Acceptability, Uptake and Safety of Intra-Operative IUCD Placement at KNH and Pumwani Maternity Hospital

A research dissertation submitted by Dr. Balleith. B. Khamis as part of fulfillment of the requirements, for the award of Master of Medicine in Obstetrics and Gynaecology.

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Declaration

This is to certify that this research in part of fulfillment of the M.Med degree in Obstetrics and Gynaecology is my original work and have not been presented before for a degree course in any other university.

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DEDICATION

This book is dedicated to my Mother for her guidance and support throughout my life.

My Husband who has been the source of my strength and inspiration and to my sons Hassan and Hussein for withstanding the long hours I was away from home.

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Acronyms and Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal clinic
Cu	Copper
FHI	Family Health International
FP	Family Planning
HIV	Human Immunodeficiency Virus
IUCD	Intrauterine Contraceptive Device
JHPIEGO	John Hopkins Program for International Education in Gynaecology and Obstetrics.
KDHS	Kenya Demographic Health Survey
KNH	Kenyatta National Hospital
LAM	Lactational Ammenorrhea Method
LAPM's	Long Acting and Permanent Methods (of Contraception)
MEC	Medical Eligibility Criteria (for contraceptive use)
MOH	Ministries of Health
NGO	Non-Governmental Organizations
NSAIDs	Non-steroidal anti-nflammatory Drugs
PGH	Provincial General Hospital
PPIUCD	Postpartum IUCD
STI/STD	Sexually Transmitted Infections/ SexuallyTransmitted Diseases
USAID	United States Agency for International Development
WHO	World Health Organization

Operational Definitions

Postpartum: The period after delivery of the products of conception until 6 weeks.

Postpartum IUCD insertion: Insertion of the IUCD during the postpartum period.

Postplacental Insertion: Insertion of the IUCD within 10 minutes after expulsion of the placenta following a vaginal delivery.

Intraoperative IUCD Insertion: Insertion of the IUCD following a caesarean delivery before the uterus is sutured.This term is used inter-changebly with transceserean IUCD placement and or intraceserean IUCD placement.

Immediate Postpartum Insertion: Insertion of the IUCD after the postplacental period but within48 hours of delivery.

Postabortion Insertion: Insertion of the IUCD following an abortion with complete expulsion of products of conception.

Interval Insertion: Insertion of the IUCD after 4 weeks of delivery or anytime in a woman's menstrual cycle as long as there is confirmation that she is not pregnant.

Acceptance: The number of clients who after counseling agreed to have the IUCD inserted postplacental**.**

Uptake: The number of clients who actually had the IUCD inserted intraceserean.This group excludes those who had prior accepted and either opted out or had medical contraindications detected intra-operative

Outcomes: The main measurable outcomes relevant to this study included postinsertion heavy bleeding, expulsion, severe cramping and sign of sepsis by the third operative day.

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Abstract

Background

Increasing number of women undergo elective cesarean section due to repeat cesarean section, breech presentation, fetal or maternal conditions, these women need effective long term contraception to allow them recuperate from surgery and for reliable means of child spacing.

Trials of IUCD placement intra-cesarean have proven to be safe, effective and feasible with even higher retention than other routes of PPIUCD. This is an innovative timing where the couples are highly motivated to use a long term method of contraception that is not offered routinely. The timing will also eliminate the need of other procedure for family planning later. It is also cost effective since same infrastructure and staff is involved. IUCD does not affect breastfeeding practice.

There were limited local studies describing the uptake and safety of IUCD placement at elective cesarean section hence information generated by the study provided a solution on how to cater for the unmet need of contraception.

Objective

To determine the acceptability, uptake, and safety of intra-operative placement of IUCD in women undergoing elective cesarean section at KNH and Pumwani Maternity Hospital.

Study Methodology

Study Design:

Descriptive cohort study.

Study Site:

Kenyatta National Hospital and Pumwani Maternity Hospital.

Study Population:

Antenatal mothers between 36weeks and term, who were booked for elective cesarean section.

Study Procedure

Women who were scheduled for elective cesarean section were offered intra-operative IUCD placement service after counseling during the period of study. Those who accepted were followed up intrapartum and had the IUCD insertion intra-operative. They were then observed for immediate postoperative outcome at 3rd postoperative day, 2 weeks and at 6 weeks.

Results

Two hundred and thirty seven women booked for elective cesarean section were enrolled. Out of these 86 (36.3%) accepted intra-operative placement, 151 declined (63.7%). Uptake of the IUCD was 80(33%). Post insertion adverse events observed included heavy bleeding 1 (1.4%), sepsis 1(1.4%), expulsion rate 1(1.4%) by the end of 6 weeks. The proportion of discontinuation was at 4 (5.6%) at the end of the puerperium. Nine (9) patients were lost to follow up by the study period.

Conclusion

Intra-operative IUCD insertion was an acceptable method among women undergoing elective cesarean section, and safety demonstrated through the minimal complication evidenced, with highest retention rates compared to other routes and timing of insertion. Low rates of discontinuation also reflect woman's satisfaction with their choice.

Recommendation

Intra-operative IUCD placement services should be routinely offered to women undergoing elective cesarean section. Antenatal counseling should create awareness of the existence of IUCD and its safety on intra-operative insertion.

CHAPTER ONE: INTRODUCTION

1.1 Background

The world contraceptive use is at 62% however contraceptive prevalence (% of women ages 15-49) in sub-Saharan Africa was last reported at 21.83, according to a World Bank report published in 2012. [1]

In Kenya the overall contraceptive prevalence is at 46%, with decline in use of modern long term contraceptive methods. This study is an effort to reinvigorate the IUCD use since its one of the most "misunderstood" method and its uptake has been declining (current national IUCD use it at 1.6%). [2]

Trials of IUCD placement intra-cesarean have proven to be safe, effective and feasible with even higher retention rates than other routes of Postpartum IUCD [3,4].

Intraoperative IUCD is an innovative timing where the couples are highly motivated to use a long term family Planning method. Since only 53% of Kenyan women receive postpartum care [2] Intra-operative IUCD insertion will enable us to discharge the patient home safe and free from unwanted pregnancy.

Women undergoing elective cesarean section need a reliable long acting method of contraception yet currently no routine antenatal counseling for appropriate postpartum family planning are done. When it is clear during pregnancy, but prior to labor, that there is a medical or obstetrical reason to choose delivery via caesarean section, obstetricians will commonly perform the operation at a scheduled time, rather than waiting for the onset of labor.

Planned caesarean sections are performed for many reasons, including history of previous caesarean section, placenta praevia, abnormal presentations, multiple pregnancy, known obstructions of labor, medical conditions or even upon maternal request .The advantages of performing the delivery at a scheduled time include use of daytime services when hospital resources are optimal, and the ability to plan and prepare for the event. In preparation the woman should ideally be counseled on postpartum family planning and be offered such services. This doesn't occur routinely hence missed opportunity.

This study therefore will assess the acceptability and uptake of intra-operative insertion of IUCD (copper T380 A) in patients undergoing elective cesarean section and elaborate on its safety and success by the end of postpartum.

Few studies have focused on Tran's cesarean IUCD insertion, acceptability, uptake and outcomes of the study will provide information to the health service providers on how to cater for the unmet need. This will also provide an opportunity to the service provider to direct visual IUCD Insertion as opposed to the actual routine blind procedure.

The IUCD is a small flexible device inserted into the uterine cavity by a trained service provider. The most widely used are the copper bearing IUCDs, which are made of plastic with copper sleeves on the arms and copper wire wound around the stem. The cu 380A is the most widely available IUCD in Kenya. It is this device considered with regard to the eligibility criteria, given in appendix A. The IUCD insertion is categorized as postpartum, postabortal and interval. Postpartum insertion could be trans-caesarean, post placental, immediate postpartum [5].

Precursor of IUCD was 1st marketed in 1902, thereafter several modifications were made. Second generation IUCD introduced in 1970's, these devices had higher surface area of copper and for the first time consistently achieved effectiveness rate of greater than 99%[6].Not only is IUCD high effective but also has immediate effectiveness, long term protection and immediate return to fertility upon removal. Other benefits include; non-interference with intercourse can be used by lactating women and helps prevent ectopic pregnancy. It limitation however is that it requires appropriate infection prevention practices, does not protect against STI/HIV, may be expelled or translocated, may increase menstrual bleeding or lochia during the first few months of insertion [6].

1.2 Literature review

Worldwide intrauterine devices are the most commonly used form of reversible contraception with 160 million women currently on this method [7]. The IUCD has virtually disappeared from the national mix of modern family planning methods in Kenya over the past 15 years, despite its proven safety, effectiveness, acceptability, and low cost. While the percentage of Kenyan women using any modern contraceptive has more than tripled since 1984, the proportion of contraceptive users choosing the IUCD is declining[2]. Despite the increased use of contraceptive methods, as more Kenyans enter reproductive age, unmet need continues to grow.

The National Reproductive Health strategy 2009-2015 and the National Reproductive Health Policy have prioritized family planning as one of the main components of RH based on both magnitude and significance of the problem. Thus such services will advocate for long term method, facilitating the Kenya Vision 2030 for sound economic growth and development.

The impact that provider enthusiasm for IUDs has on their utilization can be seen in isolated reports of unusually high acceptance rates. In Kenya our IUCD prevalence is declining and currently at 1.6% [2]. A survey conducted in 2004 revealed clearly that only 11% of facilities in Kenya had adequate items for quality and standard IUCD insertion and removal [8].

In an effort to a more balanced and sustainable family planning method mix, the Ministry Of Health together with FHI has embarked on initiative to RE-introduce IUCD. The initiative focuses on four areas: consensus building and advocacy, building capacity and improving service delivery, demand creation, and monitoring and evaluation [9]. This study will thus help reintroduction of IUCD by utilizing the postpartum timing; the study will help create awareness of the existence and advantages of intraopertive insertion of IUCD which are major determinants of demand. Often clients are not aware of the IUCD as a contraceptive option, or they have misconceptions about the method [2]. According to the KDHS 2009-2010, IUCD is among the most misunderstood method of FP.

Acceptability is known to be high in women who are offered IUCD insertion services at the postpartum period. Mohamed et al.[10] reported that women who received their IUDs immediately after delivery were 10 times more likely to have IUDs placed than were women who said they planned to return for IUD placement after they had uterine involution. A study conducted in turkey in 1990 reported 95% of postpartum women were willing to use

contraception method immediately after delivery, however more than 70% who were admitted for delivery left the institution without receiving contraception [11]

PPIUCD was recommended more than 4 decades ago in 1967[12]. However, the uptake of this method has been rather slow except in countries such as China and Mexico where it is widely used. In October 1990, Kenya became the first countries in Sub Saharan Africa to initiate postpartum IUCD insertion programs [13] More than 20 years later the method is still inadequately utilized in Kenya, as evidenced by the low rates of IUCD use. The MOH in conjunction with some nongovernmental organizations e.g. USAID, JHPEIGO, FHI among others are involved in the training of postpartum IUCD counselling and insertion techniques to clinical staff country wide to enhance the uptake of this method.

Given the need for immediate convenient contraception and the low expulsion rates that have been reported with placement at the time of cesarean delivery, intra-operative placement has definite appeal. This study will provide a chance of FP counseling and services during the continuum of care from the antenatal through postpartum periods. A local study recommended that routine counseling is adequate to allow for increased uptake of post placental IUCD, and the information is to be given during the antenatal visits.[14]

Postpartum IUCD has been proven to be both safe and feasible [15] Trans-cesarean IUCD placement has not only been proven to be safe [3, 16] but also recognized to be of innovative timing .The utility of Hospital resources and expense to the patient is limited to the cost of IUCD as the device is inserted by the same surgeon doing the cesarean section, under the same infrastructure; moreover the patient is under anaesthesia and no pain or discomfort is felt, unlike in interval insertion.

Outcomes of immediate post placental insertion like increase in postpartum blood loss were earlier thought to be significant this has been disputed by studies showing minimal or no increase in postpartum blood loss. [17]. IUCD is a safe method that doesn't increase the incidence of STI / STD acquisition[18] , PID in HIV positive women [19], ectopic pregnancy[20], or shedding of the H I V virus [21] as earlier thought.

Most mothers post elective cesarean will require a long term contraception and IUCD would be the option of choice. They will also have the opportunity to have their IUCD inserted by the most experienced health providers. There has been a debate on whether rates of expulsion differ with providers training and experience, time and technique of insertion. A study done

in Africa (Kenya and Mali) shows the importance of training and experience in the uptake of immediate postpartum IUCD, the expulsion rate in Nyeri PGH was only 1%, rates comparable or even lower than that of the interval insertion. These low rates were attributed to the extensive training and experience of the Kenyan providers as compared to Mali. [22].Many similar studies confirm that limited clinical training and experience are associated with greater expulsion rates [13,22,23,24]

There are minimal completed trials that examined IUCD at the time of elective cesarean section, however ongoing trial is comparing immediate insertion at cesarean section verses delayed insertion. Case series report [3, 16] also suggest that insertion at Cesarean section have a lower expulsion rate of 1.2% to insertion immediately after Vaginal birth 9.6%.[4,25,26]

Many of the early reports were with tailless IUCD. A recent pilot study of women undergoing elective C section and had T- Cu380A places through the uterine incisions and the elongated tail strings were threaded within the placement tubing through the cervix into the vagina, all IUCD stayed in a fundal position throughout uterine involution and tail strings were always available in the vagina to facilitate easy IUCD removal should complication occur [27]

Some researchers have tried to suspend the IUCD with chromic sutures at time of insertion to reduce expulsion rates. This however was seen to have no impact on clinical outcomes [4,28, 29]. The type of IUCD models studied earlier are now outdated however copper bearing IUCDs generally had lower expulsion rates [30] thus suggesting the popularity of the Copper T 380A IUCD for postpartum insertion.

Uterine perforation rates of IUCD insertion are a rare event during interval insertion the risk being about 1.0 per1000 women [31]. Studies have shown that uterine perforation following post placental IUCD insertion is almost unheard of with most studies having no complication of perforation [13, 15, 32].

Multiple studies have shown no increased risk of cervical or uterine malignancy in IUCD users[33, 34] . Several reviews have indicated that women using Copper IUCDs actually have decreased risk of cervical malignancies with increasing duration of use, suggesting that copper ions may protect against cervical malignancies[34,35,36].

IUCD is one of the most effective methods of contraception. The copper T 380A and the hormone releasing IUCD's confer contraceptive protection similar to that achieved with tubal sterilization with cumulative pregnancy rates of 2 % [37]. The pregnancy rates of post placental IUCD insertion has shown a rate varying from 0% to 2% [13, 15, 32].

Women who opt for IUCD removal should be offered an alternative form of birth control immediately after removal of IUCD. Women attempting pregnancy after IUCD removal conceive at a similar rate to those discontinuing other methods of contraception with approximately 80% achieving pregnancy the first year. [38]

1.3 Rationale

Family planning is a key intervention in reducing maternal, newborn and child mortality and morbidity through preventing unintended pregnancies, as well as those that are spaced too closely together. The postpartum period represents a critical window of opportunity for women to receive family planning services because many will access health services during pregnancy and childbirth at which point they can be introduced to and linked with PPFP services. In Kenya the antenatal attendance 92% as opposed to 53% of women do not attend postnatal care [2].

Family planning strategies need to be put in place and every opportunity utilised to inform and offer women these services. Modern family planning services bring a wide range of benefits for women, their families and society yet the unmet need for contraception is at 26% [2]. They improve women's health and enhance their status and rights, protect the health of infants and children, and improve the well-being of families. However, a substantial proportion of women who want to avoid a pregnancy—whether to postpone or to stop childbearing are not using modern contraceptives [35].

Maternal deaths in developing countries could be slashed by 70 per cent and newborn deaths by nearly half, if the world doubled investments in family planning and pregnancy-related care [39].

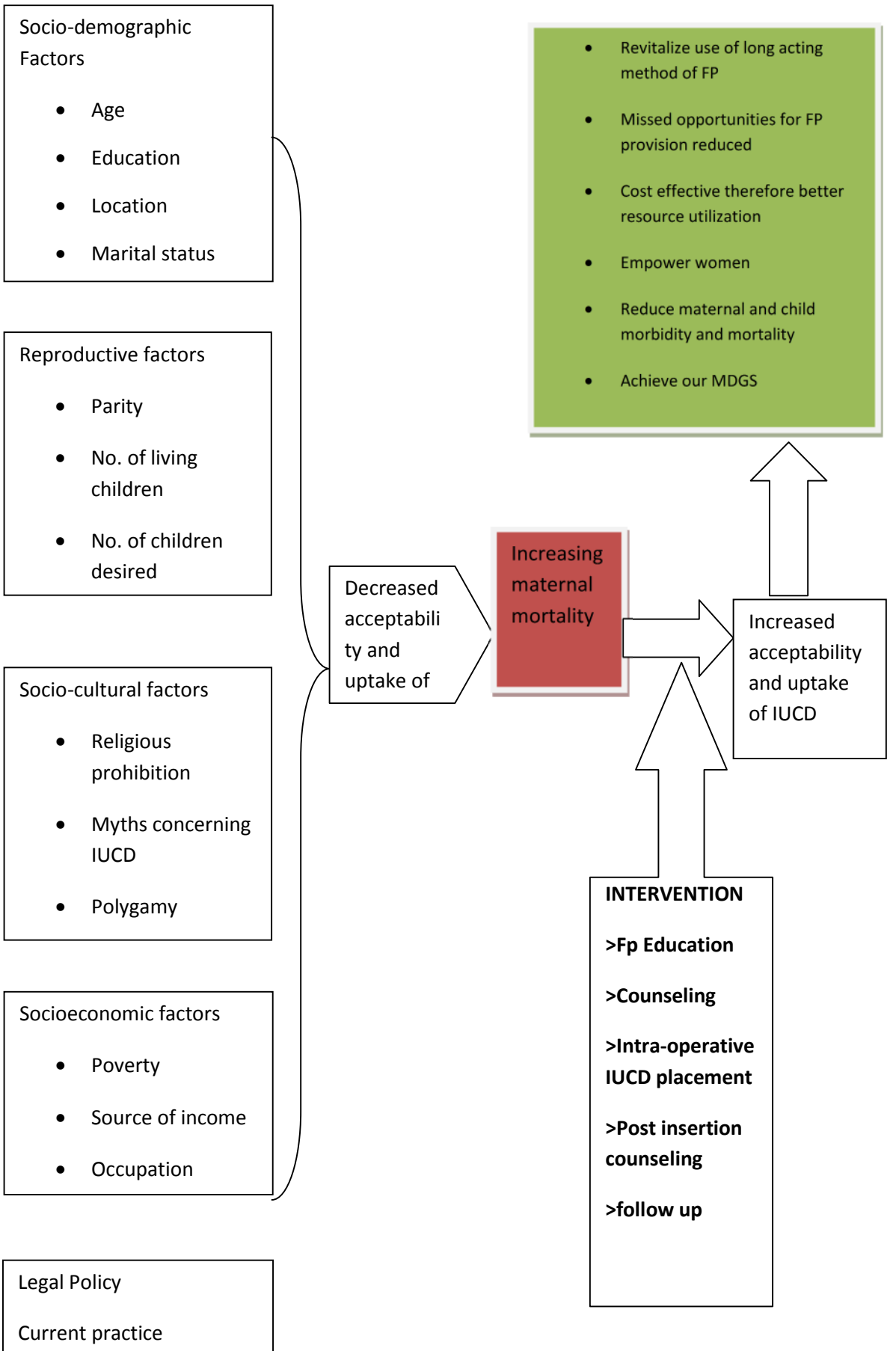
IUCD is a convenient method and requires little effort by the client in terms of compliance, it's also more effective (% efficacy) when compared with other methods of contraception.[5] it is however becoming progressively unpopular[2] The current national IUCD use rate is at 1.6%.

IUCD is a good contraceptive method for a lactating mother because it has no effect on the quantity or composition of breast milk [36]. There has been concern based on a few case reports and a small case control study, that insertion during lactation might involve a higher risk of uterine perforation. Results from international clinical trials conducted by FHl have been largely reassuring [36].

Insertion during an elective cesarean-section will ensure aseptical technique thus further decrease the risk of infections. Direct visual insertion will eliminate the risk of perforation.

Few studies have focused on transcesarean IUCD insertion, acceptability, uptake and post insertion adverse events hence the study will provide information to the public health policy makers, and help provide solution on how to cater for the unmet need.

1.3 The Conceptual Framework



Unfortunately, a large number of women who wish to delay or prevent future pregnancies receive little or no information on safe, available, effective contraceptives. This trend has led to an increasing population growth rate; high maternal and child mortality posing great threats to our envisioned MGDs. Development efforts to achieve the MDGs must recognize the benefits of slowing population growth. One way to slow population growth is to satisfy the current unmet need for family planning (FP). Many married women report having mistimed or unintended pregnancies or a desire to space or limit future pregnancies, but are not using modern contraceptive methods.

Determinant of acceptability and uptake of intra-operative IUCD placement at elective cesarean section include; Socio-demographic factors, Reproductive factors, Socio-cultural factors, Socio-economic factors and finally availability of legal policy and current practice offered by the providers. All the mentioned factors are interrelated. At the societal level, rapid population growth adds to the number of people in need of healthcare, education, livable wages, and other social services which, in turn, requires additional human, financial, material, and natural resources. At the household level, high fertility affects the health of women, their children, and families, thereby increasing the risk of maternal, child, and infant mortality.

1.4 Research Question

Is intra-operative IUCD placement acceptable, safe and sustainable among women undergoing elective cesarean section in KNH and Pumwani maternity Hospital?

1.5 Broad Objective

To determine the acceptability, uptake, safety and retention of intra-operative placement of IUCD for women undergoing elective cesarean section in K.N.H and Pumwani Maternity Hospital.

1.6 Specific Objectives

1. To determine acceptability of intra-operative placement of IUCD among antenatal women booked for elective cesarean section

2. To determine uptake rates of intra-operative insertion of IUCD at elective cesarean section.

3. To determine adverse events and expulsion rates (rates of heavy bleeding, sepsis, expulsion) of intra-operative placement of IUCD in puerperium.

4. To determine the proportion of discontinuation by the end of postpartum period

1.7 Measured Outcomes

The primary study outcome was to assess the acceptability of intra-operative IUCD insertion in women undergoing elective cesarean section, Acceptability was measured at the patient level using a binary (yes/no) variable depending on whether a woman accepts to have an IUCD inserted during delivery or not.

The secondary measured outcome was the uptake of IUCD, this variable will be used to calculate an overall uptake rate presented as the percentage of participants with an IUCD inserted intra-operatively.

Other secondary outcome of interest were the adverse events within puerperium and these specifically included heavy bleeding, puerperal sepsis, and expulsion rates within the peurperium period.

The proportion of discontinuation during the postpartum period was also assessed.

Acceptance*:* The number of clients who after counseling agreed to have the IUCD inserted post placental. (Tranceserean))

Acceptance rate = yes (for intervention)/ Sample size

Uptake: The number of clients who actually had the IUCD inserted intracesarean. This group excludes those who had prior accepted and either opted out or had medical contraindications detected intra-operative

Uptake rate= number of IUCD inserted/ Sample size

Post-insertion outcomes: The main measurable outcomes relevant to this study included post insertion heavy bleeding, expulsion and sign of sepsis by the end of the puerperium.

Heavy bleeding = bleeding in clots and or change of more than 4 fully soaked pad a day.

Puerperal sepsis = 2 or more of the following signs;

- Pyrexia
- Foul smelling lochia
- Subinvoluted uterus with uterine tenderness

Proportion of discontinuation; the proportion of women who would have discontinued using IUCD by the end of peurperium in the uptake group. Discontinuation would either be due to expulsion or personal desire to remove the IUCD.

Proportion of discontinuation = (number of women who had their IUCD expelled + removed IUCD due to personal request)/ uptake

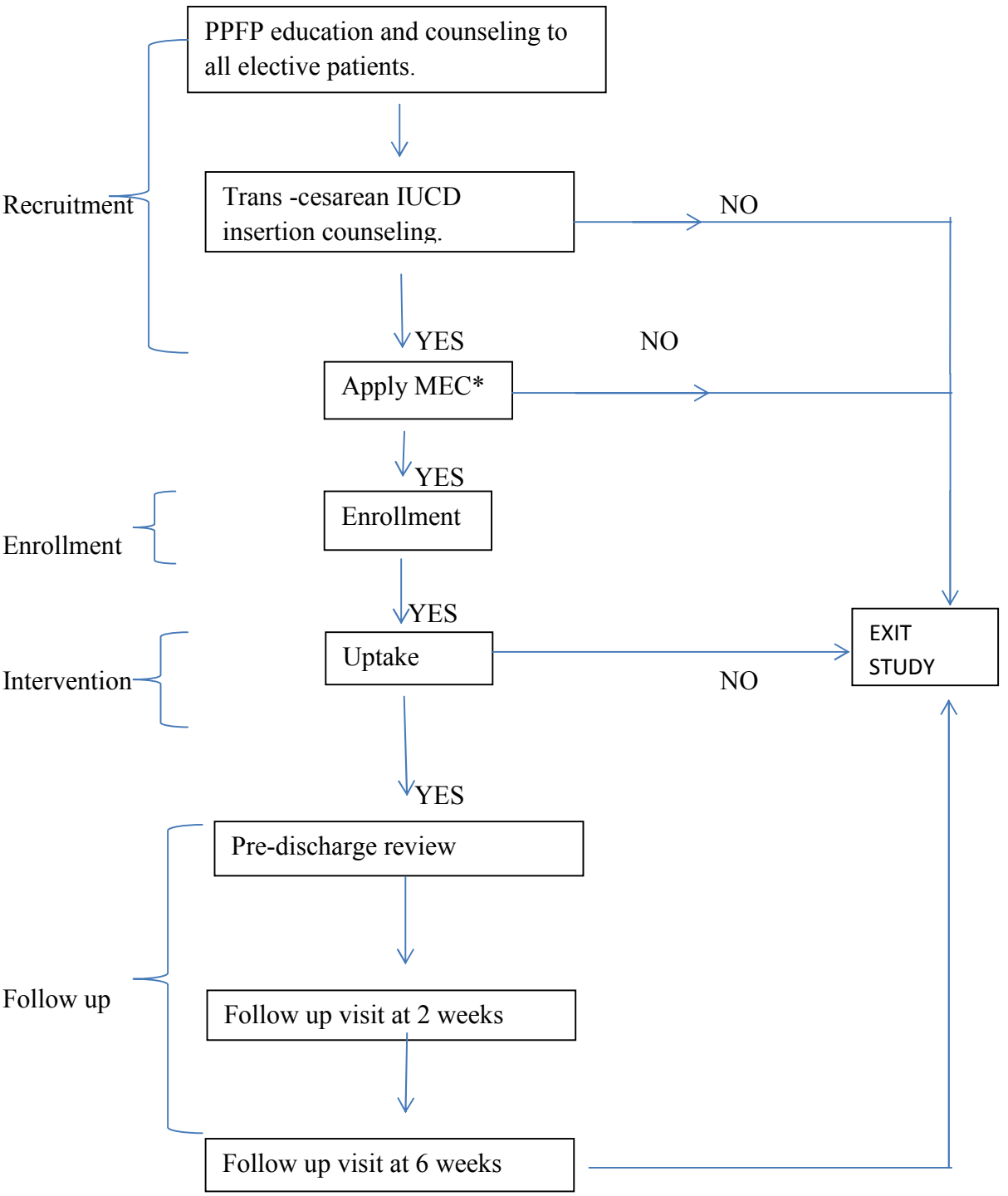
CHAPTER TWO: STUDY METHODOLOGY

2.1. Study Design

This is a descriptive cohort study. Women eligible for the study and consented for intra-operative IUCD placement were longitudinally followed at 3 days, 14 and 42 days post-operatively.

The acceptability, uptake, immediate and late outcomes of intra-operative insertion of IUCD at elective cesarean section was documented.

2.2 Schematic representation



NOTE:

- Intervention: IUCD insertion intra-operative
- Follow up: Assessment of the measured adverse events during peurperium.
- * MEC; Medical eligibility criteria (for contraceptive use) Appendix A

2.3 Study Site

The study was conducted at Kenyatta National Hospital, a tertiary referral and university teaching hospital located in Nairobi, Kenya. Patients at the hospital are referred from lower level facilities within Nairobi and the hospital also serves as one of the two national referral hospitals. Obstetrics services at the hospital are provided by a team of Consultants, Registrars, House officers and Medical officer interns with Nursing staff responsible for nursing care. The 2000 bed hospital has an independent obstetrics theater and operating facilities and a 100-bed obstetrics and gynaecology unit. Approximately 500 normal deliveries and 80 elective caesarean sections are conducted monthly at the hospital. At current there is no active promotion of this service (intra-operative insertion of IUCD).

KNH provides family planning services through its out-patient clinic. Below is the service statistic for the year 2011 in the female welfare clinic (clinic 66)

a) IUCD : total insertions =420
b) Implants: total insertions =619
c) Oral contraceptive cycle dispensed =1883
d) Inject able (Depo-Provera) = 713
e) Female condoms dispensed = 700
f) Male condoms dispensed = 37,315.

NOTE; the IUCD mostly used is the cuT380A. Implants include Jadelle, implanon and norplant.

Mothers who are planned for elective cesarean are booked for operation at 38 completed weeks; booking is done as the approach term.

5 days of elective cesarean section per week is conducted in the maternity theatre. Mothers are admitted a day prior the operation.

Patients who deliver via cesarean section are booked for postnatal clinic at interval of 2 weeks and 6 weeks.

The second site will be at Pumwani maternity Hospital, established by the Nairobi city council. It has 350 bed capacity. Pumwani Maternity Hospital has a high turnover of mothers, an approximate of 70 deliveries are carried out daily, of which an average of 10 are emergency cesarean section. Elective cesarean section is conducted by consultant from Tuesday to Friday, a minimum of 12 elective cesarean sections conducted per week. Antenatal clinic are conducted from Monday to Friday, mothers who are for elective cesarean section are booked for theatre at around 36 weeks by the consultants who conduct the operation. Family planning services are offered in the family planning clinic throughout the weekdays. Currently no active advocation of PPFP in labour wards or theatre.

The most common indication of elective cesarean section in the two sites includes;

1) 1 previous scar with CPD or other complications. E.g. (PET, GDM etc.)
2) Two or more previous scar.
3) Malpresentation.
4) Multiple pregnancy
5) Placenta previa
6) Term HIV women with high viral load.

2.4 Study Population

The study population included pregnant women between gestational ages of 36 weeks ant term who attended antenatal care and were eligible for insertion of IUCD during delivery through Elective caesarean section.

Patients who were in the antenatal wards and were planned for an elective cesarean section were also recruited.

Eligibility criteria

Inclusion criteria

- ✓ Ages eligible for study 18years -49 years.
- ✓ Consented to the study.
- Eligible for IUCD insertion according to Medical eligibility Criteria(appendix A)
- Scheduled for elective cesarean section.
- IUCD as her family planning method of choice

Exclusion criteria

Women eligible by inclusion criteria above were excluded if the subject had any of the following;

- ✓ Known allergy to copper.
- ✓ History of pelvic inflammatory disease, or complication of IUCD use.
- ✓ HIV/AIDS stage 4 diseases.
- ✓ Women with pelvic cancers (endometrial, cervical or ovarian cancer).
- ✓ Women known to have pelvic TB.
- ✓ Women with anatomic abnormalities of the uterus or the cervix which will interfere with insertion, retention of removal of the IUCD.
- ✓ Women with fibroids distorting the uterine cavity.

- ✓ Women who have high individual likelihood of exposure to gonorrhea/and or Chlamydia.

2.5 Sample Size

The study sample size was calculated based on assumption that the proportion (*p*) of women who would agree on intra-operative insertion of IUCD would be 50% since no data is available on the same. Working with this assumption and based on the following sample size formula for estimation of sample size for cohort studies, at 95% (*z=1.96*) confidence and an error margin (*ME*) of 5% the study will require to enroll 197 participants.

Adjusting for 20% loss to follow up and/or those who would end up having emergency cesarean instead of elective cesarean section, we will recruit 237 participants.

Sample size:

$n = [(z^2 * p * q) + ME^2] / [ME^2]$

$= [(1.96^2 X 0.5 x0.5) + 0.05^2] / [0.05^2]$

Where;

Z is the critical Z score at 95% confidence level = 1.96

p is the estimated proportion of women who accept intra-CS insertion of IUCD ~=50%

q = 1-p = is the estimated proportion of women who decline intra-CS insertion of IUCD ~=50%

ME is the margin of error set at 5%

NOTE:

Sample size distribution shall be done at a ratio of 1:1.both sites will be recruiting concurrently.

2.6 Study Procedure

Women (237) were enrolled in this study during late prenatal care; at the time they were booked for the elective cesarean at 36 weeks of gestation and onwards. Routine counseling was done, and a questionnaire filled appropriately. Those who accepted for the intervention signed the consent form (appendix B) and were followed through and insertion done intra-operative, thereafter followed up till 6 weeks postoperative. While those who declined filled the first part of the questionnaire (appendix C) and exit the study, reassurance of continuation of service without discrimination was made. The Cu T380A is the most widely available in Kenya, and it is the model that was used in this study.

Recruitment

Recruitment was done concurrently on both sites at a ratio of 1:1, thus each site recruited half of the sample size.

ANC

Pregnant women between the gestational ages 36 and term who attended antenatal clinic and were booked for elective cesarean section were approached by the principal investigator or the research assistant. A detailed explanation of the study purpose, procedure, benefit and risk was provided during the counseling session.

The patients were then asked if they would accept IUCD as their family planning method of choice.

Those who agreed were subjected to Medical Eligibility Criteria for IUCD use. Clients who agreed and were eligible were enrolled in the study.

Counselling Process

Routine health talks in the ANC were given as part of group counseling that normally takes place in the ANC. This was followed by one to one counseling session in a private room. The following steps were followed.

1. The patient was greeted and asked to take a seat.
2. The counselor (a trained ANC nurse) introduced herself or himself and created a rapport.
3. The patient was asked of her previous contraceptive experience, knowledge about FP and in particular PPIUCD.

4. The counsellor then explored the woman's knowledge about the benefit of pregnancy spacing and future reproductive goals, together with assessment of risk of contracting HIV/STI.
5. A brief explanation of different methods was given together with advantages and disadvantage of each FP method. Any related need such as protection from STI/HIV by using dual protection.MEC criteria was then applied.
6. Focus was then shifted to transcesarean IUCD insertion during elective cesarean; Visual aids (posters, IUCD) were used during counseling.
7. Key information was discussed together with its benefit and limitation. See (appendix D).
8. At the end of the session the clients were encouraged to ask questions and express any concerns.

Enrollment

Ante-natal clinic

Patients who had met the Medical eligibility criteria and had agreed to participate in the study then underwent the process of enrollment.

A recap of the study purpose, procedures and follow up, study benefits and risks was availed to the patient and questions entertained. This was done by a qualified nurse at the ANC

The patient was asked whether she would like to have an intracesarean insertion of IUCD. Enrollment consent was taken immediately the patient was willing, or taken on a return visit, at a later date. Women were advice to discuss with their spouse before consenting.

Those who did not consent for the method were asked to fill the first part of the questionnaire; they were adviced on the need to use any other method of contraception suitable to them.

Those enrolled had a sticker on their files and were also given a note for identification on admission.

In the wards

Study subjects were identified through the accompanying note that they were given during ANC and or the sticker on their antenatal files.

On admission Consent was taken together with the elective cesarean consent after the normal required investigations were done pre-operative. Section two of the questionnaire was filled

appropriately by the research assistant (nurse who has prior training on PPIUCD). A sticker was then stuck on their inpatient file cover to identify the IUCD acceptors.

In the theatre

In theatre a reconfirmation of the consent was done using her consent form for the study and also the Hospital consent form. This was done by the receiving nurse at the receiving area in theatre.

After removal of placenta and membranes the uterus was exteriorized and wiped. The uterine cavity was inspected for any abnormality. IUCD was placed through the lower uterine segment incision to the fundus and the tail string directed towards the cervix. A standard instruction of visual fundal placement of IUCD was provided to ensure uniformity of technique. (Appendix E). IUCD placement was within 10 minutes of placental removal. The lower uterine segment was then stitched closed.

Data was collected during immediate post-operative period as per the availed standard questionnaire by the surgeon conducting the operation. If unsuccessful the surgeon noted that including the reason for not inserting the IUCD.

Elective cesarean section was done by either Consultants, Senior registrars, or the Senior housing officer who are all skilled in IUCD insertion.

Note;

IUCD was supplied by the Division of Reproductive Health. Register will be kept in the maternity theatre to record those who had an intra-operative insertion.

IUCD used was the copper T 380 A which offers a 12 year interval of contraception.

The staff in theatre was sensitized on this study and the maternity theatre nurse in charge per shift will be the custodian of the IUCD.

A half day workshop was conducted to familiarize all the registrars on intra-cesarean IUCD insertion together with the theatre nurses. Video aid to demonstrate intra-operative insertion was provided.

To standardize infection prevention in the two sites the following was done

- Use of aseptic technique during manual insertion of the IUCD
- Sterile gloves did not need to be changed before insertion if not contaminated.
- Ensure IUCD package was opened only if the patient is eligible after intra-operative assessment.
- Ensure IUCD package is unopened and undamaged and expiring date checked.
- IUCD placed in the sterile field together with the sterile instruments.
- Sterilization of equipment and disposal of waste was carried out as per infection prevention guidelines.

Pre discharge review

Review was made on the 3rd post-operative day by the research assistants assessing any complication and data collected was filled in the questionnaire booklet (part D), the mother at that time was also reassured of the method and given both Oral and written instructions (Pamphlets containing post insertion instructions), follow up visit return note (having booked dates and the venue) this will also act as an identity for the study subjects, and lastly instruction note on how to check for the strings (appendix F,G and H)

Follow up (Postnatal clinic)

On 2nd week puerperium IUCD acceptors were reviewed at the postnatal clinic by the researcher or research assistants. The following was checked,

- Any complain
- Any fever?
- Pallor?
- Healing of the incisional wound?
- Uterine involution?
- Foul smelling lochia?
- Heavy lochia flow?
- Severe abdominal cramping?
- Willingness to continue with IUCD as a method of contraception?

Data collected was filled in part E of the questionnaire.

On 6th week postpartum

The visibility of string was verified at 6weeks postpartum. Trimming of the string was done where necessary.

Reassessment was done as for 2nd week.

Data collected was filled in section F of the questionnaire

Clients were reviewed at the postnatal clinic, their files were identified by a sticker stuck on the file cover indicating the study title and therefore channeled by the nurse in charge to the allocated consulting room.

Note:

The following was done to ensure minimal loss to follow up during the postnatal period;

- The clients contact was taken and reminder calls were made prior their appointments.
- In case the patients failed to turn up on the appointed day she would be called and next nearest appointment rebooked.
- During the post insertion counselling importance of postnatal follow up was emphasized.

Any complications or complaints arising in between allocated visits were reviewed in casualty room 7. My contacts and the contacts of the research assistants were given to the clients for any further queries or incase of any help required.

The clients were given a note that identified them as study subjects post the intervention. So that appropriate help is given when required.

Clients who did not wish to continue with IUCD had the device removed and was helped to acquire other method of family planning.

2.7 Data Collection

Data was collected prospectively for each participant using a structured questionnaire as a tool of collection. The initial data collection was done during recruitment or at the earliest appointment attended by an eligible woman. Women were approached after their antenatal appointment and assessed for study eligibility. Consent was obtained by a research assistant. Participation was explained, any question answered and those who agreed signed consent forms. The recruited women were asked to fill in a demographic questionnaire and were also provided with relevant information concerning their pregnancy and other relevant obstetric, gynaecological, medical history.

The second contact with the study team was made during admission for delivery. The women were asked to consent for IUCD insertion along with the consent for elective caesarean section. A section of the questionnaire was filled on admission. During the operation the surgeon filled section c of the questionnaire and also documented on the operation notes whether the IUCD insertion was conducted as planned and this information was collected by the research team during the early post-operative period. Women were also reviewed on the 3rd postoperative day.

During discharge from hospital the women were booked for a follow up appointment at two weeks post-delivery. Each woman was examined during the appointment to establish any complication arising. At 6 weeks postoperative a speculum examination was done to visualize the string.

There was a standardized section on the questionnaire for each planned visit (A-F) and a place to add any valid additional information.

The Research Team

The research team included five individuals, these are the researcher (Dr Balleith.B Khamis) and 2 research assistant in each site. The researcher;

- Supervised the two sites and provided materials to the sites.
- Conducted a half day work to sensitise the staff on the study.
- Assisted in postnatal reviews and managed any arising complications.
- Collected the filled questionnaires.
- Made reminder calls to patients.

The research assistants are qualified nurses working in the mentioned sites. At least one of them had been trained on PPIUCD. Their roles were:

- Counselling and recruitment of patients in the ANC.
- Revisit the patients in the ward once they were admitted by the admitting doctor. Part B of the questionnaire was filled at this point.
- Third post operative day review and filling of the questioner, post insertion counselling and provision of the materials for post insertion instructions.
- Post discharge follow up at 2^{nd} and 6^{th}, filling of the questionnaire.

2.8 Data Management and Analysis

Data entry was conducted in a continuum during the patients follow up. The research assistants inspected all questionnaires for completion during the final follow up and any missing data filled in.

Data was collected using structured questionnaires and entered into a password protected Microsoft Access Database. The hard copy data forms were stored in a lockable cabinet either in the statistician's office or the Principal Investigator's locker. Upon completion of Data entry, hard copy forms were compared with the entered data to identify errors and corrections made appropriately.

Descriptive statistics was carried out where discrete variables were summarized with frequencies and percentages while continuous variables were summarized using measures of central tendency such as mean, median, mode and standard deviation.

The rate of acceptance of intra-operative insertion of IUCD was estimated using simple proportions. Factors associated with acceptance of intra-operative insertion of IUCD were identified using Chi-squared tests and Fisher's exact tests for nominal variables and t-tests for continuous variables. During multivariate analysis, independent factors associated with acceptance of intra-operative insertion of IUCD were identified using multinomial logistic regression.

2.9 Ethical Considerations

Permission to conduct this study was obtained from the Department of Obstetrics and Gynaecology at the University of Nairobi. Approval from the Kenyatta National Hospital Ethical review committee was obtained. In addition the following ethical principles were considered throughout the conduct of the study.

Beneficence

At the time of counseling the opportunity was taken to make participants aware of the currently available methods of family planning if they opted not to participate in the study or desire short term methods of family planning. These clients were referred to appropriate providers if they intended to use the other methods. Patients who enrolled in the study were sensitized on IUCD as a family planning method prior to insertion during the antepartum period. Any misconceptions about IUCD and other family planning methods were noted and appropriate information provided to clients. Advantages of IUCD as a long term method which does not interfere with lactation was emphasized.

Confidentiality

Personal identifiers like clients' names were not collected in the questionnaire. On being recruited into the study every participant was allocated a unique identifying number. This number was used as the identifier for clinical and demographic information within the study databases. Access to this information was restricted to the researcher and individuals involved in the study at the data collection or analysis stages. Information obtained shall ONLY be used for the purpose of the study alone.

At the completion of the descriptive study information linking personal identities (name, location of dwelling) to a study identification number will be archived in a separate file and removed from any existing research database.

Individual Consent Process

Written informed consent was taken after explaining the study objective the procedures to potential participants. Participation was voluntary and participants were informed that the decision not to participate will not impact on the quality of care they receive. Consent was taken by research assistant knowledgeable on the study and adequately trained on effective communicate with patients.

Infection prevention measures

Since this was an interventional study, infection prevention strategies were put in place, sterility of the procedure was diligently preserved, so as not to expose the subjects to any harm. (See page 22)

Any complication arising

Patients were well taken care of and any complaint was carefully listened to and assessed. Removal of IUCD was done for those who requested removal. Imaging studies were done for the missing IUCD string at 6 weeks to ascertain location with the right management instituted immediately.

Feedback of information

The hospital will be informed on the clients' views concerning provision of IUCD and family planning as a whole at the facility.

2.10 Study limitations

Generalisability of findings

The general applicability of the study findings could be limited by the study setting due to the following;

The expertise of providers may differ in other sites therefore it may be difficult to generalize results of expulsion and complication rates.

The patient population attending KNH and Pumwani maternity Hospital can be considered to be an atypical population because they were more likely to be referrals and the hospital is set in an urban location. Most facilities in the country are rural and most deliveries occur in first and second level referral facilities. These factors could introduce selection bias in the study.

Self-selection bias

The relationship between IUCD uptake and participants' characteristics could be different for women who participated in the study and those eligible for recruitment, including women who refused to participate. Refusal to participate that result from procedures used to select subjects i.e. voluntary participation and other factors that influence study participation have the potential to introduce self-selection bias in the study.

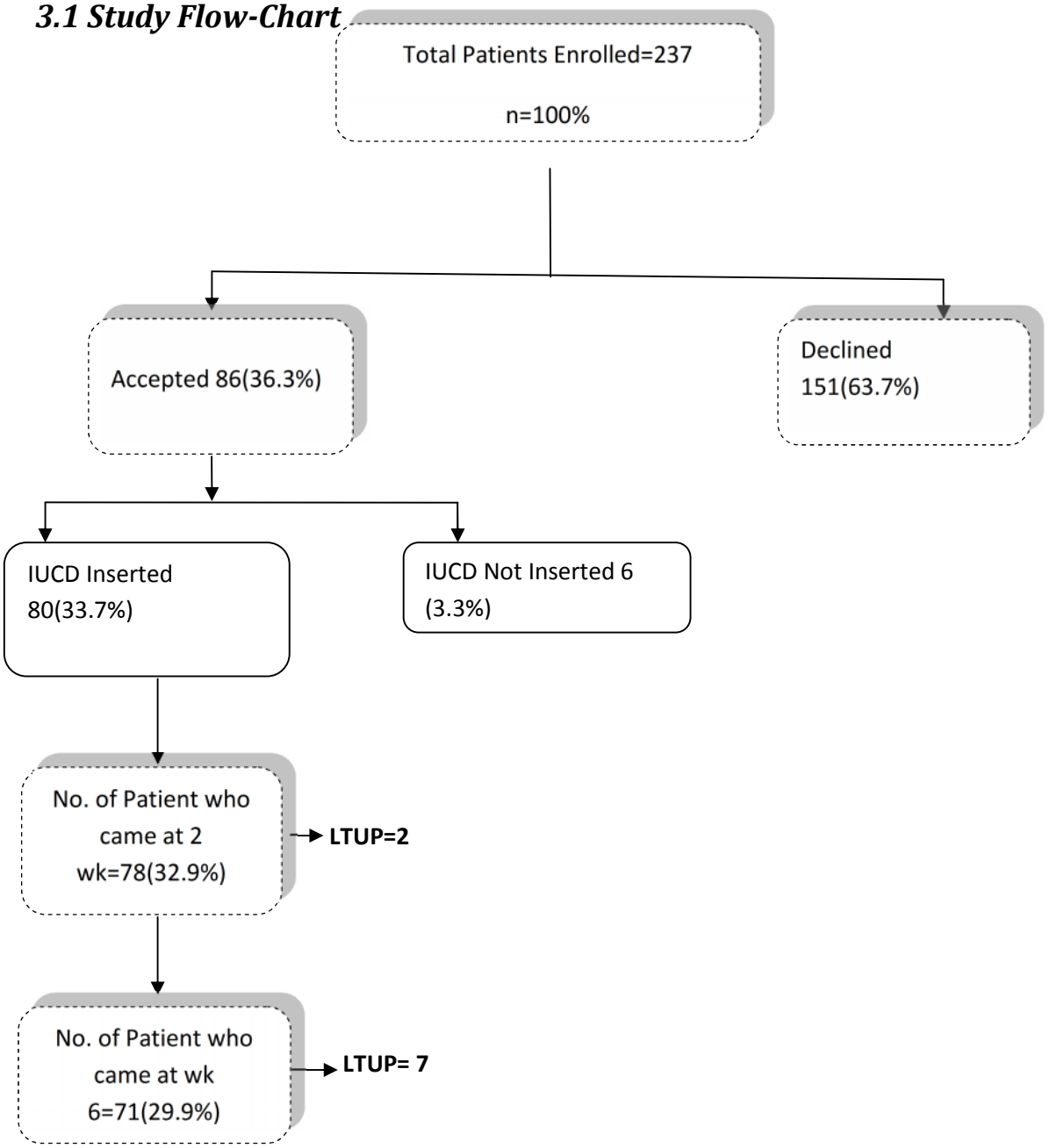
Follow up

The scope of the study is limited to short time follow up of patients in the postpartum period. This is rather short length of follow up is imposed by the time period available for the study. Longer time follow-up would be desirable to determine whether there is sustained use of IUCD beyond the postpartum period.

Lost to follow up, in the study 9 subjects were lost to follow up.

CHAPTER THREE: RESULTS

3.1 Study Flow-Chart



Above is a flow chart of the study population, a total of 237 eligible antenatal mother were approached and all accepted to participate in the study. Routine counseling was done on postpartum family planning and transceserean IUD insertion . A total of 81 antenatal mothers accepted for the intervention. Intra-operative IUCD was inserted in 80 of the patients.

Six of the mothers who accepted intra-operative IUCD did not take up the method due to the following reasons;

1. 4 underwent emergency c/s
2. One had PPH secondary to uterine atony
3. One had intramural fibroid that was distorting the uterine cavity

Follow up was done at 3rd post operative day, at 2 weeks and 6 weeks post operative. At 2 weeks 2 patients were to follow up, and by 6th week a total of 9 patients were lost to follow up.

3.2 Findings

Two hundred and thirty seven (237) mothers booked for elective caesarian sections were studied in Kenyatta National Hospital and Pumwani Maternity Hospital. The mothers mainly belonged to 25-29 years and 30-34 years age group contributing 76.8% of all the mothers studied. Majority of the mothers were married (85.4%) and high literacy level with only one (0.4%) mother reporting no education. In addition, there was a high rate of unemployment with 49.3% of the mothers being unemployed while 27.8% were self-employed and 22.8% in salaried employment (Table 1). Majority of the mothers had given birth to at least a child before with 11.4% being nulliparous and 48.1% and 34.6% para 1 and 2 respectively (Figure 1). Similarly, 42.6% and 31.6% of the mothers were gravidae 1 and 2 respectively (Figure 2).

Table 1: Socio-Demographic Characteristics of the Study Population

(n =237)

Variable	n	%
Age		
20 - 24	31	13.1
25 - 29	96	40.5
30 - 34	86	36.3
35 - 39	21	8.9
40+	3	1.2
Marital Status		
Single	27	11.4
Married	202	85.2
Divorced	6	2.5
Windowed	2	0.9
Level of Education		
None	1	0.4
Primary	87	36.7
Secondary	87	36.7
University	62	26.2
Employment		
Unemployed	117	49.4
Self-employed	66	27.8
Salaried Job	54	22.8

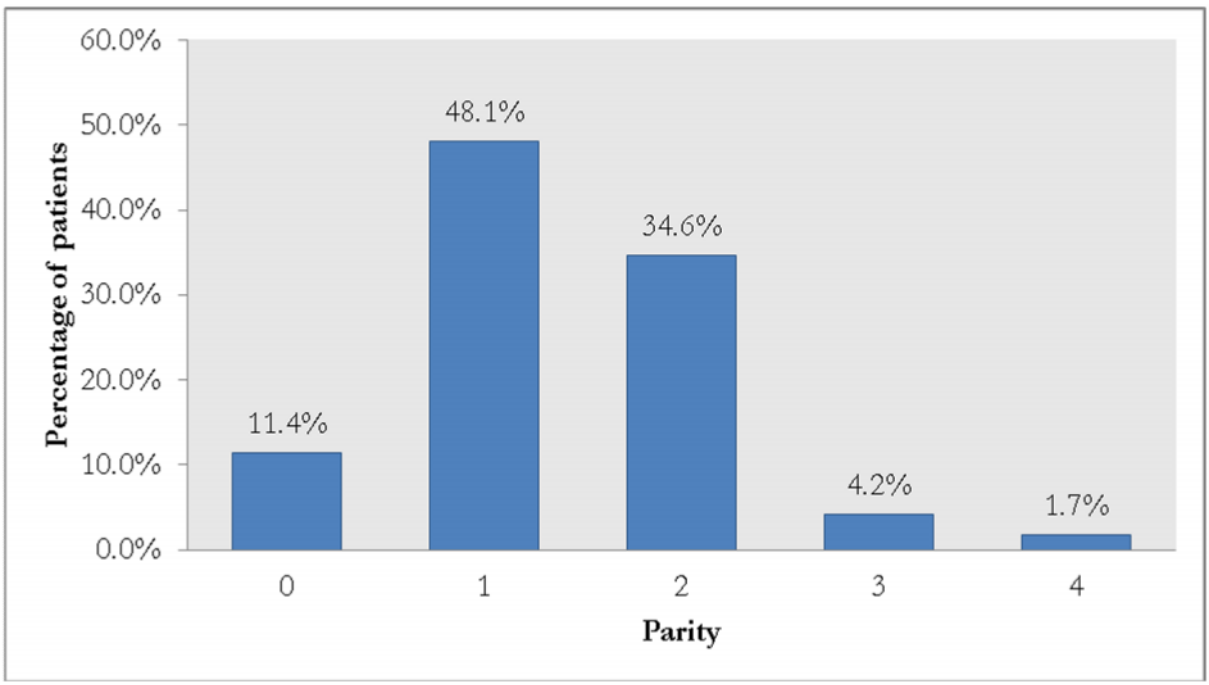


Figure 1: Parity

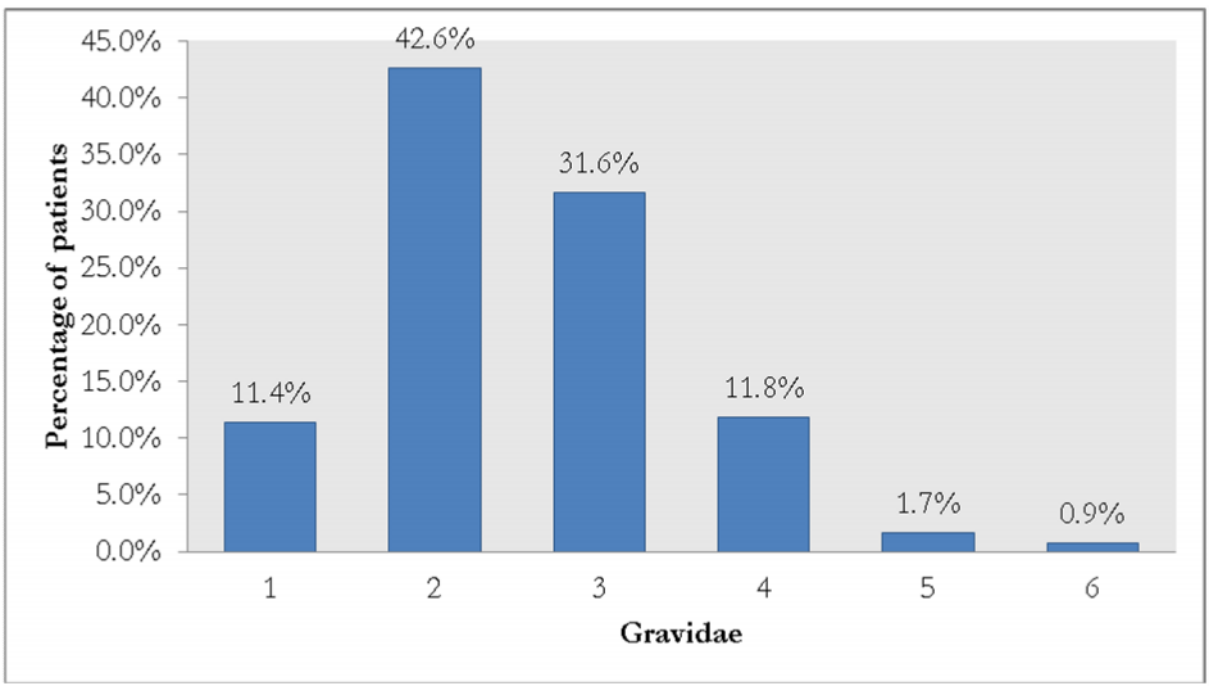


Figure 2: Gravida

3.2.1 Acceptance and uptake of Intra-operative IUCD

Acceptance rate of IUCD insertion stood at 36.3% (95% CI 30.1-42.5%). Uptake rate of IUCD was 91% with 9% of the mothers accepting the method but IUCD was not inserted (Figure 3).

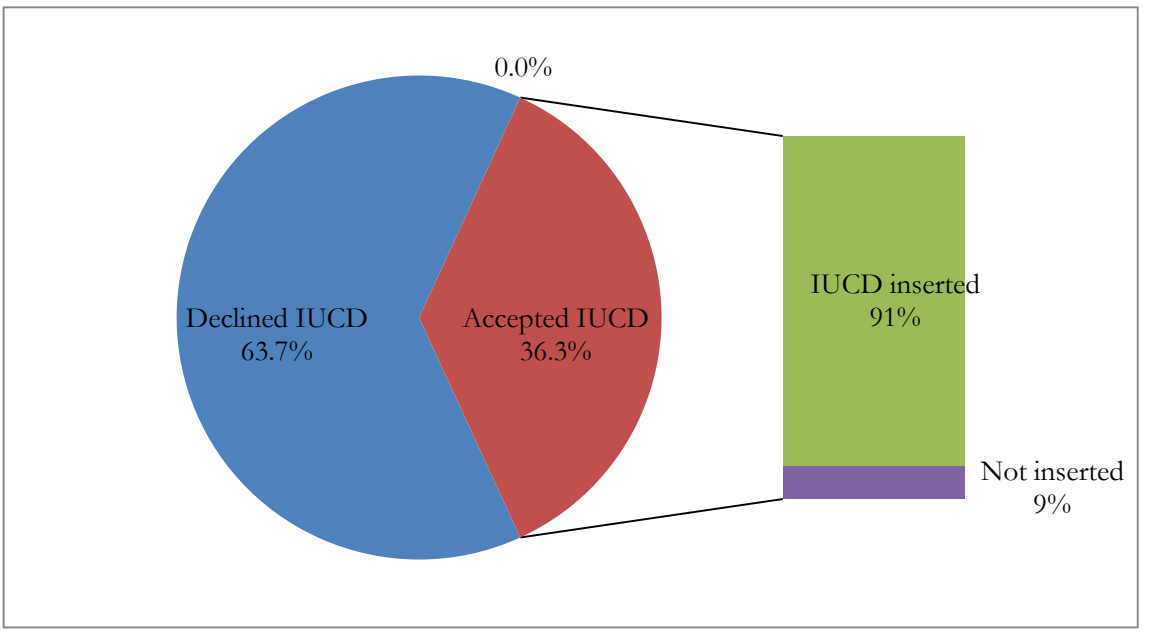


Figure 3: Acceptance and uptake of Intra-operative IUCD Placement

The 9% difference between the acceptance and uptake was strictly due to loss to eligibility criteria at the time of Cesarean Section, 3 underwent emergency section, one had intramural fibroid and one had PPH secondary to uterine atony.

Mothers who declined (63.7%) gave reasons for their decline. The most frequently stated reason was that IUCD might migrate to other parts of the body, according to 30.5% of the mothers. A substantial proportion (21.2%) of the mothers thought IUCD might irritate the partner during sexual intercourse while 14.6% thought it was a foreign body hence their refusal to take up. Some other reasons given by the mothers for declining IUCD were their fear that it can cause abortion (10.6%) or cancer (6%) while 9.3% were satisfied with their family planning previous methods (Figure 4).

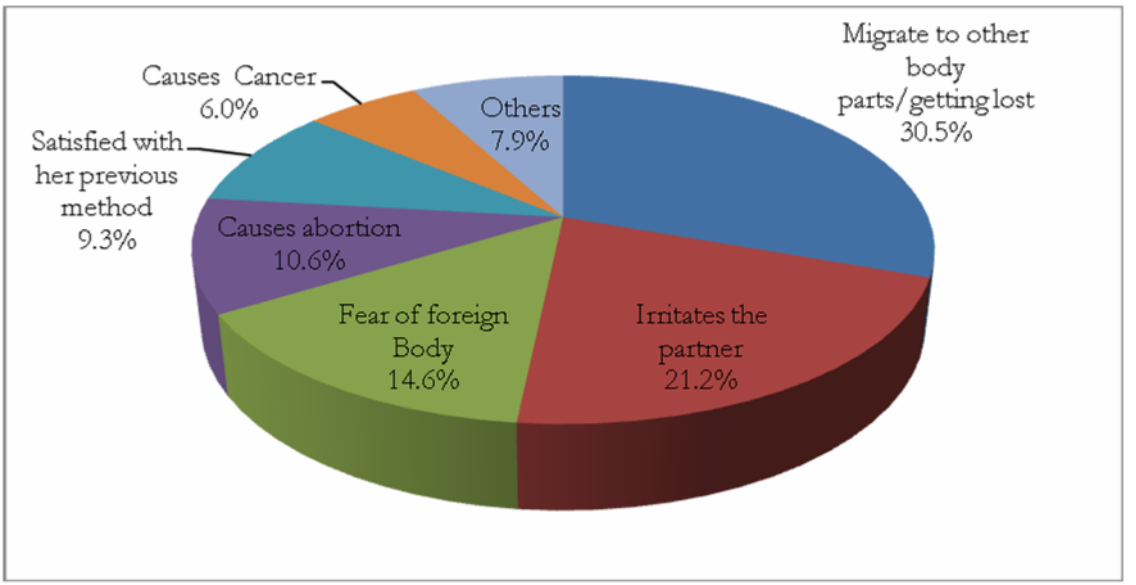


Figure 4: Reason for refusal of intra-operative IUCD insertion (n=151[63.7%])

3.2.2 Socio-demographic factors associated with acceptance of intra-operative IUCD

As compared to the single mothers, those who were married were more likely to accept IUCD insertion, OR 2.5 (95% CI 1.0-6.0), p=0.038. Also, higher education increased the chances that the mother would accept IUCD. Those with university level of education were at a higher chance of accepting the method as compared to those with primary level of education or lower, OR 2.5 (95% CI 1.2-4.9), p=0.009. the same trend was seen among those with secondary level of education who were 1.8 times more likely to accept than those with lower education, though it was on borderline statistical significance (p=0.060). Similarly, being employed increased the mothers likelihood of accepting IUCD insertion, OR 1.7 (1.0-2.9), p=0.049. Age of the mother did not influence significantly whether a mother accepted or declined intra-operative IUCD (Table 2)

Table 2: Association between socio-demographic factors and acceptance of Intra-operative IUCD

Variable	Acceptance of Intraoperative IUCD				OR (95% CI)	P value
	Yes		No			
	n= 86	%	n=151	%		
Age						
20 - 24	8	9.3	23	15.3	1.0	
25 - 29	40	46.5	56	36.7	2.1 (0.8-5.2)	0.104
30 - 34	31	36.0	55	36.7	1.6 (0.6-4.1)	0.300
35 - 39	7	8.1	14	9.3	1.4 (0.4-4.8)	0.557
40+	0	0.0	3	2.0	-	0.314
Marital Status						
Single	7	8.1	20	16.0	1.0	
Married	79	91.9	123	82.0	2.5 (1.0-6.0)	**0.038**
Level of Education						
Primary and below	23	26.7	64	43.3	1.0	
Secondary	34	39.5	53	34.7	1.8 (1.0-3.5)	0.060
University	29	33.7	33	22.0	2.5 (1.2-4.9)	**0.009**
Employment						
Unemployed	35	1.2	82	2.7	1.0	
Employed	51	30.2	69	26.7	1.7 (1.0-2.9)	**0.049**

3.2.3 Association between obstetric factors and acceptance of intra-operative IUCD insertion

Increased parity was seen to have a three-fold likelihood of acceptance of IUCD method as compared to nulliparous mothers, OR 2.8 (95% CI 1.0-7.6), p=0.040. Similarly, gravida 2 or more mothers were more likely to accept IUCD insertion compared to gravida 1 mothers, OR 3.7 (95% CI 1.3-11.1), p=0.013. Also, women who desired more children were more likely accept IUCD as compared to those who did not want any more children. Those who desired 1 more child were 1.8 times more likely to accept IUCD while those who desired 2 or more were 2.5 times more likely to accept method. Other factors such as duration since last delivery and child spacing preference was not significantly associated with whether a mother accepted or declined IUCD method (Table 3).

Table 3: Association between obstetric factors and acceptance of intra-operative IUCD

Variable	Acceptance of Intraoperative IUCD				OR (95% CI)	p value
	Yes		No			
	n=86	%	n= 151	%		
Parity						
0	5	5.8	22	14.6	1.0	
1 or more	81	94.2	129	85.4	2.8 (1.0-7.6)	**0.040**
Gravida						
1	4	4.7	23	15.2	1.0	
2 or more	82	95.3	128	84.8	3.7 (1.3-11.1)	**0.013**
Duration since last delivery						
< 1	3	3.7	3	2.3	3.3 (0.7-15.3)	0.118
1 - 3	25	30.9	54	41.9	0.8 (0.3-1.7)	0.511
4 - 5	39	48.1	49	38.0	1.3 (0.6-2.9)	0.503
5+	14	17.3	23	17.8	1.0	
How many more children						
0	31	36.0	80	53.0	1.0	
1	33	38.4	47	31.1	1.8 (1.0-3.3)	0.054
2 or more	22	25.6	23	15.9	2.5 (1.2-5.1)	**0.012**
How long do you wish to wait						
1 - 3	21	38.2	39	54.9	1.0	
4 - 6	31	56.4	29	40.8	2.0 (1.0-4.1)	0.065
7+	3	5.5	2	4.2	2.8 (0.4-18.0)	0.266

3.2.4 Adverse Events of Intra-operative IUCD Placement.

There were minimal complications recorded between the day of IUCD insertion and 6 weeks later. The complication that was noted immediately after insertion was PPH that occurred in 1.3% of the mothers. Three days later, 3.8% of the mothers had heavy lochia flow and another 3.8% had severe cramping. Sepsis was recorded among 3.8% of the mothers after 2 weeks post-operation and heavy lochia in 2.6% of the mothers. At 6 weeks, the only complication that was noted was sepsis in 1.4% of the mothers while the rest were normal with 84.5% having resumed sexual activities. Strings were visualized in 93% of the mothers (Table 4).

Table 4: Adverse Events of Intra-operative IUCD insertion

Variable	n	%
Immediate (n=80)		
PPH	1*	1.3
Expulsion	0	0.0
Severe Cramping	0	0.0
None	79	98.8
3rd Post Op day (n=80)		
Heavy Lochia flow	3	3.8
Signs of infection	0	0.0
Severe Cramping	3	3.8
None	74	92.4
2 wks Post op (n=78)		
Sepsis	3	3.8
Heavy Lochia flow	2	2.6
None	73	93.6
6 wks Post op (n=71)		
Sepsis	1**	1.4
Heavy Lochia loss	0	0.0
None	70	98.6.
Visualization of strings (n=71)		
Yes	66	93.0
No	5***	7.0

.*Only 1 out of the 80 who had intra-operative insertion had PPH immediate postoperative this was due to uterine atony which was managed by utero-tonics. There was no expulsion of IUCD despite heavy bleeding.

**By 6th week only 1 out of the 71 was noted to have foul smelling per vaginal discharge. She was covered with antibiotics and asked to be reviewed in 2 weeks with a plan of removal of IUCD in case there was persistence of

infection. Note 3 cases of puerperal sepsis at 2weeks were covered with antibiotic and all resolved by 6 weeks appointment.

***Out of the 71 patriurents 66(93%) had their strings visualized and 5 (7%) had no string protruding at the external os. Imaging done showed fundal placement of the IUCD in three patients who had sub involutes uterus, one was displaced IUCD and one had expelled (1.4%). Removal was done for the displaced IUCD .Alternative family planning method was chosen by the two patients.

3.2.5 Discontinuation of IUCD at 6 weeks

Out of 71 mothers who were still in the study at 6 weeks, the rate of discontinuation of IUCD was 5.6% (4/71), (Figure 5) .Out of the four who discontinued, (2/71) two had self request for removal due to opposition from their husbands, one (1/71) had IUCD removed due to displacement and one had unknowingly expelled the IUCD. For all who discontinued alternative FP methods were discussed and chosen. (. Among the 94.4% who wished to continue with the IUCD method, there was an average satisfaction of 8 measured on a scale 1 to 10 (1 being the least and 10 the utmost satisfaction).

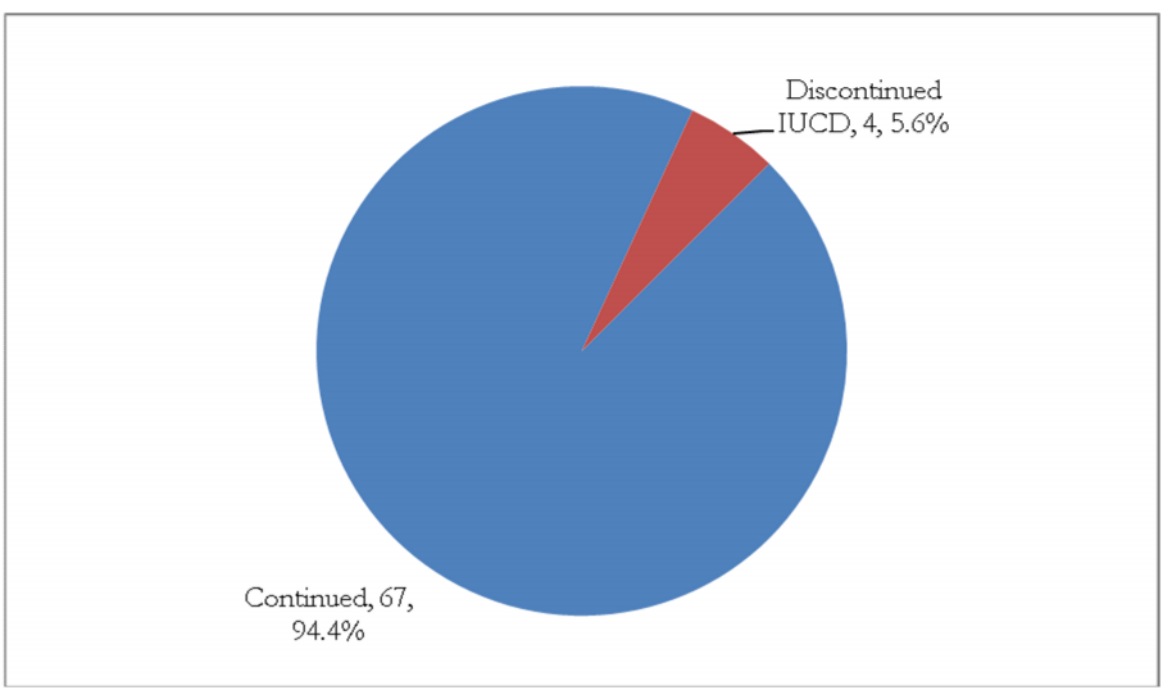


Figure 5: Discontinuation of IUCD after intra-operative placement

Reason for discontinuation included 1(1.4%) expulsion, 1(1.4%) displacement, 2(2.8%) spouse dissatisfaction with their choice of family planning. Removal was done at 6 weeks and other choice of FP was given.

3.3 Discussions

This study was carried out to determine acceptability, uptake and outcome of intra-operative IUCD placement together with assessing the success that is the continuation rate at the end of the puerperium in a cohort of mothers who underwent elective cesarean section and required a long term reversible method of contraception.

Intra-operative IUCD acceptance rate was 36% and uptake was at 33% this being higher uptake compared to the trend in current contraceptive use where IUCD has only been taken up by 1.6 % of the general population [2] .A study conducted in Embu PGH by Ndegwa et al found acceptability of post placental IUCD at72% and uptake at 63% for immediate postpartum IUCD through both vaginal and intracesarean routes. This higher acceptance and uptake in Embu is expected since it is the centre of PPIUCD revitalization in Kenya [14]hence awareness of PPIUCD in Embu was greater than in our study population. Nationwide however intraceserean insertion is rare and almost non existent in our service delivery statistics. Our findings therefore suggest that, just offering the service resulted in higher uptake than the national rates; however sensitization as done in Embu can increase the uptake significantly.

Misconception and fear for IUCD still exist; only 9.3% of those who refused had an alternative Family Planning method of their choice. 90.7% either feared IUCD as a choice or had a misconceptions such as “IUCD causes cancer”, “IUCD causes abortion”, and “migrates to other body parts”. This is also reflected in the data provided by the Kenya Demographic Health Survey [2]

Marital status and parity were the two reproductive characteristics that influenced acceptance. Increased parity and being married more than doubled acceptance. This finding compares with a local study that showed married women were more likely to take up postpartum IUCD than the unmarried [14]. Knowledge and employment were noted to be key exposures to accepting intra-operative IUCD placement. .

Safety of its use has also been demonstrated in this study as evidenced by minimal complications. Puerperal sepsis was at 1.4 % these rates are comparable to local study done on immediate post placental IUCD (Ndegwa et al) rate of 1.8% of pelvic infection [14].

Tranceserean Insertion is known to have lower rates of expulsion at 1.2% compared to vaginal 9.6% in a study done in China by Chi IC et al [23] such low rate were reflected in our study having expulsion rate of 1.4%, whether this very high retention rate relates to the direct visual

fundal placement by the surgeon or to the undilated cervix at the time of elective cesarean is unclear. A Cochrane database of systematic reviews 2003 reports an expulsion rate of 2.4 to 5.2% by the end of first year [15].

The success rate of intra-operative IUCD placement can be measured by the continuation rates which were at 94.4% This results are similar to local studies[14, 22] which reported continuation rate of postpartum IUCD at 90.5% in 6 weeks and 80% in 6 months respectively. A regional study done in Uganda at Mulago hospital by Lester et al compared intra-cesarean insertion of the copper T 380A verses 6 week post cesarean insertion found that uptake was better in immediate intra-cesarean insertion compared to interval insertion with better continuation rate of 83% in immediate verses 53% in delayed insertion at 6 months[40].

Longer duration of follow up to asses on the rate of expulsion and discontinuation would have been informative in these patients. Follow up on the antenatal mothers who declined insertion would have also helped in assessing the relative risks of the mentioned outcomes.

This study had minimal loss to follow up (9 study subjects).

This study was done in KNH and Pumwani maternity hospital thus capturing mothers from wider area which could almost reflect the population of antenatal mothers booked for elective cesarean section in other hospitals, thus generalisabilty of our findings can be safely applied to urban and peri -urban setting.

3.4 Conclusion

The acceptability of intra-operative placement of IUCD in mothers undergoing elective cesarean section was high. Its uptake (93% of those who accepted) has been encouraging and its safety demonstrated. With highest retention rates (1/71) compared to other timings and routes of insertion and low rate of discontinuation at 6 weeks.

Maternal marital status, education and employment are seen to play a role in the acceptance of IUCD thus with a progress in these two sectors the acceptance and uptake of Intra-operative IUCD placement is likely to increase. The demand on the hospital resources and expense to the patient shall be limited to the cost of an IUCD as the device is inserted by the same surgeon doing the cesarean.

Such practices shall reduce missed opportunities for long acting reversible contraception and subsequent revisits for IUCD procedures at a later date from time of delivery.

3.5 Recommendations

Intra-operative IUCD placement services should be routinely offered to eligible antenatal mothers planned for elective cesarean section.

Antenatal counseling should create awareness of the existence of IUCD and it safety on intra-operative insertion.

The ministry of health should develop policies for innovative application of IUCD use to increase its uptake.

More studies to be done to evaluate the relative risk of anticipated complications with longer follow up. Similar studies are also to be done outside the tertiary facility.

Active advocacy for IUCD to reduce the widespread misconception, create awareness and access for the Device.

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Appendices

Appendix A

MEDICAL ELIGIBILITY CRITERIA (MEC)

Category 1

(Who should use IUCD)

- Women of reproductive age
- Parous women of any parity
- Women who want long-term, highly effective protection against pregnancy
- Women who are 4 weeks or more postpartum
- Women following first trimester abortion or ectopic pregnancy
- Women who have delivered by caesarean section
- Women with irregular menstrual cycles without heavy bleeding
- Women with cervical ectopion (erosion), and those with uterine fibroids without distortion of uterine cavity
- Women with past history of PID who have subsequently conceived
- Women with non-pelvic TB
- Women with multiple risk factors for CVD
- Women with current IHD, DVT/PE, stroke and uncomplicated valvular heart disease
- Women with diabetes with or without complications
- Women with breast disease and those with benign ovarian tumours
- Women with liver and gall bladder diseases

Category 2

(Use with care)

- Women aged <20 years
- Nulliparous women
- Postpartum less than 48 hours (or immediately after expulsion of placenta)
- Following second trimester abortion (where there is no sepsis)
- Past PID without subsequent pregnancy
- Increased risk of STIs including HIV or is HIV infected, as well as those with AIDS but doing well on ARVs
- Women having heavy and/or prolonged vaginal bleeding (may be regular or irregular)
- Women with endometriosis or severe dysmenorrhea
- Anemia's– Iron deficiency anaemia, Sickle cell disease, Thalassaemia
- Women with valvular heart disease (complicated by pulmonary hypertension, risk of atrial fibrillation and those with history of SBE)
- Women whose partners are at increased risk of STI

Category 3/ 4

(who should not use)

- Postpartum women after 48 hours and before end of 4 weeks
- Women with peuperal sepsis or immediately post septic abortion
- Women with unexplained vaginal bleeding before evaluation
- Women with trophoblastic disease, bening or malignant
- Women with pelvic cancer (cervical,endometrial and ovarian cancers)
- Women with fibroids distorting the uterine cavity
- Women with anatomical abnormalities of the uterus and cervix which interfere with insertion and retention of IUCD.
- Women with current PID or current purulent cervicitis
- Women who have high individual likelihood of exposure to gonorrhea and/ or chlamydia
- Women known to have pelvic T.B

Appendix B

INFORMED CONSENT FORM FOR "ACCEPTABILITY , UPTAKE AND SAFETY OF INTRAOPERATIVE IUCD PLACEMENT ."

This Informed Consent Form has two parts:

1. Information Sheet (to share information about the research with you)

2. Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

My name is Dr Balleith Bukhite Khamis. I am a doctor who is studying to specialize in the field of Obstetrics and Gynecology. I' m currently conducting research that is titled "Acceptability, Uptake And Safety Of Intra-operative IUCD Placement ".

Purpose of the study

The purpose of this study is to assess the acceptability of intra-operative IUCD placement in patients who undergo elective cesarean. This study will help us offer long term family planning method to women who need such a service and prevent missed opportunity.

I am going to give you information and invite you to be a participant of this research. There may be some words that you do not understand. Please ask me to stop as we go through the information and I will explain.

Type of Research

This study is to asses acceptability of intra-operative IUCD insertion on patients who are undergoing elective cesarean section. A total of 237 mothers will be recruited in the study and for those who consent will have IUCD placement intra-operative.

Voluntary Participation /Right to Refuse or Withdraw

It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this hospital for your condition. You have a right to refuse or withdraw your participation in this study at any point.

Procedures and Protocol

Mec criteria

You will be asked some few questions to ensure you are eligible to use this method.

Counselling

If you agree to be interviewed you will undergo a brief counseling session on Postpartum family planning in general .The method of immediate insertion of IUCD intra-operative will be introduced to you and all the advantages and disadvantages discussed.

You will thereafter be free to ask any question where you do not understand. For those who choose to participate in the study a written consent shall be signed.

For those who would opt out this shall be your exit point in this study.

You shall receive the exact same services whether or not you are part of this research.

Enrollment

Once the counseling session is done you will be asked whether you want to participate in this study. You will be encouraged to inform your partner and make an informed decision.

Section one of the questionnaire shall be filled at this point.

On admission

Consent will be taken for intra-operative IUCD insertion together with the consent for elective cesarean section. Section b of the questionnaire shall be filled.

In theatre

A reconfirmation of the consent shall be done. The surgeon shall do a second screening to assess suitability of the IUCD on the patient. Intra-operative IUCD shall be placed by the surgeon doing the cesarean section after removal of the placenta for those eligible, following the standard procedure outlined.

Immediate post-operative

You shall have close observation to ensure you have no complication post operation.

Pre discharge review

Before you are discharged a doctor will ensure you are well and that you have no problems. You will be advised on symptoms that will need you to come back to the hospital before the follow up appointment. You will also be told how to take care of your birth canal and check whether the IUCD is still in place.

You shall be given post insertion instruction pamphlets, a card containing information on the type of IUCD inserted and date and venue for follow up visit.

You shall also be advised on the importance of follow up visit and shall be given appointment at two weeks and 6 weeks postoperative.

Follow up visits

First visit

At 2 weeks you will undergo a physical examination where we will check for wound healing, any signs of infection. We will also ask a few questions on whether the IUCD has suited you. The review shall be done by the doctor (researcher or research assistant)

You will then be given your clinic card and asked to return after 6weeks for a review by the doctor. If you don't attend the follow up visit you will be telephoned and reminded of the visit. Should you not be able to attend a telephone interview will be carried out and you will further be advised on the importance of the follow up visit and the need to do so. You will be provided with your clinic number and asked to come back at you earliest convenience.

Second visit

Reassessment shall be done as of week 2, Trimming of the strings shall be done if necessary and your satisfaction assed.

This shall be the end of the study, incase of any queries after the 6 weeks you can be seen in clinic 66 or casualty gynaecology room.

Risks and Discomforts of being in the study.

In this study we may ask you personal questions that may cause discomfort e.g. HIV status, your future fertility plans etc. You do not have to answer any questions you do not wish to.

The abdominal and pelvic exam may be uncomfortable and cause you some discomfort and embarrassment.

The intrauterine device may be expelled and require you to come back to the clinic before time of your appointment. Heavier and more painful menses ,especially first few cycles may be experienced. The IUCD does not protect against STI's including HIV/AIDS. There may be a small risk of uterine perforation.

At any time during the study if you become distressed or uncomfortable, the contact person will be readily to assist you.

Benefits

You may benefit from this study by increasing your knowledge about family planning methods, having the IUCD inserted at a convenient time and going home after delivery with a long term reversible family planning method which does not interfere with lactation. You will have an opportunity to be inserted IUCD by the surgeon himself.

Confidentiality

The information obtained will be treated with confidentiality and only available to the principal investigator and those within the ward should you be admitted. Your name will not be used. Any information about you will have a number on it instead of your name. It will not be shared with or given to anyone. We will not be sharing the identity of those participating in the research.

Sharing the Results

The knowledge that we get from doing this research will be shared with the policy makers in the Ministry of Medical Services, Ministry of Public health Services and doctors through publication and conferences. Confidential information will not be shared

Compensation

There is no compensation offered in this study.

Alternatives to participation

You may choose not to participate in the study. If so, you will still continue to receive antenatal care, delivery and postnatal care from KNH. You will also continue to receive counselling on family planning methods as is part or antenatal and postnatal care. You will still be referred to the family planning clinic for contraceptive methods when you are comfortable to seek them. Your relationship with staff will not be affected in any way if you do or do not participate or if you enter and withdraw later.

Who to Contact

If you wish to ask questions later, you may contact:

Dr Balleith Bukhite Khamis

Mobile Number; 0722675666

If you have any ethical concerns you may contact;

KNH/UON-ERC

P.O.BOX 19676 Nairobi (code 00202)

Telephone no. 254-020-2726300 Ext 44355

This proposal has been reviewed and approved by UON- Department of Obstetrics/Gynaecology - Kenyatta National Hospital Ethics Committee, which is a committee whose task it is to make sure that research participants are protected from harm.

PART II: Certificate of Consent

I have read the above information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant_____

Date _____

If Non -literate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ Thumb print of participants.

Signature of witness _____

Date _____

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that an interview will be conducted to collect information. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name of Researcher:_____

Signature of Researcher /person taking the consent_____

Date _____

KISWAHILI VERSION

FOMU YA MAKUBALIANO YA KUJIUNGA NA UTAFITI

ANWANI: Acceptability,Uptake And Safety Of Intra-operative Iucd Placement .

Fomu hii ya makubaliano ina sehemu mbili

1. Habari itayokukusaidia kukata kauli
2. Fomu ya makubaliano(utakapo weka sahihi)

Utapewa nakala ya fomu hii.

Sehemu 1: Ukurasa wa habari

Kitambulizi

Jina langu ni Dr Balleith Bukhite Khamis. Mimi ni Daktari ninaesomea Ugainakologia. Kwa sasa nafanya utafiti kwa inwani ya "Acceptability, Uptake And Safety Of Intra-Operative IUCD Placement ."

Nia Ya Utafiti Huu

Nia ya utafiti huu ni kutathmini kama wazazi wangependa kuwekewa IUCD wakati wanapofanyiwa upasuaji wa kuzalisha. Utafiti hii itatusaidia kuboresha njia za upangaji uzazi. Kufahamu haya kutawawezesha washika dau kuwashauri wanawake wengi wajawazito kuhusu njia hii ya upangaji uzazi hasaa ambao hufika hospitalini wakati wa kujifungua na wanaoweza kuhitaji mbinu za kupanga uzazi.

Nitakupatia habari ya utafiti huu na kukualika ujiunge na utafiti huu. Kukikuwapo na ujumbe wowote usioufahamu. Tafadhali nisimamishe popote patakopoleta tashwishi.

Aina Ya Utafiti

Utafiti huu ni kutathmini kama wazazi wangependa kuwekewa IUCD wakati wanapofanyiwa upasuaji wa kuzalisha.

Haki ya kukataa utafiti

Unaweza ukachagua kutoshiriki katika utafiti huu. Ukiamua kutoshiriki, utapata uuguzi wa kabla na baada ya kujifungua katika hospitali kuu ya Kenyatta . Pia utaendelea kupokea

ushauri kuhusu njia za kupanga uzazi. Aidha, utaelezwa ni njia zipi za kupanga uzazi ambazo unaweza kuzitumia. Uhusiano wako na wafanyikazi wa hopspitali hautatiwa mashakani iwapo utakosa kujihusisha na utafiti huu. Niuamuzu wako kama ungependelea kuendelea na utafiti.Uko na haki kamili ya kujitoa katika utafiti wakati wowote unapoamua.

Utaratibu wa utafiti

Mec criteria

Utatakikana kujibu maswali kadhaa kubaini iwapo unaweza kutumia njia hii ya kupanga uzazi.

Ushauri

Utashauriwa kuhusu njia tofauti za kupanga uzazi. Utafahamishwa kuhusu njia ya kupanga uzazi ya IUCD na kuelezwa mema na mabaya ya njia hiyo. Pia, utakaribishwa kuuliza maswali kuhusu chochote ambacho haukielewi. Aidha, una fursa ya kukataa kuyajibu maswali yetu na hautaiweka fursa yako ya kutibiwa matatani. Iwapo utakubali kufanya mahojiano, utalazimika kutia sahihi barua ya kueleza kuwa unakubali kuhojiwa.

Kujiunga na utafiti.

Baada ya ushauri utaulizwa kama ungependa kujiunga na utafiti huu. *Utaelezwa kuwa ni bora ikiwa utazungumza na mpenziwe ili mfanye uamuzi pamoja. Utapewa muda wa kujadiliana na mwenzako kabla ya kutupa uamuzi wako.*

Sehemu ya kwanza ya Orodha ya maswali itajazwa wakati huu.

Unapowasili hospitali kuu

Katika wadi ya kujifungua, utaulizwa maswali kadhaa kuhusu chaguo lako na hisia zako. Ruhusa na uamuzi wako wakufanyiwa operasheni na kuwekewa kifaa cha kupanga uzazi(IUCD)itathibitishwa,na utahitajika kutia sahihi kwa fomu ya makubaliano.

Sehemu ya pili ya orodha ya maswali itajibiwa wakati huu.

Chumba cha upasuaji

Thibitisho ya sahihi zako itafanya kabla hujaingizwa chumba cha upasuaji. Utafanyiwa ukaguzi wakati wa operasheni kuhakikisha kuwa bado unaweza kushiriki utafiti huu. Daktari atakagua kizazi chako na kubaini kuwa huna magonjwa yoyote.

Baada ya opareshen i

Utakakulia kuhakikisha kuwa huna shida yoyote babada ya upasuaji.

Ukaguzi kabla ya kuenda nyumbani

Kabla ya kuruhusiwa kuenda nyumbani, daktari atakufanyia ukaguzi kubainisha kuwa huna shida yoyote. Utapewa ushauri kuhusu ni nini hasaa unapaswa kujikinga nacho kabla hujarejea hospitalini kwaukaguzi zaidi. Zaidi, utapewa ushauri kuhusu jinsi bora ya kuchunga eneo lako la uzazi na kuangalia iwapo kifaa hicho kiko sawa.

Utapewa ushauri kuhusu umuhimu wa ukaguzi zaidi na kuulizwa ufike hospitalini baada ya wiki mbili na sita. Utapewa kadi itakayokuwa na ujumbe wako wote na siku na pahali ambapo utatrajiwa kufika.

Ukaguzi wa baadaye

Ziara ya kwanza

Wakati wa ukaguzi huo, utafanyiwa uchunguzi wa kiafya ya kubaini iwapo kidonda kimepona ,na dalili yoyote ya ugonjwa kutokana na kifaa hicho. Utaulizwa maswali zadii kuhusu mema uliyoyapata kutokana na kifaa hicho cha IUCD.Ukaguzi itafanywa na mtafiti mwenyewe au wasaidizi wake.

Kisha utapewa kami yam zahanati na kuulizwa kurejea katika zahanati baada ya wiki sita kwa ukaguzi zaidi na wauguzi katika zahanati ya kupanga uzazi. Ukikosa kuhudhuria ukaguzi huo, utapigiwa simu kukumbushwa. Iwapo hautaweza kufika katika zahanati, ukaguzi utafanyika kupitia njia ya simu na utaelezwa umuhimu wa ukaguzi na kufika hospitalini. Utapewa nambari ya zahanati na kuulizwa ufike kwa muda mfupi zaidi.

Ziara ya pili

Ukaguzi utafanywa kama ule wa wiki ya pili baada ya upasuaji, Nyuzi za IUCD zitakaguliwa na kupunguzwa inapopaswa.

Na hii ndio mwisho wa utafiti, patakapo tokea shida yoyote tunakunasihi urudi kuoneka na daktari, zahanati 66 au casualty chumba numberi 7. Hatari Na Usumbufu Katika Utafiti

Utafiti huu utakuuliza maswali ya kibinafsi kuhusu hali yako ya ukimwi

na pia niya yako ya uzazi hapo mbeleni.. Si lazima uyajibu maswali haya iwapo hautaki.

Ukaguzi wa kiafya unaweza ukakupa maumivu.

Kifaa cha IUCD kinaweza kikatoka na kukulazimu kurejea katika zahanati kabla ya wiki sita kupita. Wakati wowote ukikumbwa na shauku au shida, kutakuwa na mtu wa kukusaidia.

Hatutaraji hatari yoyote katika utafiti huu.ijapokuwa unaweza kupata adaa ya mwenzi kwa wingi miezi za kwanza, kuna uwezekano ya kifaa kutoboa kizazi,ijapokuwa hali hii ni duni sana.

Faida Za Utafiti

Unaweza ukafaidika kutokana na utafiti huu kwa kujiongezea ufahamu wako wa njia za kupanga uzazi. Utafaidika pia kwa kuwekewa kifaa hicho cha IUCD kwa muda ufaao na kuelekea nyumbani na njia madhubuti ya kupanga uzazi. Utafaidika na kuwekewa kifaa hicho cha IUCD na daktari mpasuaji mwenyewe.

Tandhima ya siri

Ujumbe kuhusu chaguo lako la kupanga uzazi na ujumbe mwingine utakuwa siri . Ujumbe kuhusu ushiriki wako katika utafiti huu utawezekana kupatikana na wewe na wanaoandaa utafiti na wala si yeyote mwingine. Jina lako halitatumika bali ujumbe wowote kukuhusa itapewa nambari badili ya jina yako.

Utumizi wa Matokeo

Matokea ya utafiti hii itatumiwa kuboresha upanganji uzazi , washika dao na idara za afya pamoja na madaktari katika makala. Ujumbe inayomhusu wahusika haitatangazwa. Gharama ya utafiti

Hakuna gharama ya kushiriki katika utafiti huu.

Njia Zingine Za Kushiriki

Unaweza ukachagua kutoshiriki katika utafiti huu. Ukiamua kutoshiriki, utapata uuguzi wa kabla na baada ya kujifungua katika hospitali kuu ya Kenyatta. Pia utaendelea kupokea ushauri kuhusu njia za kupanga uzazi. Aidha, utaelezwa ni njia zipi za kupanga uzazi ambazo unaweza kuzitumia. Uhusiano wako na wafanyikazi wa hopspitali hautatiwa mashakani iwapo utakosa kujihusisha na utafiti huu.

Nambari za wahusika

Ungependelea kuuliza maswali yoyote, piga simu nambari:

Dr Balleith Bukhite Khamis,

Nambari ya simu; 0722675666

Wahusika wa maslahi yako katika utafiti;

KNH/UON-ERC

P.O.BOX 19676 Nairobi(code 00202)

Nambari ya simu. 254-020-2726300

EXT 44355

SEHEMU YA PILI: FOMU YA MAKUBALIANO

Nimeelezewa utafiti huu kwa kina. NakubaIi kushiriki utafiti huu kwa hiari yangu. Nimepata wakati wa kuuliza maswali na nime elewa kuwa iwapo nina maswali zaidi, ninaweza kumwuliza mtafiti mkuu au watafiti waliotajwa hapa juu.

Jina la Mshiriki_____

Sahihi ya mshiriki_____

Tarehe_____

Kwa wasioweza kusoma na kuandika

Nimeshuhudia usomaji na maelezo ya utafiti hii kwa mshiriki,na mshiriki alipewa nafasi ya kuuliza maswali. nathibitisha kuwa mshiriki alipeana ruhusa ya kushiriki bila ya kulazimishwa.

Jina la shahidi_____ Alama ya kidole ya mshiriki.

Sahihi la shahidi_____

Tarehe _____

Ujumbe kutoka kwa mtafiti/mwenye kuhusika

Nimemsomea mshiriki ujumbe kiwango ninavoweza na kuhakikisha kuwa mshiriki amefahamu yote yanayohusika katika utafiti huu.Nahakikisha kuwa mshiriki alipewa nafasi ya kuuliza maswali na yote yakajibiwa vilivyo.Na thibitisha kuwa mshiriki alitoa ruhusa bila ya kulazimishwa.

Jina la mtafiti:_____

Sahihi ya Mtafiti /Anaechukua ruhusa_____

Tarehe_____

Appendix C

Questionnaire

QUESTIONNAIRE FOR A STUDY TO DETERMINE ACCEPTABILITY,UPTAKE AND SAFETY OF INTRA-OPERATIVE IUCD INSERTION IN MOTHERS UNDERGOING ELECTIVE CESAREAN SECTION AT KENYATTA NATIONAL HOSPITAL/PUMWANI MATERNITY HOSPITAL.

Patient No. | | | | |

Contact no.(mobile)_____

Part A: Socio-demographic characteristics

1. Age (years) _____
2. Parity

   (Para_____ Gravida _____)
3. Marital status
   a) Single
   b) Married
   c) Divorced/separated.
   d) Widowed
4. Level of education
   a) None
   b) Primary
   c) Secondary
   d) University/college
5. Employment
   a) Unemployed
   b) Self employed
   c) Salaried job
   d) Housewife

6. Reason for elective cesarean_____

_____-

7. Reason for first previous scar (if patient is a previous scar)_____

_____

8. History of postpartum bleeding in previous pregnancy
    a) Yes
    b) No

Index pregnancy

9. LMP (dd/mm/yyyy) ___ / ___ / _____
10. Estimated date of delivery (dd/mm/yyyy) ___ / ___ / _____
11. Duration since last delivery
    a) Less than 1 year
    b) 1-3 year
    c) 3-5 years
    d) Above 5 years.
12. How many more children do you like?_____
13. How long would you like to take before having the next baby?_____
14. Have you ever used any method of contraceptive before? If yes which method was used?
    a) IUCD
    b) Injectable
    c) Barriers method
    d) Contraceptive pills
    e) implants
15. Did you attend ANC?
    a) Yes
    b) NO
16. If yes to question 14 where was your first ANC visit
    a) KNH
    b) Pumwani maternity hospital
    c) Elsewhere

17. At what gestation did you attend first clinic.
    a) 20 weeks or earlier
    b) 21-28 weeks
    c) 29-36 weeks
    d) 36 weeks and above.
18. How many times did you attend?_____
19. Was the following checked ,Tick if yes
    a) Estimation of fetal weight
    b) Pelvimetry
    c) Serial weight
    d) Haemoglobin level
    e) HIV
    f) Blood group and rhesus
    g) Urinalysis
    h) Rbs
    i) VDRL
20. Do you have any medical condition? If yes explain

    _____

21. Do you have regular menses?
    - Yes
    - No
22. Is your flow
    - Light
    - Moderate
    - Heavy

23. Have you been previously treated for any of the following.
    - Pelvic inflammatory disease
    - Recurrent sexual transmitted disease
24. Do you accept intra-operative IUCD insertion by the surgeon?
    - Yes
    - No

If no state why _____

_____

Part B: On Admission

25. Date and time of admission:

Date (dd/mm/yyyy) ___ / ___ / _____

Time----------

26. Date of the scheduled c/s

Date (dd/mm/yyyy) ___ / ___ / _____

27. Investigation done and the result

a) U/E/C_____

b) HIV test_____

c) U/S_____

d) Heamoglobin/PCV_____

28. Diagnosis at admission._____

_____

Part C: Filled by the surgeon doing the elective c/s

29. Date of elective caesarean section done

Date (dd/mm/yyyy) ___ / ___ / _____

30. Intra-operative insertion of copper T380A within 10 minutes of removal of the placenta.

- successful
- failed: reason

a) PPH

b) Uterine fibroids

c) Poor fetal outcome

d) Massive adhesion.

e) Signs of infection evident

f) Others

Specify_____

_____

31. Any complication in the immediate post operative period.

a) Heavy Bleeding

b) Expulsion

c) severe cramping

d) None

Part D: On the day of discharge (3rd post op day)

31. Any complains?

a) Yes

b) NO

If yes state_____

32. Report on Lochia flow

a) Light

b) Moderate

c) Heavy

33. Vitals signs

a) temperature

b) pulse rate

Part E: 2 weeks postpartum

34. Any complains_____

- Yes
- No

If Yes State_____

35. Any sepsis detected?

- Yes
- No

If yes, specify signs

- Foul smelling lochia
- Fundal height
    - Normal Involution
    - Abnormal Involution
- Uterine tenderness Yes/No

36. Blood loss: Number of pads per day _____; presence of clots

- Yes
- No

Part F: 6 weeks post op

37. a) Resumption of sexual activity
    - Yes
    - No
38. Any complains
    - Yes
    - No

    If Yes State_____
39. Any sepsis detected?
    - Yes
    - No

If yes, specify signs

- Foul smelling lochia
- Fundal height
    - Normal Involution
    - Abnormal Involution
- Uterine tenderness Yes/No

40. Blood loss: Number of pads per day _____; presence of clots
    - Yes
    - No
41. Checking of the strings and possible trimming via speculum examination.
    - String visualized
    - String not visualized
42. Willingness to continue with IUCD.
    - Yes
    - No

44.On a scale of 1 to 10 (with 10 being the most) how satisfied are you with your IUCD overall?

At 2 weeks postoperative 1 2 3 4 5 6 7 8 9 10

At 6 weeks postoperative 1 2 3 4 5 6 7 8 9 10

Appendix D

Techniques: Cesarean Section .The steps are as follows (after delivery of the placenta and after controlling the bleeding from the uterine incision):

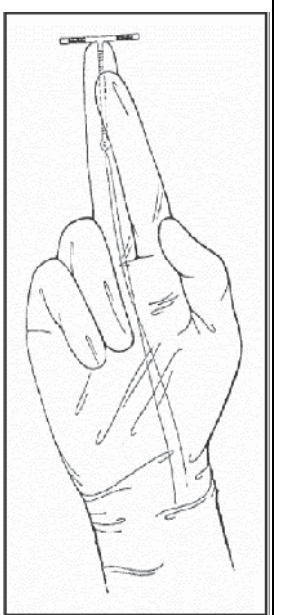
1. Massage the uterus until bleeding subsides.
2. Insect the uterine cavity for malformation which limits the woman successful use of the IUCD(e.g. septate uterus, bicornuate uterus, submucosal or distorting intramural fibroids)
3. Place the IUD at the top (fundus) of the uterine cavity manually .(see below)
4. Before closing the uterine incision, place the strings in the lower uterine segment.
5. Close the uterus and abdomen.
6. Do VVT as normal.

Manual placement technique

For postplacental manual insertion, use the same sterile gloves for operation

Grasp and hold the IUD by gripping its vertical rod between the index and middle fingers of the dominant hand(figure 1)

(Figure 1)



- ✓ Move the non dominant hand up onto the fundus to stabilize the uterus.
- ✓ Slowly insert the IUD-holding hand into the uterus through the lower uterine segment incision.
- ✓ Gently move the IUD-holding hand in an upward motion toward the fundus ,taking care to follow the contour of the uterine cavity.
- ✓ Release the IUD at the fundus and slowly remove the hand from the uterus. Take particular care not to dislodge the IUD as the hand is removed.
- ✓ Keep the non dominant hand in place to stabilize the uterus until the other hand is completely out of the uterus.
- ✓ Close the uterine incision ,taking special care not to incoperate the IUCD strings into the suture.

NOTE;

The strings can be pointed toward the cervix but should NOT be pushed through the cervical canal. This helps prevent both uterine infection (caused by contamination of the uterine cavity with vaginal flora) and displacement of the IUD from the fundus (caused by drawing the strings downward toward the cervical canal).Strings will spontaneously pass-through the cervix into the vagina after involution.

Appendix F

POST-INSERTION INSTRUCTIONS

Ensure the patient understands all the post- insertion instructions:

1. Tell the patient what type of IUCD she had inserted and provide card showing

Type of IUCD used , date of insertion.

2. Review the possible side effects and what to do with if they occur.

3. Inform patient when to return for IUCD check-up.

4. Review warning signs.

5. Review how to check for underpants/ pads for expulsion and what to do in

Case of expulsion, considering if patient is breastfeeding.

6. Explain how to check for strings if she wants.

7. Assure client that IUCD doesn't affect breastfeeding.

8. Review when she can safely resume sexual activity.

Give the written post insertion instructions.

Post insertion IUD Instructions

It is important to give the PPIUD client clear instructions to help her use this method safely, effectively, and with satisfaction. Pathfinder International recommends giving instructions both orally and in writing. The provider uses simple language when speaking to or writing for the client and gives instructions in a language the client can easily understand.

The procedure for giving oral instructions is as follows: Ask the woman what she already knows about IUDs.

Tell the woman what kind of IUD she has received. Show her either a sample or picture

Of the IUD so that she can see how it looks and how large it is. Explain that the copper T IUD will prevent pregnancy for 10 years.

Assure the woman that the IUD has no effect on breast milk and that she can breastfeed her baby.

Tell the woman that she may have sexual intercourse as soon as it is comfortable for her.

Explain that within a few weeks, the IUD strings will probably come from the womb into the vagina. Tell her that a health care worker will shorten the strings during the follow- up visit if they are troublesome.

Discuss the possibility that the IUD may be expelled, especially during the first few weeks or months after insertion. An expulsion frequently follows lower abdominal cramping. Tell the client that she may find the IUD if it is expelled. She should then come to the clinic immediately. Explain that the woman can have another IUD inserted, if she chooses, or she may have another method. If the IUD is expelled during her postpartum hospital stay, a second insertion can be done while she is in the hospital. Otherwise, the IUD can be replaced at the four or six week postpartum visit, or later. Repeat how to check for the IUD strings.

Tell the woman that she should:

1. Wash her hands, using soap if possible. This helps to reduce the chance of

infection.

2. Sit in a squatting position, or stand with one foot up on a step or ledge.

3. Gently insert her finger into her vagina and feel for the cervix, which feels firm, like the tip of the nose.

4. Feel for the strings, but do not pull the strings as that could move the IUD or cause it to come out.

Tell the woman that she should do this at least once a month, after her period, but should not check for the strings until after six weeks postpartum. Emphasize that the client should return to the clinic if the strings seem to have become shorter or longer than when previously checked or if they seem to be missing and she can no longer feel them.

Tell the client that once menstruation returns, some women with IUDs have more cramping and heavier bleeding during their periods, longer periods, or spotting or bleeding between periods. These side effects usually go away after a few months of IUD use.

Tell the client that the IUD will not protect her or her partner against HIV infection or other STDs. Aside from abstinence, latex condoms offer the best protection against HIV infection and other STDs.

If at any time you have more than one sexual partner or your partner has sex with anyone else, the IUD is not a good method for you, because a sexually transmitted disease could become more severe with the IUD in place.

Describe the warning signs for potential complications: late period or other signs of pregnancy; bleeding or spotting between periods or after intercourse; unusual discharge from the vagina beyond six weeks postpartum; missing, shorter, or longer strings; feeling the IUD when checking for the strings.

Tell the woman where to seek help if a problem occurs.

Assure the client that she can have the IUD removed if she changes her mind about the method. Tell her that it is best if she not try to remove the IUD herself.

Tell the woman when she needs to return for routine follow-up and removal. The first follow-up visit for PPIUD clients is usually done at a four or six-week postpartum checkup. Thereafter, an annual pelvic exam is recommended.

Encourage the woman to go to a health facility at any time if she is concerned about any aspect of IUD use.

Give the woman written instructions .If she has difficulty reading, ask her to identify someone in her family or neighborhood who can read the instructions to her.

Appendix G

Sample Client Instructions for Women
Receiving intra-operative IUCD

Name: _____ Insertion Date: _____

Clinic Address: _____Reasercher's Phone _____

Information about your IUD

The name of your IUD is the Copper T380A.

This IUD is effective for 10 years. You may have it removed any time you want.See your health care worker or return to the clinic for removal.

You may breastfeed your baby. The IUD has no effect on breastmilk.

When your menses return, the periods may be heavier and longer than without an IUD. Over a period of several months, your menstrual periods will probably become lighter.

If at any time you have more than one sexual partner or your partner has sex with anyone else, the IUD is not a good method for you. You could get a sexually transmitted disease, which may become more severe with the IUD.

Please follow these instructions for safe and effective contraceptive use of your IUD:

The IUD will sometimes come out, usually in the first few weeks or months. Some women will not feel the IUD come out. So check your underclothes when

undressing and check the toilet after use. If your IUD comes out, return immediately to the clinic or your health provider so that a new IUD can be inserted, if you like, or another family planning method can be provided. Use another method of family planning until you can return to the clinic. Be sure to return to postnatal clinic 18 for your two and six-week check-up. When you return to the clinic, your health provider will show you how to check the

IUD strings yourself, so you can be sure your IUD is in place. If you experience any of the following, return to the clinic:

- Pain in your belly or pain when you have sex.
- Foul-smelling discharge from your vagina.
- Fever or chills (especially if this is accompanied by pain in your belly or a foul smelling vaginal discharge).
- You are late for your period or otherwise think you might be pregnant. Any sign that your IUD has come out.
- You have bleeding between periods that is increasing over time.
- Cramping that does not decrease over time or with medication
- Excessive bleeding
- Strings missing or suddenly longer

Resumption of sexual activity after 6 weeks post operation. Your IUD will not protect you against sexually transmitted diseases (STDs), including HIV/AIDS. If you believe you are at risk of getting an STD, use a condom or other barrier method and see your health provider. The IUD may not be the best method for you in this situation.

If you would like to check the strings do the following:

1. Wash your hands with soap and water.

2. Squat or stand with one foot up on a ledge or a step.

3. Gently insert your hand into the vagina. Feel for the cervix (a firm feeling)

4. Feel for the strings but do not pull the strings.

5. If the strings protrude don't worry, the strings may only need to be shorted.

Return to clinic for this.

If you have any questions, feel free to ask a health provider at the hospital, clinic, or in your community who is familiar with IUDs.

Source: Adapted from draft by Betty Gonzales and Douglas Huber (1990) and from AVSC,

Postpartum IUD Insertion: Clinical and Programmatic Guidelines, 1994.

Appendix H

FOLLOW UP VISIT RETURN NOTE

The named is a participant of the acceptance of intra-operative insertion of IUCD being held at KNH/Pumwani maternity Hospital. She is scheduled for a follow up visit at the postpartum clinic .

- ✓ 2nd week post op
- ✓ 6th week post op

Study Number _____

Hospital IP Number _____

Date of Delivery _____

Date of Return _____

In case of any queries or problem, please call 0722675666

Note:

Ensure you protect yourself from STD's. In case you think you have acquired one Please return for help.