ASSESSMENT OF HORMONAL CONTRACEPTIVE USE AMONG WOMEN AT KENYATTA NATIONAL HOSPITAL

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DECLARATION

This research dissertation is my original work and has not been presented to any other academic institution for evaluation for research and examination.

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DEDICATION

To my dear son, Nathan Mutugi, my motivation.

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ABBREVIATIONS AND ACRONYMS

CCC: Comprehensive Care Centre

CiCs: Combined Injectable Contraceptives

CoCs: Combined Oral Contraceptives

FAM: Fertility Awareness Method

FSH: Follicle Stimulating Hormone

GnRH: Gonadotropin Releasing Hormone

HIV: Human Immunodeficiency Virus

IUD: Intrauterine Device

KDHS: Kenya Demographic and Health Survey

KNH: Kenyatta National Hospital

LAM: Lactational Amenorrhoea Method

LH: Luteinizing Hormone

MDGs: Millennium Development Goals

MEC: Medical Eligibility Criteria

OCPs: Oral Contraceptive Pills

POICs: Progestin only Injectable Contraceptives

PoPs: Progestin only Pills

USA: United States of America

WHO: World Health Organisation

OPERATIONAL DEFINITIONS OF TERMS

Amenorrhoea: no bleeding or spotting during a 90 day period

Back up contraceptive: include abstinence, male and female condoms, spermicides and withdrawal.

Contraceptive failure: categorised either method failure or user failure. Contraceptive failure in women who use the contraceptive method properly is considered a method failure while failure that takes into account the user's ability to follow instructions correctly and consistently is user failure or typical use failure.

Contraceptive Prevalence Rate: percentage of women who are currently using or whose sexual partner is currently using, at least one method of contraception regardless of the method used. It is reported for married or women in union aged 15 to 49 years.

Frequent bleeding: more than 5 bleeding or spotting episodes within a 90 day period.

Infrequent bleeding: less than 3 bleeding or spotting episodes within a 90 day period.

Prolonged bleeding: one or more bleeding or spotting episodes lasting more than 14 days within 90 days.

Reproductive age: 18 to 49 years.

Unintended pregnancy: mistimed or unwanted pregnancy

Unmet need for Contraception: percentage of women of reproductive age, either married or in union, who want to stop or delay child bearing but are not using any method of contraception.

ABSTRACT

Background

Contraceptives are used mainly to prevent unintended pregnancies and this is ensured by consistent and correct use of contraceptives to prevent contraceptive failure. Appropriate use and counselling on side effects contribute to the consistent and correct use of contraceptives therefore maintaining the desired effectiveness.

Objectives

To assess the prevalence, types, level of knowledge on the correct use and prevalence of side effects of hormonal contraceptives among women of reproductive age at Kenyatta National Hospital.

Methodology

A cross-sectional study was carried out between 1st May 2014 and 30th June 2014 targeting 400 women in their reproductive age. Convenient sampling was used to identify study sites while participants were selected using simple random sampling. Ethical approval was sort from the Kenyatta National Hospital and University of Nairobi Ethical and Research Committee. Data was collected using an interviewer administered questionnaire and analyzed using the statistical software, Statistical Package for the Social Sciences version 20.

Results

The study population comprised mainly of married women between 18-37 years with secondary and post-secondary education in formal employment and others unemployed. Majority were Christians. The use of contraceptives was at 42.8%. Contraceptive use was associated with number of children [OR 1.7 (1.3-2.1)] $p<0.0001$. 56.1% of contraceptive users were on hormonal contraceptives. Injectable contraceptives were the most preferred followed by implants and pills while the contraceptive patch, coitus interruptus and lactational amenorrhoea method were least used. The choice of contraceptive methods was associated with age [OR 2.003 (1.330-3.017)] $p=0.001$ and level of education [OR 1.697 (1.135-2.539)] $p=0.010$. Least side effects, long duration of action and effectiveness were the main criteria of choosing a hormonal contraceptive method among the users. Health practitioners were the main source of contraceptive information while government facilities were the main source of the contraceptives. The level of knowledge

on the correct use of hormonal contraceptive use was limited and it was associated with the level of education [OR 1.389 (1.144-2.051)] p=0.000. The prevalence of side effects among hormonal contraceptive users was 75% and it depended only on the type of hormonal contraceptive (p=0.037).

Conclusion

The gap between contraceptive knowledge and use is still wide. Injectable contraceptives are the most preferred hormonal contraceptives. The level of knowledge on the correct use of hormonal contraceptive is low and contraceptive side effects are common.

Recommendations

Programs should be developed to increase the use of contraceptives and contraceptive counseling should be made mandatory at every visit to the family planning clinic. Studies should be carried out to investigate the gap between contraceptive knowledge and use while others investigate how to increase correct use of contraceptive.

CHAPTER ONE: INTRODUCTION

1.1 Background

Contraception is the intentional use of temporary, long-term or permanent methods to prevent pregnancy as a consequence of sexual intercourse by inhibiting viable sperm from coming into contact with a mature ovum or by preventing a fertilized ovum from implanting successfully in the endometrium (1,2). Contraceptive methods are either modern methods or traditional methods. The modern methods include combined oral contraceptives (CoCs /pill), progestin only pills (PoPs / minipill), combined injectable contraceptives (CiCs/ monthly injectables), progestin only injectable contraceptives (POICs), copper Intrauterine device (IUD), levonorgestrel IUD, male and female condoms, male and female sterilization, lactation amenorrhoea method (LAM) and emergency contraception. Traditional methods are coitus interruptus (withdrawal) and fertility awareness methods (FAM or natural family planning or periodic abstinence) (2).

Contraception plays a major role in preventing pregnancy-related health risks. Women's health and well-being are affected negatively by occurrence of unintended pregnancies. Reduction of unintended pregnancies proportionately reduces the rate of unsafe abortions. Contraception allows for delaying and spacing of pregnancies in young women who are at an increased risk of health problems and maternal mortality from early child bearing while it prevents high risk pregnancies in older women. Limiting the size of families is also made possible by use of contraception. This contribute to achievement of millennium development goal (MDG) 5 in improving maternal health (2,3). Closely spaced and ill-timed pregnancies and births which contribute significantly to infant mortality can be prevented by use of contraception since it allows for the spacing of pregnancies. Reduction in infant mortality contributes to the achievement of MDG 4 (2,4).

In Kenya, knowledge of contraception is almost universal. Ninety-five per cent of women and 97% of men aged between 15 to 49 years know at least one modern method of contraception. The contraceptive prevalence rate in Kenya is 46% of which 39.4% use modern methods of contraception while 6.1% use traditional methods. The level of contraceptive use in all sexually active women in Kenya is 51.1% (5). The prevalence of unintended pregnancies, which include both mistimed and unwanted pregnancies, in married Kenyan women was at 43% in 2008-2009

(5). The main cause of unintended pregnancy is contraceptive failure and non-use of contraceptives (6).

Hormonal contraceptives exert their contraceptive action by interfering with the feedback mechanism that regulates the release of progesterone and oestrogen consequently interfering with either ovulation, fertilization, implantation or all the three processes. Hormonal contraceptives include combined oral contraceptives (CoCs), combined injectable contraceptives (CiCs), contraceptive patch, combined vaginal ring, progestin only pills (PoPs), implants, Progestin only injectable contraceptives (PoICs) and Progestin IUD. CoCs, CiCs, patch and vaginal ring contain both a progestin and an oestrogen in varying amounts while PoPs, implants, PoICs and Progestin IUDs contain a progestin only. The Progestin IUD is more than 99% effective as compared to the pills, injectables, patch and ring which are about 91% effective in preventing pregnancy. CoCs and PoPs are administered orally on a daily basis with emphasis on strict timing for the PoPs. CiCs and vaginal ring are administered monthly while the patch is applied weekly. Implants are effective for 3-5 years, PoICs for 12-13weeks and Progestin IUD for 5 years (2,7–9).

The Medical Eligibility Criteria (MEC) is evidence based guidelines for safe contraceptive use. It addresses criteria for initiation and continued use of all contraceptive methods depending on the comorbidities the woman has (7). The MEC categories are shown in table 1:

Table 1: Medical Eligibility Criteria categories

Categories	**Explanation**	
1	Can use method	No restrictions
2	Can use method	Advantages generally outweigh theoretical or proven risks
3	Should not use method unless no other method is appropriate	Theoretical or proven risks generally outweigh advantages
4	Should not use method	Unacceptable health risk

Kenya has adopted the WHO 2009 MEC in the National family planning guidelines for service providers (10).

1.2 Problem statement

The knowledge of contraception in Kenyan women is 95% according to the Kenya Demographic and Health Survey (KDHS) 2008-09. This is not commensurate to the prevalence of contraceptive use in sexually active women which is 51.1%. It is therefore not surprising that the prevalence of unintended pregnancy in married women is at 43% due to the gap between contraceptive knowledge and contraceptive use (5).

Unintended pregnancies are mainly caused by contraceptive failure and non-use of contraceptives. The consequences of unintended pregnancies affect the woman, the family and the society at large. One of the consequences of unintended pregnancies is unsafe abortion which could lead to maternal morbidity and mortality. There could also be risky maternal behaviour such as alcohol intake, cigarette smoking and illicit drug use which have negative effects on the developing foetus. The woman may also not seek for antenatal care leading to poor birth outcomes such as low birth weight, prematurity and still births. After birth, the mother may not breastfeed the child leading to morbidity and mortality, malnutrition and impaired child development. Postpartum depression could develop leading to child abuse. As all these happen, marital and family instability could be present aggravating the poor mental health of the woman (6,11). Unintended pregnancies reduce the chances of attaining formal education in colleges and universities especially in teenage women. This leads to decreased chances of being part of the paid workforce and consequently reduced economic stability. Unplanned pregnancies and birth reduce earnings both in the short and long term. Heightened conflict and decreased satisfaction in relationships may arise from unintended pregnancies; relationships are more likely to dissolve after an unintended pregnancy. Individuals who experience unintended pregnancy are more likely to experience depression, anxiety and lower levels of happiness (12).

Improvement of contraceptive use and counselling on contraceptive use could play a major role in prevention of unintended pregnancies and their negative effects (6).

1.3 Purpose of the study

Unintended pregnancies are mainly due to non-use of contraceptives and contraceptive failure which is either user failure or method failure. Appropriate contraceptive use averts the occurrence of unintended pregnancies. This study therefore sought to find out the prevalence of

contraceptive use, the type of hormonal contraceptives used, level of knowledge on the correct use and the prevalence of side effects among hormonal contraceptive users.

1.4 Objectives

1.4.1 Broad objective

To assess the use of hormonal contraceptives among women at Kenyatta National Hospital.

1.4.2 Specific objectives

1. To determine the prevalence of contraceptive use among women in their reproductive age at KNH.
2. To find out the type of hormonal contraceptives used by women in their reproductive age at KNH between 1st May 2014 and 30th June 2014.
3. To assess the level of knowledge on the correct use of hormonal contraceptives among users at KNH.
4. To find out the prevalence of side effects among hormonal contraceptive users at KNH.

1.5 Research questions

1. What proportion of women in their reproductive age at KNH used contraceptives?
2. Which types of hormonal contraceptives were the women at KNH between 1st May 2014 and 30th June 2014 using?
3. Did the women at KNH know how to use the hormonal contraceptives correctly?
4. What was the prevalence of side effects of hormonal contraceptives at KNH?

1.6 Significance of the study

The study sought to establish whether hormonal contraceptive users understood the instructions of use and therefore used the contraceptives appropriately. It also sought to find out the most prevalent side effects which would hinder correct and consistent use of hormonal contraceptives. Appropriate and consistent use of hormonal contraceptives ensures that contraception is achieved and occurrence of unintended pregnancies is prevented.

The study will assist reproductive health workers to formulate strategies to improve quality of counselling during initiation and continued use of hormonal contraceptive methods. Improved counselling will assist hormonal contraceptive users to use the contraceptives correctly and consistently therefore preventing unintended pregnancies.

In addition, the study will serve as a reference for the prevalence and pattern of hormonal contraceptive use, level of knowledge on the correct use and prevalence of side effects of hormonal contraceptives in Kenya.

1.7 Limitations

Some of the women were not able to identify the hormonal contraceptive method they were on leading to exclusion. Response bias and interviewer bias might have occurred. Contraception is a personal, private and sensitive issue therefore some of the women might have responded in the negative concerning the use of the same to conceal potentially embarrassing information. Participants who used hormonal contraceptives were interviewed on how they used the contraceptives. The PI asked the questions on the knowledge of correct use of hormonal contraceptives and as the participant gave her responses spontaneously, the PI indicated their response by ticking the corresponding option. This might have led to the interviewer interpreting the responses in their own understanding despite the questions being close-ended to minimise interviewer bias.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This chapter analyses relevant studies that have been carried out with respect to the prevalence of contraceptive use, the types of contraceptives used, level of knowledge on the correct use and the prevalence of side effects of hormonal contraceptives.

2.2 Prevalence of contraceptive use

Contraceptive use has been on the rise worldwide though some regions like Africa, the levels are lower compared to Latin America and Asia (2,13,14). Studies have shown the rate of contraceptive use is high in developed than underdeveloped countries (15,16). In the USA, 76% of women are on a form of contraceptive method (17). The level of contraceptive use is similar in Canada and Australia at 74% and 70% respectively. In Europe, the same scenario is replicated with contraceptive use in France at 75%, 72% in Germany and 76% in Switzerland (17).

In Asia, contraceptive use has been shown to be 33.5% in Nepal (18), 53% in Pakistan (19), and 57% in Bangladesh (20). In an Indian study, 53.8% of the women at a tertiary institute were practising contraception (21). This was similar to the contraceptive prevalence in an Indian urban health centre at 53.84% (22). 44.8% of women at a Saudi health care centre were using contraception (23). These levels are lower than those of North America and Europe but similar to those of South American countries such as Chile where the contraceptive use is at 65% and Guatemala at 50%. However, some South America countries have high rate of contraceptive use such as Brazil, Uruguay and Argentina (17).

Africa has the countries with the lowest rates of contraceptive use such as South Sudan at 8.2% and Chad at 8%. South Africa, Zimbabwe, Swaziland and Egypt have the highest levels of use in Africa at 65% (17). In Nigeria, the contraceptive prevalence has a wide range of 18.8% to 73.7% depending on the region (16,24,25). Closer to Kenya, the rate in Uganda is at 36%, 41% in Tanzania, 36% in Ethiopia, 26% in Somalia, 55% in Rwanda and 30% in Burundi (17).

The contraceptive use in Kenya has also been on the increase with variations from region to region. The contraceptive prevalence rate in Kenya was at 46% according to KDHS 2008-09. Contraceptive use was highest in Central province followed by Nairobi province and Eastern province came in third. North Eastern province had the lowest contraceptive use level (5). In a

study at the Kenyatta National Hospital Comprehensive Care Centre, 44.2% of the women were using one or more form of contraception (26). Level of contraceptive use among the youth was at 58% in a study carried out in Kisumu (27).

This variation is possibly due to the differences of social, economic and cultural backgrounds (15). The level of knowledge of contraceptives is high in most of the African countries but utilisation is quite low. This discrepancy mainly arises from the poor accessibility to family planning services and poor level of knowledge on fertility (16).

The number of women who have ever used contraceptives is usually higher than those currently using since some stop using due to various reasons. In a European study, 88.1% of the women had ever used contraceptives. Romania had the lowest level of ever use while Sweden had the highest level (28). In Nepal, 65% of the women had used family planning methods before the study while the current use was at 33.5%. The reasons for discontinuation of contraceptive use were experiencing side effects, desire for another child, separation from the partner and inaccessibility of methods (18). A Nigerian study revealed that 44% of the women were currently using a contraceptive method while 59% had previously used. The reasons given for contraceptive non-use were fear of loss of fertility, fear of side effects, intention to have more children, objection by partner, reduced accessibility, unaffordability and not sexually active (29). 64% of Ethiopian women had ever used a method of contraception while 43% were still using. The reason for not using contraception were similar to those in Nepal and Nigeria (30). According to the KDHS 2008-09, the contraceptive ever use was 58% for all women while it was 76% for sexually active unmarried women and 73% for currently married women (5) .

The extent of hormonal contraceptive use in Kenya has not been explored.

2.3 Types of contraceptives

Variation in the types of contraceptives used is also present. In an Indian tertiary institute, tubal ligation was the most practised method followed by vasectomy, male condoms, IUDs, fertility awareness and finally OCPs (21). The picture was different in an Indian urban health centre where condoms were the most used form of contraception. OCPs were second in line while tubal ligation was the least used followed by vasectomy (22). A Pakistani study at an urban health centre, the most common contraceptive method was copper IUD followed by condoms. The least

used method was tubal ligation (31). A similar study carried out in a rural health centre in Pakistan found out that the most common method was injectables followed by pills and IUDs. The least common method was the condom (32). A Nepali study revealed that the most of the participants used injectables as their preferred method of contraception followed by tubal ligation. Fertility awareness, IUDs and vasectomy were the least preferred methods (18). At a Saudi health centre, pills were popular with the women followed by IUD. LAM was the least used method (23).

In a European study, oral contraceptive pills, condoms and IUDs were popular while hormonal patch, vaginal ring and fertility awareness method were least used. OCPs were most popular in Germany, France and Sweden in decreasing frequency while condoms were preferred in UK and Romania. IUDs were the third most popular especially in Sweden (28). OCPs were the most used contraceptive method used in USA, Italy, Spain, Germany and UK followed by male condoms. Abstinence and coitus interruptus were the least used methods (33).

According to a study at an antenatal clinic in urban South Eastern Nigeria, the fertility awareness method was the most used method while tubal ligation was the least used. Condoms were not used at all (34). In another antenatal clinic in a different urban setting of South Eastern Nigeria, condoms were the most preferred method followed by coitus interruptus and OCPs. The least used methods were LAM and IUCDs (24). The scenario was different in rural south eastern Nigeria where injectable hormonal contraceptives were the most common followed by IUDs. The least common was female sterilization followed by sub-dermal implants (35). There was a similar picture in urban South Nigeria where the women also preferred Injectables and IUDs. Sterilization and barrier methods were the least preferred (36). In another rural setting, IUCDs, OCPs, condoms were popular compared to injectables which were the least used (16).

According to KDHS 2008-09, injectables were the most used contraceptives followed by pills while the least used methods were IUDs and condoms followed by female sterilisation and fertility awareness method (5). The male condom was the preferred method of contraception for the youth in Kisumu followed by fertility awareness method while OCPs and abstinence were the least popular (27). In a study of the contraceptive use among HIV infected women attending CCC at KNH, condoms were used by majority of the women who were on contraception while the least used methods were injectables and implants (26).

The variation is due to personal preference, source of contraceptive information, health status, socioeconomic and cultural differences, changing contraceptive trends with time and provider bias (5,15,16).

The reasons for using one method of contraception and not the other as a matter of personal preference are numerous. Effectiveness, cost, side effects, permanence and easy availability were cited by Pakistani women when selecting a family planning method (32). Nigerian rural women considered safety, partner's input, complexity of instructions of use and duration of action when choosing a method (34). In a Southern city of Nigeria, the reasons for the choice of a contraceptive were least side effects, easy availability, cost effectiveness, not user dependent, not invasive and privacy of use (36).

Women acquire contraceptive knowledge from a number of sources. In Pakistan, the sources include doctors, community health workers, family planning clinic, radio, mass media and family/relatives (15,37). According to a Nepali study, majority of the women obtained knowledge from media while others obtained from friends/relatives and health workers (18). A Saudi study found out that family/relatives, mass media, health workers and the internet served as point of reference for contraceptive knowledge (23). Nigerian women obtained information from health professionals, electronic and print media, relatives/family, friends and social workers (24,25,36).

Provider bias arises due to the various sources contraceptives can be obtained from. In Nigeria, women get family planning methods from government clinics, private clinics, pharmacies or chemist and friends (16). At KNH CCC, majority of the women obtained their contraceptives from public health institutions while the others obtained from private institutions (26). The KDHS 2008-09 found out that government facilities supplied majority of the contraceptive methods followed by private medical facilities. Other sources included shops and friends or relatives (5).

2.4 Level of knowledge on the correct use of hormonal contraceptives

Appropriate use of contraceptive methods is critical to ensure there is no contraceptive failure which is the main cause of unintended pregnancies (6). Contraceptive failure is either method failure or user failure (1). Unfortunately, the level of knowledge on appropriate use was

generally poor in a study conducted in Pakistan (38). Knowledge for the appropriate use of condoms was 5% for female participants. 36% of the female participants had the knowledge on the appropriate use of OCPs while only 15% knew the appropriate use of IUDs. Though more women had knowledge for the appropriate use of OCPs and IUDs than condoms, the level of knowledge was generally low for all contraceptive methods to ensure effectiveness.

Among Saudi women, 79.3% knew that they needed to take an extra pill if they forgot to take one in less than 12 hours. 6.5% were aware that they needed to take an extra pill and use extra protection for the next 7 days if they missed taking OCPs for more than 12 hours. Only 9.8% of the women knew to take an extra pill in the case of vomiting while 13.5% knew to take an extra pill and use protection for the next 7 days if diarrhoea persisted. Basically, most of the women were unaware of missed pills instructions and instructions in case of diarrhoea and vomiting (39).

In Brazil, 84.5% of the women knew that the pill should be taken daily and at the same time always. 80.7% correctly reported what to do if they forgot to take the pill. 65.9% and 41.7% were aware that a new pack should be started within the first five days of commencement of menstruation and the subsequent pill should be within 7 days after end of the previous pack respectively (40).

The scenario is replicated in a public health family planning clinic in USA, where 94% of women knew what to do if they missed one pill, 19% knew what to do if they missed 2 pills and only 3% knew what to do after missing 3 pills (41). The missed pills instructions are complicated and not easy to recall as the number of missed pills increases.

Studies to assess the knowledge of appropriate use of hormonal contraceptives in Kenya have not been done hence the need for this study.

2.5 Prevalence of side effects of hormonal contraceptives

Side effects are a major cause of discontinuation of the use of contraceptives and some women do not use contraception for the fear of side-effects (16,18,31). Counselling patients on the common side effects of contraceptives assists them in recognising them and coping with them as they wait for them to resolve or change to another contraceptive method (42). Studies have been done to establish the common side effects of hormonal contraceptives.

In a Saudi study on the safety of the oral contraceptive pill, the most reported side effect was weight gain or increased appetite followed by nausea, tender breasts, acne, abnormal vaginal bleeding and diarrhoea in decreasing frequency (39). A survey on the experience with side effects among women using OCPs in Honduras, headaches were the most experienced followed by nausea and vomiting, irregular bleeding, amenorrhoea and abdominal pain in decreasing frequency (43). A German study exploring the satisfaction of women with the birth control they were on, the women who had ever used OCPs complained of weight gain, headaches, breast tenderness and nausea in that order (44).

Commonly reported side effects of the hormonal contraceptive patch are breast tenderness, headaches, application site reactions, nausea, upper respiratory tract infections, dysmenorrhoea and abdominal pain (45). In a pooled analysis of the safety and tolerability of the contraceptive patch, breast tenderness was the most reported side effect followed by headache, application site reaction, Nausea, upper respiratory tract infections and dysmenorrhoea. In a comparative arm of the study, headaches were most frequent with the patch compared to OCPs, then nausea, application site reaction, breast tenderness, upper respiratory tract infections, dysmenorrhoea and abdominal pain (46). Basically the contraceptive patch causes similar side effects as other hormonal contraceptives except for the additional mild to moderate application site reaction and higher frequencies of breast tenderness (45,46).

According to a survey in Honduras on experience with side effects among injectable contraceptive users, 72% of the 300 participants experienced side effects with headaches being reported by majority of the participants. Irregular bleeding, absence of menstruation, nausea and vomiting and abdominal pain were also reported in that decreasing frequency (43). In an American trial, the most common adverse events were headache, weight increase, intermenstrual bleeding, amenorrhoea and decreased libido while in the European/Asian arm, amenorrhoea, intermenstrual bleeding and headache were the most reported. Other side effects experienced in both trials were fatigue, injection site pain, menometrorrhagia, menorrhagia and acne (47).

In London, implant users were interviewed on their experience of side effects and they reported to have experienced abnormal bleeding, mood swings, weight gain, acne, anaemia, headaches, abdominal pains and discomfort at the insertion point. Majority of the users complained of abnormal bleeding while the least bothersome side effects were abdominal pains and pain at the

point of insertion (48). In a Swiss study, bleeding abnormalities which included infrequent bleeding, amenorrhoea, prolonged bleeding and menometrorrhagia were the most reported side effect on the first follow-up visit in women using the implant, followed by dizziness, acne, weight gain, mood swings, breast tenderness, headache, loss of libido, abdominal pain, depressive mood and hot flushes. In the second follow up, only acne had increased in prevalence while the other side effects had reduced (49). According to a pilot study on the efficacy and safety of implants in Thailand, implant users complained of intermenstrual bleeding, amenorrhoea, infrequent bleeding, headache, dizziness, weight gain, breast tenderness and acne (50).

For the levonogestrel IUD, women remove it earlier than scheduled due to abnormal bleeding, bloating, headaches, weight gain, depression, breast tenderness, excessive hair growth acne, sexual disinterest, abdominal pain, premenstrual syndrome and vaginal discharge. The pattern was similar to the levonogestrel IUD in that abnormal bleeding was the most reported while abdominal pain was the least reported (51).

Similar to the prevalence and pattern of hormonal contraceptive use and level of knowledge of correct use in Kenya, no studies have been done to explore the prevalence of side effects among hormonal contraceptive users in Kenya.

2.6 Summary

The use of contraceptives and types of contraceptives used vary from region to region most likely due to socioeconomic and cultural differences, health status and provider bias. The knowledge on appropriate use of contraceptives is generally low for all contraceptive methods. The side effects experienced with hormonal contraceptives are similar only varying in frequency for each particular method.

CHAPTER THREE: 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 that were taken to enhance validity and reliability of the data.

3.2 Research design

The study was a cross sectional study that was carried out between 1st May 2014 and 30th June 2014. This design was deemed suitable because it achieved the objectives of the study since the collection of information was done at one point. An interviewer-administered questionnaire was used to collect the required information from the participants.

3.3 Location of study

The study was carried out at Kenyatta National Hospital (KNH) in the departments of Obstetrics and gynaecology, Internal medicine, Paediatrics and Surgery wards which are located from the ground floor to the eighth floor of the main tower block. The General Outpatient clinic for walk-in patients was also used as a study site. KNH is located along Hospital Road, Upper Hill, Nairobi. Within the KNH complex there is University of Nairobi's College of Health Sciences, Kenya Medical Training College, Kenya Medical Research Institute and National Laboratory Service (Ministry of Health). The hospital has 50 wards, 22 outpatient clinics, 24 specialized theatres and an Accident & Emergency department. KNH was deemed suitable for the study because it is the largest referral hospital in East and Central Africa serving the population in the aforementioned region and therefore the study participants were representative.

3.4 Target population

The study population comprised of women aged between 18-49 years within the study locations. This included patients of KNH and their care givers, students of various learning institutions on clinical rotations and the staff in the study locations. These women were in their reproductive years and were deemed likely to be using contraceptives.

3.4.1 Inclusion criteria

Women of reproductive age (18-49 years) who consented to the study were eligible for inclusion in the study.

3.4.2 Exclusion criteria

Women who were using hormonal contraceptive methods for any other indication besides contraception, pregnant women, post-menopausal women, those who had undergone hysterectomies and those who didn't give consent were excluded from the study.

3.5 Sample size

The prevalence of contraception use in all sexually active women in Kenya is 51.1% (5).

By use of Fisher's formula, sample size was calculated (52).

$$n = \frac{Z^2 \times P(1-P)}{d^2}$$

Where n = sample size

Z = the value of the normal deviate at a given confidence level. Confidence interval selected is 95%, therefore Z=1.96

P = proportion of women who use contraception, in this case, P=51.1%

d =5% degree of precision/accuracy

$$n = \frac{1.96^2 \times 0.511(1-0.511)}{0.05^2}$$

n=383.9

Sampling was done until the sample size was attained. For this study, 400 women were sampled.

3.6 Sampling technique

Convenient sampling was used to identify the specific study sites within KNH. Simple random sampling of patients, students and staff within the reproductive age in the departments of Obstetrics and gynaecology, Internal medicine, Paediatrics and Surgery wards and the General Outpatient clinic for walk-in patients was done. A coin was tossed after approaching a woman and if it landed on heads, the participant was included in the study as long as they consented. This was the best method to enhance the external validity of the findings. The process was done by the Principal Investigator (PI) from Monday to Friday, 8.00am to 5.00pm during the data collection period.

3.7 Data collection techniques

The research instrument was a pre-tested interviewer-administered questionnaire formulated based on The Ministry of Public Health and Sanitation Division of Reproductive Health National Family Planning Guidelines for Service Providers and the World Health Organization Family Planning Global Handbook for Providers (Appendix II) (2,10). Women who consented were interviewed by the PI in privacy and the responses entered in the questionnaire. The doctor's rooms within the wards and clinic were used for the interviews to ensure privacy. Samples of hormonal contraceptive method formulations used in Kenya were availed to assist the women to identify which one they were on. The data was collected over a period of 2 months between 1st May 2014 and 30th June 2014.

3.8 Study procedures and methods

Recruitment of study participants took place at the departments of Obstetrics and gynaecology, Internal medicine, Paediatrics and Surgery wards and the General Outpatient clinic for walk-in patients between 1st May 2014 and 30th June 2014 from Monday to Friday, 8.00am to 5.00pm by the PI. The PI introduced herself to a potential participant and gave a brief summary of the research study to be undertaken including the procedures to, benefits, potential risks, and contact information of the primary investigator. She then sought for written consent to recruit the individual into the study. Upon meeting the inclusion criteria and giving written consent, an individual was recruited into the study where participants underwent an interviewer-administered questionnaire.

The PI administered a questionnaire through a face to face interview. The interview included sociodemographic information, contraceptive use, knowledge on use and side effects for hormonal contraceptive users. Interview was conducted in a doctor's room where both the PI and interviewee were seated. The PI asked the questions and recorded the responses on the questionnaire. The interviewee was at liberty to decline to answer a question, stop the interview at any time as well as ask questions about the study.

In case the participant did not know their weight and height, they were measured by the PI. Body weight was measured by having the participant stand on a pre-calibrated weighing scale with back straight and eyes facing forward and reading was recorded in the questionnaire. Height was measured with participant standing against a measuring tape mounted on a wall without

shoes and with back straight and eyes facing forward and the reading was recorded in the questionnaire.

For the participants who did not use contraceptives and those who used non-hormonal contraceptives, the interview ended after inquiring on their contraceptive practices. In case contraceptive non-users were interested in initiation into contraceptive use, they were referred to clinic 66, the family planning clinic in KNH.

Participants who used hormonal contraceptives were interviewed further on how they used the contraceptives and side effects they had experienced. The PI asked the questions on the knowledge of correct use of hormonal contraceptives and side effects experienced and as the participant gave her responses spontaneously, the PI indicated their response by ticking the corresponding option. If the participant had the use of the hormonal contraceptive they were on wrong, the PI gave them the right instructions after they have finished responding to the questionnaire. In case of any uncertainties, the participant was referred to clinic 66.

3.9 Data quality control

The interviewer-administered questionnaire was pretested before use by randomly interviewing 10 women by the PI. The questionnaire was then adjusted accordingly.

The data entered was checked for accuracy and completeness. Errors and omissions were rectified.

3.10 Data security

All filled questionnaires were kept under lock and key by the PI. The personal computer on which the data was analysed was accessed only through a private password. Backups in form of secured external hard disks and hard copies of summarized results were kept under lock and key by the PI.

3.11 Data analysis

A database of the data collected was created using Epi Info version 7. The data was then analysed using SPSS version 20. Descriptive statistics which included frequencies and percentages were derived from the data. P-values were calculated using Chi-square with the significance level set at 0.05. Multivariate analysis was done using logistic regression.

3.12 Ethical and logistical considerations

Authorisation to conduct the study was sought from the Kenyatta National Hospital/ University of Nairobi Ethical and Research Committee (Appendix III).

Permission was sought from the respective Nursing officers-in-charge of Obstetrics and gynaecology, Internal medicine, Paediatrics and Surgery wards and the General Outpatient clinic before collecting data.

Informed consent from the study participants who met the inclusion criteria was sought. Each participant was requested to sign a consent form before inclusion into the study (Appendix I).The study participants were interviewed privately and all the information obtained was treated with confidentiality. Serial numbers were used instead of the patient's name to protect their identity.

CHAPTER FOUR: RESULTS

4.1 Introduction

This chapter focuses on the findings of this research. The data is summarised into tables of frequencies, percentages and p-values. The results are organised based on the sociodemographic characteristics of the study participants, prevalence of contraceptive use, type of hormonal contraceptives used, level of knowledge on the correct use and prevalence of side effects of hormonal contraceptives.

Sociodemographic characteristics

Majority of the participants (40.8%) were aged between 28 and 37 years (Table 2). Only 25 (6.2%) were above 47 years. 62% were married while the rest were either formerly married or had never been married. Most of the respondents had either tertiary level education or secondary level education and minority had primary level education or no formal education at all. More than half (68.0%) of the women were Christian-protestant whereas 109 (27.7%) were Christian-catholic. Muslims and Hindus were both below 5%. Most of the participants were either unemployed or formally employed while those in informal employment and self-employed were fewer. Majority of the women (44.0%) had 1-2 children while only 2.3% had more than 6 children. Over eighty per cent were non-breastfeeding participants. Almost all of the women (99.2%) were non-smokers. Most of the respondents (44.8%) had normal weight while 131 (33.0%) were overweight and 2.0% were underweight.

Hypertension was the most prevalent morbidity with 10 (2.5%) women having the condition followed by HIV (Table 3). The participants' medication history was also sought to counter check for interaction with the hormonal contraceptives they were on (Appendix V).

Table 2: Sociodemographic characteristics

Characteristics	Frequency (n)	Percentage (%)
Age (years)		
18-27	140	35.0
28-37	163	40.8
38-47	72	18.0
48-57	25	6.2
Marital status		
Never married	100	25.1
Currently married	249	62.4
Formerly married	50	12.5
Highest Education level		
None	5	1.3
Primary	99	24.8
Secondary	125	31.3
Tertiary	170	42.6
Employment status		
Unemployed	152	38.2
Informal employment	49	12.3
Formal employment	110	27.6
Self-employed	87	21.9
Religion		
Christian-Protestant	268	68.0
Christian-Catholic	109	27.7
Muslim	13	3.3
Hindu	4	1.0
Number of children		
0	99	24.9
1-2	175	44.0
3-4	91	22.9
5-6	24	6.0
>6	9	2.3
Breastfeeding		
Yes	68	17.2
No	328	82.8
Smokes		
Yes	3	0.8
No	397	99.2
Body Mass Index (BMI)		
<18.5	8	2.0
18.5-24.9	178	44.8
25-29.9	131	33.0
>30	80	20.2

Table 3: Morbidities of the study population

Morbidity	Frequency (n)	Percentage (%)
Hypertension	10	2.5
HIV	8	2.0
Cancer of the endometrium	4	1.0
Bone fractures and soft tissue injuries	3	0.8
Diabetes Mellitus	3	0.8
Gestational trophoblastic disease	3	0.8
Cancer of the cervix	3	0.8
Cancer of the ovaries	2	0.5
Sickle cell anaemia	2	0.5
Pneumonia	2	0.5
Asthma	2	0.5
Deep Venous Thrombosis	1	0.2
Migraines	1	0.2
Peptic ulcers	1	0.2
Vaginal candidiasis	1	0.2
Vesico-vaginal fistula	1	0.2
Uterine fibroids	1	0.2
Pelvic Inflammatory Disease	1	0.2
Cancer of the vulva	1	0.2
Leukaemia	1	0.2
Arthritis	1	0.2
Tuberculosis	1	0.2

4.2 Prevalence of contraceptive use

The use of contraceptives among the study population was at 42.8% as shown in table 4. For those who were not currently using contraceptives, 58.1% had previously used (Table 5).

Table 4: Prevalence of contraceptive use

Contraceptive Use	Frequency (n)	Percentage (%)
Yes	171	42.8
No	229	57.2
Total	400	100

Table 5: Level of previous contraceptive use

Previous contraceptive use	Frequency (n)	Percentage (%)
Yes	133	58.1
No	96	41.9
Total	229	100

Contraceptive use was found to be associated with marital status, employment status, number of children, breastfeeding and the BMI after bivariate analysis (Table 6). Married women were more likely to be using contraceptives compared to those who had never been married or were formerly married. Majority of the participants in formal employment were contraceptive users compared to the unemployed, of whom majority were not using. The more number of children a respondent had the higher the chances that they were on contraceptives. Breastfeeding women had a higher likelihood of using contraceptives. More than half of underweight and obese participants were on contraception compared to those who had normal weight or were overweight.

However, after logistic regression the only independent predictor of contraceptive use was number of children [OR 1.7 (1.3-2.1)] $p<0.0001$.

Table 6: Relationship between contraceptive use and sociodemographic characteristics

Characteristics	Yes n (%)	No n (%)	P value
Age (years)			
18-27	49 (35.3)	90 (64.7)	0.076
28-37	81 (49.7)	82 (50.3)	
38-47	30 (42.3)	41 (57.7)	
48-57	9 (36.0)	16 (64.0)	
Marital status			
Never married	17 (17.0)	83 (83.0)	<0.0001
Currently married	137 (55.2)	111 (44.8)	
Formerly married	15 (30.6)	34 (69.4)	
Highest Education level			
None	1 (20.0)	4 (80.0)	0.084
Primary	40 (40.4)	59 (59.6)	
Secondary	45 36.0)	80 (64.0)	
Tertiary	83 (49.4)	85 (50.6)	
Employment status			
Unemployed	51 (33.6)	101 (66.4)	0.018
Informal employment	23 (46.9)	26 (53.1)	
Formal employment	57 (52.8)	51 (47.2)	
Self-employed	37 (42.5)	50 (57.5)	
Religion			
Christian-Protestant	113 (42.3)	154 (57.7)	0.363
Christian-Catholic	48 (44.4)	60 (55.6)	
Muslim	6 (46.2)	7 (53.8)	
Hindu	0 (0.0)	4 (100.0)	
Number of children			
0	16 (16.2)	83 (83.8)	<0.0001
1-2	85 (48.9)	89 (51.1)	
3-4	53 (58.9)	37 (41.1)	
5-6	11 (45.8)	13 (54.2)	
>6	4 (44.4)	5 (55.6)	
Breastfeeding			
Yes	37 (54.4)	31 (45.6)	0.027
No	130 (39.9)	196 (60.1)	
Body Mass Index (BMI)			
<18.5	5 (62.5)	3 (37.5)	0.006
18.5-24.9	60 (33.7)	118 (66.3)	
25-29.9	60 (45.8)	71 (54.2)	
>30	43 (55.1)	35 (44.9)	

After bivariate analysis, previous contraceptive use was associated with age, marital status, education level, religion, number of children and BMI (Table 7). The higher the age of a participant, the higher the chances that she had used contraceptives before. Formerly married women had a higher likelihood of having used contraception previously compared to those who have never been married. Educated respondents were more likely to have ever used contraceptives compared to those who had not received any formal education. More Christian-protestants had previously used contraceptives compared to Christian-catholics, Muslims and Hindus. The higher the number of children a participant had the higher the likelihood she had used contraceptives before. Overweight and obese women were more likely to have previously used contraceptives.

Logistic regression revealed that the independent predictors of previous use of contraceptives were marital status [OR 0.456 (0.262-0.795)] p=0.006, education level [OR 0.531 (0.341-0.828)] p=0.005 and number of children [OR 0.317 (0.192-0.524)] p=0.000.

Table 7: Relationship between previous contraceptive use and sociodemographic characteristics

Characteristics	Yes n (%)	No n (%)	P value
Age (years)			
18-27	34(37.8)	56(62.2)	<0.0001
28-37	51(61.4)	32(38.6)	
38-47	34(82.9)	7(17.1)	
48-57	10(62.5)	6(37.5)	
Marital status			
Never married	23(27.7)	60(72.3)	<0.0001
Currently married	79(70.5)	33(29.5)	
Formerly married	26(76.5)	8(23.5)	
Highest Education level			
None	0(0.0)	4(100.0)	0.021
Primary	40(67.8)	19(32.2)	
Secondary	46(57.5)	34(42.5)	
Tertiary	43(50.0)	43(50.0)	
Employment status			
Unemployed	47(46.5)	54(53.5)	0.083
Informal employment	16(61.5)	10(38.5)	
Formal employment	32(61.5)	20(38.5)	
Self-employed	33(66.0)	17(34.0)	
Religion			
Christian-Protestant	92(59.4)	63(40.6)	0.047
Christian-Catholic	34(56.7)	26(43.3)	
Muslim	2(28.6)	5(71.4)	
Hindu	0(0.0)	4(100.0)	
Number of children			
0	17(20.5)	66(79.5)	<0.0001
1-2	66(73.3)	24(26.7)	
3-4	32(86.5)	5(13.5)	
5-6	10(76.9)	3(23.1)	
>6	3(60.0)	2(40.0)	
Breastfeeding			
Yes	20(64.5)	11 (35.5)	0.337
No	109(55.3)	88 (44.7)	
Body Mass Index (BMI)			
<18.5	1(33.3)	2 (66.7)	0.014
18.5-24.9	56(47.5)	62 (52.5)	
25-29.9	46(63.9)	26 (36.1)	
>30	26(74.3)	9 (25.7)	

4.3 Types of hormonal contraceptives

Different women use different types of contraceptives depending on personal preference, source of contraceptive information, health status, socioeconomic and cultural differences, changing contraceptive trends with time and provider bias. The types of contraceptive used by the study population and the factors influencing choice were sought and the findings were as follows.

4.3.1 Pattern of contraceptive use

The 171 women who were using contraceptives were on various types as shown in figure 1. Injectables, intrauterine devices, implants and pills were popular types while the contraceptive patch, coitus interruptus and LAM were least used. Other methods that were being used by the women were barrier methods, sterilization and FAM. 96 (56.1%) of the contraceptive users were on various hormonal contraceptives (Figure 2) while 75 (43.9%) were on non-hormonal contraceptives. POICs and implants were used by majority of the hormonal contraceptive users while the contraceptive patch, POPs and progestin IUD had less the 5 users each.

Figure 1: Type of contraception

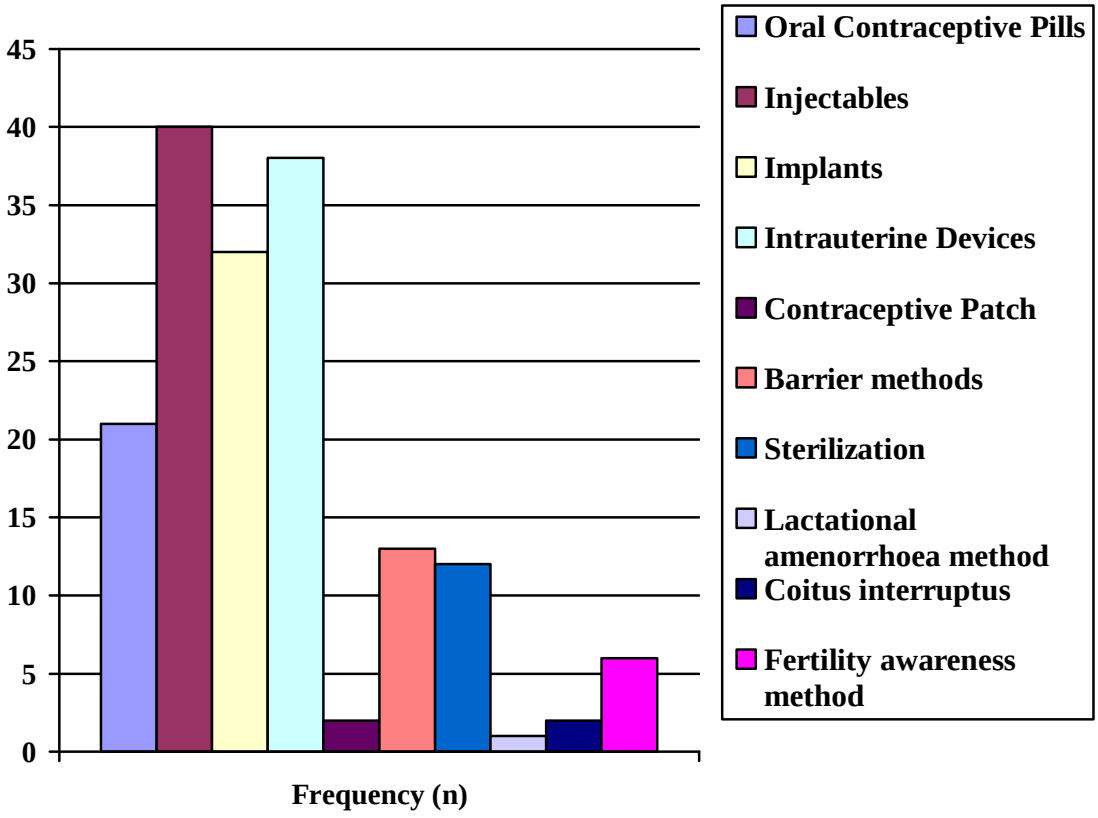
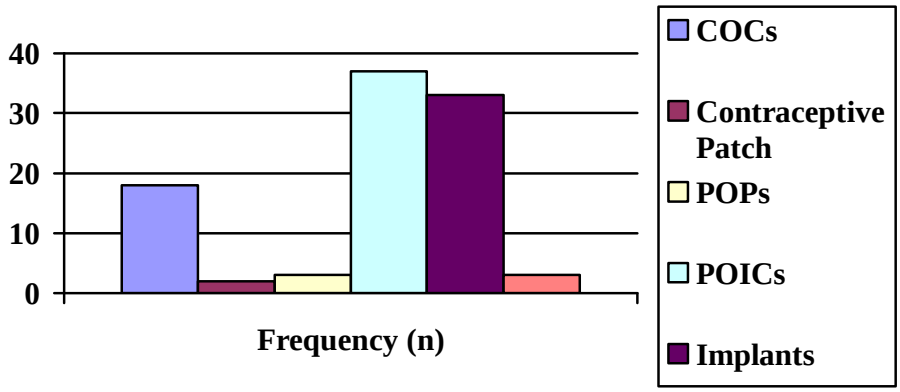


Figure 2: Type of hormonal contraceptives



The choice of contraceptive methods was found to be associated with age, marital status, level of education, number of children and breast feeding after bivariate analysis (Table 8). The younger participants were inclined to hormonal contraceptives compared to the older participants. Married women were more likely to be using hormonal contraceptives compared to the women who had never been married or were formerly married. The educated respondents were hormonal contraceptive users compared to the respondents who had not received any formal education who preferred non-hormonal contraceptives. Breastfeeding women were more likely to be using hormonal contraceptives compared to those who were not breastfeeding.

Multivariate analysis revealed that the independent predictors of use of hormonal contraceptives were age [OR 2.003 (1.330-3.017)] p=0.001 and level of education [OR 1.697 (1.135-2.539)] p=0.010.

Table 8: Relationship between the form of contraceptives and sociodemographic characteristics

Characteristics	Hormonal n (%)	Non-hormonal n (%)	P value
Age (years)			
18-27	32 (65.3)	17 (34.7)	0.003
28-37	51 (63.8)	29 (36.2)	
38-47	12 (40.0)	18 (60.0)	
48-57	1 (11.1)	8 (88.9)	
Marital status			
Never married	5 (31.2)	11 (68.8)	0.008
Currently married	86 (62.8)	51 (37.2)	
Formerly married	5 (33.3)	10 (66.7)	
Highest Education level			
None	0 (0.0)	1 (100.0)	0.033
Primary	29 (72.5)	11 (27.5)	
Secondary	28 (62.2)	17 (37.8)	
Tertiary	39 (47.6)	43 (52.4)	
Employment status			
Unemployed	34 (68.0)	16 (32.0)	0.155
Informal employment	12 (52.2)	11 (47.8)	
Formal employment	27 (47.4)	30 (52.6)	
Self-employed	23 (62.2)	14 (37.8)	
Religion			
Christian-Protestant	63 (55.8)	50 (44.2)	0.179
Christian-Catholic	30 (62.5)	18 (37.5)	
Muslim	1 (20.0)	4 (80.0)	
Hindu	0 (0.0)	0 (0.0)	
Number of children			
0	5 (31.2)	11 (68.8)	0.011
1-2	56 (65.9)	29 (34.1)	
3-4	31 (58.5)	22 (41.5)	
5-6	4 (36.4)	7 (63.6)	
>6	0 (0.0)	3 (100.0)	
Breastfeeding			
Yes	26 (72.2)	10 (27.8)	0.048
No	70 (53.8)	60 (46.2)	
Body Mass Index (BMI)			
<18.5	3 (60.0)	2 (40.0)	0.464
18.5-24.9	38 (64.4)	21 (35.6)	
25-29.9	30 (50.0)	30 (50.0)	
>30	24 (55.8)	19 (44.2)	

4.3.2 Reasons for contraceptive choice

Least side effects, long duration of action and most effective were the main reasons why hormonal contraceptive users choose one method over the others. Other reasons included recommendation by a health practitioner, doesn't have to ingest daily or change weekly, immediate return to fertility, most available method, least cost and privacy of choice with less than ten of the hormonal contraceptive users citing them as reasons of choice (Table 9).

Table 9: Reason for choosing the hormonal contraceptive method

Reason	Frequency (n)	Percentage (%)
Most effective method	17	17.7
Most available method	4	4.1
Least side effects	33	34.3
Least cost	2	2.0
Immediate return to fertility	5	5.2
Long duration of action	25	26.0
Recommended by health practitioner	9	9.3
Privacy of choice	2	2.0
Does not have to remember to take daily or change weekly	9	9.3

NB: Some women had multiple reasons

4.3.3 Source of contraceptive information

Health practitioners were the main source of contraceptive information followed by family and friends (Table 10). Other sources included media and advertisement, coursework in school and internet.

Table 10: Source of hormonal contraceptive information

Source	Frequency (n)	Percentage (%)
Media and advertisement	5	5.2
Family and friends	24	25.0
Health practitioner	65	67.7
Covered in a unit at school	5	5.2
Internet	2	2.0

NB: Some women had multiple sources

4.3.4 Source of hormonal contraceptives

More than half of the hormonal contraceptive users obtained the contraceptives from government health facilities while 27.8% got from private health facilities. The rest purchased from community pharmacies (Tables 11).

Table 11: Source of hormonal contraceptives

Source	Frequency (n)	Percentage (%)
Government health facility	56	57.7
Private health facility	27	27.8
Community pharmacy	14	14.5
Total	96	100.0

4.3.5 Contraceptive counselling

Majority of the women (74, 77.1%) were counselled on how to use the contraceptives they were using (Table 12). The counselling was done mainly by nurses and medical practitioners (Table 13).

Table 12: Number of women counselled on how to use hormonal contraceptives

Counselled	Frequency (n)	Percentage (%)
Yes	74	77.1
No	22	22.9
Total	96	100

Table 13: Source of hormonal contraceptive counselling

Source	Frequency (n)	Percentage (%)
Medicine practitioner	25	33.8
Pharmacy practitioner	4	5.4
Nursing practitioner	45	60.8
Total	74	100.0

4.3.6 Pattern of previous contraceptive use among current non-users

Injectables and pills were the most used contraceptives by participants before they stopped using them while the contraceptive patch and FAM were the least ever used methods (Figure 3). Experience with side effects, desire for more children and cessation of sexual activity were the main reasons for not using contraceptives (Table 14).

Figure 3: Type of contraception previously used by current non-users

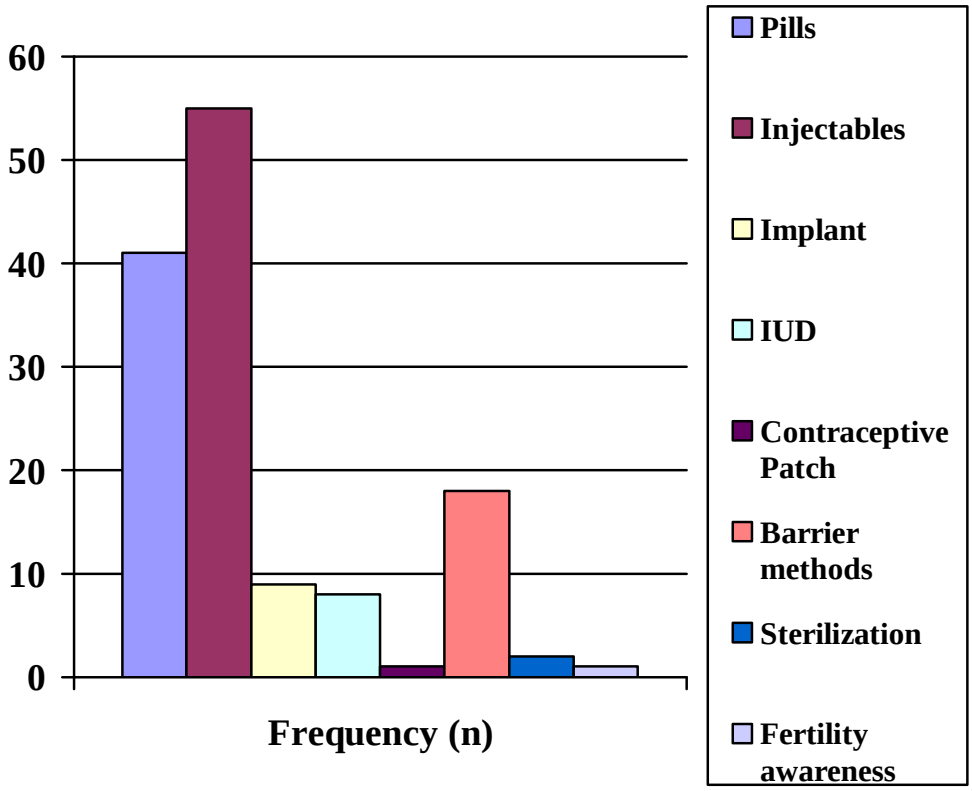


Table 14: Reasons for stopping the use of the contraception

Reason	Frequency (n)	Percentage (%)
Side effects	49	36.8
Wanted more children	40	30.1
Unavailability	2	1.5
High costs	1	0.8
Not sexually active	40	30.1
Failure of methods used prior	1	0.8
After medical advice against it	8	6.0

NB: Some women had multiple sources

4.4 Level of knowledge on the correct use of hormonal contraceptives

Use of hormonal contraceptives correctly is critical for their effectiveness. How well hormonal contraceptive users were using the particular type they were on was sought and the findings are below. Level of knowledge was assessed on an "all or none" basis according to the Ministry of Public Health and Sanitation Division of Reproductive Health National Family Planning Guidelines for Service Providers and the World Health Organization Family Planning Global Handbook for Providers as the standard references.

4.4.1 Combined Oral Contraceptives

Out of the eighteen COCs users, 88.9% and 66.7% were conversant with the correct timing of initiation and daily intake respectively (Table 15). 38.9% of COC users knew the signs to look out for when using the pills. Slightly more than half of the women (52.9%) knew what to do after missing one or two pills or starting a new pack one or two days late. Only 11.1% were correct on what to do after missing three or more pills in the first or second week or starting a new pack three or more days late. 22.2% women knew what to do after missing three or more days in a row in the third week, after vomiting within two hours of taking the pill and after vomiting or having diarrhoea for more than two days.

Table 15: Level of knowledge on the correct use of combined oral contraceptives (N=18)

Instruction	Frequency (n)	Percentage (%)
Timing of initiation of COCs	16	88.9
Time to take COCs	12	66.7
Warning signs of COCs	7	38.9
What to do after missing one or two pills or starting a new pack one or two days late	9	52.9
What to do after missing three or more pills in the first or second week or starting a new pack three or more days late	2	11.1
What to do after missing three or more days in a row in the third week	4	22.2
What to do after vomiting within two hours of taking the pill	4	22.2
What to do after vomiting or diarrhoea for more than two days	4	22.2

NB: Frequency refers to the number of users with correct responses

4.4.2 Progestin only Injectable contraceptives

All the thirty seven women knew the duration of action of the method they were using. Only 28.9% knew how early or late they could go for the repeat injection while 62.1% knew what measures to take if they went for the repeat injection later than the stipulated time.

Table 16: Level of knowledge on the correct use of progestin only injectable contraceptives (N=37)

Instruction	Frequency (n)	Percentage (%)
Duration of effectiveness	37	100
How early or late the repeat injection can be given	11	28.9
What to do after going later than the stipulated time for the repeat injection	23	62.1

NB: Frequency refers to the number of users with correct responses

4.4.3 Implants

Almost all the implant users (97%) knew the duration of effectiveness of the method. Slightly more than 15% of the women were conversant with the care of the site of insertion immediately after insertion. 61.3% were aware of the danger signs to look out for at the point of insertion of the implant.

Table 17: Level of knowledge on the correct use of implants (N=33)

Instruction	Frequency (n)	Percentage (%)
Duration of effectiveness	32	97.0
What to do after insertion; duration to keep the point of insertion dry	5	15.1
What to do after insertion; duration to keep the adhesive on	2	6.2
Signs to look out for at the point of insertion	19	61.3

NB: Frequency refers to the number of users with correct responses

4.4.4 Contraceptive patch, Progestin only Pills and Progestin IUDs

Both women who were using the contraceptive patch knew the sites of applying the patch, duration of action of each patch, how many weeks one should apply the patch, how long one should not apply the patch and measures to take after a patch detached for more than 24 hours during the first week of the menstrual cycle. However, both women did not know the measures to take if a patch detached for less or more than 72 hours during the second and third week of the menstrual cycle.

All the three women who were using POPs knew the timing of daily intake of the pills. However, only one was conversant with the measures to take if they missed one or more pills by three hours despite their menses having resumed or not.

All the three women who were on the progestin IUD knew the duration of effectiveness of the method while two were conversant with how to confirm if the device is still in position and the warning signs to look out for.

Level of knowledge on the correct use of hormonal contraceptives was found to be associated with type of hormonal contraceptive, level of education, employment status and religion after bivariate analysis as shown in table 18. Progestin IUD users were more conversant with the use of their method compared to contraceptive patch users. Respondents with tertiary level education were using the hormonal contraceptive they were on correctly compared to those who had no formal education. Women in formal employment had a higher likelihood of using hormonal contraceptives correctly compared to those that were unemployed, self-employed and in informal employment. Muslim participants were conversant with the use of the use of their contraceptive choices compared to Christians.

After logistic regression, the independent predictor of correct use of hormonal contraceptives was level of education [OR 1.389 (1.144-2.051)] p=0.000.

Table 18: Correctness of use of hormonal contraceptive and sociodemographic characteristics

Type of hormonal contraceptives	Correct use n (%)	Incorrect use n (%)	P value
COCs	1 (5.6)	17 (94.4)	0.011
Patch	0 (0.0)	2 (100.0)	
POPs	1 (33.3)	2 (66.7)	
POICs	5 (13.5)	32 (86.5)	
Implants	1 (3.0)	32 (97.0)	
IUD	2 (66.7)	1 (33.3)	
Total	10 (10.4)	86 (89.6)	
Characteristics			
Age (years)			
18-27	1 (3.1)	31 (96.9)	0.103
28-37	9 (17.6)	42 (82.4)	
38-47	0 (0.0)	12 (100.0)	
48-57	0 (0.0)	1 (100.0)	
Marital status			
Never married	1 (20.0)	4 (80.0)	0.585
Currently married	9 (10.5)	77 (89.5)	
Formerly married	0 (0.0)	5 (100.0)	
Highest Education level			
None	0 (0.0)	0 (0.0)	0.019
Primary	2 (6.9)	27 (93.1)	
Secondary	0 (0.0)	28 (100.0)	
Tertiary	8 (20.5)	31 (79.5)	
Employment status			
Unemployed	1 (2.9)	33 (97.1)	0.019
Informal employment	1 (8.3)	11 (91.7)	
Formal employment	7 (25.9)	20 (74.1)	
Self-employed	1 (4.3)	22 (95.7)	
Religion			
Christian-Protestant	5 (7.9)	58 (92.1)	0.010
Christian-Catholic	4 (13.3)	26 (86.7)	
Muslim	1 (100.0)	0 (0.0)	
Hindu	0 (0.0)	0 (0.0)	
Number of children			
0	1 (20.0)	4 (80.0)	0.806
1-2	6 (10.7)	50 (89.3)	
3-4	3 (9.7)	28 (90.3)	
5-6	0 (0.0)	4 (100.0)	
>6	0 (0.0)	0 (0.0)	
Breastfeeding			
Yes	4 (15.4)	22 (84.6)	0.331
No	6 (8.6)	64 (91.4)	
Body Mass Index (BMI)			
<18.5	0 (0.0)	3 (100.0)	0.194
18.5-24.9	4 (10.5)	34 (89.5)	
25-29.9	1 (3.3)	29 (96.7)	
>30	5 (20.8)	19 (79.2)	

4.5 Prevalence of side effects of hormonal contraceptives

Out of the 96 hormonal contraceptive users, 72 (75%) had experienced side effects.

4.5.1 Combined Oral Contraceptives

Weight changes were the most prevalent side effects at 38.9% followed by headaches at 27.8% (Table 19). The least reported side effects were breast tenderness, frequent bleeding, backache and acne. Other side effects were headaches, dizziness, nausea and mood changes.

Table 19: Side effects experienced by Combined Oral Contraceptives Users (N=18)

Side effect	Frequency (n)	Percentage (%)
Breast tenderness	1	5.6
Frequent bleeding	1	5.6
Weight changes	7	38.9
Mood changes	2	11.1
Headaches	5	27.8
Backache	1	5.6
Acne	1	5.6
Dizziness	3	16.7
Nausea	3	16.7

NB: Some women had experienced multiple side effects

4.5.2 Progestin only Injectable contraceptives

Slightly more than half of POICs users (55.3%) had experienced amenorrhoea and 34.2% of the women had experienced weight changes (Table 20). Dizziness was the least reported side effect. Other side effects were abdominal bloating and discomfort, headache, decrease in sex drive, prolonged bleeding, infrequent bleeding, frequent bleeding, back ache, mood changes and acne.

Table 20: Side effects experienced by progestin only injectable contraceptives users (N=37)

Side effect	Frequency (n)	Percentage (%)
Prolonged bleeding	4	10.5
Mood changes	2	5.3
Infrequent bleeding	4	10.5
Acne	2	5.3
Frequent bleeding	3	7.9
Backache	3	7.9
Amenorrhoea	21	55.3
Weight changes	13	34.2
Abdominal bloating and discomfort	8	21.1
Headaches	7	18.4
Decrease in sex drive	7	18.4
Dizziness	1	2.6

NB: Some women had experienced multiple side effects

4.5.3 Implants

Amenorrhoea and mood changes were the most reported side effects by implant users at 53.1% and 34.4% respectively. The least prevalent side effects were insertion site complications, migration and expulsion of rod and decreased libido.

Table 21: Side effects experienced by implant users (N=33)

Side effect	Frequency (n)	Percentage (%)
Lighter bleeding and fewer days of bleeding	6	18.8
Breast tenderness	4	12.5
Frequent bleeding	4	12.5
Mood changes	4	12.5
Infrequent bleeding	4	12.5
Weight changes	11	34.4
Prolonged bleeding	3	9.4
Amenorrhoea	17	53.1
Acne	4	12.5
Headaches	5	15.6
Insertion site complications	1	3.1
Dizziness	3	9.4
Migration and expulsion of rod	1	3.1
Nausea	2	6.3
Decreased libido	1	3.1

NB: Some women had experienced multiple side effects

4.5.4 Contraceptive patch, Progestin only Pills and Progestin IUDs

Out of the two women who were using the contraceptive patch; lighter bleeding and fewer days of bleeding, increased libido and headaches had been experienced by one of them.

None of the three POPs users experienced any side effects.

Lighter bleeding and fewer days of bleeding, breast tenderness, nausea, weight changes, prolonged bleeding, white vaginal discharge and headaches were reported by at least one of the three Progestin IUD users.

Prevalence of side effects was associated with the type of hormonal contraceptive that was being used.

Table 22: Prevalence of side effects by type of hormonal contraceptives

Type of hormonal contraceptive	Had side effects	Had no side effects	
	n (%)	n (%)	P value
COCs	12 (66.7)	6 (33.3)	0.037
Patch	2 (100.0)	0 (0.0)	
POPs	0 (0.0)	3 (100.0)	
POICs	29 (78.4)	8 (21.6)	
Implants	26 (78.8)	7 (21.2)	
IUD	3 (100.0)	0 (0.0)	
Total	72 (75.0)	24 (25.0)	

CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

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

5.2 Discussion

Consistent and accurate use of contraceptives is crucial in the prevention of unintended pregnancies and consequently reduction in maternal and infant mortality (6).

In this study, more than 75% of the participants were between 18-37 years which is comparable to other findings (5,26). About sixty per cent of the women were married, a quarter had never been married and 12.5% were formerly married quite similar to the respondents in KDHS 2008-09 where majority were married and minority were either widowed, divorced or separated. The marital status also mirrored the study at KNH CCC. Majority of the respondents had tertiary or secondary education which contrasts previous findings probably due to the different study site and population demographics. This could influence the prevalence and pattern of contraceptive use and their correct use (5,26). The employed participants were more than the unemployed ones; more than eighty per cent of the women were Christians while Muslims and Hindus were less than 5% accumulatively similar to other studies (5,26).

Prevalence of contraceptive use in this current study was at 42.8%. This was close to the findings of KDHS 2008-09 where the contraceptive prevalence rate was at 46% while contraceptive use among all sexually active women was 51.1% (5). In a study at the KNH CCC, 44.2% of the women were using a form of contraceptive method (26). The results are comparable to the rate of contraceptive use in the other countries in the region (17,30,53). The rate is higher than the use in countries such as Sudan, Chad and Somalia but lower than the level of use in South Africa, Zimbabwe and Egypt (17). The findings are similar with those of some countries in Asia and Latin America (17–23) probably due to the similarity in the social and demographic characteristics. However, this rate was lower than the levels of contraceptive use in Brazil, USA, Canada, Australia and Europe since the latter are quite developed (17).

The level of previous contraceptive use among current non-users in the study was 58.1%. The observation was consistent to the findings of the KDHS 2008-09 (5). Similar rates were observed in Nepal, Nigeria and Ethiopia (18,29,30). At 88.1%, the level of contraceptive ever use in Europe is far much higher than the findings of this study (28).

These variations are possibly due to the differences of social, economic and cultural backgrounds (15). The level of knowledge of contraceptives is high in most of the African countries but utilisation is quite low. This discrepancy mainly arises from the poor accessibility to family planning services and poor level of knowledge on fertility (16).

In this study, the rate of current and previous contraceptive use was associated with marital status, level of education, employment status, number of children, breastfeeding and BMI. On multivariate analysis, the independent indicator of contraceptive use was the number of children. This is similar to what has been observed in other studies (26). Education level of Sudanese couples was the major determinant in the use of contraceptives (54). Indicators of contraceptive use among Ethiopian married women included literacy, age, the number of children and positive attitude towards family planning (30). According to a Nigerian study, use of family planning was influenced by proximity to health facilities, parity, knowledge of contraception and spacing of children (16). Age, education, contraceptive knowledge and employment status were reported to have effect on contraceptive use. Employment status and education had the greatest impact after multivariate analysis was carried out (23). In a Nepali study, contraceptive use was associated with the occupation of the women, age, residence, ethnicity and level of education (18). Education is a common predictor in the use of contraceptives. Schooled women are probably more aware of contraceptives therefore using them to enable them advance their careers by delaying child bearing and spacing (39). The differences in determinants are probably due to different objectives of the studies, sociodemographic characteristics and study sites.

Injectable contraceptives were most used by the women followed by IUDs, Implants and OCPs. Contraceptive patch, coitus interruptus and LAM were the least used methods. Other methods in use were barrier methods, sterilization and FAM. This was consistent with the findings of KDHS 2008-09 whereby injectables and OCPs were popular types of contraceptives (5). On the contrary, IUDs were the least popular. According to studies in South and urban South eastern Nigeria, injectables and IUDs were preferred by the participants (35,36). A Nepali study also

revealed that injectables were preferred by the respondents while FAM, IUDs and sterilization were least used (18). Injectables were also preferred by respondents in a Pakistan health centre (32). The method was preferred since it was not coitus dependent like condoms, long duration of action, high effectiveness, not user dependent, privacy of choice, easy availability and affordability (35,36).

However, the findings differed with observations where condoms was preferred by the women attending KNH CCC and youth in Kisumu (26,27). In various parts of Nigeria, the different patterns of contraceptive use deviated from this study (16,24,34). In a European study, oral contraceptive pills, condoms and IUDs were popular while hormonal patch, vaginal ring and fertility awareness method were least used (28). Indian women used condoms and tubal ligation as their preferred methods while some Pakistani women preferred copper IUD (21,22,31). The variation is due to personal preference, source of contraceptive information, health status, socioeconomic and cultural differences, changing contraceptive trends with time and provider bias (5,15,16) .

The form of contraceptive used was associated with age, marital status, level of education, number of children and breast feeding. The independent predictors of choice of contraceptive were age and level of education. These findings were similar to the observations of other studies (55,56). Social, demographical and cultural factors have influence on the choice of contraceptive methods consequently having an effect on the pattern of contraceptive use.

Least side effects, long duration of action and most effective were the main reasons why hormonal contraceptive users choose one method over the others. Other reasons cited were recommendation by a health practitioner, weekly or monthly change times, immediate return to fertility, most available method, least cost and privacy of choice. This was consistent with studies in Nigeria and Pakistan (25,32,35,36). This shows that side effects are a major concern for the women who use contraceptives and should be addressed during initiation and throughout the use of the contraceptives.

Healthcare practitioners were the main source of contraceptive information followed by family and friends. Other sources included media and advertisement, coursework in school and internet. This was similar to studies done in Pakistan, Nepal, Nigeria and Saudi Arabia (15,18,23–

25,36,37). Contraceptive information should be accurate, adequate and appropriate therefore health workers are better placed in dissemination. Information from other sources could be incomplete or incorrect. The majority of the respondents were counselled on how to use the contraceptives mainly by nurses and medical practitioners, mainly because the family planning clinics are run by nurses and medical practitioners. Pharmacy practitioners played a minor role in contraceptive counselling probably because pharmacies/chemists were not a main source of contraceptives.

Government health facilities were the main source of hormonal contraceptives followed by private health facilities. The rest purchased from community pharmacies. These findings were similar to studies in Kenya and Nigeria(5,16,26). The preference of government facilities as a source of contraceptives is probably because family planning services are offered at no cost.

Among current non-users of contraceptives, injectables and pills were the most previously used contraceptives while the contraceptive patch and FAM were the least. Experience with side effects, desire for more children and cessation of sexual activity were the main reasons for not using contraceptives (5,24).

Combined oral contraceptives and POP users had considerable knowledge on the timings of initiation and daily intake of the pills. However, there was poor knowledge on the instructions to follow and measures to take after missing pills, vomiting and having diarrhoea. POICs users were well conversant with duration of effectiveness of the method but they were not knowledgeable on the grace period between repeat injections and measures to taken if they delayed to go for the next injection. The scenario was replicated with implant and progestin IUD users. The women were well conversant with the duration of effectiveness of the methods but did not know how to take care of the insertion site and the warning signs to look to for. Contraceptive patch users had substantial information on the location and duration of application of the patch but their knowledge on the instructions to follow and measures to take after detachment of a patch was limited.

These findings were consistent with other studies done to explore the knowledge of correct use of contraceptives (38–41,57,58). The simple instructions of contraceptive use were well understood but as they become more complex, fewer women were conversant with them. In an

effort to make the instructions understandable various measures have been put in place but the knowledge on correct use of contraceptives is still limited (41,58).

Level of knowledge on the correct use of hormonal contraceptives was associated with type of hormonal contraceptive, level of education, employment status and religion. After logistic regression, the independent predictor of correct use of hormonal contraceptives was level of education. This was similar to a Saudi study where higher compliance was associated with higher education level and years of contraception use (39). In Brazil the correct use of contraceptive was correlated positively with high education levels and family income (40). On the contrary the literacy levels did not have an effect on the understanding of contraceptive use in an American study probably due to the high levels of education in the American population (41).

Out of all the hormonal contraceptive users, majority had experienced side effects. This was similar to the findings of a study in Honduras (43). However, it differed with the occurrence of side effects in women who were using the contraceptive patch (45).

Prevalence of side effects depended on the type of hormonal contraceptive that was being used.

These findings are consistent with the observation of other studies albeit in different frequencies (39,43–51). Side-effects should be addressed by the providers during initiation to a method since they affect the consistent and correct use of contraceptives. They are also major cause of cause of contraceptive discontinuation.

5.3 CONCLUSION

The gap between contraceptive knowledge and contraceptive use is still wide. Contraceptive knowledge is almost universal yet contraceptive use is still low. Hormonal contraceptive users prefer injectables, implants and OCPs due to the least side effects, long duration of action and high effectiveness. The level of knowledge on the correct use of hormonal contraceptives is very low therefore reducing the effectiveness due to inconsistent and incorrect use. The prevalence of side effects of hormonal contraceptives is high with majority of the users experiencing them. During initiation and subsequent continued use, hormonal contraceptive users should be taken through the instructions of use and possible side effects and how to cope with them.

5.4 RECOMMENDATIONS

5.4.1 Recommendations for policy and practice

Programmes should be developed to increase the use of contraceptives targeting the women who are less likely to be using contraceptives due to perceived misconceptions such as they don't require to use or fear of side effects. The target groups should include women who are not in union, uneducated women and women of low parity.

Contraceptive counselling should be made mandatory at every visit to the family planning clinic with emphasis on the instructions of use and side effects and how to cope with them.

5.4.2 Recommendations for research

Further studies should be done to find out the causes of the gap between contraceptive knowledge and contraceptive use in Kenya and how to overcome them. Larger studies targeting specific hormonal contraceptives should be carried out to assess the level of knowledge on the correct use of the users. Other studies could explore the means through which the level of correct use of hormonal contraceptives can be increased and how women cope with the side effects.

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APPENDICES

6.1 APPENDIX I: CONSENT FORM

To be read in a language that the participant is fluent in.

Title of the study: Assessment of hormonal contraceptive use among women at Kenyatta National Hospital.

Institution

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Ethical Approval

Kenyatta National Hospital/ University of Nairobi Ethical and Research Committee, P.O BOX 20723-00202, Nairobi. Tel 2726300/2716450 Ext 44102

Introduction

In this study I, Dr. Nancy Gakii Nkonge, a student of Master of Pharmacy in Clinical Pharmacy at the University of Nairobi, will be assessing hormonal contraceptive use among women at Kenyatta National Hospital.

Purpose of the study

To find out the prevalence of women on contraceptives, the type of hormonal contraceptives used, level of knowledge of the correct use and the prevalence of side effects among hormonal contraceptive users.

Permission is requested from you to enroll in this research study. The following general principles which apply to all participants in a medical research:

i. Your agreement to participate in this study is voluntary. You will get the same care and medical treatment from this or any other ward/clinic whether you participate in this study or not.

ii. You may withdraw from the study at any time without necessarily giving a reason for your withdrawal without consequences to the services you receive from this ward/clinic.

iii. After you have read the explanation please feel free to ask any questions that will enable you to understand clearly the nature of the study.

Procedure to be followed

With your permission, I will ask you some questions about the contraceptive method you are on. If you are on hormonal contraceptives, I will enquire how you use them and the side effects you might have experienced since you started using them. All information will be handled with confidentiality and will only be used for the purpose of this study.

Benefits and rewards

I will counsel you on the type of hormonal contraceptive you are on in case you are not well conversant with the instruction of use and side effects. If you are not on any contraceptive method and you are interested in starting, I will direct you to the family planning clinic. There will be no reward to participate in the study.

Discomfort and Risks

Some questions you will be asked will be of a personal nature and may make you uncomfortable. If this happens you may refuse to answer if you so choose. You may also stop the interview at any time. Participation may add approximately 15-20 minutes to the time you wait before you receive your routine services.

Assurance of confidentiality

All information obtained from you will be kept in confidence. At no point will you or your name be mentioned or used during data handling or in any resulting publications. Serial numbers will be used instead.

Contacts In case you need to contact me, my academic department or the Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee concerning this study please feel free to use the contacts provided above.

Informed consent

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. 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 _____

Investigators statement

I, the undersigned, have explained to the participant in a language she understands, the procedures to be followed in the study and the risks and benefits involved.

Investigator _____

Sign _____ Date _____

6.2 APPENDIX II: QUESTIONNAIRE ON HORMONAL CONTRACEPTIVE USE

Questionnaire number _____

A. SOCIODEMOGRAPHIC CHARACTERISTICS

1. Age

□ 18-27 □ 28-37 □ 38-47 □ 48-57

2. Marital status

□Never married □Currently married □Formerly married

3. Highest Education level

□ None □ Primary □ Secondary □ Tertiary

4. Employment status

□ Unemployed □ Informal employment □ Formal employment □ Self-employed

5. Religion

□ Christian-Protestant □ Christian-Catholic □ Muslim □ Hindu □ Buddhist □ Traditional

6. Number of children

□ 0 □1-2 □ 3-4 □ 5-6 □ >6

7. Breastfeeding

□ Yes □ No

8. Smokes

□ Yes □ No

9. Weight _____

10. Height _____

11. Comorbidities □ Yes □ No

    Which one(s)? _____

12. Medication history

B. CONTRACEPTIVE USE

1. Do you use any form of contraception?

□ Yes □ No

2. If yes, which one?

□Pills □Injectables □Implant □ IUD □Patch □Vaginal ring □ Barrier methods □ Sterilization

□ Lactational amenorrhoea method □ Coitus interruptus □Fertility awareness method

3. If on pills, what is the trade name? _____

4. If on Injectables, how often do you go for the injections?

□Every month □Every 3 months

5. If on IUD, how often are you meant to change the device?

□Every 5years □Every 10years

6. Where do you obtain you hormonal contraception?

□Government health facility □Private health facility □Community pharmacy

□Others, Specify _____

7. For how long have you used that method of hormonal contraception?

□< 1 year □1-2 years □3-4 years □>4 years

8. Why did you settle on that method of hormonal contraception?

□Most effective method □Most available method □Least side effects □Least cost

□Others, Specify _____

9. Where did you get information on the hormonal contraception?

□Media and advertisement □Family and friends □Health practitioner

□Others, Specify _____

10. Were you counselled on how to use the hormonal contraception?

□Yes □No

11. If yes, by whom?

□Medicine practitioner □Pharmacy practitioner □Nursing practitioner

□Others, Specify _____

12. If not on any contraceptive method, have you ever used any contraceptives?

□Yes □No

13. If yes, which ones?

□Pills □Injectables □Implant □ IUD □Patch □Vaginal ring □ Barrier methods □ Sterilization

□ Lactational amenorrhoea method □ Coitus interruptus □Fertility awareness method

14. Why did you stop using the methods?

□Side effects □Wanted more children □Unavailability □High costs

□Others, specify _____

C. LEVEL OF KNOWLEDGE ON THE CORRECT USE OF HORMONAL CONTRACEPTIVES

1. Combined oral contraceptives (COCs)

a) On initiation, when did you start taking your pills?

□Same day you were dispensed with the pills □On a Sunday

□Within 5 days of commencing the next menstruation □Any day

b) What time do you take your pills?

□Any time I remember □Same time everyday

□Morning only □Evening only

c) What warning signs are you meant to look out for when taking COCs?

□Abdominal Pain □Chest pain □Headache □Eyes problems □Severe leg pain

□Others, specify _____

d) What should you do if you miss one or two pills or start a new pack one or two days late?

□Take a pill as soon as possible □Take two pills as soon as possible

□Use back up contraceptives with emergency contraception □I don't know

e) What should you do if you miss three or more pills in the first or second week or started a new pack three or more days late?

□Take a pill as soon as possible

□Use a backup method for the next seven days

□If there was intercourse without backup method, emergency contraceptives should be used

□ I don't know

f) What should you do if you miss three or more days in a row in the third week?

□Take a pill as soon as possible

□Finish the current pack of pills and start the next pack without a hormone free interval

□Use back up contraception for the next seven days

□If there was intercourse without back up, emergency contraceptives should be used

□I don't know

g) What should you do if you vomit within two hours of taking the pill?

□Take another pill as soon as possible

□Take two pills as soon as possible

□Use back up method and emergency contraceptive

□I don't know

h) What should you do if you vomit or diarrhoea for more than two days?

□Take another pill as soon as possible

□Take two pills as soon as possible

□Use back up method and emergency contraceptive

□I don't know

2. Combined injectable contraceptives (CICs)

a) How long is the method of contraception effective?

□2 weeks □4 weeks □8 weeks □I don't know

b) How early or late can you go for the next injection?

□ 7 days □10 days □12 days □I don't know

c) What do you do if you go later than the stipulated time for the next injection?

□Abstain from intercourse

□Use condoms, spermicides or coitus interruptus

□Use emergency contraceptive pills if engages in intercourse

3. Contraceptive patch

a) Where can you apply the patch?

□Gluteal region □Abdomen □Upper torso □Upper arm

b) How long do you apply each patch?

□7days □14days □21days □28days

c) How many weeks do you apply the patches?

□1week □2weeks □3weeks □4weeks

d) How many weeks don't you apply the patches?

□1week □2weeks □3weeks □4weeks

e) What should you do if a patch detaches for more than 24 hours during the 1st week of the menstrual cycle?

□Put on a new patch as soon as possible

□Maintain the same patch change day

□Make a cycle of 3 patches

□Back up for 7days with or without emergency contraception

□I don't know

f) What should you do if a patch detaches for less than 72 hours during the 2nd or 3rd week of the menstrual cycle?

□Put on a new patch as soon as possible

□Maintain the same patch change day

□Finish the cycle and start new patch cycle without hormone free interval

□Finish the cycle and start new patch cycle after a hormone free interval

□I don't know

g) What should you do if a patch detaches for more than 72 hours during the 2nd or 3rd week of the menstrual cycle?

□Put on a new patch as soon as possible

□Maintain the same patch change day

□Finish the cycle and start new patch cycle without hormone free interval

□Back up for 7 days with or without emergency contraception

□I don't know

4. Combined vaginal ring

a) On initiation, when do you insert the ring?

□Immediately after being issued with a ring

□Within 5 days of commencement of menstruation

□On a Sunday

□I don't know

b) How many days do you put in the vaginal ring?

□7days □14days □21days □28 days

c) How many days do you stay without the vaginal ring?

□7 days □14 days □21 days □28 days

d) If the ring falls out, what are you meant to do?

□Dispose it and buy another ring

□Reinsert immediately

□Rinse with warm water and reinsert within 3 hours

□I don’t know

e) What should you do if the vaginal ring is not in place for more than 3 hours in the 1st week of your menstrual cycle?

□Insert the ring as soon as possible

□Maintain the scheduled removal day

□Back for 7 days with or without emergency contraception

□No need for back up and emergency contraception

□I don’t know

f) What should you do if the vaginal ring is not in place for less or more than 72 hours in the 2nd or 3rd week of your menstrual cycle?

□Insert the ring as soon as possible

□Maintain the scheduled removal day

□Back for 7 days with or without emergency contraception

□Start new cycle without hormone free interval

□I don’t know

5. Progestin only pills (POPs)

a) What time do you take your pills?

□Any time you remember □At exactly the same time every day

□Morning only □Evening only

b) What should you do if you miss one or more pills by more than three hours and menses have resumed?

□Take one pill as soon as possible

□Use a backup method

□If intercourse had taken place, emergency contraceptive should be used

□I don’t know

c) What do you do if you miss one or more pills by more than three hours and menses have not resumed?

□Take one pill as soon as possible

□Use a backup method

□If intercourse had taken place, emergency contraceptive should be used

□I don’t know

6. Progestin only injectable contraceptive

a) How long is the method of contraception effective?

□4-6 weeks □12-13weeks □14-16 weeks □I don’t know

b) How early or late can you go for the next injection?

□4weeks □6weeks □8weeks □I don’t know

c) What should you do if you go later than the stipulated time for the next injection?

□Abstain from intercourse

□Use a condom, spermicides or coitus interruptus

□Use emergency contraceptives in case of intercourse without backup

□I don’t know

7. Implants

a) How long is the method of contraception effective?

□3 years □5 years □10 years □I don’t know

b) How long are you meant to keep the point of insertion dry?

□2 days □3 days □4 days □I don’t know

c) After how long are meant to remove the adhesive plaster put at the point of insertion?

□3 days □5 days □7 days □I don’t know

d) What signs are you supposed to look out for at the point of insertion?

□Pain □Pus □Swelling □Expulsion of rod □I don’t know

8. Progestin IUD

a) How long is the progestin IUD effective?

□5 years □7 years □10years □I don’t know

b) How should you check whether the progestin IUD is in position?

□Go to the hospital every month

□Check for the strings at the end of menstruation

□Lookout for IUD on the tampon/pad during menstruation

□I don’t know

c) What symptoms are you meant to look out for when using the progestin IUD?

□Pelvic pain □Dyspareunia □Excessive bleeding □Foul discharge □I don’t know

D. SIDE EFFECTS OF HORMONAL CONTRACEPTIVES

1. Have you experienced any side effects since you started using the hormonal contraceptive you are on?
   □ Yes □ No
2. If yes, which side effects have you experienced? (Tick the appropriate response)

I. Combined oral contraceptives (COCs)

Which of the following have you experienced since you started taking the COCs?

Side effect	**Yes**	**No**
Lighter bleeding and fewer days of bleeding		
Frequent bleeding		
Infrequent bleeding		
Amenorrhoea		
Headaches		
Acne		
Dizziness		
Nausea		
Breast tenderness		
Weight changes		
Mood changes		
Myocardial infarction		
Stroke		
Venous thrombosis or embolism		

Others, specify _____

II. Combined injectable contraceptives (CICs)

Which of the following have you experienced since you started using CICs?

Side effect	**Yes**	**No**
Lighter bleeding and fewer days of bleeding		
Frequent bleeding		
Infrequent bleeding		
Prolonged bleeding		
Amenorrhoea		
Headaches		
Acne		
Dizziness		
Nausea		
Breast tenderness		
Weight changes		
Mood changes		

Others, specify _____

III. Contraceptive patch

Which of the following have you experienced since you started using the contraceptive patch?

Side effect	**Yes**	**No**
Skin irritation or rash where the patch is applied		
Lighter bleeding and fewer days of bleeding		
Frequent bleeding		
Infrequent bleeding		
Prolonged bleeding		
Amenorrhoea		
Headaches		
Nausea		
Vomiting		
Breast tenderness or pain		
Abdominal bloating and discomfort		
Flu symptoms/upper respiratory infection		

Others, specify _____

IV. Combined vaginal ring

Which of the following have you experienced since you started using the combined vaginal ring?

Side effect	**Yes**	**No**
Skin irritation or rash where the patch is applied		
Lighter bleeding and fewer days of bleeding		
Frequent bleeding		
Infrequent bleeding		
Prolonged bleeding		
Amenorrhoea		
Headaches		
Irritation, redness or inflammation of the vagina(vaginitis)		
White vaginal discharge		

Others, specify _____

V. Progestin only pills (POPs)

Which of the following have you experienced since you started taking the POPs?

Side effect	Yes	No
Frequent bleeding		
Infrequent bleeding		
Prolonged bleeding		
Amenorrhoea		
Prolonged postpartum amenorrhoea		
Headaches		
Dizziness		
Nausea		
Mood changes		
Breast tenderness		
Abdominal pain		

Others, specify _____

VI. Progestin only injectable contraceptives

Which of the following have you experienced since you started using progestin only injectable contraceptives?

Side effect	Yes	No
Prolonged bleeding		
Infrequent bleeding		
Frequent bleeding		
Amenorrhoea		
Weight gain		
Headache		
Dizziness		
Mood swings		
Acne		
Pathological bone fractures?		
Abdominal bloating and discomfort		
Decrease in sex drive		

Others, specify _____

VII. Implants

Which of the following have you experienced since you started using the implant?

Side effect	Yes	No
Lighter bleeding and fewer days of bleeding		
Frequent bleeding		
Infrequent bleeding		
Prolonged bleeding		
Amenorrhoea		
Headache		
Dizziness		
Nausea		
Breast tenderness		
Mood changes		
Weight changes		
Abdominal pain		
Acne		
Insertion site complications: infection, allergic reaction		
Migration of rod(s)		

Others, specify _____

VIII. Progestin IUD

Which of the following have you experienced since you started using progestin IUD?

Side effect	Yes	No
Lighter bleeding and fewer days of bleeding		
Infrequent bleeding		
Frequent bleeding		
Prolonged bleeding		
Amenorrhoea		
Acne		
Headaches		
Breast tenderness or pain		
Nausea		
Weight gain		
Dizziness		
Mood changes		

Others, specify _____

6.3 APPENDIX III: KENYATTA NATIONAL HOSPITAL/ UNIVERSITY OF NAIROBI ETHICAL AND RESEARCH COMMITTEE APPROVAL

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/151 Link:www.uonbi.ac.ke/activities/KNHUoN

15th May 2014

Nancy Gakii Nkonge
Dept.of Pharmaceutics and Pharmacy Practice
School of Pharmacy
University of Nairobi

Dear Dr. Nkonge

RESEARCH PROPOSAL: ASSESSMENT OF HORMONAL CONTRACEPTIVE USE AMONG WOMEN AT KENYATTA NATIONAL HOSPITAL (P50/02/2014)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 15th May 2014 to 14th May 2015.

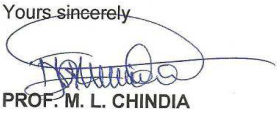
This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website **www.uonbi.ac.ke/activities/KNHUoN.**

Protect to Discover

Yours sincerely



PROF. M. L. CHINDIA
SECRETARY, KNH/UON-ERC

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
The Chairperson, KNH/UoN-ERC
The Assistant Director, Health Information, KNH
The Dean, School of Pharmacy, UoN
The Chairman, Dept. of Pharmacetics and Pharmacy Practice,UoN
Supervisors: Dr. P.N. Karimi, Dr.E.M. Guantai

6.4 APPENDIX IV: MEDICATION HISTORY OF THE STUDY POPULATION

Medication	**Frequency (n)**	**Percentage (%)**
Antibacterial agents		
Amoxicillin+ clavulinic acid	7	1.8%
Erythromycin	2	0.5%
Cotrimoxazole	4	1.0%
Flucloxacillin	3	0.8%
Metronidazole	5	1.2%
Antifungals agents		
Fluconazole	1	0.2%
Antitubercular agents		
Rifampicin	1	0.2%
Isoniazid	1	0.2%
Pyrazinamide	1	0.2%
Ethambutol	1	0.2%
Antiretroviral agents		
Zidovudine	3	0.8%
Tenofovir	2	0.5%
Lamivudine	5	1.2%
Efavirenz	5	1.2%
Antihypertensive agents		
Atenolol	4	1.0%
Furosemide	3	0.8%
Amlodipine	1	0.2%
Nifedipine	4	1.0%
Losartan	1	0.2%
Enalapril	1	0.2%
Telmisartan	1	0.2%
Hydrochlorthiazide	3	0.8%
Lipid lowering agents		
Atorvastatin	1	0.2%
Antidiabetic agents		
Metformin	2	0.5%
Insulin	1	0.2%
Analgesic agents		
Paracetamol	2	0.5%
Diclofenac	8	2.0%
Aceclofenac	1	0.2%
Anticoagulant agents		
Enoxaparin	1	0.2%
Warfarin	1	0.2%
Antifibrinolytic agents		
Tranexamic acid	1	0.2%
Antineoplastic agents		

Cyclophosphamide	3	0.8%
Doxorubicin	4	1.0%
Vincristine	3	0.8%
Methotraxate	4	1.0%
Cytarabine	1	0.2%
Etoposide	3	0.8%
Dactinomycin	3	0.8%
Cisplatin	5	1.2%
Bleomycin	1	0.2%
Carboplatin	1	0.2%
Paclitaxel	1	0.2%
Hydroxyurea	2	0.5%
Vitamin supplements		
Ferrous sulphate	2	0.5%
Cachnerve®	1	0.2%
Pyridoxine	1	0.2%
Antacids		
Aluminium hydroxide+ Magnesium hydroxide+ Simethicone	1	0.2%
Antimigraine agents		
Sumatriptan	1	0.2%
Beta2 agonists		
Salbutamol inhaler	2	0.5%
Corticosteroids		
Dexamethasone	3	0.8%