employment
   - □ Housewife
5. Highest level of formal education attained
   - □ None
   - □ Primary
   - □ Secondary
   - □ College/University

6. Place of residence

□ Slum □ Middle class estate

□ Up market estate □ Rural home

7. Number of previous pregnancies

0 .1 2 3 4 >4

B. LEVEL OF KNOWLEDGE ON DRUG USE IN PREGNANCY

8. How do you know when you are pregnant?

□ By missing my periods □ By testing

□ By feeling malaria like symptoms

9. Have you ever heard that some drugs are more dangerous to the foetus than others?

□Yes □No

10. If yes, where did you get the information from?

□ Pharmacist □ Gynaecologist □ Nurse

□ Media □ Friend/Relative

11. What adverse effects that drugs can cause in pregnancy do you know of?

□Miscarriage □ Deformation to the foetus □ Not sure

12. In what trimester of pregnancy are these adverse effects most likely to occur?

□1st trimester □ 2nd trimester □ 3rd trimester □ Not sure

13. Which specific drug(s) do you know of as the most dangerous to use in pregnancy?

□Antimalarials in general □Antibiotics in general

□Quinine □Chloroquin

□Aspirin □Tetracycline

□Contraceptives □Not sure

14. If Not sure about the safety of a particular drug in pregnancy, whom would you prefer to consult?

□Pharmacist □Gynaecologist

□Nurse □Herbalist □Friend

15. Have you received any counselling on drug use in pregnancy?

□Yes □No

16. If yes, who provided the counselling?

□Pharmacist □Gynaecologist

□Nurse □Herbalist □Friend

C. SELF MEDICATION DURING PREGNANCY

17. Have you ever used medications without a prescription while pregnant?

□Yes □No

18. If yes give as many examples as you can remember
19. Where did you obtain them from?
20. Have you ever experienced any problem with your pregnancy?

□Yes □No

21. If yes, what was the nature of the problem?
22. If the problem was a malformation, what part of the body was affected?

D. DRUGS OF ABUSE USED BY THE RESPONDENT DURING PREGNANCY

23. Are there any drugs/substances of abuse that you have been using during this pregnancy?

□Yes □No

24. Are you aware that drugs of abuse such as tobacco and alcohol can harm the baby if consumed during pregnancy?

□Yes □No

25. Give examples of the drugs you have used

E. DRUGS PRESCRIBED TO THE RESPONDENT DURING THE PERINATAL PERIOD

NAME OF DRUG	PHARMACOLOGICAL CLASS	FDA CATEGORY

Appendix2; Swahili Translation of the questionnaire

To be read in a language that the respondent is fluent

NB. Only the Questions were translated as these were the only parts of the questionnaires to be read out to the respondent. The rest of the parts of the questionnaire was in English

Questionnaire number.....

A. SOCIODEMOGRAPHIC CHARACTERISTICS OF THE RESPONDENT

1. Sababu ya kulazwa

□ Kuzaa Kawaida

□ Kuzaa kwa dharura

□ Ugonjwa katika uja uzito

□ Magonjwa ya kizazi

2. Umri wako (kwa miaka ziliokamilishwa)

□ >15 □ 15-24 □ 25-34 □ 35 na zaidi

3. Kipindi cha uja uzito

□ Kipindi cha kwanza □ kipindi cha pili □ kipindi cha tatu

4. Kazi

□ Kazi ya kuajiriwa

□ Kubarua

□ Kazi ya Kibinafsi

□ Mke wa nyumbani

5. Kiwango cha juu ya Elimu uliotimiza

□ Sikumaliza shule ya msingi

□ Nilimaliza shule ya msingi

□ Nilimaliza shule ya upili

□ Nilimaliza Chuo/ Chuo kikuu

6. Makaazi

□ Kitongoji duni □ Makao ya wastani

□ Makao ya kifahari □ Mashambani

7. Nambari ya mamba zilizopita

0 1 2 3 4 >4

B. LEVEL OF KNOWLEDGE ON DRUG USE IN PREGNANCY

8. Je, huwa unajuaje ya kwamba uko mja mzito?

□ Kwa kukosa hedhi □ Kwa kupima kwa kliniki

□ Kwa kuhisi maumivu mwilini kama ya malaria

9. Je umesikia ya kwamba kuna madawa hatari kwa mtoto aliye tumboni mwa mama?

□ Ndiyo □La

10. Kama ndiyo, uliyasikia hayo kutoka kwa nani?

□ Daktari wa madawa □ Daktari wa akina mama □ Muuguzi

□ Vyombo vya habari □ Jamaa/ Marafiki

11. Je, ni madhara yepi yanayosababishwa na madawa katika uja uzito unayoyajua?

□Mimba kutoka □ Mtoto kutoumbika vizuri □ Sina uhakika

12. Katika kipindi gain cha uja uzito ndiya haya madhara yanaweza kutokea kwa kiwango cha juu?

□ Kipindi cha kwanza □ kipindi cha pili □ kipindi cha tatu □ Sina uhakika

13. Ni madawa gain haswa unayoyatambua kuwa hatari mno ikitumiwa na mama aliye mja mzito?

□ Dawa za malaria □ Dawa za Bacteria

□ Quinine □ Chloroquin

□ Aspirin □Tetracycline

□ Dawa za kuzuia mimba □ Sina uhakika

14. Ukiwa hauna uhakika na usalama wa dawa Fulani ikitumiwa katika uja uzito, utapendelea kumuuliza nani?

□Daktari wa madawa (Pharmacist) □Daktari wa akina mama (Gynaecologist)

□Muuguzi (Nurse) □Mtabibu wa kienyeji (Herbalist) □Rafiki (Friend)

15. Je, umewahi kupewa mawaidha kuhusu jinsi ya kutumia madawa katika uja uzito?

□ Ndiyo □ La

16. Kama ndiyo, ulipewa hayo mawaidha na nani?

□Daktari wa madawa (Pharmacist) □Daktari wa akina mama (Gynaecologist)

□Muuguzi (Nurse) □Mtabibu wa kienyeji (Herbalist) □Rafiki (Friend)

C. SELF MEDICATION DURING PREGNANCY

17. Je, umewahi kutumia madawa bila idhini ya Daktari ukiwa mja mzito?

□ Ndiyo □ La

18. Kama ndiyo, hebu taja ni madawa gani uliyoyatumia
19. Uliyapata hayo madawa kutoka wapi?
20. Je, umewahi kuwa na shida yeyote kwa uja uzito?

□ Ndiyo □ La

21. Kama ndiyo, ni shida gani?
22. Kama shida ilikuwa ya viungo kutoumbika vizuri, ni kiungo gain kilichoadharika?

D. DRUGS OF ABUSE USED BY THE RESPONDENT DURING PREGNANCY

23. Je, kuna madawa yoyote ya kulevya uliyotumia katika uja uzito?

□Ndiyo □La

24. Je, una habari kwamba madawa kama pombe na sigara yanaweza kudhuru mtoto tumboni ikitumiwa na mama katika uja uzito?

□ Ndiyo □ La

25. Ni Madawa gain ya kulevya uliyotumia katika uja uzito?

E. DRUGS PRESCRIBED TO THE RESPONDENT DURING THE PERINATAL PERIOD

NAME OF DRUG	PHARMACOLOGICAL CLASS	FDA CATEGORY

Appendix 3: Informed Consent explanation and Consent Form

TITLE OF THE STUDY: A SURVEY OF DRUG USE IN PREGNANCY AT KNH

Institution: Department of Pharmaceutics and Pharmacy practice, School of Pharmacy,

University of Nairobi

Box 30197- 00400, Nairobi. Tel.....

Investigator: Maurice Onditi Kodhiambo

Box 11488-00400, Nairobi, Tel, 0724468162

Supervisors:

Dr. James N. Ombega, Senior Lecturer, Dept. Of Pharmaceutics and

Pharmacy Practice

Dr. Margaret O. Oluka, Lecturer, Dept. Of Pharmacology and Pharmacognosy

Permission is requested from you to enrol in this medical research study. You should understand the following general principal which apply to all in medical research, whether normal or patient volunteers.

Your agreement to enrol in this study is entirely voluntary.
You may withdraw from the study at any time without necessarily giving any reason for such withdrawal.
After you read the explanation, please feel free to ask any questions that will enable you to understand clearly the nature of this study.

Introduction

In this study, I am assessing drug use practices by mothers from time of onset of pregnancy to delivery

Purpose of the study

The purpose of this study is to establish the level of safety of drug use practices by mothers during pregnancy and at delivery.

Procedures to be followed

I will request you to provide answers to questions that I will read out to you and the answers will be filled into a questionnaire by me in confidence. The questions will be about the drugs you have been using during this pregnancy. I will also, with your permission, refer to your ANC file from the records department of this hospital.

Risks

No risks are foreseen to accrue from this study since all information you will provide will be handled confidentially and will be used for the purposes of this study only.

Benefits

No monetary rewards will accrue from this study. However, it is hoped that the results of this study will be useful in making pregnancy and motherhood safer. All participants will also be given an information leaflet on drug use in pregnancy.

Assurance on confidentiality

All information you provide will be kept confidential and used for the purposes of this study only. Your name will not be used during data handling or in any resulting publications. Codes will be used instead.

Contacts

In case you need to contact me, my supervisors or my academic department with any queries concerning this study, please feel free to use the contacts provided above.

Informed Consent Form

I, the undersigned, willingly agree to participate in this study, the nature and purpose of which have been fully explained to me by the investigator/translator. I understand that the information gathered will be used for the purposes of this study only and maximum confidentiality will be maintained.

Respondent.....

Sign.....**Date**.....

Witness (investigator).....

Sign.....**Date**.....