COMPARING SOCIODEMOGRAPHIC, REPRODUCTIVE AND CLINICOPATHOLOGICAL CHARACTERISTICS ASSOCIATED WITH HORMONAL CONTRACEPTIVE USE AMONG WOMEN WITH UNCOMPLICATED DIABETES MELLITUS AT KENYATTA NATIONAL HOSPITAL

A Research Dissertation submitted in Partial Fulfillment of the Requirements for the Award of the Degree of Master of Medicine in Obstetrics & Gynecology

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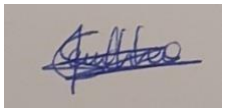
DECLARATION

This research was undertaken in part fulfillment of the Master of Medicine in Obstetrics and Gynecology and is my original work and has not been undertaken and presented for a degree in any other university.

Signed:  Date: 10/2/2022

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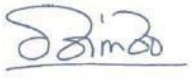
Signature:  Date: 14/2/2022

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DEDICATION

I dedicate this work to my parents, Achieng' and Koga.

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Finally, I would like to thank my patients for their constant source of inspiration.

LIST OF ABBREVIATIONS

CIC	:	Combined Injectable Contraception
COC	:	Combined Oral Contraceptive
CPR	:	Contraceptive Prevalence Rate
DM	:	Diabetes mellitus
DMPA		Depot Medroxyprogesterone acetate
DOPC	:	Diabetic Outpatient Clinic
ERC		Ethics and Research Committee
FP	:	Family planning
GOPC	:	Gynecology Outpatient clinic
IUCD	:	Intrauterine Contraceptive Devise
IUD	:	Intrauterine Devise
KDHS	:	Kenya Demographic and Health Survey
KNH	:	Kenyatta National Hospital
LNG-IUS	:	Levonorgestrel Intrauterine System
MEC	:	Medical Eligibility Criteria
OCP	:	Oral contraceptive pill
POIC	:	Progesterone-only Injectable Contraception
POP	:	Progesterone-only Pill
SES	:	Socio-Economic Status
UK	:	United Kingdom
UN		United Nations
US(A)	:	United States of America
WHO	:	World Health Organization

OPERATIONAL DEFINITIONS

Contraception – the deliberate use of artificial methods or other techniques to prevent pregnancy as a result of sexual intercourse.

Contraceptive Prevalence Rate – the percentage of women of reproductive age who are currently using, or whose sexual partner is currently using, at least one contraceptive method, regardless of the method used. (Reported for women 15 – 49 years who are married or in-union)

Family planning – the practice of controlling the number of children and the interval of births by individuals or couples, by means of contraception or treatment of involuntary infertility (WHO).

Unmet need for family planning – the percentage of married or in-union women of reproductive age who want to stop or delay childbearing but are not using any method of contraception.

Diabetes mellitus - a group of chronic metabolic diseases characterized by high blood glucose levels resulting from defects in insulin secretion, action or both which leads to long-term damage and dysfunction of blood vessels, nerves, the eyes, heart and kidneys (American Diabetes Association).

Diabetes mellitus type 1 – immunologically mediated destruction of pancreatic Islet of Langerhans cells leading to absence or insufficient insulin production resulting in elevated levels of blood glucose.

Diabetes mellitus type 2 – a combination of resistance to insulin action, insufficient insulin production and excessive inappropriate production of glucagon that results in elevated blood glucose levels.

Uncomplicated diabetes mellitus – diabetes mellitus without microvascular or macrovascular disease such as retinopathy, nephropathy, neuropathy, coronary artery disease, peripheral arterial disease and cerebrovascular accidents.

Complicated diabetes mellitus – diabetes mellitus with microvascular or macrovascular disease.

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ABSTRACT

Introduction: Planned pregnancy is recommended for women with diabetes mellitus due to increased maternal and perinatal risks and adverse outcomes in pregnancy. The need for effective reversible and safe contraception is therefore essential to prevent pregnancy while the maternal metabolic conditions are optimized for pregnancy. Historically, all women with diabetes mellitus were restricted to non-hormonal methods due to potential adverse events from hormonal methods. Newer studies have, however, documented the safety of these methods in women with uncomplicated diabetes mellitus. Uncomplicated diabetes mellitus has no vascular disease while complicated diabetes mellitus is attended by microvascular or macrovascular disease. Hormonal contraception is, thus, safe, and effective for women with uncomplicated diabetes mellitus following the WHO Medical Eligibility Criteria for contraceptive use. Data on the use of hormonal methods by women with uncomplicated diabetes mellitus is lacking.

Objective: To compare sociodemographic, reproductive and clinicopathological characteristics between women with uncomplicated diabetes mellitus who are using versus those not using hormonal contraception at Kenyatta National Hospital.

Methods: A comparative cross-sectional study of 171 women with diabetes mellitus was undertaken at Kenyatta National Hospital. Sexually active, non-sterilized women with uncomplicated diabetes mellitus between 18 – 49 years of age were recruited from the Family planning, Gynecology and Diabetic outpatient clinics from October 2020 to December 2020. Fiftyfive of the participants recruited were using hormonal contraception while one hundred and sixteen lacked contraception or were on non-hormonal contraception. The Medical Eligibility Criteria was used as the theoretical framework and eligibility for hormonal contraception

determined at Category 1 and 2. Data was collected using an interviewer-administered structured pre-tested questionnaire. Quantitative data obtained was analyzed using STATA version 14.3 software. Bivariate analysis was used to determine factors associated with hormonal contraceptive use at 95% confidence interval and a statistical significance level of $p<0.05$. Multivariable logistic regression was done on significant factors identified from bivariate analysis according to their individual p value at 95% confidence interval and a statistical significance level of $p<0.05$.

Results: Between October 2020 and December 2020, 300 women were screened and 60% found to be eligible for hormonal contraceptive use. Of those who were eligible, 8 were excluded because of failure to sign consent for the study. The sociodemographic characteristics were comparable between the two populations. Hormonal contraceptive use was less likely among those who had received contraceptive counselling ($p=0.011$). However, it was more likely with those who were satisfied with the counselling received (95% CI 4.2 [1.93-8.81]; $p<0.01$) and those who used the information received to choose the contraceptive method (95% CI 7.00 [3.06-16.3]; $p<0.01$). Women on hormonal contraception were also 2.24-fold (95% CI 1.11-4.47; $P=0.026$) more likely to make the decision in consultation with a partner. Presence of a complicated previous pregnancy was more likely with hormonal contraceptive users (95% CI 2.38 [1.17-4.79]; $p=0.018$). Having an unplanned previous pregnancy was also more among hormonal contraceptive users (25.5% vs 14%). It was found that hormonal contraception users were 3.76-fold (95% CI 1.32-10.43; $p<0.01$) more likely to have the method being used recommended by a doctor than other health care providers. Those who had been screened for neuropathy were 3.84-fold (95% CI 1.73-8.29; $p<0.01$) and screened for thrombosis 3.57-fold (95% CI 1.68-7.53; $p<0.05$) more likely to be using hormonal contraception. However, after adjusting for confounders, the two populations were found to be comparable in sociodemographic, reproductive and clinicopathological characteristics.

Conclusions: Hormonal contraceptive use is not associated with poorer sociodemographic, reproductive and clinicopathological characteristics in women with uncomplicated diabetes mellitus.

Key words: Hormonal contraception, preconception care, family planning, diabetes mellitus

CHAPTER ONE

1 INTRODUCTION

Family planning is designed to help individuals achieve their specific reproductive goals. The use of contraception enables couples and individuals to attain their basic right to decide freely if, when and how many children to have. This provides significant health and social benefits especially to women and children by reducing unintended pregnancies, pregnancy wastage and unsafe abortions and also enabling spacing of births(1)(2). The United Nations' Population Division reported the worldwide contraceptive prevalence rate at 63% in 2017(3). Overall, the use of contraception for family planning has been increasing in many countries in the world but remains low in SubSaharan Africa.

The World Health Organization (WHO) in 2017 reported that an estimated two hundred and fourteen million women from low-middle income countries who do not desire pregnancy are not employing any contraceptive method. The decision to use contraception and choosing a specific method is a complex process. Limited access to contraception; limited choice of method; contraceptive side effects; health conditions; religion and cultural prohibition; poor service quality; user and provider bias; together with gender-based barriers have been proposed as possible reasons. Many of these challenges can be addressed and overcome with the provision of quality contraceptive services and the use of ideal modern contraceptive methods.

An ideal contraceptive method is expected to be widely accepted, affordable, safe, simple to use, highly effective and should require minimal motivation, supervision, and maintenance. Modern reversible contraceptive methods are largely ideal for those women who want to retain their fertility. They include the male/female condoms, cervical cap, diaphragm and spermicides, intrauterine device, oral contraceptive pills, hormonal patches, hormonal implants, and depot injections. Of these, barrier methods, natural methods and the use of spermicides are known to be less effective compared to hormonal methods and the intrauterine devices. Hormonal methods involve the administration of estrogen and/or progestin to prevent pregnancy. While the wellmotivated woman can use barrier methods, long-term highly effective reversible methods like the copper and inert IUCDs and hormonal methods (implants, depot injections, skin patches and progestin IUCDs) are more ideal.

1.1 Effect of Diabetes mellitus on Reproductive health

Diabetes mellitus is the most common metabolic disorder globally. The prevalence is increasing worldwide and is of public health concern(4)(5). Global prevalence was approximately 9.3% (about 463 million people) in 2019 as reported by the International Diabetes Federation. It is projected that prevalence will rise to 10.2% (about 578 million people) by 2030(6). This burden of disease demands the need for more resources invested in health promotion for persons living with diabetes mellitus. The chronic hyperglycemia causes dysfunction of various organs such as the eyes, heart, kidneys, nerves, and blood vessels including those in the placenta and thereby adversely affecting the reproductive health of women with diabetes mellitus. This is especially significant in pregnancy. Diabetes mellitus has been found to be the commonest medical complication in pregnancy and is increasing with increasing prevalence of the disease in the general populace. A cohort study in the UK showed the trends as follows: Diabetes mellitus type 1 in pregnancy had risen from 1.56 in every 1000 pregnancies (1995) to 4.09 in every 1000 pregnancies (2012). Diabetes mellitus type 2 in pregnancy had also risen between 1995 and 2008 from 2.34 to 5.09 in every 1000 pregnancies and furthermore to 10.62 in 2012(7).

It has further been established that women with diabetes mellitus have worse pregnancy outcomes than the general population, particularly if their glycemic control is poor in the period before and during pregnancy. Evidence from a retrospective multi-cohort study in Ontario, Canada in 200506 reported that diabetes mellitus in pregnancy predisposed women to worse outcomes compared to those of the general obstetric population(8). Another multicenter prospective study in Denmark showed that adverse outcomes were significantly more in type 1 diabetic women than the general population and were mostly in pregnancies with higher HBA1C levels. Perinatal mortality was at 3.1% in women with type 1 diabetes in contrast to 0.75% in the general populace (RR 4.1[95% CI 2.9-5.6]) and the still births were at 2.1% in comparison to 0.45% in the general populace (RR 4.7[3.2-7.0]). Congenital malformations were 5% in the study population versus 2.8% in the comparison group (RR 1.7[1.32.2]). Pregnancies that had grave poor outcomes were characterized by high HBA1C levels before and through the pregnancy. These pregnancies were also characterized by lower maternal self-management and poor preconception care(9). In Kenya, a six-year survey at the Kenyatta National Hospital in Nairobi by Fraser RB showed that pregnancies complicated by diabetes mellitus had five times the perinatal mortality rate of those of non-diabetic mothers(10).

1.2 Preconception care and contraception in Diabetes mellitus

Unplanned pregnancy and poor glycemic control during conception will increase the chances of adverse outcomes for women with diabetes mellitus. These include maternal complications like pre-eclampsia/eclampsia, abruptio placentae, traumatic vaginal deliveries and caesarian section. The perinatal complications include spontaneous abortions, stillbirths, and congenital anomalies among others(11). Prevention of these complications can be achieved by ensuring optimal maternal health in the preconception period(12). Preconception care has been found to be effective in lowering HBA1C levels and reducing pregnancy complications(13)(14). The proposed model for diabetes preconception care encompasses educating the patient on the interaction between diabetes mellitus, pregnancy and family planning. Additionally, patients should be educated on self-management skills and medical therapy should be used to ensure good metabolic control(11)(15). Good metabolic control is demonstrated by achieving and maintaining for at least 3 months a fasting blood sugar of less than 5 mmol/L and a postprandial blood sugar of less than 7.8mmol/L or HBA1C level less than 6.5%. This requires a multidisciplinary healthcare team of diabetologists/internists, obstetricians/gynecologists, nurses and nutritionists.

Family planning and the use of contraception is therefore key in ensuring good glycemic control before pregnancy. Women with diabetes mellitus are a special group when considering contraceptive methods because of altered metabolic functions and potential complications when the methods interact with the disease process. The most significant of these complications are worsening of hyperglycemia and altered serum lipid levels that result in vascular disease due to atherosclerosis and/or thrombosis. This population, therefore, must be screened comprehensively and counselled appropriately when managing their contraceptive health.

The choice of contraceptive method is determined by the severity of the diabetic condition. In this regard, diabetes mellitus can be classified into uncomplicated diabetes and complicated diabetes. In uncomplicated diabetes there is no evidence of vascular disease while in complicated diabetes there is presence of vascular disease that increases morbidity and mortality. The vascular complications can be microvascular such as retinopathy, nephropathy and neuropathy or macrovascular such as coronary artery disease, peripheral arterial disease and cerebrovascular disease. Screening for microvascular disease in diabetes is done by fundoscopic examination for retinopathy; renal function tests, urinalysis and renal ultrasonography for nephropathy; pinprick, temperature sensation, ankle reflex and vibration sensation for neuropathy. To detect

macrovascular disease; electrocardiography and echocardiography are done to diagnose coronary artery disease and other cardiac disease; ankle-brachial index and doppler ultrasonography/angiography is done to screen for peripheral arterial disease. These screening procedures are important in early detection of significant complications in diabetes mellitus. Interventions can be instituted to mitigate progression which reduces morbidity and mortality. The significance of this in reproductive health is an already increased risk of thromboembolic events in women with diabetes mellitus who have complicated disease. Therefore, estrogen-containing contraceptives that further increase the risk of thromboembolism should be avoided. Women with uncomplicated diabetes mellitus have a low risk of potential adverse vascular events or worsening of hyperglycemia and/or hyperlipidemia. Studies have shown the safety of hormonal methods of contraception for this sub-cohort as outlined in the WHO Medical Eligibility Criteria(16)(17). The WHO Medical Eligibility Criteria provides guidelines on the safe use of various methods of contraception in specific health conditions like diabetes mellitus. The recommendations in this tool are based on the latest clinical and epidemiological data(18). Historically, utilization of hormonal contraception was discouraged for all women with diabetes mellitus. The postulated altered glucose and lipid metabolism together with the implications in disease progression and development of complications were of concern(19)(20). Recent data has, however, now shown that hormonal methods are generally safe and appropriate for use by women with uncomplicated diabetes mellitus(5). However, providers still vary in the evaluation of the risk-benefit equation for women with diabetes mellitus resulting in wide variations in contraceptive counselling practice. Local guidelines from the Ministry of health in Kenya are contained in the sixth edition of the National

Family Planning guidelines for Service Providers. This has been updated to adopt the

2015 WHO Medical Eligibility Criteria. Hormonal methods can be used by women with uncomplicated diabetes mellitus who have a duration of disease less than 20 years and who have no risk factors for or evidence of vascular disease. The current guidelines provide a wider range of choice of contraceptive method to cater for the different preferences and circumstances of these women. This promotes adherence to contraception, proper planning of pregnancy and improves the overall sexual and reproductive health of women with diabetes mellitus.

There is, however, a challenge in the proportion of diabetic women who undergo preconception care and plan their pregnancies(5). Lack of comprehension about the high risk of unplanned pregnancy in diabetes

mellitus, the choice of reliable contraception and compliance to a method is of concern. Understanding the factors associated with the use of long-term highly effective reversible contraception like hormonal methods can help in efforts to optimize contraceptive uptake and the promotion of planning of pregnancies by women with diabetes mellitus. Sociodemographic factors like age, parity, religion, culture, marital status, education, and socioeconomic status; coupled with the knowledge of different methods of contraception and comorbid risks in pregnancy will influence an individual's motivation to use contraception. Health providers also have an important role in guiding clients to choose an appropriate method of contraception while considering their preferences and contraindications in specific health conditions. Hormonal contraceptive use among women with diabetes mellitus has not been well documented in Kenya. This study therefore seeks to highlight the sociodemographic, reproductive and clinicopathological factors associated with hormonal contraceptive use among women with uncomplicated diabetes mellitus to identify gaps that can be addressed to improve the appropriate use of hormonal methods.

CHAPTER TWO

2 LITERATURE REVIEW

2.1 Epidemiology of contraception and diabetes mellitus

Contraceptive prevalence rate for in-union women improved worldwide from 54.8% to 63.3% between 1990 and 2017(3). The unmet need for family planning also improved with a decrease from 15.4% to 12% (3)(21). Modern contraceptive methods were the most frequently used worldwide at 58%. These numbers are impactful in the global commitment to achieve the Sustainable Development Goals (SDGs) by the year 2030. Decreasing the unmet need for family planning is an important step in the fight against the high rates of unsafe abortions and in reducing maternal and perinatal morbidity and mortality. It has been shown that by increasing contraceptive use in low-middle income countries, maternal deaths reduce by up to 40% in the general population(1). This is a step towards achieving the Sustainable Development Goals 3, 4 and 5 that aim to ensure good health, quality education, and gender equality for all people(22). Therefore, identifying the gaps in contraceptive management and formulating interventions to meet demand will assist in accomplishing the set targets by 2030.

The Kenya Demographic and Health survey of 2014 (KDHS 2014) reported that the national contraceptive prevalence rate was 58% in women aged 15 – 49years. Greater than half of married women

were found to be using a modern method of contraception at 53%. This is an increase from 39% in 2008-09. Hormonal contraception was used by 44% of women. The injectable contraceptives were the most used by married women at 26% while implants were at 10% and the pill at 8%. Contraceptive use among sexually active unmarried women was 61% with the use of injectables at 22% and the male condom at 21%. This data indicates that hormonal methods are preferred by majority of Kenyan women. Furthermore, the unmet need for family planning was 18%, which was a substantial decline from 26% in 2008-09(23). This trend in contraceptive utilization, with projections in the continued growth of contraceptive users, indicates the need for greater investment in sexual and reproductive health to ensure the appropriate and effective use of hormonal contraceptive methods when required.

The use of contraception for family planning is imperative for women with diabetes mellitus. Contraception is needed to delay pregnancy while optimizing maternal metabolic conditions for pregnancy. Previously, the burden of disease in Kenya has been communicable disease for which interventions have been instituted to better the health of the general population. However, due to the increasing numbers of persons living with diabetes mellitus and other non-communicable diseases, the health status of the population has stagnated. Diabetes mellitus prevalence in Kenya was estimated to be 3.3% by the WHO and is projected to rise to 4.5% by 2025(24)(25). Shukri et al also estimated the prevalence in Kenya to be 2.4%; with 51% of this being females(25). This epidemic warrants careful consideration of strategies to combat the health implications of diabetes mellitus including its effects on sexual and reproductive health.

Contraceptive management for women with diabetes is thus essential. It is one of the strategies in preconception care to ensure good glycemic control before pregnancy and thereby reducing adverse pregnancy outcomes(15). There is paucity of data in Kenya on the state of contraceptive use among women with diabetes mellitus especially in regard to hormonal contraceptive methods. Correlates of the use of these methods are also unknown.

2.2 Hormonal contraceptive use among women with diabetes mellitus

Despite the wide range of contraceptive methods available, women with diabetes mellitus still have suboptimal use of highly effective reversible contraceptive methods. A cross-sectional study among women between 15 – 49 years in the UK in 1999 found that out of the 938 diabetic women and a comparison group, 25% of those with diabetes mellitus, and 32% of those without diabetes mellitus had received a hormonal contraceptive. Diabetic women had a higher probability of receiving a COC than

a POP but had a 2.12 times higher probability of receiving a POP than women without diabetes mellitus (95% CI; 1.65-2.72). The study concluded that these differences highlighted the variations in general practitioner and patient evaluation of risks and benefits when choosing a contraceptive method(26). Another cross-sectional study conducted in the UK in 2008, matched 947 women with diabetes mellitus type 1 and 365 women with diabetes mellitus type 2 aged between 15-44 years with age comparison groups. The study found that it was less likely for women with diabetes mellitus to use hormonal contraception compared to the background population [type 1 DM RR 0.83(95% CI 0.59-0.93) type 2 DM RR 0.60(95% CI 0.42-0.83)]. Women with type 1 diabetes mellitus were more likely to receive a COC than a POP. They were also more likely to receive a POP than were women without diabetes mellitus [RR 1.65(95% CI 1.26-2.13)]. Those with type 2 diabetes mellitus were less probable to receive a COC [RR 0.39(95% CI 0.24-0.62)]. The use of Depo Provera was considerably higher in women without diabetes mellitus than those with type 1 DM [RR 1.56(95% CI 1.12-2.11) and type 2 DM [RR 3.57(95% CI 2.15-5.60)]. The findings also showed significant variations in prescription practices for type 1 and type 2 diabetes mellitus where the COC was more likely to be used by those with type 1 DM and the POP more likely to be used by those with type 2 DM. Studies have not shown a difference in risk profile for hormonal contraceptive use between women with type 1 and type 2 DM(27).

A national cross-sectional study conducted in the USA in 2007-09 showed that out of the 5548 women sampled, sexually active women with prediabetes and diabetes mellitus between 24 to 32 years, had an increased odd of not using contraception ([adjusted OR 1.90, 95% CI; 1.25 -2.87]) compared to those without diabetes mellitus. The use of contraception that was more effective (hormonal methods and IUDs) was at 37.6% while 33.6% used less effective contraception (barrier methods) and 28.8% had no contraception. The study concluded that women with diabetes mellitus mostly used less effective contraceptive methods(28).

The current research shows suboptimal use of contraception by women with diabetes mellitus and the preference for less effective methods. The factors that influence these patterns have, however, not been determined. The studies have also compared women with diabetes mellitus to women without diabetes mellitus who have different risk profiles and eligibility for the use of the different methods of contraception.

2.3 Sociodemographic, reproductive and clinicopathological characteristics of women with diabetes mellitus using hormonal contraception

Sociodemographic characteristics have been found to influence the health-seeking behavior and motivation for accepting preventive health practises in an individual. Reproductive and clinicopathological characteristics of women with co-morbidities also influence their contraceptive choices. A 2018 systematic review in Google Scholar, Scopus, EBSCO, Web of Science and the Cochrane library found the importance of the biopsychosocial model in selection of a hormonal contraceptive method. The findings showed that the psychological, social relationships, sexual and cultural domains are important to acknowledge and to address during individual counselling. This ensures that the selected method is best suited to the personal needs and lifestyle of the woman which maximizes on compliance and well-being(29).

A national survey in the USA in 2002 of 5,955 women aged between 20 - 44 years reported that sexually active women with diabetes mellitus had a higher odd of lacking contraception compared to those who were not diabetic (odds ratio [OR] 2.61 [95% CI 1.22-5.58]). In multivariable models, older women (>30years vs 20-29years), of black race, cohabiting, desirous or indecisive about getting pregnant, with history of treatment for infertility had a significantly higher probability to lack contraception. The study concluded that older diabetic women who desire pregnancy should be targeted for preconception management(30). Furthermore, a 1-year survey in Italy in 2004 found that out of 667 fertile women with diabetes mellitus; 30.4% were on hormonal contraception, 12% used intrauterine devices, 47% used barrier/natural methods while 10.7% did not use any contraception. In regard to the provider; 60.4% of the contraceptives had been prescribed by a gynecologist, 11.2% by a diabetologist and 13.4% by other health care providers. Oral contraceptive users were similar between type 1 and type 2 diabetics (29.4% vs 27.8%, chi (2) =ns). Thirty percent of the women on hormonal contraception were smokers. Regarding the level of education: 37% university graduates, 32% high school graduates, 28% secondary school leavers and 15% elementary school leavers were on oral contraceptives. The mean number of deliveries was 1.14+/-1.1, miscarriages were 1.3+/- 0.7 and induced abortions were 0.17+/- 0.5. Twenty-nine percent reported planning at least 1 pregnancy(31).

Factors associated with contraceptive use among women with diabetes mellitus were also highlighted by a systematic review of 17 studies in MEDLINE, PsycINFO, CAB abstracts, CINAHL, Embase, and Science direct from 2008 to 2015. Challenges and solutions in contraception for women with diabetes mellitus were investigated. It was found that there was lack of knowledge and understanding on the high risk of unplanned pregnancy and therefore the necessity of effective contraception. Most were unsure about suitable contraception and could not

recall conferring with a health provider on pregnancy and contraception(5). This was also apparent in another cross-sectional study done in Brazil in 2008 among 106 women with diabetes mellitus. It was found that 70.8% of the women had limited knowledge about the appropriate methods of contraception for women with diabetes mellitus. Among the study participants, 98.1% used at least one contraceptive method with 47% of these being hormonal methods. Among those on contraception, 11.6% used a method not in line with the MEC and risked their health. Professional input in the choice of method was reported in 47% while 53% lacked professional input(32).. Identifying the specific sociodemographic, reproductive and clinicopathological factors associated with hormonal contraceptive use can establish the underlying causes of poor contraceptive uptake and highlight areas that need to be addressed.

Majority of the studies conducted compared women with diabetes mellitus to those without diabetes mellitus. Comparing women with the same risk profile of diabetes mellitus will help us better understand the factors associated with hormonal contraceptive use. The association of these factors (sociodemographic, reproductive and clinicopathological characteristics) with hormonal contraceptive use has also not been documented. Currently, there is no published data documenting the patterns of the use of the various hormonal methods by women with diabetes mellitus in Kenya and indeed in the whole African continent.

2.4 Theoretical framework

The WHO Medical Eligibility Criteria for recommendation of contraceptives is a document containing guidelines for the indication and contraindication of contraceptive methods in specific health conditions(18). Both modern hormonal and non-hormonal methods are categorized in terms of safety. The appropriate use or restriction of different methods of contraception is summarized in 4 categories:

Category1 – there is no restriction regarding utilization of the method of contraception in the specific medical condition.

Category 2 – the benefits of utilizing the method of contraception generally outweigh the theoretical or established risks for the specific medical condition.

Category 3 - the theoretical or established risks generally outweigh the benefits of utilizing the method for the specific medical condition.

Category 4 – there is presence of an undesirable risk to health should the method be utilized in the specific medical condition.

Table 2.1. Hormonal Contraception in Diabetes Mellitus: 2015 WHO Medical Eligibility Criteria(18)

Evaluation of women with Diabetes Mellitus				
Contraceptive method	Duration of DM < 20 years		Duration of DM > 20 years	
	No risk factors	One or more risk factors	Absence of complications in target organs	Presence of complications in target organs
COC	2	3 /4	3 / 4	3 /4
CIC	2	3 / 4	3 / 4	3 / 4
POP	2	2	2	2
POIC	2	3	3	3
LNG/ETG Implants	2	2	2	2
LNG-IUD	2	2	2	2
Contraceptive patch	1	1	1	**1**

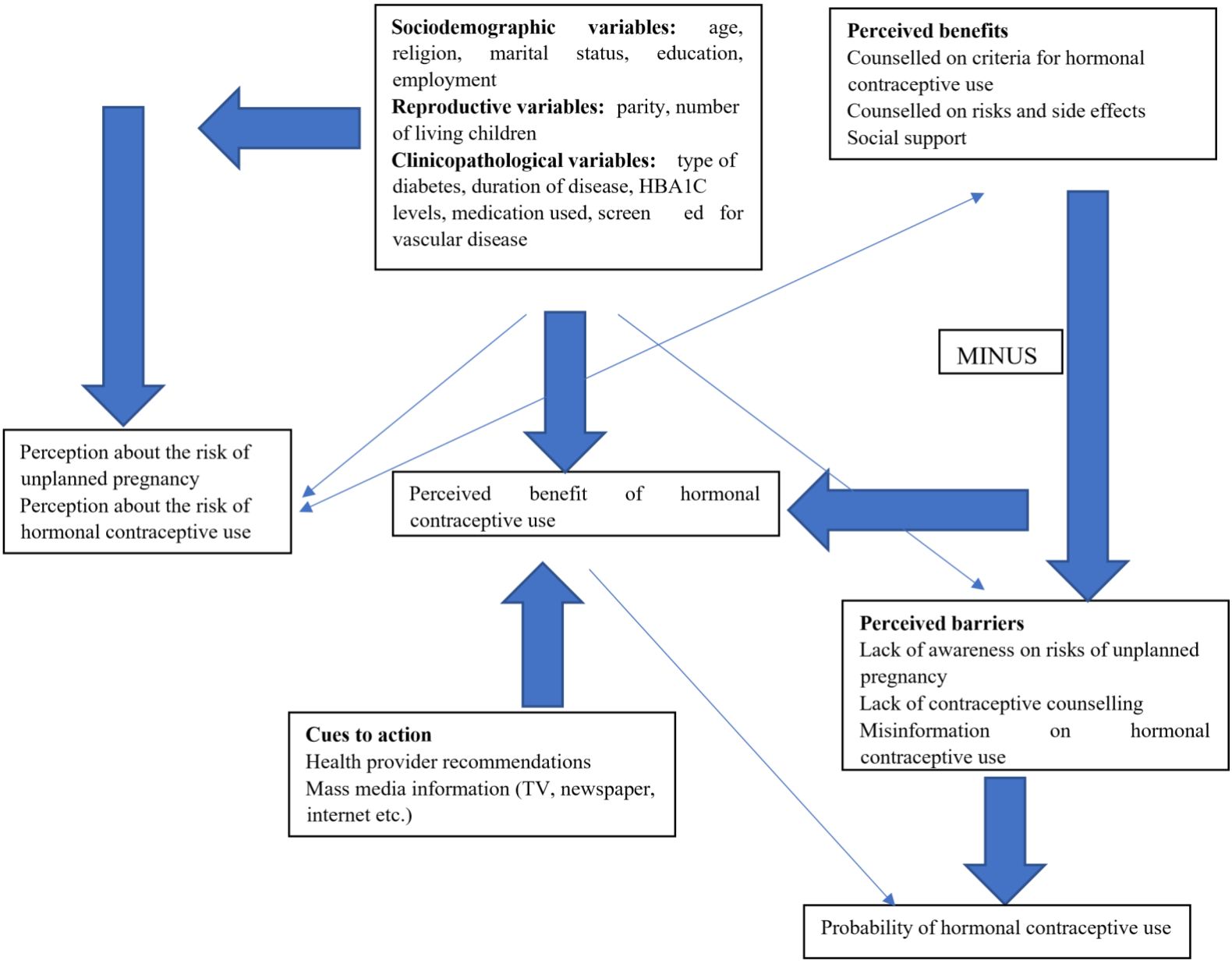
Source: WHO (2015)

The participants recruited for this study were those whose clinical status allowed them the use of the specific hormonal methods at Category 1 and 2 where there were no risks at all or the benefits outweighed postulated risks. Cardiovascular risk factors evaluated include dyslipidemia, hypertension, smoking and presence of albuminuria.

2.5 Conceptual Framework: Health belief model

The health belief model that is applied for preventive health behavior and compliance to medical regimens integrates the various aspects of health decision making. In this model, we propose that women with diabetes mellitus are more likely to use hormonal contraception if they perceive the threat of not using them to be serious, if they feel they are personally susceptible to adverse events of unplanned pregnancy and if they perceive that there are more benefits than risks when using hormonal methods. The cognitive perception of the individual and processes that lead up to this realization are influenced by individual characteristics and external factors. Individual factors include the sociodemographic and reproductive characteristics while external influences stem from the health system. The health system, specifically the healthcare providers, is responsible in providing information on the necessity, benefits and risks of hormonal contraceptive use to all women.

Conceptual framework Individual beliefs **Modifying factors** **Probability**



of action

2.7Problem statement

The fate of the pregnant woman with diabetes mellitus and her fetus is largely determined by good glycemic control at conception. This indicates the need to delay pregnancy by use of contraception while interventions are instituted to improve glycemic control. The decision to use contraception is thus important in these women, and directly impacts on the quality of their sexual and reproductive health. Previous practice discouraged the use of hormonal contraception by all women with diabetes mellitus due to the potential adverse events. Newer studies have however demonstrated the safety of hormonal contraception in women with uncomplicated diabetes mellitus. This has directed the current recommendations on their use(18). Unplanned pregnancy among women with diabetes mellitus with the resultant reproductive health risks and the increasing burden of disease is a problem for investigation. A challenge in adequate preconception care and contraceptive management for women with diabetes mellitus has been identified in previous research. Data on hormonal contraceptive use by women with diabetes mellitus and the associated factors has also not been documented in Kenya.

2.8Study Justification

Contraceptive management has been recognized as integral in combating unplanned pregnancy and improving reproductive health for women. While previous research has studied the safety and potential metabolic effects of hormonal contraceptives in women with diabetes mellitus; few have studied the translation of this evidence into practice. This should be demonstrated by adequate contraceptive management and use of hormonal contraception by women with uncomplicated disease if desired.

This study therefore seeks to document the different hormonal contraceptive methods used by women with uncomplicated diabetes mellitus and the associated factors through a comparative cross-sectional design. Comparison to be made on the sociodemographic, reproductive and clinicopathological characteristics of study participants. Information obtained from this research will assist in formulation and strengthening of already existing policy programs and strategies to cater for the unmet need for family planning for women with diabetes mellitus. It will also aid in training of health professionals and also guide the planning and allocation of health resources. The data acquired herein also has the potential to assist in the development of contraceptive

decisionmaking tools that incorporate the MEC guidelines and client factors to promote shared decisionmaking between clients and providers. This will result in improved contraceptive counselling, client experience and better reproductive health outcomes for women with diabetes mellitus. This research will also serve as a baseline for further research needed to evaluate the effects of hormonal contraceptives in women with diabetes mellitus in Kenya.

2.9Research question

Are there differences in women with uncomplicated diabetes mellitus using hormonal contraception compared to those not using hormonal contraception at Kenyatta National Hospital?

2.10Hypothesis

2.10.1Null hypothesis

There is no statistically significant difference in sociodemographic, reproductive or clinicopathological characteristics between women with uncomplicated diabetes mellitus using hormonal contraceptives versus those not using hormonal contraceptives at Kenyatta National Hospital

2.10.2Alternative hypothesis

There is a statistically significant difference in sociodemographic, reproductive and clinicopathological characteristics between women with uncomplicated diabetes mellitus using hormonal contraceptives versus those not using hormonal contraceptives at Kenyatta National Hospital

2.11Study Objectives

2.11.1Broad objective

To compare the sociodemographic, reproductive and clinicopathological characteristics between women with uncomplicated diabetes mellitus who are using versus those not using hormonal contraception at Kenyatta National Hospital.

2.11.2Specific objectives

Among women with uncomplicated diabetes mellitus at Kenyatta National Hospital, to:

i.) Compare the sociodemographic characteristics between those using and those not using hormonal contraception

ii.) Compare the reproductive characteristics between those using and those not using hormonal contraception

iii.) Compare clinicopathological characteristics between those using and those not using hormonal contraception

CHAPTER THREE

3.0METHODOLOGY

3.1Study design

This research is a comparative cross-sectional study among women with uncomplicated diabetes mellitus on follow up at Kenyatta National Hospital. Participants using hormonal contraception were compared to those not using hormonal contraception at a ratio of 1:2. The exposures evaluated were the sociodemographic, reproductive and clinicopathological characteristics with the main outcome being the use of hormonal contraception. This design was appropriate for this study as many variables could be analyzed and many factors associated with the use of hormonal contraception could be evaluated.

3.2Study site and timeline

The study was undertaken in the Family planning, Diabetic outpatient and Gynecology outpatient clinics at the Kenyatta National Hospital (KNH) between October and December 2020. KNH is the oldest and the largest public national referral hospital in East and Central Africa. It was founded in 1901 and serves as the teaching hospital for the University of Nairobi. It is located in southwest of Nairobi's central business district with an urban population of approximately 4.4 million(33). The hospital serves close to 70,000 inpatients and 500, 000 outpatients annually. It has a two thousand bed inpatient capacity and twenty-two outpatient clinics. Being a national and regional referral hospital, specialized health services such as reproductive health and fertility, endocrinology, open-heart surgery, renal transplants and other sub-specialized medical services are offered.

The Obstetrics & Gynecology specialty department houses the family planning and gynecology outpatient clinics where modern contraceptive services are offered. This is under the care of obstetricians/gynecologists, resident doctors and reproductive health nurses. The methods of contraception offered include male and female condoms, OCPs, progestin implants, hormonal patches, depot injections and the IUCDs. These services are available to both adolescents and adult women. The FP clinic and GOPC run from Monday to Friday from 8am to 5pm. Clients are screened and assessed from medical history and physical examination then counselled for suitable

contraceptive method (s) in the FP clinic. The client is guided in choosing a preferred contraceptive method and follow up is done on individual basis.

Patients seen in the GOPC are managed for various gynecological conditions like abnormal uterine bleeding, genital tract infections and fertility issues among others. Complications arising from contraceptive use are also managed in this clinic.

The Diabetic outpatient clinic offers routine follow up and sub-specialized services under the care of endocrinologists/diabetologists, resident doctors, clinical officers, diabetic nurses, nutritionists and counsellors. The clinic enrolls all diabetic patients from the age of 13 years. The routine clinic runs from Monday to Thursday from 8am to 5pm while the Specialist clinic runs on Friday from 8am to 5pm. Patients are evaluated by history and physical examination. The standard care offered includes monitoring of blood sugar and HBA1C, renal function tests, lipid profile, doppler studies, electrocardiogram and echocardiogram among others, to detect complications. Drug prescription and review of appropriate medications is also done. Nutritional counseling and diabetic wound management is also offered in the clinic. Screening for retinopathy is done in the Eye clinic. The FP, Gynecology, and Diabetic outpatient clinics see an average of 415 women with diabetes mellitus monthly (KNH Information and Statistics).

3.3Study population

The target population comprised all women with uncomplicated diabetes mellitus between eighteen (18) to forty-nine (49) years of age who were eligible for hormonal contraceptive use and were clinic attendants of the KNH Diabetic, Gynecology, and Family planning clinics. The Medical Eligibility Criteria (Category 1 and 2) was used to screen for eligible participants. Therefore, women with micro-vascular or macro-vascular disease and other co-morbidities such as hypertension, dyslipidemias and malignancy that limited the use of hormonal methods were not included in this population.

3.31Inclusion criteria

I. All sexually active women with a diagnosis of diabetes mellitus aged between 18 - 49 years (Sexually active will be taken as those who confirm at least 1 episode of sexual intercourse monthly, with a male partner; which is necessary for pregnancy)

II. Those willing to give informed consent

3.32Exclusion criteria

I. Any woman with a medical emergency such as diabetic ketoacidosis and hypoglycemia at the time of data collection
II. Any woman in the process of in-patient admission at the time of data collection
III. Any woman being initiated on contraception for the first-time at the time of data collection
IV. Any woman who had undergone sterilization or hysterectomy
V. Any woman suspicious for COVID 19 disease at the time of data collection

3.4Sample size determination

The sample size was calculated using the formula for comparing two means as shown below: -

Formula (Rosner, 2011)

$$n_1 = \frac{(\sigma_1^2 + \sigma_2^2/K)(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

Parameters

$\Delta = |\mu_2 - \mu_1|$ = absolute difference between two means
σ_1, σ_2 = variance of mean #1 and #2
n_1 = sample size for group #1
n_2 = sample size for group #2
α = probability of type I error (usually 0.05)
β = probability of type II error (usually 0.2)
z = critical Z value for a given α or β
k = ratio of sample size for group #2 to group #1

Calculation was done based on a similar study by Napoli et al (31) where the mean age for women with diabetes mellitus on hormonal contraception (exposed group) was 33.1 years and for those on non- hormonal contraception (unexposed group) was 35.9 years. The following assumptions were applied as below: -

Study Parameters	
Mean age, hormonal contraceptive (years)	33.1±6
Mean age, non-hormonal contraceptive (years)	35.9
Standard deviation	6
Alpha	0.05 (Critical value 1.96)
Beta	0.2 (Critical value 0.84)

Power	0.8

Calculation

$$n_1 = \frac{(6^2 + 6^2/2)(1.96 + 0.84)^2}{2.8^2}$$
$$n_1 = 54$$
$$n_2 = K * n_1 = 108$$

Fifty (54) participants using hormonal contraception and 108 participants not using hormonal contraception were required. An additional 10% was added to the sample size to cater for missing data and/or recall bias. Therefore, the number to be recruited in the exposed group was 60 and those in the unexposed group was 119.

3.5Sampling Techniques

Probabilistic systematic sampling was used to select the women participants from the DOPC, GOPC, and FP clinics for both the study group and the comparison group. This ensured the sample population was truly representative of the population. It involved the selection of participants on an ordered sampling frame starting at a random point and with a fixed period interval. Starting with ***i,*** every ***ith*** element in each group was selected. During the period of this study, the estimated number of women with diabetes mellitus who had been booked in the clinics was 1245 (415 monthly). We randomly took ***i=3*** to accommodate the required sample size (179) in the projected population size of the target group (1245) according to the ordered sampling frame to be used. Therefore, starting on the first day of data collection, we started with the third woman on the booking list and selected every ***ith*** woman until sample size saturation was reached. Five women on average were recruited per day.

3.6Participant recruitment

The use of hormonal contraception was taken as those who were using any hormonal method of contraception at the time of data collection (current use). Nonuse of hormonal contraception was taken as any woman who was on any other method of contraception apart from hormonal contraception or was not using any method of contraception at the time of data collection.

Eligibility for hormonal contraceptive use was done using the Medical Eligibility Criteria.

Enquiry was made of any diagnosed vascular disease, hypertension or malignancy. This information was corroborated from patient files to ensure the patient was eligible for hormonal contraceptive use.

Participant recruitment and data collection was done daily from Monday to Friday starting at 8am to 5pm during the period of study. Recruitment was done after the scheduled clinic visit was complete so as not to interfere with care. Interviews were conducted in a designated private area within the DOPC, GOPC and FP clinics. The Ministry of Health COVID 19 safety protocols were strictly adhered to during recruitment and data collection. On the day of data collection, potential respondents were approached and assessed for eligibility after systematic sampling. The purpose and objectives of the research were explained carefully in the language they were proficient in, and they were informed that participation was solely voluntary. They were also informed of their freedom to terminate participation in the study at any point without any effect on their care at Kenyatta National Hospital. Consent to participate in the study was sought and confirmed by signing the consent form after which the participant was enrolled into the study and assigned a unique identification number. The research tools were only then administered.

3.7Data Variables Table 0.7 Sources of data variables

Variable	Definition	Data source
Dependent	Current hormonal contraceptive use	Study Questionnaire
Independent	Age, parity, marital status, religion, education, employment status, number of living children	Study Questionnaire
Independent	Type of diabetes, duration, therapy in use, HBA1C levels, pregnancy complications, contraceptive counselling	Study Questionnaire

3.8Data Collection Procedures

Three research assistants with a medical background were trained on ethics, COVID 19 safety protocols and data collection procedures before commencement of data collection. This research was undertaken during the COVID 19 pandemic and hence safety protocols were put in place to ensure the safety of the participants and researchers. The body temperature of all participants and researchers were recorded daily during the period of data collection before administration of

research tools. Any participant/ researcher who was suspicious for COVID 19 was excluded from participating in the study. All participants and researchers were required to wear a protective facemask covering the mouth and nose. They sanitized their hands with 70% alcohol-based sanitizer or washed them with soap and running water before and after the interviews. A social distance of 1.5 meters between the participant and researcher was always maintained during administration of the research tools and the interviews were conducted in a well-aerated spacious room.

A signed informed consent was obtained from the participant before the research tools were administered. All definition of terms and the purpose of this research was explained clearly to the participant in the language they were proficient in before the study questionnaire was administered. The questionnaire was administered to the participant for about 20 to 30 minutes and filled by the principal investigator/ research assistant on their behalf in a designated secluded room. The information given was corroborated from the patient file and confidentiality was strictly maintained. After completion of administration of the research tools, the participant was thanked and given contacts of the principal investigator for any further query.

3.9Study instruments

A structured and pretested interviewer-administered questionnaire was used to record primary data for the study. The questionnaire was made up of three parts: part I captured the sociodemographic and reproductive characteristics of the participants. Part II captured information on the use of contraception and part III captured information on diabetes mellitus and its reproductive health risks. The questionnaire contained 27 questions.

3.10Quality Assurance

3.10.1Validity of the Instrument

Content validity was ensured by pilot testing the instrument. Data collection on fifteen respondents was done to evaluate whether the instrument was likely to work as anticipated. Questions that were found to be difficult to understand, ambiguous, those that combined two or more issues and those that made respondents feel uncomfortable were corrected.

3.10.2Reliability of the Instrument

Reliability was enhanced by standardizing the conditions under which data collection occured. All participants were interviewed after completing their consultation. The time taken between the first set of data collection and the next was short to safeguard a high reliability co-efficient. Data was collected daily from Monday to Friday.

3.11Ethical Considerations

Permission to conduct the study was sought from the UON/KNH Department of Obstetrics &Gynecology and KNH Department of Internal Medicine. Clearance to conduct the research was obtained from KNH/UoN Ethics & Research Committee (ERC) before data collection. During this time of the COVID 19 pandemic, safety measures were put in place in accordance with The Ministry of Health guidelines to ensure safety of both participants and researchers. The proper wearing of face masks, washing/sanitization of hands and 1.5-meter social distance was ensured. Body temperature, inquiry of contact with a COVID case and symptom assessment was done for both the participants and researchers and those under suspicion were excluded to further ensure minimized risk of exposure to COVID 19 disease during the study.

The purpose and nature of the study was explained clearly to all potential respondents. Upon understanding the objectives of the study, participants signed the consent form before enrolment into the study and administration of any of the research tools. To ensure confidentiality, names of study participants were not recorded on questionnaires and information obtained was used for study analysis and write up only. In addition, all participants were informed of their right to terminate their participation from the study at any stage without any consequence.

3.12Data Management

3.12.1Data cleaning and entry

Data was cleaned during collection, data entry and analysis. The study questionnaires were reviewed for completeness and detection of errors at the end of each day during the period of data collection. Quantitative data entry was done from the questionnaires into Microsoft excel before transfer to the statistical program STATA version 14.3 for analysis.

3.12.2Data protection and security

Paper records were stored under lock and key and were only accessible to the Principal Investigator. The computer was password protected with up-to-date Kaspersky antivirus, Internet firewall protection and backed up in an external drive. Access to both the hard copy and soft copy data was strictly regulated and limited to the researchers, research assistants and data analysts.

3.12.3Data sharing

Data was encrypted when shared through the internet with the statistician. Identifiable characteristics like date of birth were removed when sharing.

3.12.4Duration of storage

The study questionnaires will be stored for seven years for legal safety of the raw data.

3.13Statistical data analysis

Quantitative data was uploaded into STATA version 14.3 software for cleaning and coding before analysis. Univariate analysis for socio demographic characteristics like age; reproductive characteristics like parity and number of children; and clinicopathological characteristics like HBA1C levels and duration of disease have been presented as means for the two groups. The proportions for sociodemographic characteristics such as level of education and marital status; reproductive characteristics such as previous pregnancy complications; and clinicopathological characteristics such as screening for vascular disease have been represented on the tables as percentages. Bivariate analysis was done using the Chi square test and Mann Whitney U test to compare the sociodemographic, reproductive and clinicopathological characteristics between the 2 groups. The association between the dependent variable (current hormonal contraceptive use) and independent variables (socio demographic characteristics, reproductive characteristics and clinicopathological characteristics) was determined at a level of confidence of 95% with a p value <0.05. These have been presented as odds ratios. The Halden-Anscombe correction test was used to avoid errors in Chi-square calculations and to enable determination of statistical significance at a p value<0.05 in cases where the value of a variable was 0. Multivariable logistic regression models were applied to further test the relationship between the dependent and independent variables after adjusting for confounders. These were the significant factors identified on bivariate

analysis according to their individual p values. The results have been presented as adjusted odd ratios at a p value <0.05.

3.14Study Results Dissemination Plan

The results of this research have been analyzed statistically for meaningful scientific interpretation and presentation. They have presented to the UON/KNH Department of Obstetrics and Gynecology. The dissertation has been developed for publishing and dissemination to the wider medical fraternity.

3.15Study strengths and limitations

3.15.1Study strengths

This research is relevant to the provision of contraceptive services and the improvement of sexual and reproductive health of women with diabetes mellitus. The results provide information on factors associated with hormonal contraceptive use among women with uncomplicated diabetes mellitus at Kenyatta National Hospital. The comparative study design enabled us to determine associated factors and measure the strength of association. Multiple independent variables could be determined and analyzed. Comparing two populations with the same risk profile (uncomplicated diabetes mellitus) for hormonal contraceptive use also further supports the findings. The study setting, which is a busy national referral hospital with specialized reproductive services and large client volumes, provided a comprehensive sample population of women with uncomplicated diabetes mellitus.

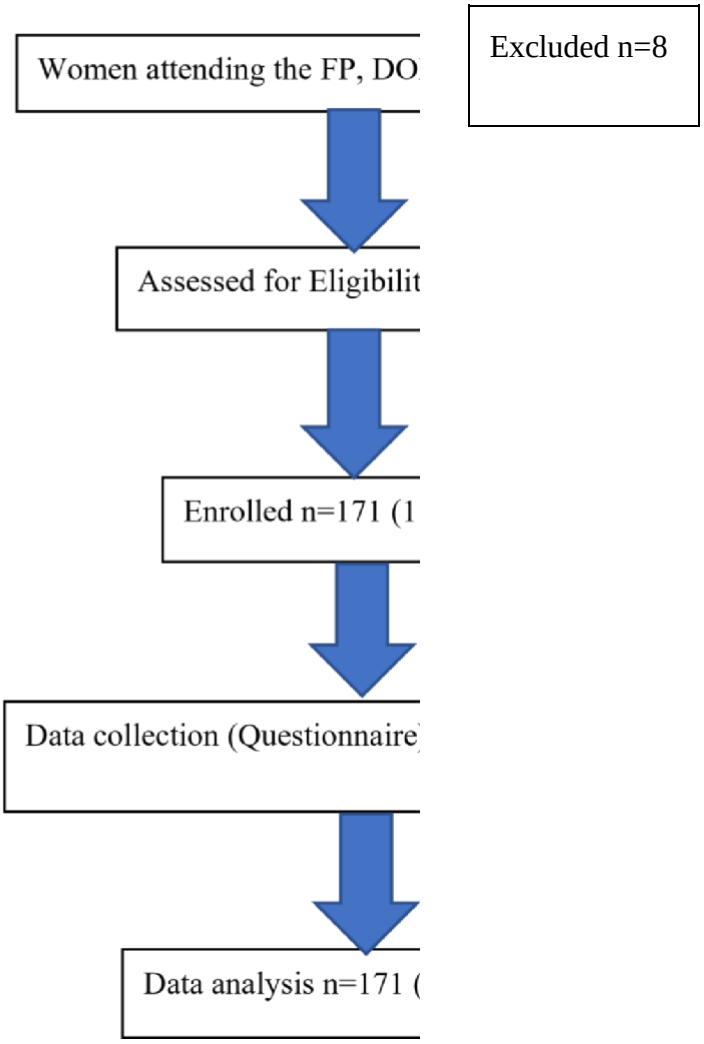
3.15.2Study limitations

Self-reported data is subject to recall and reporting bias. We overcame this by corroborating information from patient files. There was also the limitation of missing data which was overcome by adding ten percent to our sample size. The small sample size obtained could result in high variability and hence affect the evaluation of strengths of association. Data collection was affected by industrial strikes and the COVID 19 pandemic. Appropriate safety measures were, however, instituted to protect both the researchers and participants. **CHAPTER FOUR**

4.0RESULTS

4.1Study flow chart

Figure 4.1 Study flow chart



4.2Comparison of sociodemographic characteristics of women with diabetes mellitus using hormonal contraception and those not using hormonal contraception

There was no statistically significant difference in sociodemographic characteristics between the two groups.

Table 0.2. Comparison of sociodemographic characteristics of women with diabetes mellitus using hormonal contraception and those not using hormonal contraception

		Hormonal (55)	Not hormonal (116)	OR (95% CI)	P value
Age [Mean±SD]		38±6	39±7		0.058
Contraceptive method					
Marital status	Married	39 (70.9)	79 (68.1)	1.14 (0.58- 2.27)	0.711
	Single	16 (29.1)	37 (31.9)	Reference	
Religion	Christian	55 (100)	113 (97.4)	-	0.229
	Other	0 (0.0)	3 (2.6)	Reference	
Education	Primary	11 (20.0)	24 (19.8)	0.98 (0.36-2.52))	0.971
	Secondary	30 (54.5)	62 (53.4)	1.03 (0.49- 2.17)	0.926
	Tertiary	14 (25.5)	30 (25.9)	Reference	
Employment					0.871
	Employed	7 (12.7)	18 (15.5)	0.84 (0.28-2.62)	0.775
	Self employed	37 (67.3)	74 (63.8)	1.09 (0.48-2.34)	0.834
	Unemployed	11 (20.0)	24 (20.7)	Reference	
Smoker	Yes	1 (1.8)	1 (0.9)	2.13 (0.11-40.7)	0.587
	No	54 (98.2)	115 (99.1)	Reference	

4.3 Comparison of reproductive characteristics of women with diabetes mellitus using hormonal contraception and those not using hormonal contraception

Previous pregnancy complications were 2.38-fold (95% CI: 1.17-4.79) higher among women with diabetes mellitus using hormonal contraception (p=0.018). Unplanned previous pregnancies were also more with hormonal contraceptive users than the control group (25.5% vs 14%) which would explain the higher probability for them to experience a pregnancy complication.

Table 0.3. Association between reproductive characteristics and hormonal contraceptive use among women with uncomplicated diabetes mellitus

		Contraceptive method			
		Hormonal (19)	Not on hormon (21)	OR (95% CI)	Pvalue
Parity	[Mean±SD]	2.9±1.5	2.8±1.5		0.817
Pregnancy loss	[Mean±SD]	0.44±0.9	0.24±0.7		0.077
Live children	[Mean±SD]	2.5±1.4	2.6±1.5		0.293
Complicated previous pregnancy					0.018
	Yes	19 (34.5)	21 (18.1)	2.38 (1.174.79)	
	No	36 (65.5)	95 (81.9)	Reference	0.069
Previous pregnancy planned				0.47 (0.221.05)	
	Yes	41 (74.5)	98 (86.0)		
	No	14 (25.5)	16 (14.0)	Reference	
	Missing	41 (74.5)	2		
Stillbirth	Yes	9 (47.4)	4 (19.0)	3.82 (0.92-13.12)	0.095
	No	10 (52.6)	17 (81.0)	Reference	
Preterm birth	Yes	7 (36.8)	3 (14.3)	3.50 (0.83-13.94)	0.148
	No	12 (63.2)	18 (85.7)	Reference	
Miscarriages	Yes	6 (31.6)	13 (61.9)	0.28 (0.08-0.99)	0.067
	No	13 (68.4)	8 (38.1)	Reference	
Congenital malformations	Yes	1 (5.3)	1 (4.8)	1.11 (0.05-22.06)	1.000
	No	18 (94.7)	20 (95.2)	Reference	
Macrosomia	Yes	1 (5.3)	3 (14.3)	0.33 (0.02-2.48)	0.607
	No	18 (94.7)	18 (85.7)	Reference	
Infertility treatment	Yes	0 (0.0)	1 (0.9)	-	0.490
	No	55 (100)	115 (99.1)	Reference	
Desire pregnancy in one year		alent 0 .0)	3 (2.6)	-	0.212

		54 No (98.2)	103 (88.8)		
				R eference	
	Yes	1	10	5. 24 (0.85-7.9)	0.083
				5	

4.4Comparison of clinicopathological characteristics of women with diabetes mellitus using hormonal contraception versus those not using hormonal contraception Participants not using hormonal contraceptives were more likely to have received contraceptive counseling which was statistically significant (p=0.011). However, participants on hormonal contraception compared to the comparison group were 4.20-fold (95% CI=1.93- 8.81) more likely to be satisfied with the counseling received (p<0.01) and 7.00-fold (95% CI=3.06- 16.3) more likely to choose a method of contraception guided by the information received (p<0.01).

Table 0.4. Comparison of contraceptive counseling between women with uncomplicated diabetes mellitus using hormonal contraception versus those not using hormonal contraception

		Contraceptive method			
		Hormonal (55)	Non hormonal (116)	OR (95% CI)	P value
Received information	Yes	52 (94.5)	116 (100)	-	0.011
	No	(5.5)	0 (0.0)	Reference	3
Satisfied with the information received	Yes	42 (80.8)	57 (50.0)	4.20 (1.93-8.81)	<0.01
	No	10 (19.2)	57 (50.0)	Reference	
	Missing	3	2		

Information guided the choice of contraceptive	Yes	43 (82.7)	43 (40.6)	7.00 (3.06-16.3)	<0.01
	No	9 (17.3)	63 (59.4)	Reference	
	Missing	3	10		
Health workers	Source of information			1.65 (0.77-3.59)	0.218
		40 (76.9)	80 (69.0)		
	Media	2 (3.8)	3 (2.2)	2.26 (0.35-12.1))	0.394
	Non-health worker	10 (19.2)	34 (28.8)	Reference	
	Missing	3			

Participants on hormonal contraception were 2.24-fold (95% CI=1.11-4.47) more likely to make the decision to use contraceptives in consultation with their partners (p=0.026) and 3.76-fold (95% CI=1.32-10.43) more likely to get the recommendations on the method of contraception from a doctor (p<0.01) (Table 4.5).

Table 0.5. Comparison of influence of decision of contraceptive use for women with uncomplicated diabetes mellitus using hormonal contraception versus those not using hormonal contraception

		Contraceptive method			
		Hormonal (55)	Non hormonal (116)		P value
Decision	Both partners	19 (34.5)	24 (20.7)	2.24 (1.11-4.47)	0.027
	Health worker	2 (3.6)	1 (0.9)	5.67 (0.63-83.0)	0.117
	Partner	3 (5.5)	3 (2.6)	2.83 (0.63-12.5)	0.788
	Self	31 (56.4)	88 (75.9)	Reference	

Provider recommendation of method	Doctor	32 (58.2)	8 (33.3)	3.76 (1.32-10.43)	<0.01
	Nurse	17 (30.9)	16 (66.7)	Reference	
	Pharmacist	6 (10.9)	0 (0.0)	-	0.026

4.6 Comparison of clinicopathological characteristics between women with uncomplicated diabetes mellitus using hormonal contraception versus those not using hormonal contraception

The type of diabetes mellitus, therapy used and status of the diabetic condition of participants using hormonal contraceptives and those not using hormonal contraception were comparable.

Knowledge of pregnancy complications in diabetes mellitus was also comparable between the two groups.

However, participants not using hormonal contraception were 3.84 times more likely to undergo screening for neuropathy ($p<0.01$) and 3.57 times more likely to undergo evaluations for vascular disease ($p<0.01$). (Table 4.6).

Table 0.7 Comparison of clinicopathological characteristics between women with diabetes mellitus using hormonal contraception versus those not using hormonal

		Contraceptive method			
		Non-hormonal (116)	Hormonal (55)		P value
Screened for Neuropathy	Yes No	102 (87.9) 14 (12.1)	36 (65.5) 19 (34.5)	3.84 (1.73-8.290	<0.01
Screened for Thrombosis	Yes No	100(86.2) 16 (13.8)	35 (63.6) 20 (36.4)	3.57 (1.68-7.53)	0.001
Diabetes type	Type 1	15 (12.9)	4 (7.3)	1.89 (0.61-5.45)	0.146
	Type 2	101 (87.1)	51 (92.7)	Reference	
Medication	Diet and exercise	8 (6.9)	1 (1.8)	4.33 (0.57-49.7)	0.146

	Insulin	44 (37.9)	22 (40.0)	1.08 (0.53-2.21)	0.822
	Insulin and oral hypoglycemic agent	16 (13.8)	6 (10.9)	1.44 (0.51-4.20)	0.492
	Oral hypoglycemic agent	48 (41.4)	26 (47.3)	Reference	
Metabolic control level)	Well controlled (HBA1C	49 (43.0)	30 (56.6)	Reference	
	Poorly controlled	65 (57.0)	23 (43.4)	1.73 (0.88-3.27)	0.101
Screened for:					
Retinopathy	Yes	111 (95.7)	48 (88.9)	2.77 (0.75-8.45)	0.093
	No	5 (4.3)	6 (11.1) 1	Reference	
Nephropathy	Yes	111 (95.7)	51 (92.7)	1.74 (0.51-6.12)	0.418
	No	5 (4.3)	4 (7.3)	Reference	
disease	Yes Heart	104 (89.7)	44 (80.0)	2.16 (0.90-5.03)	0.084
	No	12 (10.3)	11 (20.0)	Reference	
Knowledge of pregnancy complications in diabetes (cut off 50%)	Poor	113 (97.4)	51 (92.7)	Reference	
	Good	3 (2.6)	4 (7.3)	2.95 (0.7611.98)	0.149

4.7Multivariable Analysis

After controlling confounders, the significance of the satisfaction with contraceptive counselling; having undergone screening for neuropathy or thrombosis; the doctor recommending method of contraception; and having previously experienced a pregnancy complication were all comparable between those using hormonal contraception and those not using hormonal contraception (Table 4.7).

Table 0.1. Multivariable logistic regression analysis

	AOR (95% CI)	P-value
Satisfaction with information received	0.61 (0.02-16.9)	0.771
Information guided choice of contraceptive method	3.88 (0.12-125.1)	0.444
Neuropathy screened	0.26 (0.01-3.99)	0.340
Thrombosis screened	2.562 (0.21-30.34)	0.456
Provider recommending method (ref=Doctor)		0.604
Nurse	0.493 (0.12-1.96)	0.316
Pharmacist	-	0.999
Previous pregnancy complicated	1.935 (0.40-9.32)	0.411

CHAPTER FIVE

5.0DISCUSSION, CONCLUSION, AND RECOMMENDATIONS

5.1DISCUSSION

In this hospital-based study, 171 women with uncomplicated diabetes mellitus were recruited from specialized clinics and are representative of an urban population in Kenya. The eligibility for hormonal contraceptive use was satisfactorily determined due to adequate risk screening done at this level of care and availability of medical records for corroboration at the clinics. The strength of this study is that we were able to compare two populations with similar risk profiles for adverse pregnancy outcomes and hormonal contraceptive use. Previous studies were comparing women with diabetes mellitus to women without the disease. The different risk profiles in these groups would influence the pattern of hormonal contraceptive use(26)(27)(28). There are no comparative studies for hormonal contraceptive use among women with uncomplicated diabetes mellitus locally. Racial and geographical differences present significant influence in clinical management and, therefore, results from this study can be compared with similar global research in the future. The baseline characteristics of the two groups such as mean age was not significantly different and there was also no difference in other sociodemographic characteristics: the level of education, marital status, religion, employment, parity, and number of living children. The two groups were

thus comparable in this regard. Previous studies had shown hormonal contraceptive users to be younger and possessing a higher level of education(31). This difference may be because the population in this study were all urban dwellers in the capital city unlike the previous study where participants were recruited from different regions.

We have established that in this study, the adjusted odds ratios are not statistically significant for the factors evaluated, therefore, studies with larger sample sizes and meticulously measured risk factors are required. Reproductive characteristics are important in the management of fertility and family planning in women. A poor obstetric history would determine the contraceptive choices of a woman as she tries to accomplish her reproductive goals while preserving her own health. Parity and number of living children were comparable in the two populations. This may be a factor of the disease process itself that causes pregnancy losses and wastage. However, the presence of a pregnancy complication in the previous gestation was significantly associated with hormonal contraceptive use with an unadjusted odds ratio of 2.38 (95% CI 1.17-4.79; p=0.018). Furthermore, majority of the pregnancy complications recorded were stillbirths (47%) and preterm births (37%) and it was found that more of hormonal contraceptive users had a previously unplanned pregnancies (25.5% versus 14%). Unplanned pregnancies have been associated with poorer obstetric outcomes worldwide not only for women with diabetes mellitus but indeed all women; indicating the magnitude of the independent risk for morbidity and mortality it carries. The choice to use a hormonal method following a pregnancy complication may be due to the realization of the need for long-term effective reversible contraception to give time for metabolic conditions to be optimized for the next pregnancy and, therefore, preventing the reoccurrence of an adverse outcome.

Unlike other studies, the type of diabetes mellitus was not shown to be significantly associated with hormonal contraceptive use. This alludes to the evaluation of similar risk profiles in type 1 and 2 diabetes mellitus in the study population while other studies showed different risk profiling for the two types of diabetes mellitus(27). More research needs to be conducted to determine whether the two types of diabetes should have different protocols for contraceptive management.

Concerns about the use of hormonal contraception by women with diabetes mellitus stem from postulated alterations in glucose and lipid metabolism. Poor metabolic control as evidenced by the levels of HBA1C in blood was not found to be associated with hormonal contraceptive use in this study. This further supports research that has found no worsening of hyperglycemia in women with diabetes mellitus who are using hormonal contraception(5)(19)(20). Comparison of lipid levels was not done in this study. A history of having undergone screening for diabetic neuropathy or

thrombosis was also positively correlated with hormonal contraceptive use ($p<0.01$ in both instances). This is important in contraceptive management to ensure sufficient mitigation of risks associated with hormonal contraceptive use in women with diabetes mellitus.

This study also demonstrates that receiving contraceptive counselling was more likely among those who were not using hormonal contraception ($p=0.011$). However, satisfaction with contraceptive counselling received [unadjusted OR 4.20 (95% CI 1.93-8.81; $p<0.01$]) and use of the information received to guide the choice of contraceptive method [unadjusted OR 7.00 (95% CI 3.06-16.3; $p<0.01$)] was more likely with hormonal contraceptive users. Clinical follow up in a specialized referral center like this would impact significantly on the quality and comprehensive contraceptive counselling received by these women enabling them to confidently choose a method that best suits them.

Although choice of contraceptive method should mainly be determined by the woman, professional input is essential for women with co-morbidities. Hormonal contraceptive users were more likely to have a doctor recommend the contraceptive method used than other health providers ($p<0.01$). This may be explained by the study setting being a specialized referral hospital hence more contact with doctors for diabetic and contraceptive management. Other studies found that lack of professional input in the choice of contraception was quite high (53%) among women with diabetes mellitus(32). The providers input in contraceptive management is important as they are the custodians of knowledge in this field. They should guide the woman in weighing benefits and risks of all available contraceptive methods while considering the desires and preferences of the woman during comprehensive contraceptive counselling. Being conversant with current evidence and guidelines is therefore essential for the provider.

5.2CONCLUSION

Hormonal contraceptive use is not associated with poorer sociodemographic, reproductive or clinicopathological characteristics in women with uncomplicated diabetes mellitus. This special group of women require quality contraceptive management to prevent adverse maternal and perinatal outcomes in pregnancy. For those who prefer a hormonal method, assessment of the benefits of a reliable method versus the risk of diabetic complications is paramount. The WHO Medical Eligibility Criteria guides the assessment of such risks and providers of contraceptive services should be aware of the wide range of methods available. Their recommendations should be guided by scientific research to promote effective family planning in women with uncomplicated diabetes mellitus. If this is done in consultation with gynecologists, there will be

marked improvement in outcomes of disease management in women with diabetes mellitus and ultimately produce a higher quality of life.

5.3RECOMMENDATIONS

Prospective studies with larger sample sizes to be conducted to evaluate the uptake and effects of hormonal contraception in the African population. Strengthening of provider training programs and frequent refresher courses on the use of the Medical Eligibility Criteria for contraceptive management to ensure familiarity with current guidelines. Multidisciplinary management of women of reproductive age with diabetes mellitus to ensure appropriate and effective contraceptive use and improve their reproductive outcomes.

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APPENDICES

Appendix I: Consent Form

PART 1: INFORMATION SHEET

Introduction

Dr. Stephanie Koga is a Postgraduate student in the Department of Obstetrics &Gynecology, University of Nairobi. She is currently undertaking a study "A Comparative assessment of the factors associated with hormonal contraceptive use among women with diabetes mellitus at Kenyatta National Hospital". You are invited to voluntarily participate in this study and no punitive measures will be taken in case you withdraw from the study at any stage. You are requested to read this document carefully at your own pace until you fully understand it.

Purpose of the study

This study aims to establish the factors associated with hormonal contraceptive use among women with diabetes mellitus at Kenyatta National Hospital.

Procedure

If you agree to participate in this study, you will be required to put down your signature/ thumb print as evidence of your free will to participate. A copy of the complete form will be made and given to you for safekeeping. Your body temperature will be recorded as part of the COVID 19 safety measures. You will also be required to properly wear a facemask, wash/sanitize your hands and maintain a social distance of 1.5 meters at all times. You will then be directed to a secluded room where you will be interviewed by the researcher privately. The researcher will ask you questions and complete the questionnaire on your behalf upon obtaining your responses to the questions. The interview is estimated to take about 30 – 45 minutes. Any member of the research team will be present to clarify any issues that may not be clear to you. Normal care and management as per Kenyatta National Hospital's protocols will not be interfered with.

Potential risks

We do not anticipate any risks in this study.

Potential benefits

During this study if you desire initiation, change or termination of a contraceptive method you will be referred to the Family planning clinic where the service can be provided. There will be no incentive or direct benefits for participation but your participation will contribute towards identifying needs and how to improve health care for the community.

Confidentiality

We guarantee that the information you provide will be confidential. Your name will not be used after consenting, but you will instead be assigned a unique identification number. The information you give will be stored safely and only the research team will have access to this information. At the end of the study, the information from all participants will be analyzed and the results will only be shared with relevant parties.

Right to refuse/withdraw

Participation in the study is solely voluntary, therefore, you do not have to take part if you do not wish to. No incentive will be given. You may withdraw from the study at any time you wish. Declining participation or withdrawing from the study will not in any way influence your current/future treatments/interventions and all your rights will be respected.

PART 11: CONSENT

I have read and understood the information provided above. I have been fully explained to about the study and I have had the opportunity to ask questions which have been explained to my satisfaction. I have agreed to voluntarily participate in this study and have not been coerced/manipulated or bribed in any way.

Participant name…….

Participant signature/thumb print……..……. Date: …… AND

Witness signature……Date……

Statement by researcher

I have explained to the participant about the study. I have given the participant an opportunity to ask questions relevant to the study and I have answered correctly to the best of my abilities. I have confirmed the participant has given consent voluntarily.

Researcher name…….

Signature……. Date: ……

Who to contact:

In case you have any queries/ concerns you can contact: -

Dr. Stephanie Koga Principal Investigator

P.O. BOX 11565-00400 NAIROBI Mobile phone number: 0721795814 Email: koga.stephanie@gmail.com

OR

Secretary, KNH-UON ERC P.O. BOX 19679-00202 Tel: (254-020) 2726300-9

Email: uonknherc@uonbi.ac.ke

Appendix II: Consent form

FOMU YA IDHINI Fomu ya idhini wa kujihusisha kwa utafiti kuhusu "Sababu zinazohusiana na utumiaji wa mpango wa uzazi wa homoni kwa wanawake walio na ugonjwa wa sukari katika Hospitali

Kuu ya Kenyatta"

Jina la mpelelezi mkuu: Dkt. Stephanie Koga

Jina la shirika: Chuo Kikuu cha Nairobi Jina

la mdhamini: Hospitali Kuu ya Kenyatta Hii

fomu ya idhini ina sehemu mbili:

- Karatasi ya habari (kueleza habari kuhusu utafiti huu)
- Cheti cha idhini (weka sahihi iwapo utachagua kushiriki)

SEHEMU YA KWANZA:

Karatasi ya habari.

Dibaji

Dkt. Stephanie Koga ni mwanafunzi wa uzamili katika uzazi na magonjwa ya wanawake katika Chuo Kikuu cha Nairobi. Utapata maelezo na kualikwa kushiriki katika utafiti huu. Kabla ya kuamua, una uhuru wa kuulizia ufafanuzi zaidi kutoka kwa mtafiti kwa starehe zako. Fomu hii ya idhini/ ridhaa huenda ikawa na maneno ambayo huyaelewi. Tafadhali uliza usipoelewa unapopitia habari, naye mtafiti atachukua muda wa kukueleza. Vilevile, kama una maswali baadaye unaweza kuuliza mtafiti.

Madhumuni/ nia ya utafiti

Utafiti huu unakusudia kubaini sababu zinazohusiana na utumiaji wa mpango wa uzazi wa homoni kwa wanawake walio na ugonjwa wa sukari katika Hospitali Kuu ya Kenyatta.

Aina ya kuingilia kati

Huu utafiti utahusisha ushiriki wako kibinafsi. Utachukua kati ya dakika thelathini hadi arobaini na tano kujibu maswali kwenye dodoso.

Ushiriki wa hiari

Ushirika wako katika utafiti huu ni kwa hiari yako mwenyewe. Ni chaguo lako kushiriki au kutoshiriki. Ukichagua kutoshiriki, huduma zote unazopokea hospitalini zitaendelea bila kubadilika.

Utaratibu

A. Tunakualika kujiunga na mpango huu wa utafiti. Ukikubali, utatia sahihi kwenye fomu hii ya idhini ili kuonyesha uamuzi wako mwenyewe kushiriki katika utafiti huu. Utahitajika kufuata sharti za kukabiliana na janga la ugonjwa wa korona zilizotolewa rasmi na Wizara ya Afya ya Kenya. Kipimo cha joto wa mwili wako kitanakiliwa na utahitajiwa kuvaa barakoa yako inavyofaa, kuosha mikono kwa sabuni au sanitaiza na kukaa umbali wa mita moja na nusu kutoka kwa mtafiti wakati wote.

B. Utakaribishwa kwenye sehemu maalamu ambapo utaulizwa maswali machache. Utajibu dodoso mwenyewe baada ya kusomewa maswali moja kwa moja na mtafiti na kusema kwa sauti jibu unalotaka liandikwe kwenye dodoso. Habari utakayotoa ni siri; jina lako halitanakiliwa kwa fomu na hakuna mwengine ila watafita maalum na mkaguzi wa takwimu (data) atakayeafikia utafiti wako.

Hatari

Hakuna hatari yoyote tunayotazamia kwa kushiriki katika utafiti huu.

Faida /malipo

Wakati wa utafiti huu, ukiwa ungependa kuanzishwa, kubadilisha au kusimamisha utumuzi wa aina ya mpango wa uzazi; utapelekwa kwenye kliniki ya mpango wa uzazi. Hakutakua na faida za moja kwa moja kwako wewe lakini kushiriki kwako huenda ikatusaidia kujua mengi kuhusiana na jinsi ya kuboresha huduma za afya katika jamii yako. Hutapewa malipo ya namna yoyote kwa kuchangia utafiti.

Kugawana matokeo

Utakachotuambia hakitajadiliwa na yeyote yule nje ya kundi hili la utafiti, na hakuna kitakachoidhinishwa jina lako. Tutachapisha majibu rasmi ndiposa wanaohusika katika huduma za afya waweze kutumia utafiti huu kuborehsa zaidi huduma hizo

Haki ya kukataa au kujitoa

Sio kwa lazima kushiriki katika utafiti huu kama huna nia ya kufanya hivo, na kuchagua kutoshiriki haitadhuru kuopokea huduma katika kliniki kwa njia yoyote ile.

Wa kuwasiliana nao

Unaweza wasiliana nasi kupitia wafwatao:

Dkt. Stephanie Koga Mtafiti mkuu Sanduku la posta 11565-00400, Nairobi Nambari ya simu 0721795814 Barua pepe koga.stephanie@gmail.com

AMA

Katibu, KNH-UON ERC Nambari ya simu 020-2726300

Barua pepe uonknherc@uonbi.ac.ke

Appendix III: Study Questionnaire

Structured Questionnaire

Date: …… Participant number: ……...…….

Study: A Comparative assessment of the factors associated with hormonal contraceptive use **among women with diabetes mellitus at Kenyatta National Hospital Instructions**

Please complete the following questionnaire. Tick where appropriate.

Part 1: Demographics

1. Age (indicate year of birth) …….
2. Marital status

Single	
Married	

3. Religion

   Christian Muslim Hindu

   Other

4. Home county …….
5. Parity …….
6. Number of living children

7. Highest level of Education

None	
Primary	
Secondary	
Tertiary	

8. Employment status

Unemployed Self-employed Employed

9. Smoker Yes ☐ No

Part II: Contraception

10. Which contraceptive method are you currently/ recently used? (Specify) COC

…… POP …….

Implant ……. Injectable

…….

IUCD ……

Hormonal IUCD ……

Other …….

None

11. How many years have you used the contraceptive method?

<1 year

1-5years

>5years

12. Are you planning to get pregnant in the next 1 year? Yes No

12. Who decides on the contraceptive method you use?

Self

Partner

Self and partner

Health worker

Others

13. Where did you receive information on contraception?

Never received information

Health worker

Media

Other person who is not a health worker

14. Who prescribed the contraceptive method you are using?

Doctor

Nurse

Pharmacist/ Pharmaceutical technologist Other

15. Did you receive information in the following areas?

Statement	Yes	No
The importance of contraception for women		
When one should use contraception		
The different methods of contraception available e.g., Male and female condoms, vaginal rings, cervical caps, intrauterine device, hormonal implants, oral pills, depot injections, transdermal patches		
How the contraceptive methods act to prevent pregnancy		
The duration of action of the contraceptive methods		
The side effects of the contraceptive methods		
The contraceptives that can be used by women uncomplicated with diabetes mellitus		
The contraceptives which can be used by women with complicated diabetes		
The risks of the different contraceptives in women with diabetes		

16. Were you satisfied with the information received? Yes No

17. Did the information received guide you in choosing the contraceptive method you are using? Yes No

18. Have you experienced any of the following side effects while using contraception?

Intermenstrual bleeding/ spotting

Lower abdominal cramps

Missed menses

Heavy menstrual bleeding

Nausea

Breast tenderness

Headache and migraines

Weight gain

Mood changes

Decreased libido

Altered vaginal discharge

19. Did the side effect experienced cause you to stop using the contraceptive method?

Yes

No

Part III: Diabetes mellitus

20. Which type of diabetes do you have?

Type 1

Type 2

21. How many years have you been diabetic?

…….

22. Which diabetic medication are you currently using?

Insulin

Oral hypoglycemic agent

None (Diet and exercise only)

23. What was your latest HBA1C level? ……

24. Which of the following have you been screened for?

Complication	Screened
Eye disease/ Retinopathy	
Kidney disease/ Nephropathy	
Heart disease	
Nerve disease/ Neuropathy	

Vascular disease/ Thrombosis	

25. What are the challenges/complications of pregnancy in a diabetic woman you know? (Tick those mentioned)

Worsening of diabetes and complications

Diabetic ketoacidosis

Hypoglycemia

Preterm delivery

Miscarriage

Still births

Congenital anomalies

Big baby and delivery complications 25. 25. Was your previous pregnancy planned?

Yes No

26. Did you experience any of the following complications in your previous pregnancy?

Miscarriage Still

birth

Preterm birth

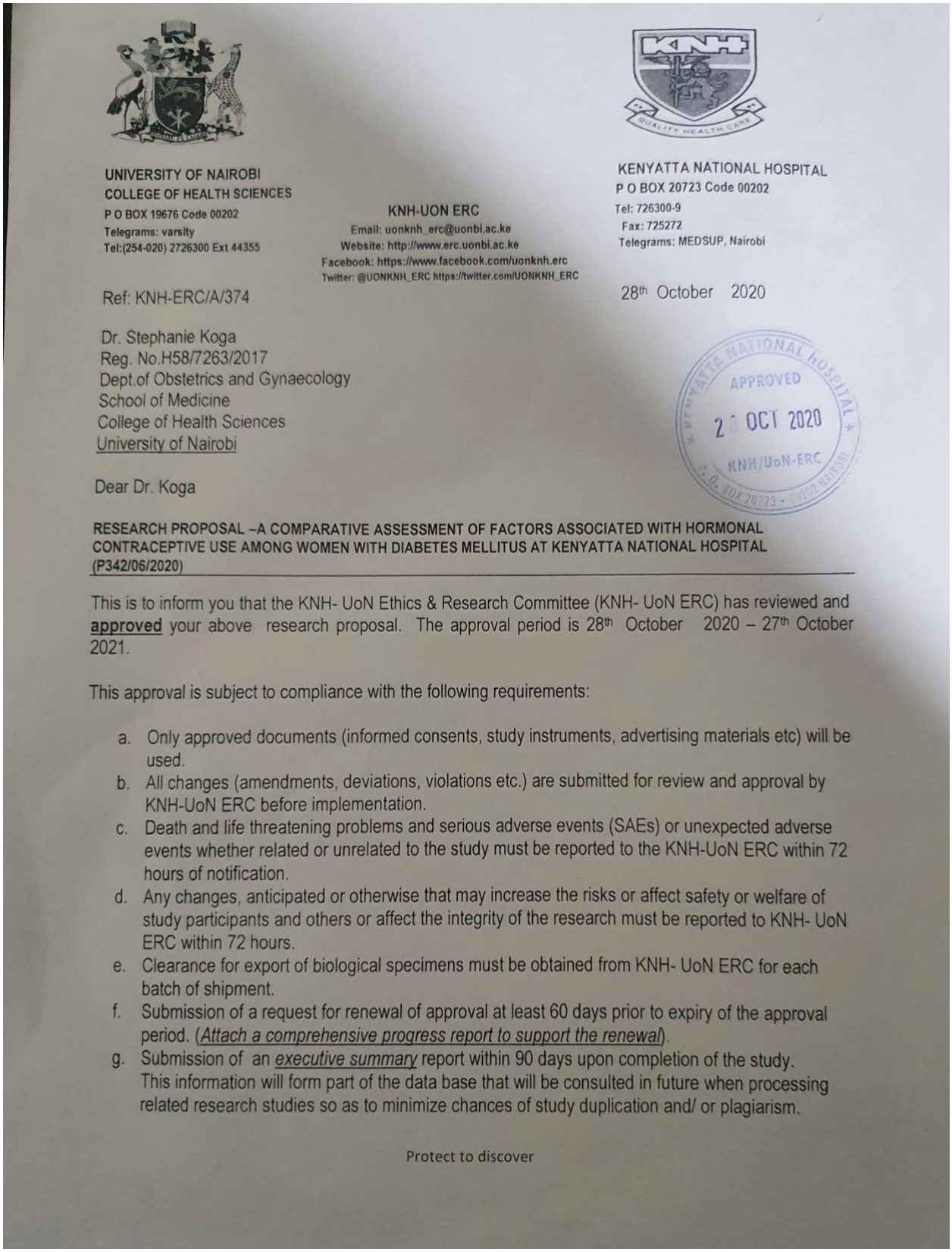
Macrosomia

Congenital malformation

27. Have you ever been treated for infertility?

Yes No

1.2 Appendix IV: ERC Approval



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Ref: KNH-ERC/A/374

28th October 2020

Dr. Stephanie Koga
Reg. No.H58/7263/2017
Dept.of Obstetrics and Gynaecology
School of Medicine
College of Health Sciences
University of Nairobi

KENYATTA NATIONAL HOSPITAL
APPROVED
21 OCT 2020
KNH/UoN-ERC
P. O. BOX 20723 - 00202 NAIROBI

Dear Dr. Koga

RESEARCH PROPOSAL –A COMPARATIVE ASSESSMENT OF FACTORS ASSOCIATED WITH HORMONAL CONTRACEPTIVE USE AMONG WOMEN WITH DIABETES MELLITUS AT KENYATTA NATIONAL HOSPITAL (P342/06/2020)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 28th October 2020 – 27th October 2021.

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 serious 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. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. 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*).
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.

Protect to discover

5.5 Appendix V: KNH Approval

KNH/R&P/FORM/01

KENYATTA NATIONAL HOSPITAL
P.O. Box 20723-00202 Nairobi

Tel.: 2726300/2726450/2726565
Research & Programs: Ext. 44705
Fax: 2725272
Email: knhresearch@gmail.com

Study Registration Certificate

1. Name of the Principal Investigator/Researcher
   DR. STEPHANIE KOGA
2. Email address: koga.stephanie@gmail.com Tel No. 0721 795 814
3. Contact person (if different from PI) N/A
4. Email address: N/A Tel No. N/A
5. Study Title
   A COMPARATIVE ASSESSMENT OF FACTORS ASSOCIATED WITH HORMONAL CONTRACEPTIVE USE AMONG WOMEN WITH DIABETES MELLITUS AT KENYATTA NATIONAL HOSPITAL
6. Department where the study will be conducted OBSTETRICS & GYNECOLOGY / ~~INTERNAL MEDICINE~~
   (Please attach copy of Abstract)
7. Endorsed by KNH Head of Department where study will be conducted.

   Name: [illegible] Signature [signature] Date 3/11/2020

   HEAD OF DEPARTMENT OBSTETRICS & GYNAECOLOGY 03 NOV 2020 KENYATTA NATIONAL HOSPITAL P.O. BOX 20723 - 00202 NAIROBI
8. KNH UoN Ethics Research Committee approved study number _____
   (Please attach copy of ERC approval)
9. I DR. STEPHANIE KOGA commit to submit a report of my study findings to the Department where the study will be conducted and to the Department of Medical Research.

   Signature [signature] Date 03/11/2020
10. Study Registration number (Dept/Number/Year) obs/594 /IKH/2020
    (To be completed by Medical Research Department)
    KENYATTA NATIONAL HOSPITAL Research & Programs 03 NOV 2020
11. Research and Program Stamp _____

All studies conducted at Kenyatta National Hospital **must** be registered with the Department of Medical Research and investigators **must commit** to share results with the hospital.

HEAD OF DEPARTMENT - 3 NOV 2020

COMPARING SOCIODEMOGRAPHIC, REPRODUCTIVE AND CLINICOPATHOLOGICAL CHARACTERISTICS ASSOCIATED WITH HORMONAL CONTRACEPTIVE USE AMONG WOMEN WITH

Submission date: 23-Dec-2021 09:41AM (UTC+0300)

Submission ID: UNCOMPLICATED DIABETES1735214272

File name: S.KOGA_-_DISSERTATION.docx (245.72K)

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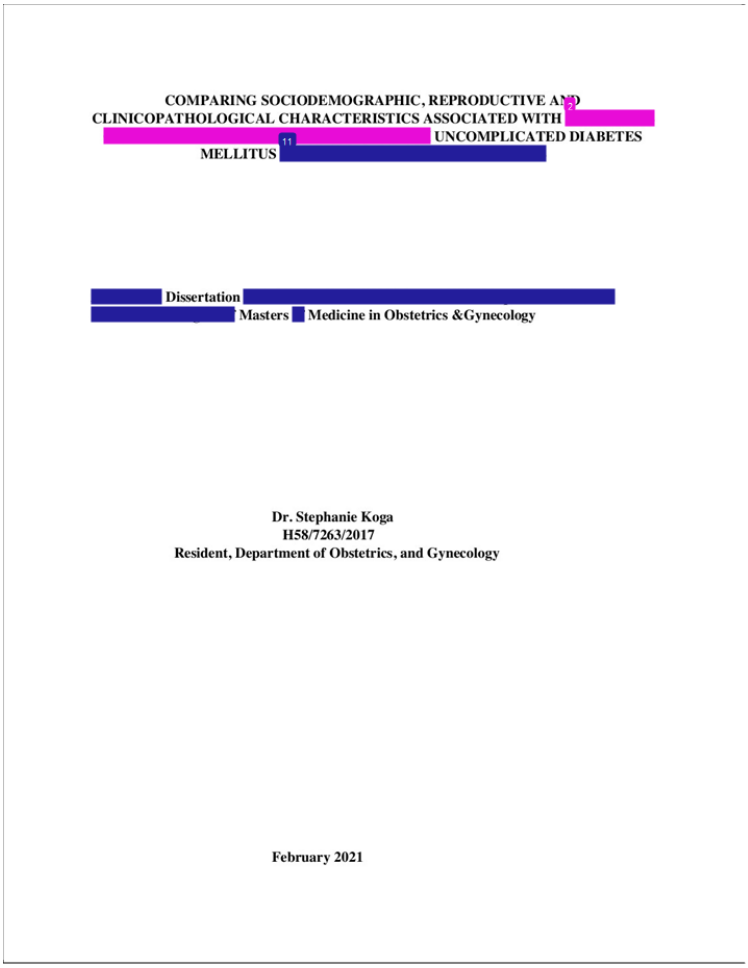

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