DETERMINANTS OF DISCONTINUATION OF CONTRACEPTIVE METHODS AMONG WOMEN AT KENYATTA NATIONAL HOSPITAL

BY

SUSAN WACERA MAINA

U51/69215/2013

DEPARTMENT OF PHARMACOLOGY AND PHARMACOGNOSY, SCHOOL OF PHARMACY, UNIVERSITY OF NAIROBI

A research thesis submitted in partial fulfillment of requirements for Master of Pharmacy degree in Pharmacoepidemiology and Pharmacovigilance of University of Nairobi

JULY 2016

SUPERVISORS' APPROVAL

This research thesis has been submitted for examination with our approval as the university supervisors.

Signature:…… **Date**:……..

Name: Dr. George O. Osanjo.

Department of Pharmacology and Pharmacognosy,

School of Pharmacy,

University of Nairobi.

Signature:……. **Date:……..**

Name: Dr. Stanely N. Ndwigah.

Department of Pharmaceutical Chemistry,

School of Pharmacy,

University of Nairobi.

Signature:…….. **Date:……..**

Name: Dr. Sylvia Opanga.

Department of Pharmaceutics and Pharmacy Practice,

School of Pharmacy,

University of Nairobi.

DECLARATION OF ORIGINALITY FORM

Name: Susan Wacera Maina

Registration number: U51/69215/2013

College: Health Sciences

School: Pharmacy

Department: Pharmacology and Pharmacognosy

Course name: Pharmacoepidemiology and Pharmacovigilance

Research title: Determinants of discontinuation of contraceptive methods among women at Kenyatta National Hospital

DECLARATION

I understand what plagiarism is and I am aware of the University's policy in this regard.

I declare that this thesis is my original work and has not been submitted elsewhere for examination, award of a degree or publication. Where other people's work has been used, this has properly been acknowledged and referenced in accordance with the University of Nairobi's requirement.

I have not sought or used the services of any professional agencies to produce this work.

I have not allowed and shall not allow anyone to copy my work with the intention of passing it off as his/her own work.

I understand that any false claim in respect with this work shall result in disciplinary action in accordance with the University's Plagiarism Policy

Signature:…….. **Date:…….**

Name: Susan Wacera Maina

DEDICATION

To my dear husband, Samuel for the constant support and motivation

To my little girl Arianna, I love you more than words can describe.

ACKNOWLEDGEMENT

I acknowledge my employer, the Ministry of Health for giving me study leave to pursue my Masters degree.

I am grateful to my supervisors; Dr. G. O. Osanjo, Dr. Stanley N. Ndwigah and Dr. Sylvia A. Opanga for their great support in the whole process of this thesis development.

Our Course coordinator Dr. F. A. Okalebo for her sacrifice and dedication to make the best Epivigilantes out of the naïve us

To all the women who agreed to participate in the study, I am truly grateful.

Esther Mwanzia, the IT technologist for being kind to us as we used the computer laboratory to do our work.

My dear classmates, it's been an enjoyable journey; we ended up being more of a family than classmates. God bless each one of you.

My lovely parents and siblings for their unconditional love

Above all, my utmost gratitude to God most high for His everlasting love and Grace

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ACRONYMS AND ABBREVIATIONS

COC	Combined oral contraceptives
DMPA	Depot Medroxy-Progesterone Acetate
FDA	Food and Drug Authority
FPAK	Family Planning Association of Kenya
FSH	Follicle stimulating hormone
HIV	Human Immunodeficiency Virus
IUD	Intra-uterine device
KDHS	Kenya Demographic Health Survey
KNH	Kenyatta National Hospital
LH	Luteinizing hormone
POP	Progesterone only pill
PPB	Pharmacy and Poisons Board
STD	Sexually transmitted diseases
UK	United Kingdom
USA	United State of America
USAID	United States Agency for International Development
USFDA	United States Food and Drug Authority
WHO	World Health Organization

OPERATIONAL DEFINITIONS

Contraceptive: Any method or device used to prevent pregnancy other than avoiding coitus or hysterectomy**.**

Contraceptive prevalence rate (CPR): The percentage of currently married women who are currently using a method of contraception.

Adverse drug reactions: A response to a drug which is harmful and unintended, and which occurs at normal doses used in human being for diagnosis, therapy or prophylaxis of a disease, or for the modification of physiological function.

Social demographic factors: These are characteristics of a population based on aspects such as age, sex, level of education and employment status

Reproductive age in women: 18 to 49 years of age

Menstrual irregularities: Any deviation from the normal menstrual cycle. This could be amenorrhea, infrequent bleeding, frequent bleeding and prolonged bleeding.

Amenorrhea: No bleeding or spotting within 90 day duration.

Infrequent bleeding: Less than 3 bleeding or spotting episodes within 90 day duration.

Frequent bleeding: More than 5 bleeding or spotting episodes within 90 day duration.

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

ABSTRACT

Introduction and literature review

Contraceptive prevalence rate in Kenya is at 58% as per the 2014 Kenya Demographic Health Survey. Several factors lead to discontinuation and switch of contraceptives. These include adverse effects, contraceptive failure, need for pregnancy, infrequent sexual intercourse, need for a more effective method, lack of access, unaffordability and inconvenience during use. Discontinuation rate as per the 2008/2009 KDHS for one year was 35.8%.

Objectives

The main objective of the study was to find out the determinants of discontinuation and switching of hormonal and IUD contraceptive methods.

Methodology

The study was cross-sectional hospital based, where data was collected by use of an interviewer administered questionnaire within Clinic 66 of Kenyatta National Hospital. This was after Ethical approval was obtained from Kenyatta National Hospital/University of Nairobi, Ethics and Research Committee. Data was collected within the period, 1st May 2015 to 30th June 2015, where 400 women were interviewed. The data was then analyzed by use of the statistical software, SPSS Version 20.

Results

The study population mainly comprised married women with a mean age of 31.45 (± 6.40) years, whom most had secondary education and above. Those who were unemployed were 35.8% with the rest being either self-employed or in formal employment. Most of the women were Christians with only 0.2% being Muslims. Most of the women had 1-2 children (65.3%). Least adverse effects was the most cited reason for choosing the contraceptive method of use while unaffordability/unavailability was the least concern. Discontinuation rate by the time of study in the study population was 60.8%, with adverse effects as the most cited reason for discontinuation. Spousal disapproval and unaffordability/unavailability were never a cause of discontinuation. Among the adverse effects, menstrual irregularities were the most common

reasons why women discontinued use of a contraceptive method. The method of contraception and presence of co-morbidity were the factors associated with discontinuation of a contraceptive. Survival analysis showed that depot injection and Jadelle® had the highest median months of use and Impanon® the least. Adherence case indexing showed that 74.7% of Combined Oral Contraceptives users had good adherence.

Conclusion

Multiple reasons for discontinuation of contraceptive use include primarily concerns for adverse effects, use inconvenience, desire to become pregnant, contraceptive failure, and doctor's advice. Comorbid conditions and contraception method are statistically associated with the discontinuation of contraceptive use.

Recommendations

Reproductive Health programs need to come up with more detailed programs that address the high levels of discontinuation of contraception use by women who are still in need. The factors underlying the discontinuations need to be addressed thoroughly during the inception of contraceptive services, and counseling continued at each visit for the services. Studies need to be done to determine the temporal relationship between hormonal contraceptive use and onset of the comorbid conditions. Studies following those who discontinue use of contraceptives while still in need of the services need to be done to determine the outcome of such action.

CHAPTER ONE: INTRODUCTION AND LITERATURE REVIEW

1.1 Background

Contraception is avoidance of pregnancy by different methods other than avoiding coitus or hysterectomy (1). A contraceptive is a drug or device that prevents or may prevent fertilization, thus preventing the formation of an embryo

Contraception use dates back to 3000B.C where condoms made from materials such as fish bladders, linen sheaths and animal intestines were first used in the now United States (US). Prior to this, women relied on withdrawal or periodic abstinence which often failed (2). The first contraceptive clinic which mainly dealt with natural methods of contraception, was opened in 1916 by Margaret Sanger, who later in 1950 underwrote the research that was necessary to create the first human birth control pill (2). The first oral contraceptive pill was approved by United States Food and Drug Authority (USFDA) in 1960 and Intra-Uterine Devices (IUDs) in 1968. In 1974, sale of a certain IUD was suspended by Food and Drug Authority (FDA) due to infections and seven documented deaths among users and most IUDs were slowly taken off the market in the subsequent years (2). In 1980s, pills with low doses of hormones were introduced along with a new copper IUD. In 1990s there was introduction of implant contraceptives, injectable contraceptive, female condoms and an emergency contraceptive. Currently more research is being undertaken on methods that protect against sexually transmitted diseases (STD) and also on contraceptives for men (2).

1.2 Contraceptive Methods

Contraception includes all measures whether temporary or permanent designed to prevent a pregnancy. An ideal contraceptive method should be easy to use, affordable, easily distributed, safe with no side effects, highly effective, rapidly reversible, widely available, acceptable, independent of intercourse, and requiring minimal monitoring during use (2,3). However, there is no single method of contraceptive which will meet all the ideal characteristics.

Contraceptives are of various classes based on their composition or mode of action. The available classes of contraceptives are hormonal contraceptives, intrauterine contraceptives,

barrier methods, natural family planning methods and sterilization (permanent methods of contraceptives) (4).

1.2.1 Natural Methods

Natural methods of contraception involve abstaining from copulation during the periods of fertility (1). Natural methods are very important as they may be the only acceptable methods to some populations due to cultural and religious beliefs. However, they have a high failure rate as compared to other methods (1).

Lactational amenorrhea method is another natural contraception method used by breastfeeding mothers where during the first six months of infant life, full breastfeeding offers more than 98 per cent contraceptive effectiveness (5). The delay in recurrence of ovulation after delivery is due in part to the hypophyseal and hypothalamic stimulation from breastfeeding (5).

1.2.2 Hormonal Contraceptives

Hormonal contraceptives became available in 1960 and are the most widely used contraceptive agents around the world (5). They include combination oral contraceptive, progesterone only contraceptive and injectables.

1.2.2.1 Combined Oral Contraceptives

Combined oral contraception (COC) was first licensed in the United Kingdom (UK), in 1961 and has been used extensively ever since. It contains a combination of a synthetic estrogen and a progestogen (6). The mechanism of action can be both centrally or peripherally. Centrally the hormones suppress the release of pituitary follicle stimulating hormone (FSH) and luteinizing hormone (LH), which in sequence prevents follicular development within the ovary, thus inhibits ovulation. Peripherally, the endometrium is altered to make implantation less likely and cervical mucus becomes more viscous to prevent the passage of spermatozoa.

Combined oral contraceptives are highly efficacious and easy to use with a theoretical effectiveness of 99.9% and use effectiveness of 97-98%, making them very attractive for the young healthy women who desire a method that is independent of intercourse (5). Most commonly used estrogen in combined oral contraceptives is ethinyl estradiol and the progestrones used are either second generation such as levonorgestrel and northisterone or third generation which are anti-androgenic such as cyproterone and drospirenone (1). The combined

oral contraceptives are available as monophasic, diphasic or triphasic preparations provided in a 21 day packs, with current preparations containing 20-50 microgram of estrogen (1).

1.2.2.2 Progesterone Only Contraceptives

Most of the hormonal contraceptives available are progestin only contraceptives. Several preparations containing progesterone only contraceptives are available for use as contraceptives. The theoretical reports of effectiveness of progesterone only contraceptives is 99% and use effectiveness is 96-97.5% (5). Progesterone only contraceptives are appropriate especially for women with contraindication for estrogen as it is with history of thromboembolism, smokers over 35 years of age, and for diabetics (6). These contraceptives are also appropriate for lactating women as they do not interfere with milk production as compared to combined oral contraceptives. Progesterone only contraceptives' mode of action is peripheral whereby they cause thickening of cervical mucus rendering passage of spermatozoa impossible and causing the endometrium to thin and atrophy thereby preventing implantation. Higher doses of progesterone only contraceptives also act centrally to inhibit ovulation by suppressing the hypothalamo-pituitary-ovarian axis (6).

Progesterone only contraceptive preparations include: the oral formulation,'mini-pill' taken as once daily pill. It is less effective compared to the combined oral contraceptive but safer in blood coagulation effects (6). They can also be given as subdermal implantations which are implanted subdermally on the inner aspect of the non-dominant upper arm, designed to release the hormone for several years. Implanon® consists of a single silastic rod which releases progesterone etonogestrel 25-70 micrograms daily. It is metabolized to desogestrel, third generation progesterone in the body. Norplant® is another progesterone subdermal implant that offers contraception effect for five years. Intramuscular medroxyprogesterone acetate is an injectable progesterone of 150mg administered intramuscularly so as to provide effective contraception for three months (6).

1.2.2.3 Postcoital or emergency contraceptives

The 'morning after pill' is a hormonal emergency contraceptive containing high dose progesterone known as levonogestrel in 1.5mg. It needs to be taken before seventy two hours post coitally (1). The hormonal emergency contraceptive provides contraception by several mechanisms. These include delay or inhibition of ovulation if the pill is taken in the first half of

the menstrual cycle, alterations in endometrial receptivity for implantation, interference with functions of the corpus luteum, production of a cervical mucus, alterations in tubular transport of sperms, egg or embryo (5). The effectiveness of emergency contraceptive is about 75% if taken on time (5).

1.2.3 Mechanical Methods of Contraception

Mechanical methods of contraception are also known as barrier methods as they block passage of sperms to the uterus (7). Studies have found that use of a spermicide with a barrier method increases the efficiency of the barrier method. Barrier methods include: - diaphragm, cervical cap, cervical shield, male condom, female condom, spermicidal foam, sponge and film. The barrier methods are only used when there is sexual intercourse. Male and female condoms offer protection against sexually transmitted infections including HIV (7).

1.2.4 Permanent Methods of Contraception

Permanent methods of contraception are also known as sterilization as they are highly effective and irreversible (8). Sterilization involves tubal ligation for women and vasectomy in men. Tubal ligation constitutes tying of both fallopian tubes. Fallopian tubes maybe blocked by use of falope rings, clips, bands, segmental destruction by use of electrocoagulation or suture ligation. Female sterilization prevents fertilization by interruption of the passage of ovum through the fallopian tube. Female sterilization is highly effective with failure rate in the U.S being at about 5 women out of 1000 becoming pregnant after one year due to incomplete closure of the tubes (8).

Female sterilization can also be achieved by use of an implant whereby a small metallic implant is placed into the fallopian tube causing tissue necrosis thus blocking the fallopian tube and preventing fertilization (8).

Vasectomy is a form of surgical sterilization for men. It involves making a cut in the scrotal sac, cutting or burning off the vas deferens and blocking both cut ends (8). This prevents the passage of the sperms into the seminal fluid by blocking the vas deferens. The procedure is very effective and failure rate is about 0.1% (8).

1.2.5 Intra uterine devices

An intra-uterine device is a small T-shaped plastic device that is placed in the uterus to prevent pregnancy (2). This is ideal for women who want long term method of contraception

independent of intercourse and where regular compliance is not required (2,8). It has a plastic string attached to its end that is left protruding from the cervix into the vagina to ensure correct placement and for ease of removal (8).

Copper bearing IUD releases a small amount of copper into the uterus which acts as a spermicide. It also works by blocking the passage of the sperm to the ovum for fertilization by immobilizing the sperm (1,5). Hormonal lased IUD releases a small amount of progestin into the uterine lining where the hormone thickens the cervical mucus preventing sperm passage to the cervix and also slows down growth of the uterine lining preventing implantation of the fertilized ovum (1).

1.3 Prevalence of Contraceptive Use

Contraceptive use prevalence in Kenya was at 45.5% in 2008/2009 as per the Kenya Demographic Health Survey (KDHS). The prevalence was based on married women who are practicing or whose sexual partners are practicing any form of contraception (9).

Figure 1.1. Trends in contraceptive use in Kenya: adapted from KDHS

In Kenya contraceptive services have been in use since 1956 when the Family Planning Association of Kenya (FPAK) started operating family planning clinics within the Ministry of Health facilities (10).

In a study conducted among women in the urban city slums, it was shown that the use of contraceptives was highest among women aged 20-39 years at 49% (10). At ages 20-29 years it was at 41% and no woman at age 50 years and above used any contraceptive. Below age 20 the use was at 4% and at 6% between 40-49 years of age (10).

Overall contraceptive use among married women has increased from 17% in 1984 to 39% in 1998 (11). Proportion of married women using sterilization method has more than doubled since 1984 and the use of long term methods (IUD and implants) rose steadily up to 1993 but declined in 1998. Use of the pill increased by 3% in 1984 to almost 10% in 1993 with a slight drop in 1998 while use of injectables has been rising over the years from less than 1 % in 1984 to 12% in 1998 (11). Only 1% of married women reported use of barrier methods (11). According to the 2008/08 KDHS, contraceptive prevalence rate was at 46%, with modern methods use being at 46% as compared to traditional methods at 6% (12).

1.4 Determinants of Contraceptive Discontinuation

Contraceptive discontinuation and switching is common as the need for contraceptives may change with time. Several factors could lead to contraceptive discontinuation or switch to a different one. The factors include adverse drug events, health risks, contraceptive failure, need for pregnancy, infrequent sexual intercourse, menopause, need for a more effective method, use inconvenience, lack of access, unaffordability or opposition from one's spouse (3,13,14). A study done in Bangladesh showed that half of women who initiate use of a contraceptive method discontinue it within a year and slightly above of two third (69%) discontinue it within two years of use (15). According to the KDHS 2008/09, one year discontinuation rate in Kenya was 35.8% (12).

An analysis of reasons for discontinuation of all forms of contraceptives (except sterilization) as per 2003 DHS in Kenya revealed that wanting to get pregnant accounted for 23.8%, adverse effects accounted for 28.7%, contraceptive failure accounted for 17.2%, use inconvenience

accounted for 3.8%, lack of access accounted for 2.1%, opposition from spouse accounted for 4.9% and need for a more effective method accounted for 4.0% (14).

1.4.1 Safety Concerns

Use of contraceptives poses health risks to the users who are women in their reproductive age. Adverse drug events are a major cause of contraceptive discontinuation and some women do not use contraceptives for fear of them (3). The adverse events could be hormonally, chemically or mechanically induced. The major health risks include cardiovascular diseases such as myocardial infarction, stroke, venous thromboembolism and cancer such as cancer of the breast, liver or cervix (3). Other adverse effects include headaches, nausea, dizziness and breast tenderness, menstrual changes associated with hormonal contraceptives and IUDs, allergic reactions associated with latex (condom) and copper IUDs, and physical sensations such as reduced penile sensitivity, pressure on pelvis walls or uterine cramping associated with mechanical methods (3,13)

1.4.1.1 Sub dermal implants and Their Adverse Effects

Implants are progesterone only contraceptives inserted sub-dermally on the upper part of the arm (6). Norplant®, the first implant was approved for use by the Food and Drug Authority in 1990 (16). In 1996, more than 6000 complaints of adverse drug reactions were reported by the user women in USA (16). The adverse effects associated with Norplant® were heavy bleeding, vision impairment, general malaise, and poor appetite among others (17). The Norplant® consisted of six silicon capsules loaded with levonorgestrel hormone each containing 36mg of the hormone (17). In 1996, media campaigns were launched and a legal counsel was sought to have FDA have Norplant® taken off the market (16).

In 2002, Wyeth-Aherst reached an out of court settlement with the victims and Norplant® 1 was taken off the market in USA but the company continued to manufacture for United States Agency for International Development (USAID), who could purchase it for women in the developing counties (16). USAID later stopped purchasing the contraceptive in the year 2006.

Norplant® 11, also known as Jadelle® is manufactured by Bayer and was approved for use by FDA in 1996, it consists of two thin silicone rods each containing 75mg of levonorgestrel (a synthetic progestin) (17). A survey by the population council in the years 1994-1998, titled

International experience with Norplant 1 & 2, found that menstrual irregularities with use of Norplant® decreased as the years progressed (17). In year 1 a mean of 54.3 bleeding days decreased to 50.3 in year 3 and to 44.1 in year 5. The study also demonstrated a small increment in mean hemoglobin levels though it was not statistically significant (17).

A study done in US, China and Dominican republic showed that headache was the most frequent single problem or symptom leading to premature removal of the Norplant® where in the three countries, 21% of discontinuation was due to headache (17) and 11.3% of all terminations in the three countries were due to weight changes with 21% of terminations in the US being caused by weight gain, 14% in the Dominican republic being due to weight gain and 4% due to weight loss (17).

Use of Norplant® can also lead to depression, accounting for 3.8% of all the removals while other adverse effects such as mood changes, anxiety, nervousness, vertigo, nausea, musculoskeletal pain, abdominal pain, circulatory and cardiovascular problems occurring though these are a bit infrequent. Skin problems such as rashes, dermatitis and acne led to 3.8-10.5% of all terminations (17).

Another study done in San Francisco and USA on the acceptance and perception of Norplant® among users in May- June 1990, following the data of five year clinical trial of Norplant® 1 and 2, it was found that 95% reported side effects, 82% reported changes in menstruation, 32% changes in weight, 24% reported headaches, 16% reported mood changes, 15% reported bad acne, 25% reported having decreased libido (18). Other reported adverse effect included frequent chest pains, numbness in the arm, increased hair growth, uterine cramping, pre-menstrual disorders and increased blood pressure. 61% of Norplant® users reported two or more side effects (18). Changes in menstruation included irregular bleeding in 38%, prolonged bleeding in 40%, spotting or bleeding between periods in 32%, bleeding more frequently in 25%, heavier bleeding in 16%, amenorrhea in 12% and lighter bleeding in 10% (18).

Implanon® is a single rod implant which is inserted sub dermally and remains effective for a period of three years (19). A study done on its efficacy and safety in nine different countries found that there were zero pregnancies in the three years of study. In the first two years, 21% discontinued the treatment and 17.2% of the discontinuations was due to bleeding irregularities

(19,20). Other reasons for discontinuation included wanting pregnancy, no longer in need of contraception, moving away from study site and 2.4% discontinued due to weight gain (20).

1.4.1.2 Oral Contraceptives

Oral contraceptives contain synthetic hormones which have been associated with an increased risk of breast cancer (3). However, in a certain study on current and former users found that the relative risk for breast cancer was 1 in current users and 0.9 on those who had previously used them (21). The results shows that oral contraceptives was not associated with a significant increased risk of breast cancer (21).

Diane-35® is a combined oral contraceptive with anti-androgenic properties comprising of 35µg ethinyl estradiol and 2mg cyproterone acetate, which was introduced in the market worldwide in 1978 (22). Diane-35® is not approved for use solely as an oral contraceptive but it is approved for treatment of skin sensitive conditions such as hirsutism and severe acne that is unresponsive to antibiotics (21,22). However, studies have shown an increase in sales of Diane 35®, and an increase in its use solely as a contraceptive (25).The main adverse drug reaction associated with Diane-35® is venous thromboembolism. A large study in the UK showed that women taking cyproterone had four times the risk of venous thromboembolism as those taking levornogestrel combination (25). Diane-35® associated venous thromboembolism develops within the first year of use. A case control study on fatal pulmonary embolism in New Zealand found adjusted odds ratio of 17.6 among cyproterone users, 5.1 among levonogestrel users and 14.9 among desogestrel or gestodene users as compared to non-users of oral contraceptives (25).

A study in California Kaiser Permanente medical care on incidences of stroke among women aged 15-44 years, using low doses of COCs showed an incidence of 11.3 per 100000 women years (26). Odds ratio for ischemic stroke among current users of oral contraceptives compared to former users and women who had never used the drug was 1.18 after adjusting for risk factors for stroke. Adjusted odds ratio for hemorrhagic stroke was 1.14. This demonstrated that low estrogen oral contraceptives do not appear to increase the risk of stroke (26).

1.4.1.3 Intrauterine Devices

There are two types of intra uterine devices, levonogestrel releasing intra uterine device and copper releasing device. Levonorgestrel releasing intra-uterine device is hormone based. A study

carried out in Finland to investigate the relationship between use of levonorgestrel releasing device and breast cancer found that there is no difference between levornogestrel system users and average Finnish female population (27).

A seven year prospective multicenter study in family planning clinics in the developing countries found that upper genital tract infections occurred at 0.6-0.7 per 100 years of use (28). Levornogestrel releasing IUD significantly decreased bleeding and spotting days in comparison to non-users and copper medicated IUD. Dysmenorrhea, vaginitis and myoma in women with the levonorgestrel IUD were markedly decreased in comparison with users of copper IUD. Rates of reported adverse effects for either IUD are highest in the first two years of use and among women below 25 years (28).

A three years comparative study on experience with levonorgestrel and copper releasing IUD found a protective effect with the levonorgestrel IUD against pelvic inflammatory disease as compared to the copper IUD (29).

1.4.1.4 Depot Injections

Depo-Provera is the trade name of a depot containing medroxyprogesterone acetate (DMPA), given as an injection at a three months interval to inhibit ovulation. It was developed by Up-John Company (now part of Pfizer) in the late 1950s. It was first approved for treatment of endometriosis and threatened or habitual miscarriage in 1960 but in 1974 it was shown to be ineffective for these purposes (30).

During the clinical trials, it was noted by the researchers that the drug caused women to stop menstruating which led to its reformulation as a contraceptive (30). In 1978, US FDA declined the request by Upjohn to approve use of the drug for contraception but in 1979 October, after a series of reviews of medical data, a toxicology review panel of the WHO concluded that there are no toxicological reasons for discontinuing it in the more that 50 international programs where it was being used (30). In July 1980, an advisory panel to the USAID recommended that Depo-Provera be made available to nations that request it and that the benefits of its use in the developing countries outweigh its risks (30).

FDA approved Depo-Provera for contraceptive use in 1992 where the approval largely depended on the results of WHO studies of women in Kenya, Mexico and Thailand that demonstrated that

the association between Depo-Provera and breast cancer was statistically insignificant and comparable to the association of other hormonal contraceptive and breast cancer (30).

Most reported adverse effects of depo-provera are menstrual irregularities (irregular bleeding and amenorrhea) in 55-60% of users by the twelfth month (28,29). Other adverse effects include abdominal pain and discomfort, weight gain, dizziness, headache, fatigue. Other less common adverse effects are acne, breast tenderness, depression, decreased libido. The major reasons for discontinuation of use are menstrual irregularities and weight gain (28,29,30).

In 2005, a post marketing study showed that use of Depo-Provera may result in a significant bone marrow density loss that increases with duration of use and may not be completely reversible. This may lead to osteoporosis and osteoporotic fractures later in life (33,34).

Studies have shown delayed fertility on an average of up to nine months from the time of last injection and may persist up to eighteen months (28,31,36)

1.4.2 Desire for pregnancy

Desire for pregnancy is one of the major reasons why women discontinue use of contraceptives (37). This is especially common in women with two or less children. An analysis of DHS for year 1999-2003, from different countries including Kenya, found that discontinuation of contraceptives with an intention to get pregnant was 24% in Zimbabwe, 7% in Phillipines and 22% in Kenya (38). About 6% of couples discontinue use of contraceptives in the first year of use due to desire for another child, 17% discontinue by the second year and about 23% by the third year (13). IUD users are least likely to stop for this reason (13).

1.4.3 Ineffectiveness (contraception failure)

A contraceptive maybe ineffective leading to pregnancy during its period of use and this will prompt the user to discontinue its future use. Contraception failure is different for different contraceptive methods**.** Medoxyprogesterone injection and IUDs report very low failure rates with the probability of conception while using either of the methods being less than 5% within the first three years of use (13). Oral contraceptives have a failure rate of 5.6% in the first year of use which rises to 15.6% by the third year of use (13). Implantable contraceptives exhibit a high contraceptive efficiency with the three year one being 99% effective in contraception prevention (39).

1.4.4 Unaffordability or unavailability

Unaffordability and unavailability are not common reasons for discontinuation of contraceptive use (37). Unaffordability and unavailability are an uncommon reason in Kenya as majority of Kenyan population obtain their contraceptives from public government institutions (12). According to the 2008/09 KDHS report, 57% of Kenyans receive their contraception services from public government institutions, 36% from private medical sources, 6% from other private source such as shops and less than 1% from community based distribution system (12). One in every five women using the modern methods of contraceptives receives the method free of charge (12).

1.4.5 Other reasons for contraceptive discontinuation

1.4.5.1 Desire for a more effective method

Method related dissatisfaction is a common reason for discontinuation and switch of contraceptive methods (13). Depot medroxyprogesterone users report the highest likelihood for stopping due to dissatisfaction. Discontinuation due to dissatisfaction is highest within the first year of use and lower in the second and third year. Oral pill users are the second most likely to suffer from method related dissatisfaction (13).

1.4.5.2 No further need

A woman may have no further need for contraceptive use in cases like marital separation, cessation of sexual intercourse and perceived inability to conceive. This is the least likely reason for contraceptive discontinuation (13).

1.5 Switching to another Method after Discontinuation

Switching to another method of contraceptive after discontinuing one is common in women who have experienced adverse effects and those who may have encountered method related issues such as desire for a more effective method (13,15). Most women switch to another method immediately and latest within three months. A study on the causes and consequences of contraceptive discontinuation, done in different countries showed that less than half of the women who had discontinued use and desired no pregnancy, had switched to another method by the third month (13). IUD users mostly switch to hormonal methods or sterilization. Oral pill users are the most likely to abandon use (15).

An analysis of the Kenyan DHS of 2003, 50.7% were at risk of pregnancy three months after discontinuing a certain method of contraceptive (13). Among those who switched to a different method, 2.8% switched to IUD, 11.2% to oral pills, 15.1% to medroxyprogesterone injection, 0.2% to sterilization and 30.3% to other methods (13).

1.6 Problem Statement

The Kenya Demographic Health Survey of 2008/2009 showed that contraceptive discontinuation rate for one year is 35.8% (12). The reasons for the discontinuation were not indicated. The prevalence of unintended pregnancy among married women is at 43% (12). This could be attributed to the high discontinuation rate of contraceptives. An analysis of the 2003 Kenyan DHS showed that 50.7% of the women who discontinued use of contraceptives were at risk of pregnancy three months after (13). Unintended pregnancies contribute to large sizes of families which are not planned for and also illegal abortions which contribute to maternal mortalities. About 14% of pregnancies in Kenya end up in abortion (49). Most of these abortions are performed by unskilled people. Unsafe abortions result in about 2600 deaths of women and girls in Kenya annually (49).

1.7 Significance of the Study

Studies on discontinuation of contraceptives have not been extensively done in Kenya. An analysis of the same was done on KDHS data for the year 2008/09 but it did not capture the reasons behind the discontinuation (12). There is no study that has been done locally to determine the factors for the discontinuation and switching of contraceptive methods from one to another.

The study will seek to establish the common reasons as to why women on hormonal contraceptives and IUDs discontinue or switch to other methods. It will also seek to find out the rate of discontinuation and switch within the study period. This will create awareness on the common reasons why women discontinue or switch from these contraceptive methods. This may help in creation of policies and strategies on which contraceptives should be mostly availed, and in counseling during initiation in order to address these determinants. Addressing the issues that would lead to discontinuation of contraceptive use will ensure better use hence prevention of unwanted pregnancies, which in turn would lead to reduction in abortion cases and maternal mortality.

The study may also inform policy on the management of adverse effects associated with the contraceptives leading to their discontinuation.

1.8 Research Questions

- How do demographic factors influence discontinuation and switch of hormonal and IUD contraceptives?
- What is the rate of discontinuation and switch of the contraceptive methods within the study period?
- What are the adverse effects that lead to discontinuation and switch of the contraceptive methods?
- What method of contraceptive do the women prefer after discontinuing any of the hormonal methods or IUD?

1.9 Study Objectives

1.9.1 Main Objective

To investigate on the determinants of discontinuation and switch of contraceptive methods, among women of reproductive age at Kenyatta National Hospital.

1.9.2 Specific Objectives

- To investigate the effect of demographic factors on discontinuation and switching of hormonal and Intra-Uterine Device contraceptive methods.
- To determine the rate of discontinuation and switching of hormonal and IUD contraceptive methods.
- To determine the adverse effects that lead to discontinuation and switching of hormonal contraceptives and IUDs.
- To determine the most preferred method of contraception after discontinuing any of the hormonal methods or the IUDs.

CHAPTER TWO: METHODOLOGY

2.1 Study Site

The study was carried out at Kenyatta National Hospital (KNH), which is the largest referral hospital in East and Central Africa. KNH outpatient clinic serves the cosmopolitan population from Nairobi County and the surrounding counties such as Kiambu, Kajiado and Machakos. This offers a good representation for the study participants. The study was based at the Specialized Reproductive Health Clinic, clinic 66. This is where outpatient contraceptives services are offered from Monday to Friday. The clinic has a workload of approximately 45 clients visiting daily for reproductive health services.

2.2 Study Design

The study design was a cross-sectional study which involved use of an interviewer administered questionnaire (Appendix II) to get information from clients on switch and discontinuation of contraceptives and preferred method after switching or discontinuation. The study period was 1st May to 30th June 2015.

2.3 Study Population

The target population comprised of women aged 18-49 years who were seeking contraceptive services at the study site during the study period.

2.3.1 Inclusion Criteria

Women of reproductive age (18-49 years), within the study location and on a contraceptive method within the study period, who consented to the study.

2.3.2 Exclusion Criteria

Women who were expectant, post-menopausal or not on any hormonal or IUD methods of contraception were excluded from the study.

2.4 Sample Size Determination

The sample size calculation was based on the Kenya Demographic Health Survey of 2008/2009, where one year contraceptive discontinuation rate in Kenya was 35.8 % (12).

Fischer's formula was used to determine the sample size (40).

$n = Z^2 \times p\ (1-p) / d^2$

Where: n – sample size

Z- Z value is the normal deviate corresponding to a significance level of 0.05 = 1.96

p- Estimated prevalence rate of discontinuation of contraceptive use= 35.8 % (Kenyan study)

d - Desired degree of accuracy for the study= 5%

$N= (1.96)^2 \times 0.358\ (1-0.358) / (0.05)^2$

N=353 plus 10% sample size 388.

Sampling was done until the required sample size was attained. For this study 400 women were interviewed.

2.5 Sampling Technique

Consecutive sampling method was used whereby every woman who met the inclusion criteria was included in the study until the sample size was attained.

2.6 Research Instrument

A predesigned and pretested interviewer administered questionnaire was used to collect information from the participant (Appendix II)

2.7 Data Collection Procedure

Clients were recruited within the Specialized Reproductive Health Clinic (Clinic 66), every Monday to Friday, between 8.00 am and 5.00 pm. The Principal Investigator (PI) introduced herself to the identified participant and gave a brief explanation of what the study was all about including the potential benefits and risks. Once the participant who met the inclusion criteria, gave consent, she was recruited to the study. She was then taken to the doctor's room where a face to face interview using a questionnaire was conducted. The information recorded included socio-demographic information, contraceptive use, discontinuation and switch and reasons for discontinuation. English or Kiswahili languages were used in the interview (Appendix I).

2.8 Data Management and Quality Assurance

The questionnaire was pre-tested on ten patients before the beginning of data collection. All the relevant data was collected and recorded in the questionnaire, whereby any errors and omissions on the tool were noted and corrected. Data collected was transferred to a pre-created computer database every week and back-up was done weekly. A statistician was selected and assigned the role of quality assurance, data verification and data analysis. International data protection act 1998 was applied (48).

2.9 Data Analysis

A database was created using Epi Info. Version 7, for storage of all the data collected. The data was then analyzed by use of SPSS software Version 20. Analysis of numerical data through descriptive and inferential statistics was done. Descriptive data analysis was determined for the various variables such as age, parity, education level, employment status. Exploratory data analysis which involved regressing the independent variables such as the demographic data, adverse effects, affordability against the dependent variables which are discontinuation rates and switching. P value to test the level of statistical significance (level pre-set at 0.05) was determined.

2.10 Study Limitations

Response bias may have occurred during the administration of questionnaires, where the client may not have been comfortable responding to some questions hence giving incorrect responses. This was minimized by having close ended questions on the questionnaire.

2.11Ethical Consideration

2.11.1 Approval to Carry Out the Study

Approval to carry out the study was sought from the KNH/UON Ethics and Research Committee. It was granted under reference number KNH-ERC/A/157 (Appendix III). Once the approval was granted from the Ethics Committee, permission was sought from the nursing officer in-charge of Clinic 66.

2.11.2 Informed Consent

Informed consent was sought from identified clients who met the inclusion criteria. Participants were required to consent in writing by signing a consent form (Appendix II) before being recruited to the study.

2.12 Confidentiality

The face to face interview was carried out in a private room and all the information obtained was stored under lock and key by the principal investigator. Serial numbers were used in place of clients' names in all the records.

CHAPTER THREE: RESULTS AND DISCUSSION

The rate of contraceptive discontinuation and switching as found in this study was 60.8%. The major reason for discontinuation and switching of contraceptives was adverse effects.

3.1 Socio-demographic Characteristics

3.1.1 Baseline characteristics of the patients

The mean age of the participating clients was 31.45 years with a range of 20 to 49 while the mean weight was 67.95 kg with a standard deviation of 11.76. This is a little different from the findings of KDHS 2014 where the highest percentage of those who participated was ages 25-29 (42). This could probably be due to different study site and study demographics. The mean age is comparable to the findings of a study done at the KNH-CCC on contraceptive use among HIV infected women, where the mean age was 34 (43).

The respondents who were married were 93.3%, while the minority were either never married or separated/divorced. This is comparable to the participants of the KDHS 2014 where majority were married and the minority were either divorced/separated or widowed (42). The respondents who had received secondary school education were 44%, 31.8% had gone through tertiary education and 23.5% had only primary level education. Only 8% had not received any education. This is a little different with the findings of the KDHS 2014 where only 42.7% had secondary school or tertiary education. This can probably be attributed to the different study sites and study demographics where the KDHS study has a representative sample for the whole country while this study was only done in a clinic in KNH (42).

The participants who were unemployed were 35.8%, 33.1% were self-employed and 8.3 % were in informal employment which is similar to other studies (43). Majority of the women (65.3%) had 1-2 children, while only 2% had more than 4 children; this is comparable to a similar study conducted at KNH where most participants had 1-2 children (44). Most of the participants were Christians and only 0.8 % were Muslims and no other religion was represented, which is comparable to the KDHS 2014 findings where majority of the participants, 91.45 % were Christians (42).

Table 3.1: Socio-Demographic Characteristics of the Study Population

Characteristic	Category	Frequency % (n)
Marital status	Single	5.5 (22)
	Married	93.3 (373)
	Divorced/Separated	1.3 (5)
Highest level of education	None	0.8 (3)
	Primary	23.5 (94)
	Secondary	44.0 (176)
	Tertiary	31.8 (127)
Employment status	Unemployed	35.8 (143)
	Informal employment	8.3 (33)
	Formal employment	22.8 (91)
	Self-employed	33.1 (132)
Parity	0	2.0 (8)
	1-2	65.3 (261)
	3-4	30.8 (123)
	>4	2.0 (8)
Religious affiliation	Christian	99.2 (395)
	Islam	0.8 (3)

3.1.2 Co-Morbid Conditions of the Study Population

Only 7.1% of the study participants had co-morbid conditions of which hypertension was the highest at 3.0%, asthma at 1.75% and diabetes mellitus at 0.8%. This is similar to findings of a study done within KNH on knowledge of correct use among hormonal contraceptive users, which found the prevalence of hypertension among its participants at 2.5%, diabetes mellitus at 0.8% and asthma at 0.5% (44).

Data on co-morbidity is important in characterizing the population of study and also to determine how it affects the discontinuation of contraceptives.

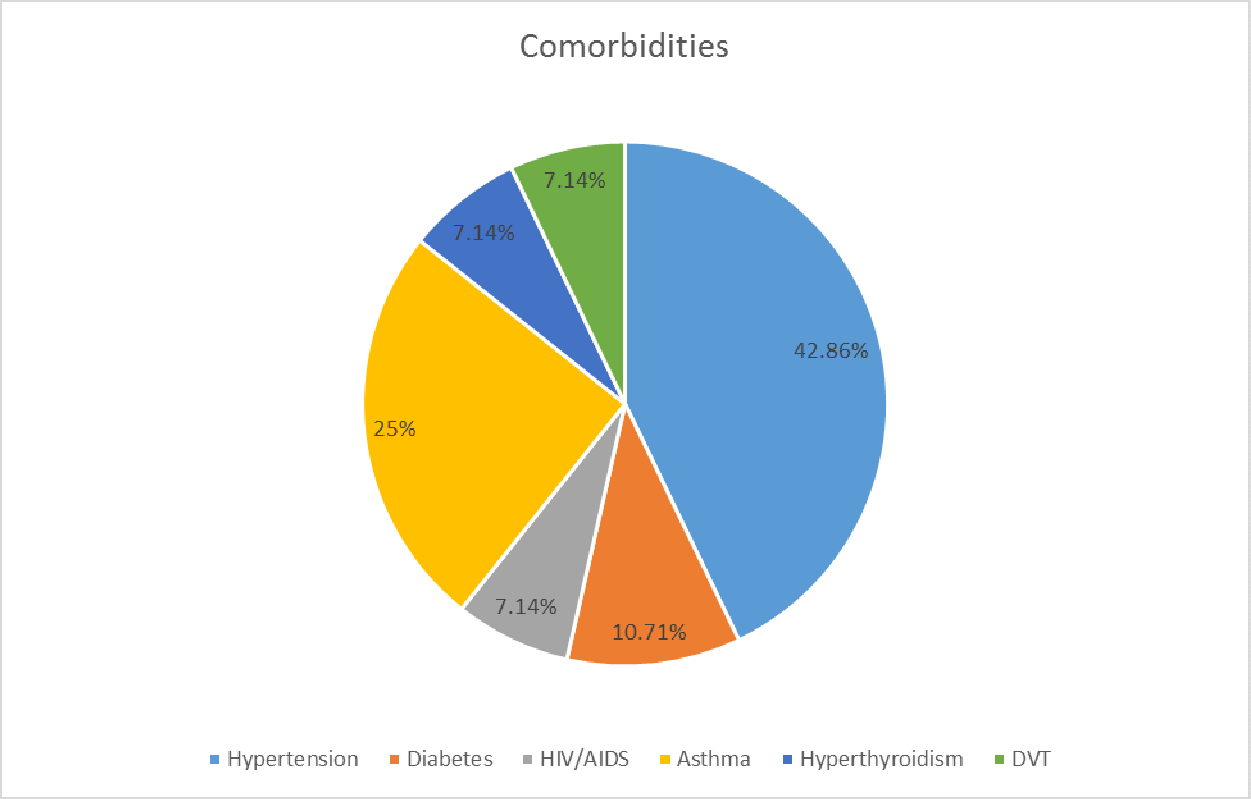

Figure 3.1: Co-Morbidities of the Study Population

3.2 History of Contraceptive Use

3.2.1 Current Use of Contraceptives

Combined oral contraceptives was being used by 29% of the study participants at the time of the study, 25% were using depot injection while both implants and IUD were at 22% in usage. This is as shown in Table 3.2. This is quite different from the findings of the KDHS 2014 where oral contraceptive pills were being used by 8%, injectables usage was at 26.4%, implants at 9.9% and IUD at 3.4% (42). Other studies show injectables as the most used among the hormonal contraceptives, followed by oral contraceptive pills and then implants (44). The disparity could be due to the different study locations and different study objectives.

Majority of the women who were using combined oral contraceptives (65.5%), cited least adverse effects as the reason for choosing it and only 5.9% gave use convenience as a reason for

choosing the method (Table 3.3). Majority of the women who were using depot injection (43.9%), gave use convenience as the reason for choosing it and only 3.1% used it because it was most available or due to doctor's advice. The implants, Jadelle® and Implanon® were mainly used due to use convenience. Most of the IUD users chose the method because of least adverse effects (59.3%)

Least adverse effects were the major reason why most women chose their current method of contraception, which was followed by use convenience (Table 3.3). Affordability or availability of a contraceptive method was a very minor reason for choosing a certain method of contraception which could be due to the fact that Government facilities are the main sources of contraceptives in Kenya, which is given at a very subsidized cost (12, 44). The reasons for choosing current methods of contraception are similar to those given in other studies (44).

Table 3.2: Current Contraceptives in Use

Current contraceptive in use	**N**	**%**
Combined Oral pills	117	29%
Depot injection	98	25%
Jadelle	48	12%
Implanon	39	10%
IUD	89	22%

Table 3.3: Reasons for Choosing the Contraceptive in Use

	Most effective	Use convenience	Least adverse effects	Most available/affordable	Doctor's advice	Others (specify)
Current contraceptive	**% (n)**	**%(n)**	**%(n)**	**%(n)**	**%(n)**	**%(n)**
Oral pills	6.7(8)	5.9(7)	65.5(78)	5(6)	15.1(18)	0(0)
Depot injection	7.1(7)	43.9(43)	40.8(40)	3.1(3)	3.1(3)	1(1)
Jadelle	18.8(9)	47.9(23)	31.3(15)	0(0)	4.2(2)	0(0)
Implanon	10.3(4)	64.1(25)	20.5(8)	0(0)	0(0)	2.6(1)
IUD	6.6(6)	14.3(13)	59.3(54)	0(0)	19.8(18)	2.2(2)
Total	8.8(35)	28(111)	49.2(195	2.3(9)	10.4(41)	1(4)

3.2.2 Previous Contraceptive Methods Use Per Woman

As shown in Table 3.4, among the interviewed women, 60.8% had used more than one contraceptive method by the time of the study. This is comparable to an analysis done from 60 demographic and health survey; in 19 countries by WHO which found that 64% of women discontinue using reversible methods of contraceptives by 36th month (45). Another DHS analysis of 20 studies for the USAID found that discontinuation rate within the first year of use was 18-63% (46). Other studies show similar discontinuation rates (47).

Table 3.4 Number of Methods of Contraceptives Used Up to Time of the Study

		N	%
Methods of contraceptives used so far	**1**	154	39.2
	2	190	48.3
	3	45	11.5
	4	4	1.0

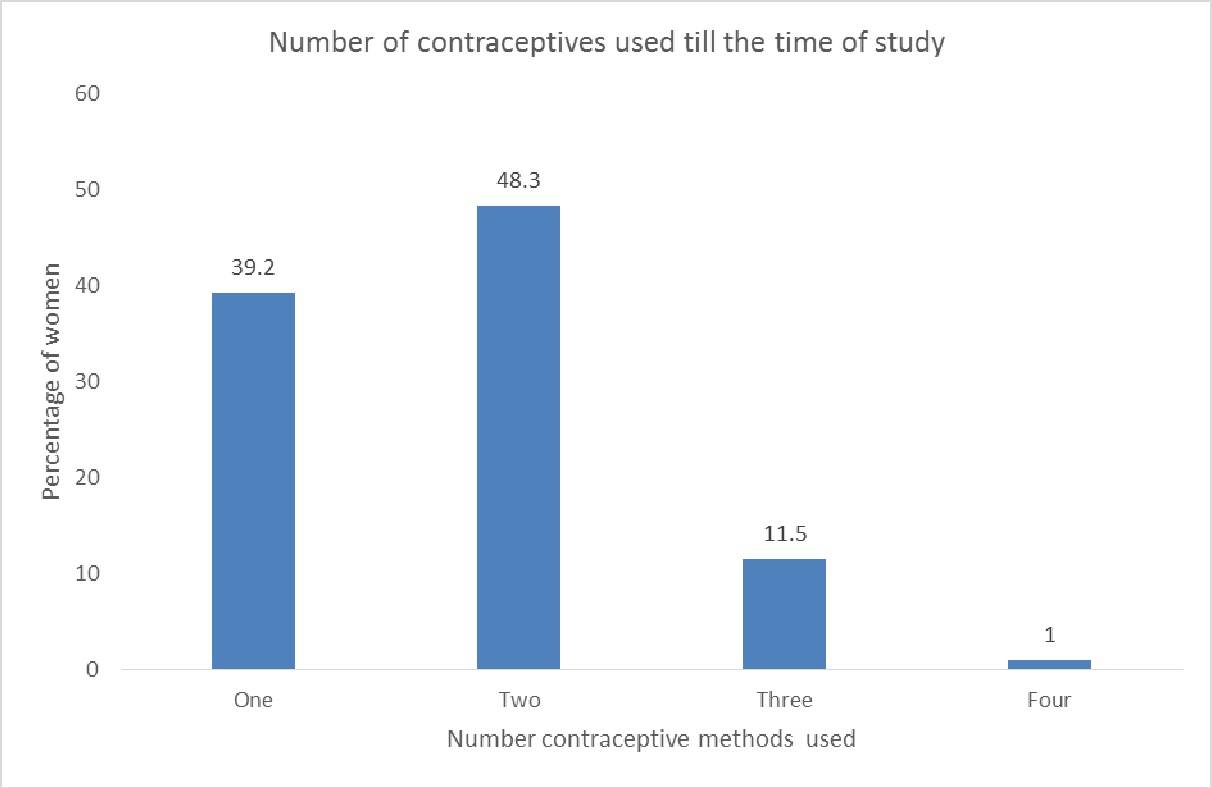

Figure 3.2 number of contraceptive methods used till the study time

3.3 Reasons For Discontinuing Contraceptive Methods

3.3.1 General Description

Majority of the women, who discontinued (n=239) using a particular method of contraceptive, did so due to adverse effects. Among those who discontinued using depot injection, 79% did so due to adverse effects, the same as 78% of Implanon® users, 76% of Jadelle® users, 60% of IUD users and 51% of Oral pill users. None of those who discontinued use of the methods cited neither spousal disapproval nor affordability/unavailability as the reason for discontinuation and only 3% of those who discontinued use of Jadelle® gave doctor's advice as the reason. Use inconvenience was never a reason among those who discontinued use of Implanon® or IUD, but was the reason among 40% of those who stopped using Oral pills. This is as shown in Table 3.5

The major reason that would make the women discontinue on their current contraceptive was adverse effects at 49.5%, followed by desire for more children at 36.0%. Unaffordability or unavailability was never a reason that would a woman discontinue their contraceptive method, as shown in Table 3.6

Table 3.5: Reasons for Discontinuing Previous Contraceptive Methods

	Adverse effects	Contraceptive failure	Desire for more children	Use inconvenience	Spouse disapproval	Unaffordability/unavailability	Doctor's advice	Other
Method	n	n	N	n	n	N	N	n
Oral pills	63 (51%)	5 (4%)	6 (5%)	49 (40%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)
Depot injection	75 (79%)	1 (1%)	8 (8%)	8 (8%)	0 (0%)	0 (0%)	0 (0%)	3 (3%)
Jadelle	26 (76%)	0 (0%)	4 (12%)	1 (3%)	0 (0%)	0 (0%)	1 (3%)	2 (6%)
Implanon	14 (78%)	1 (6%)	2 (11%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (6%)
IUD	9 (60%)	2 (13%)	4 (27%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
TOTAL	187(65.4%)	9(3.14%)	24(8.4%)	58(20.28%)	0(0%)	0(0%)	1(0.35%)	7(2.45%)

Table 3.6: Why One Would Discontinue Current Contraceptive Method

What would make one switch or discontinue the current method	**(n)**	**%**
Adverse effects	198	49.5
Contraceptive failure	4	1.0
Desire for more children	144	36.0
Use inconvenience	26	6.5
Spouse disapproval	1	0.2
Unaffordability/unavailability	0	0.0

3.3.2 Adverse Effects

Adverse effects were the major reason why people discontinued the contraceptive methods. Among those who suffered adverse effects 78.7 % reported the same to the clinician, 3.8 % did

not think it was necessary to report and 0.8% were not sure the adverse effect was due to the contraceptive method (Table 3.7)

Majority of those who suffered adverse effects (68.4%, n=91) reported it as being mild, 30.8% reported the adverse effects as being severe and only 0.8% reported them as very severe as shown in Figure 3.3.

Table 3.7: Reporting of Adverse Effects to the Clinician

	n	%
Side effects reported	48	78.7
Did not think it was necessary to report	15	3.8
Was not sure the adverse effect was due to the contraceptive method	3	0.8

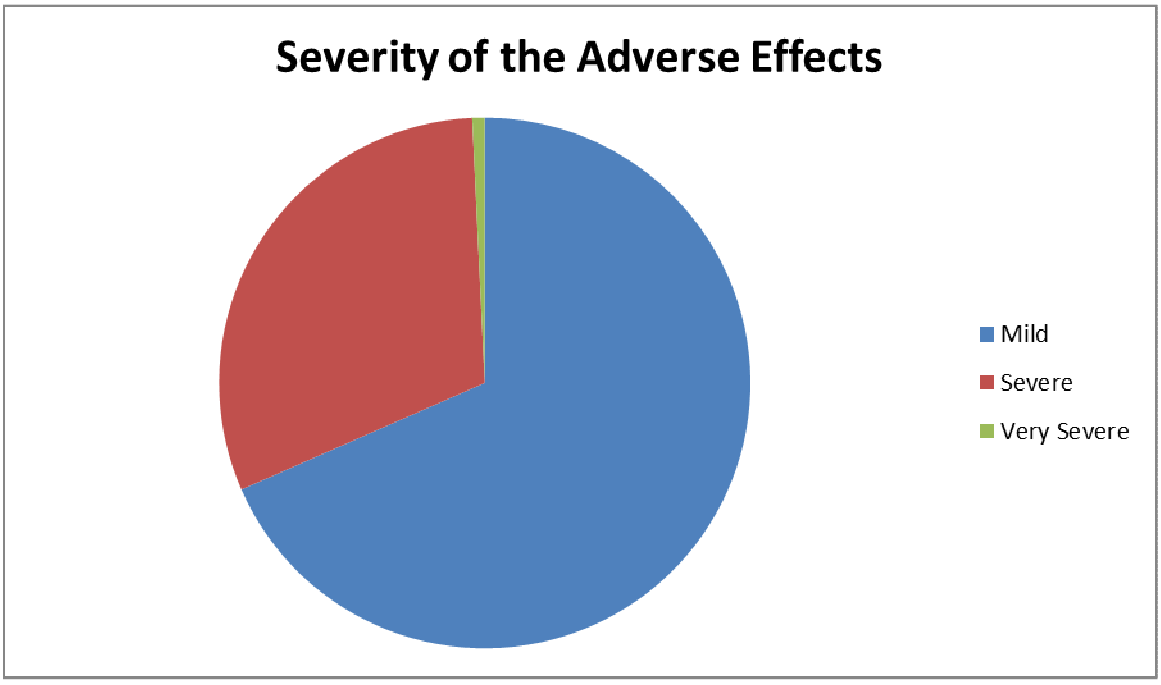

Figure 3.3: Severity of the Adverse Effects

Menstrual irregularities were the commonest adverse effects experienced by Oral pill users with prolonged bleeding being the most common adverse effect. Nausea and vomiting was also quite common among oral pill users as shown in Table 3.8

Dizziness was the most common adverse effect among depot injection users followed by low libido. Menstrual irregularities, specifically prolonged bleeding was the most common adverse effect among Jadelle® users while headache and dizziness were the commonest adverse effects among Implanon® users. IUD users reported the least adverse effects

.

Table 3.8: Specific Adverse Effects Experienced Per Contraceptive Method

		Oral pills		Depot injection		Jadelle®		Implanon®		IUD	
		n	%	n	%	n	%	n	%	n	%
Headache		2	1.7	3	3.1	3	6.2	1	2.6	6	6.6
Dizziness		5	4.2	5	5.1	7	14.6	0	0.0	3	3.3
Nausea and vomiting		0	0.0	6	6.1	0	0.0	2	5.1	9	9.9
Menstrual irregularities	Amenorrhea	8	19.5	0	0.0	2	16.7	1	25.0	5	45.5
(specify)	Prolonged bleeding	28	68.3	3	50.0	7	58.3	1	25.0	4	36.4
	Heavy bleeding	5	12.2	3	50.0	3	25.0	2	50.0	2	18.2
Acne		0	0.0	0	0.	0	0.0	0	0.0	1	1.1
Weight changes	Weight gain	3	75.0	0	0.0	2	100.0	0	0.0	9	75.0
(specify)	Weight loss	1	25.0	1	100.0	0	0.0	0	0.0	3	25.0
Mood changes		0	0.0	0	0.0	1	2.1	0	0.0	1	1.1
Low libido		2	1.7	0	0.0	2	4.2	0	0.0	3	3.3
Bloating and constipation		0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
Discomfort at injection/insertion site		0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Discomfort during insertion		0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Pelvic inflammatory disease		0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Dislocation of the device		1	0.8	0	0.0	0	0.0	0	0.0	0	0.0

3.4 Duration of Use Before Discontinuation

Survival analysis was done as an alternative way to represent all cause discontinuation of contraceptive use. The median length of use which represents the length of time by which half of the women have stopped using a certain contraceptive method was calculated for the four methods as shown in Table 3.9. Duration of use of the contraceptives varied across the methods. The longest users were the depot injection users, mean months of usage of 41 followed by oral pills and IUD users with mean months of usage at 32. Implanon® had the lowest mean months of usage which was at 16 (Table 3.9)

Depot injection users indicated the longest mean months of intended use (86 months), when asked for how long they were intending to be on the current method of contraceptive as shown in Table 3.10. This was followed by IUD users who had mean months of intended use as 84. Implanon® users gave the lowest intended mean months of use (52) followed by oral pill users whose mean was 61.

Table 3.9: Duration of Use of Current Contraceptives in Months

Current contraceptive on use	Mean	Median	Minimum	Maximum
Oral pills	32	13	1	144
Depot injection	41	24	1	132
Jadelle	27	24	2	96
Implanon	16	12	1	60
IUD	32	16	1	120

Table 3.10: Intended Duration of Use of Current Contraceptive

Current contraceptive on use	intended duration to be on the current method of contraception (months)				
	Mean	Median	Minimum	Maximum	Standard Deviation
Oral pills	61	48	1	210	49
Depot injection	86	84	3	252	48
Jadelle	64	60	6	120	38
Implanon	52	36	8	120	38
IUD	84	120	10	150	46

Methods of contraceptives used before the study and their use duration before discontinuation are presented in Table 3.11. Method 1 is the very first contraceptive method that the study participants used as reported in the interview, method 2 is the second method they use and for those who used more than two methods, method 3 is their third method of use. Women use Oral pills, depot injection and IUD for a longer period if it's the very first method of contraception they are using than if it's the second method of contraception. Implants (Jadelle® and Implanon®) were used for longer duration if they are used as second or third methods of contraception as compared to when they are use as the first method.

When IUD is used as the first method of contraception, it had the highest median length of use (60 months), followed by Jadelle® while Implanon® had the least median length of use. Jadelle® had the highest length of use when used as a second method of contraception, followed by Implanon and Oral Contraceptive pills had the least median length of use. A WHO analysis of several DHS (including Kenya 2003 DHS) on causes and consequences of contraceptives discontinuation showed similar results with IUD having the highest median length of use (40 months) and depot injection the lowest, though it did not include implants (Jadelle® and Implanon®) in the study (45). This can be due to the fact that IUD is a long term method of contraception, and can be effective for over ten years once inserted.

Table 3.11 Previous use of contraceptives and their duration of use

Duration of use (months)		Oral pills	Depot injection	Jadelle	Implanon	IUD
Method 1	Mean	31	25	36	15	44
	Median	12	12	36	10	60
	Minimum	1	3	4	2	8
	Maximum	120	120	96	36	72
	Standard Deviation	33	29	25	12	28
Method 2	Mean	24	13	53	29	8
	Median	3	9	60	30	8
	Minimum	1	3	1	18	5
	Maximum	138	60	120	36	12
	Standard Deviation	50	14	44	9	3
Method 3	Mean	-	-	72	-	-
	Median	-	-	60	-	-
	Minimum	-	-	36	-	-
	Maximum	-	-	120	-	-
	Standard Deviation	-	-	43	-	-

3.5 Adherence Case Indexing

Adherence case indexing to the dosing regimen for the oral pill users was done by use of a Case Adherence Index Questionnaire (adapted from Manheimer et al, 2006; Wakibi et al, 2011). It was found that majority of the pill users had good adherence which was above 10 (74.7%). The average adherence index was 13. Only 25.3% of the oral pill users had an index score of 10 and below.

Table 3.12: Adherence Case Indexing Scores for Oral Pill Users

Index Score	N	%
6	1	1.3%
7	5	6.7%
8	4	5.3%
9	8	10.7%
10	1	1.3%
11	2	2.7%
12	2	2.7%
13	13	17.3%
14	1	1.3%
16	38	50.7%

3.6 Socio-demographic Factors and Discontinuation of Contraceptive Use

Bivariate analysis was done through logistic regression, to determine how several factors affected the discontinuation of contraceptives. Marital status, level of education, religious affiliation, employment status and parity were all not associated with discontinuation of contraceptives. It was only co-morbidity and the method of contraception that were associated with discontinuation of contraceptive use (P-value = 0.001 & <0.0001 respectively) as shown in Table 3.13. This is different from a similar study carried out in Pakistan in 2012, which showed that family size (parity) is strongly associated with discontinuation of contraception (37). The difference in findings could be due to the different study populations and probably different study design and objectives.

Table 3.13: Bivariate Analysis: Factors Associated With Discontinuation

		Discontinued				
		No		Yes		
		n	%	N	%	P value
Marital status	Single	16	72.7%	6	27.3%	0.853
	Married	263	70.5%	110	29.5%	
	Divorced/Separated	3	60.0%	2	40.0%	
Highest level of education	None	1	33.3%	2	66.7%	0.356
	Primary	70	74.5%	24	25.5%	
	Secondary	120	68.2%	56	31.8%	
	Tertiary	91	71.7%	36	28.3%	
Employment status	Unemployed	103	72.0%	40	28.0%	0.590
	Informal employment	26	78.8%	7	21.2%	
	Formal employment	63	69.2%	28	30.8%	
	Self-employed	89	67.4%	43	32.6%	
Parity	0	7	87.5%	1	12.5%	0.145
	1-2	191	73.2%	70	26.8%	
	3-4	80	65.0%	43	35.0%	
	>4	4	50.0%	4	50.0%	
Religious affiliation	Christian	278	70.4%	117	29.6%	0.888
	Islam	2	66.7%	1	33.3%	
Co-morbidity	No	266	72.9%	99	27.1%	0.001
	Yes	12	42.9%	16	57.1%	
Contraceptive method	Oral pills	77	64.7%	42	35.3%	<0.0001
	Depot injection	86	87.8%	12	12.2%	
	Jadelle	29	60.4%	19	39.6%	
	Implanon	32	82.1%	7	17.9%	
	IUD	55	60.4%	36	39.6%	

3.7 Multivariate Logistic Regression Analysis.

Multivariate analysis on model building showed that only co-morbidity had a significant association with discontinuation of the contraceptives, with a P=0.001 and an Odds Ratio of 3.582 (1.637-7.840), which means that the presence of a co-morbid condition increases the odds of discontinuing a contraceptive method by 3.6 times

Table 3.14 Independent predictor(s) of discontinuation of contraceptives

	Coefficient	S.E. of coefficient	P value	OR	95% C.I. for OR	
					Lower	Upper
Comorbidities	1.276	0.400	0.001	3.582	1.637	7.840

CHAPTER FOUR: CONCLUSION AND RECOMMENDATIONS

4.1 Conclusion

Multiple reasons for discontinuation of contraceptive use include primarily concerns for adverse effects, use inconvenience, desire to become pregnant, contraceptive failure, and doctor's advice. Spousal disapproval and unaffordability or unavailability are not determinants of discontinuation of contraception use. Presence of a co-morbid condition on the user and the method of contraception are the statistically significant factors when it comes to discontinuation of contraceptives.

4.2 Recommendations

4.2.1 Recommendation for policy and practice

Reproductive Health programs that deal with contraceptives need to come up with more detailed programs that address the high levels of discontinuation of contraception use by women who are still in need. Family planning programmers and stakeholders need to identify women who strongly want to avoid pregnancy and find ways to help the couples successfully initiate and maintain appropriate contraceptive use. The factors underlying the discontinuations need to be addressed thoroughly during the inception of contraceptive services, and counseling continued at each visit for the services. Treatment guidelines should include deliberate, rigorous and regular screening for comorbid conditions and the relevant clients advised accordingly.

4.2.2 Recommendation for research

More studies need to be done to determine the temporal relationship between hormonal contraceptive use and onset of the comorbid conditions. Wider studies on the adequacy of contraceptive services and client satisfaction with the methods also need to be carried out. Follow up studies on those who discontinue contraceptive use while still in need should be carried out to determine the outcome of the discontinuation.

REFERENCES

1. Monga AK, and Dobbs SP (2011). Gynaecology by Ten Teachers. 19th ed. BookPower; P59.

2. Thompson KMJ (2013). A Brief History of Birth Control in the U.S. Available from: http://www.ourbodiesourselves.org/health-info/a-briefhistory-of-birth-control/ Accessed Dec. 2014

3. Hatcher RA, and Trussell J (2007). Contraceptive Technology. 20th ed. Ardent Media; P 941.

4. U.S. Food and Drug administration (2014) Available from: http://www.consciencelaws.org/background/procedures/birth014-001.aspx. Accessed Jan.2015

5. Joel G, and Hardman LEL, editor. Goodman & Gilman's The pharmacological basis of therapeutics. 10th ed. McGraw-Hill Medical Publishing Division; P 1623.

6. Brown MJ, and Bennett PN (2003) Clinical Pharmacology. 9th ed. Churchill Livingstone; P37.

7. Marshall S. (2014) Barrier methods of birth control. Available from: www.webmd.com/sex/birth-control/barrier-methods-of-birth-control-19059. Accessed Jan. 2015

8. Samra OM. (2014) Birth control, permanent methods. Available from: www.emedicinehealth.com/birth-control-permanent-method/article-em.htm Accessed Jan.2015

9. World Bank (2009)**.** Graph on World Bank indicators-Kenya reproductive health. Available from: www.tradingeconomics.com/Kenya/contraceptive-prevalence-percent of women-ages-15-49-wb-data.html. Accessed Dec.2014

10. Wawire NW. (2011) Contraceptive use among women of reproductive age in Kenya's city slums. Int J Bus Soc Sci. Vol.2 No.1.

11. Magadi MA, and Curtis SL (2003). Trends and Determinants of Contraceptive Method Choice in Kenya. Stud Fam Plann. 2003 Sep 1;34(3):149–59.

12. Kenya Demographic and Health Survey 2008/09. Kenya National Bureau of Statistics; 2010.

13. Cleland J, Ali MM and Shah IH. (2012) Causes and consequencies of contraceptive discontinuation, evidence from 60 demographic health surveys. WHO.

14. Sarah EK, Bradley, Schwandt HM and Khan S. (2009) Levels, trends and reasons for contraceptive discontinuation. DHS analytical studies 20. USAID.

15. Syeda SH and Mushiur R (2007) Factors associated with contraceptive failure, discontinuation and switching among married women in Bangladesh. *J. Fam. Welf.* 53: 43-55.

16. Steven W. Mosler EC. (2012) How Norplant 1 was discontinued. weekily briefing.

17. Sivin I. (1988) International Experience with NORPLANT and NORPLANT-2 Contraceptives. Stud Fam Plann. 1988 Mar 1;19(2):81–94.

18. Darney PD, Atkinson E, Tanner S, MacPherson S, Hellerstein S, Alvarado A. (1990) Acceptance and Perceptions of NORPLANT Among Users in San Francisco, USA. Stud Fam Plann. 1990 May 1;21(3):152–60.

19. Croxatto HB, Urbancsek J, Massai R, Bennink HC, Beek AV. (1999) A multicentre efficacy and safety study of the single contraceptive implant Implanon ®. Hum Reprod. 1999 Apr 1;14(4):976–81.

20. Blumenthal PD, Gemzell-Danielsson K, Marintcheva-Petrova M. (2008) Tolerability and clinical safety of Implanon®. Eur J Contracept Reprod Health Care. 2008 Jan 1;13(s1):29–36.

21. Marchbanks PA, McDonald JA, Wilson HG, Folger SG, Mandel MG, Daling JR (2002) Oral Contraceptives and the Risk of Breast Cancer. N Engl J Med. 2002 Jun 27;346(26):2025–32.

22. The Society of Obstetricians and Gynecologists of Canada. (2013). Diane-35 and risk of venous thromboembolism (VTE). (2013 Feb 19); Available from: http://sogc.org/wp-content/uploads/2013/04/medDiane35VTE130219.pdf accessed Jan 2015

23. The Canadian Press. National Post (2014) Health Canada to review Diane-35, acne and contraceptive drug linked to women's deaths from blood clots. [cited 2014 Dec 2]. Available from: http://life.nationalpost.com/2013/01/31/health-canada-to-review-diane-35-acne-and-contraceptive-drug-linked-to-womens-deaths-from-blood-clots/ accessed Jan. 2015

24. Seaman HE, Vries CS de, Farmer RDT. (2003 Mar 1).The risk of venous thromboembolism in women prescribed cyproterone acetate in combination with ethinyl estradiol: a nested cohort analysis and case–control study. Hum Reprod.;18(3):522–526.

25. Wooltorton E. (2003) Diane-35 (cyproterone acetate): safety concerns. Can Med Assoc J. 2003 Feb 18;168(4):455–456.

26. Petitti DB, Sidney S, Bernstein A, Wolf S, Quesenberry C, Ziel HK. (1996) Stroke in Users of Low-Dose Oral Contraceptives. N Engl J Med. 1996 Jul 4;335(1):8–15.

27. Backman T, Rauramo I, Jaakkola K, Inki P, Vaahtera K, Launonen A. (2005) Use of the Levonorgestrel-Releasing Intrauterine System and Breast Cancer: Obstet Gynecol. 2005 Oct;106(4):813–7.

28. Sivin I, Stern J**.** (1994) Health during prolonged use of levonorgestrel 20 micrograms/d and the copper TCu 380Ag intrauterine contraceptive devices: a multicenter study. International Committee for Contraception Research (ICCR). Fertil Steril. 1994 Jan;61(1):70–7.

29. Toivonen J. Luukkainen T. Allonen H. (1991) Protective Effect of Intrauterine Release of Levonorgestrel on pelvic infection. A three year comparative experience of levonorgestrel and copper releasing intrauterine devices: Obstetrics & Gynecology. Obstet Gynecol 1991 feb; 77(2): 261-264

30. Gold RB, Willson PD. (1980) Depo-Provera: New Developments in a Decade-Old Controversy. Int Fam Plan Perspect. 1980 Dec 1;6(4):156–60.

31. Bigrigg A, Evans M, Gbolade B, Newton J, Pollard L, Szarewski A, Thomas C, Walling M. (1999) Depo Provera. Position paper on clinical use, effectiveness and side effects. Br J Fam Plann. 1999 Jul;25(2):69–76.

32. Nash HA. (1975) Depo provera®: A review. Contraception. 1975 Oct;12(4):377–93.

33. Wooltorton E. (2005) Medroxyprogesterone acetate (Depo-Provera) and bone mineral density loss. Can Med Assoc J. 2005 Mar 15;172(6):746–746.

34. Cromer BA, Blair JM, Mahan JD, Zibners L, Naumovski Z. (1996) A prospective comparison of bone density in adolescent girls receiving depot medroxyprogesterone acetate (Depo-Provera), levonorgestrel (Norplant), or oral contraceptives. J Pediatr. 1996 Nov;129 (5):671–6.

35. Pardthaisong T. (1984) Return of fertility after use of the injectable contraceptive Depo Provera: up-dated data analysis. J Biosoc Sci. 1984 Jan;16(01):23–34.

36. Fotherby K, Howard G. (1986) Return of fertility in women discontinuing injectable contraceptives. J Obstet Gynaecol. 1986 Jan 1;6(s2):S110–5.

37. Farwa Rizvi GI. (2012) Reasons for discontinuation of contraceptive methods among couples with different family size and educational status. Dep Community Med; 2012

38. Evens E. Curtis S. Sambisa W. (2011) Contraceptive discontinuation and unintended pregnancy: An imperfect relationship. Intern.pers.on sexual & reprod.health 2011 June; 37(2): 58-66

39. Graesslin O, Korver T. (2008) The contraceptive efficacy of Implanon®: A review of clinical trials and marketing experience. Eur J Contracept Reprod Health Care. 2008 Jan 1;13(s1):4–12.

40. Daniel WW. Biostatics: (2009) Basic concepts and methodology for the Health Sciences. Wiley series in probability and statistics; 2009. pp113

41. Rizvi F, and Irfan G (2012) Reasons for discontinuation of contraceptive methods among couples with different family size and educational status. *J. Ayub. Med. Coll. Abbottabad* 24:101-4.

42. Kenya National Bureau of Statistics.(2014) Kenya Demographic and Health Survey; 2014

43. Mutiso SM, Kinuthia J and Qureshi Z (2008) Contraceptive use among HIV infected women attending Comprehensive Care Centre. *East Afr. Med. J.* 85: 171–7.

44. Nkonge NG, Opanga SA, Guantai EM and Karimi PN (2014). Knowledge of correct use among Hormonal Contraceptive users in a Kenyan Referral Hospital *Afr. J. Pharmacol. Ther.* 3: 105-111.

45. Mohamed AM, Cleland JG, Shah IH (2012). Causes and consequences of contraceptive discontinuation, evidence from 60 demographic health surveys. World Health Organization.

46. Bradley SEK, Schwandt HM, and Khan S (2009). Levels, trends and reasons for contraceptive discontinuation. DHS analytical studies 20. USAID.

47. Wethoff CL and Heartwell S (2007). Oral contraceptives discontinuation: Do side effects matter? *Am. J. Obstet. Gynecol*.196: 412.e1–412.e7.

48. Data protection act (1998), Version 4.0, Chapter 29 Information Commissioners Office

49. Mumah J, Kabiru CW, Mukiira C, Brinton J, Mutua M, Izugbara C, Birungi H, Askew I. (2014). Unintended pregnancies in Kenya: A country profile. Available on, http://www.popcouncil.org/uploads/pdfs/2014STEPUP_KenyaCountryProfile.pdf Accessed June 2016.

5. I: Consent Form
(English version)

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

Title of the study: Determinants of discontinuation of contraceptive methods among women at Kenyatta National Hospital.

Institution

Department of Pharmacognosy and Pharmacology, School of Pharmacy, University of Nairobi, P.O. BOX 30197-00400, Nairobi.

Investigator

Dr.Susan Wacera Maina, P.O BOX 30197-00100. Tel 0720177393

Supervisors

Dr. G. O Osanjo PhD

Department of Pharmacognosy and Pharmacology

Dr. S. N. Ndigwah PhD

Department of Pharmaceutical Analysis

Dr. S. Opanga Mpharm

Department of Pharmaceutics and Pharmacy Practice

Ethical Approval

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

Introduction

I, Dr. Susan Wacera Maina, a student of Master of Pharmacy in Pharmacoepidemiology and Pharmacovigilance at the University of Nairobi, will be assessing on the determinants of contraceptive discontinuation among women at Kenyatta National Hospital.

Purpose of the study

To find out on the determinants that lead to discontinuation of hormonal contraceptives and IUDS, to determine the rate of discontinuation and switch of the contraceptives, to determine the adverse effects leading to discontinuation and switch and also to determine the most preferred contraceptive method that patients switch to.

Permission is requested from you to enroll in this research study. The following are 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. I will enquire whether you have ever discontinued or changed a contraceptive method and the reasons for discontinuing or changing. All the information given will be handled with confidentiality and will only be used for the purpose of this study.

Benefits and rewards

You may ask any question you may be having in regard to the contraceptive method you are using, I will also offer counsel on the contraceptive method you are using or any other method you may be interested in. There will be no monetary reward for participating 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……

Toleo la Kiswahili

Mada: vigezo vinavyofanya wanawake waache kutumia ama wabadilishe njia za kupanga uzazi

Shule: Shule ya Famasia, Chuo Kikuu cha Nairobi. Sanduku la Posta 30197-00400, Nairobi

Mtafiti: Dr. Susan Wacera Maina, Nambari ya Simu- 0720177393 Rununu: mainasue@gmail.com

Maadili: Hospitali Kuu ya Kenyatta / Chuo Kikuu Cha Nairobi – Kamati ya Maadili na Utafiti (KNH/UON –ERC) Simu; 02002726300 ext. 44102 S.L.P 20723-00202, Nairobi

Kuanzishwa:

Mimi, Dr. Susan Wacera Maina, mwanafunzi wa Famasia katika Chuo Kikuu Cha Nairobi, ninafanya utafiti wa vigezo vinavyofanya wanawake waache kutumia ama wabadilishe njia za kupanga uzazi, katika Hospitali Kuu ya Kenyatta.

Kusudi la utafiti:

Utafiti wa vigezo vinavyofanya wanawake waache kutumia njia za kupanga uzazi, kuamua kwa kiwango cha wanaowacha ama kubadilisha njia za kupanga uzazi, utafiti wa athari mbaya zinazofanya wanawake waache kutumia ama wabadilishe njia za kupanga uzazi, na pia kutafiti wa njia ya uzazi inayotumika zaidi na wanawake waliyobadilisha njia zingine.

Ninaomba unikubalishe nikuandikishe kwa huu utafiti. Zifuatazo ni kanuni zinazojumulisha washiriki wote wa utafiti wa kimatibabu:

i. Kukubali kwako kwa kushiriki kwa huu utafiti ni kwa kujitolea. Utapata matibabu sawa kutoka kwa hii hospitali ukikubali na hata usipokubali kushiriki
ii. Unaweza kujiondoa kutokana na huu utafiti kwa wakati wowote, bila kupeana sababu zozote na haitaathiri huduma unazopata kwa hii hospitali
iii. Ukishaelewa hii maelezo, tafadhali jisikie huru kuuliza swali lolote litakalokufanya uelewe zaidi huu utafiti.

Utaratibu utakaofuatwa:

Kwa idhini yako, nitakuuliza maswali kuhusu njia ya kupanga uzazi unayoitumia. Nitauliza kama kwamba ushawahi acha kutumia ama kubadilisha njia yoyote ya kupanga uzazi, na sababu zilizokufanya uache ama ubadilishe. Habari zote utakazopeana zitabaki siri na zitatumika kwa huu utafiti pekee.

Faida na marupurupu:

Unaweza uliza swali lolote kuhusiana na njia za kupanga uzazi, nitakupee ushauri kuhusu njia ya kupanga uzazi unayotumia ama ingine yoyote ambayo ungependa. Hakutakuwa na malipo yoyote ya kifedha kwa kushiriki kwa huu utafiti.

Usumbufu na hatari:

Maswali mengine utakayoulizwa ni ya kibinfsi na inaweza kukufanya ukuwe na wasiwasi. Hii ikifanyika unaweza kosa kujibu hilo swali. Unaweza pia kusimamisha hii mahojiano kwa wakati wowote. Kushiriki kwa hii mahojiano inaweza kufanya kuongezeka kwa muda wako wa kungoja huduma ya matibabu, kwa dakika 15-20.

Uhakika wa usiri:

Habari yoyote utakayopeana itawekwa kwa usiri. Hakuna wakati wowote jina yako itatajwa ama kutumika kwa utafiti huu ama kwa kuchapisha huu utafiti huu. Nambari ninazopeana ndizo zitakazotumika.

Mawasiliano:

Ikiwa kwa wakati wowote ungependa kuwasiliana nami, idara taaluma ya masomo ama kamati ya maadili na utafiti kuhusu utafiti huu, jisikie huru kutumia nambari za mawasiliano zilizopeanwa.

Ridhaa:

Mimi, niliyetia sahihi, kwa hiari yangu nimekubali kushiriki kwa huu utafiti, asili na kusudi yake imeelezewa kiwazi na mtafiti. Ninaelewa kwamba habari ninazopeana zitatumika kwa huu utafiti pekee na usiri mkuu utafanyika.

Mwenye kujibu :……..

Tarehe……

Shahidi (Mtafiti)…….

Tarehe……

Taarifa ya mtafiti:

Mimi, niliyetia sahihi, nimemwelezea mshiriki kwa lugha anayoelewa, taratibu zitakazofuatwa kwa huu utafiti na pia usumbufu na hatari zinazoweza kutokea.

Mtafiti……

Tarehe…….

5.2 Data Collection Tool

Determinants of discontinuation of Hormonal contraceptives and IUDs methods.

Serial number…….

Tick where appropriate.

A. Study population description

I).Age (years)

……

2).Marital status

1.[ ] Single 2.[ ] married 3.[ ] divorced/separated

3) Highest level of education

1.[ ] None 2.[ ] primary 3.[ ] Secondary 4.[ ] tertially

4).Employment status

1. [ ] unemployed 2. [ ] informal employment 3. [ ] formal employment 4. [ ] self employed

5).Parity

1. [ ] 0 2. [ ] 1-2 3. [ ] 3-4 4. [ ] >4

6). Religious affiliation

1.[ ] Christian 2.[ ] islam 3.[ ] Hindu 4.[ ] others (specify)……

If Christian which denomination?

1.[ ] catholic 2. [ ] protestant 3.[ ] Pentecostal 4.[ ]others (specify)…….

7). Weight……

8). Height…….

9). Cormobidities 1.[ ] yes 2.[ ] no

If yes, which one? 1.[ ] hypertension 2.[ ] diabetes 3.[ ] Hiv/Aids 4.[ ] others (specify)…….

B) History of contraceptive use

10) Current contraceptive on use

1.[ ]oral pills 2.[ ] depot injection 3.[ ] jadelle 4.[ ] implanon 5. [ ] IUD 6.[ ]BTL 7.[ ] None

8.[ ]others (specify)…….

11) For how long have you used the method? (In months)……

12) Why did you choose the current method?

1.[ ] most effective 2.[ ]use convenience 3) [ ] least adverse effects 4.[ ]most available/affordable

5.[ ]doctor's advice 6.[ ]others (specify)……..

13) How many methods of contraceptives have you used so far?

1.[ ] one 2. [ ] two 3.[ ] three 4.[ ] four

14) If more than one, which ones are they?

1.[ ]oral pills 2.[ ]depot injection 3.[ ]jadelle 4. [ ] implanon 5.[ ]IUD

7. [ ] Others (specify)……..

14) Why did you stop using the method?

Method 1 1.[ ]oral pills 2.[ ] depot injection 3.[ ] jadelle 4. [ ] implanon 5.[ ]IUD

1.[ ]adverse effects 2.[ ]contraceptive failure 3.[ ]desire for more children 4.[ ] use inconvenience 5.[ ]spouse disapproval 6.[ ] unaffordability/unavailability 7.[ ]others (specify)……

For how long did you use the method? (in months) …….

Method 2 1.[ ]oral pills 2.[ ] depot injection 3.[ ] jadelle 4. [ ] implanon 5.[ ]IUD

1.[ ]adverse effects 2.[ ]contraceptive failure 3.[ ]desire for more children 4.[ ] use inconvenience 5.[ ]spouse disapproval 6.[ ] unaffordability/unavailability 7.[ ]others (specify)……

For how long did you use the method?(in months) ……

Method 3 1.[ ]oral pills 2.[ ] depot injection 3.[ ] jadelle 4. [ ] implanon 5.[ ]IUD

1.[ ]adverse effects 2.[ ]contraceptive failure 3.[ ]desire for more children 4.[ ] use inconvenience 5.[ ]spouse disapproval 6.[ ] unaffordability/unavailability 7.[ ]others (specify)……

For how long did you use the method? (in months) ……

15) If it was because of adverse effects, did you report to the clinician? 1.[ ] yes 2.[ ] no

If no, why? 1.[ ]did not think it was necessary

2.[ ] was not sure the adverse effect was due to the contraceptive method

3.[ ] others
(specify)……..

16) How severe was the adverse effect?

1.[ ] mild 2. [ ] severe 3.[ ]very severe

17) For how long are you intending to be on the current method of contraception? (Months)……

18) What would make you switch or discontinue the method?

1.[ ]adverse effects 2.[ ]contraceptive failure 3.[ ]desire for more children 4.[ ] use inconvenience 5.[ ]spouse disapproval 6.[ ] unaffordability/unavailability 7.[ ]others (specify)……

C) Adverse effects leading to discontinuation of contraceptives

Contraceptive method 1: 1.[ ]oral pills 2.[ ] depot injection 3.[ ] jadelle 4. [ ] implanon 5.[ ]IUD

Adverse effect	Tick as appropriate
Headache	
Dizziness	
Nausea and vomiting	
Menstrual irregularities (specify)	1.[ ]amenorrhea 2.[ ]prolonged bleeding 3.[ ]heavy bleeding
Acne	
Weight changes (specify)	1.[ ] weight gain 2.[ ] weight loss
Mood changes	

Low libido	
Bloating and constipation	
Discomfort at injection/insertion site	
Discomfort during insertion	
Pelvic inflammatory disease	
Dislocation of the device	
Others (specify)	

Contraceptive method 2: 1.[ ]oral pills 2.[ ] depot injection 3.[ ] jadelle 4. [ ] implanon 5.[ ]IUD

Adverse effect	Tick as appropriate
Headache	
Dizziness	
Nausea and vomiting	
Menstrual irregularities (specify)	1.[ ]amenorrhea 2.[ ]prolonged bleeding 3.[ ]heavy bleeding
Acne	
Weight changes (specify)	1.[ ] weight gain 2.[ ] weight loss
Mood changes	
Low libido	
Bloating and constipation	
Discomfort at injection/insertion site	
Discomfort during insertion	
Pelvic inflammatory disease	
Dislocation of the device	
Others (specify)	

D) For those on oral pills

CASE ADHERANCE INDEX QUESTIONNAIRE

(Adapted from Mannheimer et.al, 2006; wakibi et al, 2011)

1.1 How often do you feel that you have difficulty in taking your oral contraceptive pills on time? (by on time we mean no more than two hours before or after the time you agreed with your doctor)

4. Never
3. Rarely
2. Most of the time
1. All the time

1.2 On average, how many days per week would you say that you missed at least one dose of your medication?

1. Everyday
2. 4-6 days per week
3. 2-3 days per week
4. Once a week
5. Less than once a week
6. Never

1.3 When was the last time you missed at least one dose of your oral contraceptive pills?

1. Within the past week
2. 1-2 weeks ago
3. 3-4 weeks ago
4. Between 1-3 months ago
5. More than 3 months ago
6. Never

Index score…….

>10-good adherence ≤10 poor adherance

5.3 Ethics Approval Letter

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: http://erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

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

Ref: KNH-ERC/A/157

8th April, 2015

Susan Wacera Maina
Dept. of Pharmacology and Pharmacognosy
School of Pharmacy
University of Nairobi

Dear Susan

Research Proposal: Determinant s of Discontinuation of Contraceptive Methods among Women at Kenyatta National Hospital (P92/02/2015)

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 8th April 2015 to 7th April 2016.

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.erc.uonbi.ac.ke**

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 Chair, KNH/UoN-ERC
The Dean, School of Pharmacy
The Chair, Dept. of Pharmacology and Pharmacognosy
Supervisors: Dr. George O. Osanjo, Dr. Stanely N. Ndwigah, Dr. Syliva Opanga