THE EFFECT OF TWO LEVELS OF COUNSELLING ON ACCEPTANCE, UPTAKE AND EARLY OUTCOMES OF THE POSTPLACENTAL INTRAUTERINE CONTRACEPTIVE DEVICE.

A research dissertation, submitted to the University of Nairobi, Department of Obstetrics and Gynaecology in partial fulfilment of the requirements, for the award of Master of Medicine in Obstetrics and Gynaecology'

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DECLARATION

1 declare that this research in part fulfilment of the M.Med degree in Obstetrics and Gynaecology is my original work and has not been presented to any university forum.

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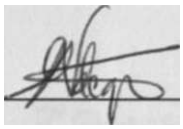
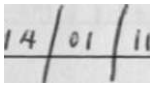
Signature: 

Date: 

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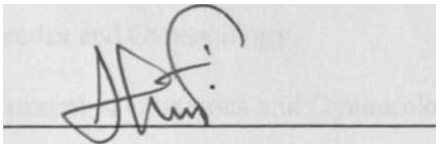
   Signature: 

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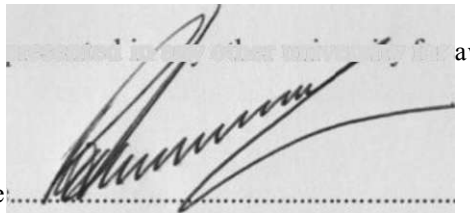
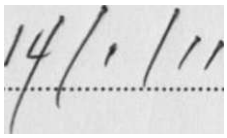
This is to certify that this dissertation is the original work of Dr. Serah Wanjiru Ndegwa, Master of Medicine student in the Department of Obstetrics and Gynaecology, registration number H58/70371/2007 University of Nairobi (2007-2011). The research was carried out in the Department of Obstetrics and Gynaecology. School of Medicine. College of Health Sciences. It has not been [illegible] award of a degree.

Signature 

Date. 

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DEDICATION

To the wonderful men in my life, my loving husband, Njuguna and my precious boys, Gacanja and Ndegwa.

To my wonderful parents. Ndegwa and Wanjiku, for believing in me and inspiring me to greater heights.

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Last but not least. I sincerely thank all the women at Embu PGH who participated in this study, through them a lot of knowledge and experience has been gained.

Acronyms and Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
EBF	Exclusive Breastfeeding
FHI	Family Health International
FP	Family Planning
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immunodeficiency Virus
IPP	Immediate Postpartum
IUCD	Intrauterine Contraceptive Device
JHPIEGO	John Hopkins Program For International Education in Gynaecology and Obstetrics.
K.DHS	Kenya Demographic Health Survey
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
PGH	Provincial General Hospital
PLWHA	People living with HIV/AIDS
PMTCT	Prevention of Mother to Child Transmission of HIV
PPIUCD	Postpartum IUCD
STI/STD	Sexually Transmitted Infections / Sexually Transmitted Diseases
USAID	United States Agency for International Development
WHO	World Health Organization

Operational Definitions

Postpartum: The period after delivery of the produets of coneeption 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.

Transcesarean Insertion: Insertion of the IUCD following a caesarean delivery before the uterus is sutured.

Immediate Postpartum Insertion: Insertion of the IUCD after the postplacental period but within 48hrs 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 counselling agreed to have the IUCD inserted postplacental.

Uptake: The number of clients who actually had the IUCD inserted postplacental. This group excludes those who had prior accepted and either opted out or had medical contraindications detected intrapartum such as chorioamnionitis.

Outcomes: The main measurable outcomes relevant to this study included IUCD expulsion, satisfaction and continuation rates at 6 weeks postpartum. Other outcomes included pelvic infection, allergic reaction and abdominal discomfort.

Routine Family Planning Counselling: This consisted of the normal ANC FP counselling that takes place in Embu PGH. This consists of a group discussion on family planning followed by a brief individual counselling session on different methods.

Intensive Family Planning Counselling: This consisted of the normal routine ANC FP counselling with the addition to longer more interactive sessions, use of counselling tools and samples of different methods, follow up visits, take home pamphlets and encouraged partner involvement.

Exit point: The final point of the study was the 6 week postpartum visit at the postnatal clinic.

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ABSTRACT

Background: Contraceptive prevalence in Kenya is low at 46% (KDHS 2008/9).There is a notable steady decline in the use of Long Acting and Permanent Method's (LAPM's) especially the 1UCD. Current national IUCD use rates are 1.6% compared to 2.4% in 2003(KDHS 2003).

Postplacental IUCD use has been known to be safe and effective. Use of this method may increase contraceptive prevalence rates as it provides contraception at a time when the woman is highly motivated to use a method.

Counselling plays a vital role in educating women, ensuring they make informed choices on the family planning method that best suits them. Improving the quality of antenatal counselling on family planning methods may increase the uptake of postplacental IUCD insertion.

Objectives: To determine the effect of two levels of counselling on the acceptance, uptake and outcomes of expulsion, pelvic infection, couple satisfaction and continuation rates at 6 weeks postpartum of the postplacental intrauterine device.

Study Site: The study was carried out at Embu PGH.

Study Subjects: Pregnant women between the gestation of age of 36 - term, who attended ANC at Embu PGH and followed up at labour ward, pre-discharge in the wards and at 6 weeks postpartum.

Study Design: A randomized "open-label" clinical trial.

Study Methodology: Eligible clients were randomized to either routine or intensive FP counselling. Those who accepted were followed up intrapartum and had the IUCD inserted within 10 minutes of placental delivery. A pre-discharge review and a follow up visit at 6 weeks (exit point) were then carried out.

Results: One hundred and twenty seven study participants were enrolled and randomized to intensive (64 women) or routine FP counselling (63 women). Seventy one percent of women (78% in the intensive FP counselled group and 66% in the routine FP counselled group) accepted to have the postplacental IUCD inserted. Forty five percent of women (63% in the intensive FP counselled

group and 64% in the routine FP counselled group) had the IUCD inserted. There was no significant difference in uptake in the two randomization arms (p-value 0.232). Complications included expulsion (3.7%), allergic reaction (1.8%), pelvic infection (1.8%) and abdominal pain (1.8%).Continuation rates, client and reported partner satisfaction were 91%, 88%. and 77% respectively at 6 weeks. The overall loss to follow up was 14 clients; six from the intensive FP counselled group and eight from the routine FP counselled group.

Conclusion: The postplacental IUCD is an acceptable method among women in this region irrespective of level of counselling.

Intensive counselling at Embu PGH did not significantly increase acceptance and uptake rates of postplacental IUCD insertion in comparison to routine counselling.

Recommendations: Routine counselling is adequate to allow for increased uptake rates of postplacental IUCD insertion, but individualization should be considered. Widespread training on this method should be provided to health care workers and information given to pregnant women during antenatal visits.

INTRODUCTION

Access to contraception is a basic right for every woman (1). As of 2005, approximately 60.5 % of women worldwide (who were between the ages of 15-49, married or in union) used a contraceptive method. In Africa, the contraceptive prevalence rates as of 2005 were estimated to be 27.4 % (2). In Kenya slightly less than half of currently married women (46 percent) are using some method of contraception, with modern method use at 39%. (K.DHS 2008-09)

The importance of contraception cannot be overemphasized as evidenced by its role as a major agenda in global reproductive and developmental forums such as the Millennium Development Goals, The Safe Motherhood Initiative Plus and The International Conference on Population and Development plus 5 Goals (3).

Family planning benefits the health of men. women and children. Contraceptive use reduces maternal mortality and improves women's health by preventing unwanted and high-risk pregnancies and reducing the need for unsafe abortions (4). Neonatal and infant deaths are prevented through adequate birth spacing (5, 6), prevention of births among very young women, and prevention of births among multiparous mothers. The couple benefits by freedom to decide timing of/ and desired family size therefore providing less emotional and financial strain, increased economic opportunities and more space for personal development.(4)

Family planning further benefits the community and the country as a whole by reducing strain on environmental resources (land, food, and water), community resources (health care, education) and allowing for greater participation by individuals in community affairs.(4)

The family planning programme in Kenya began in 1967. This led to a decline in the total fertility rate (TFR) from a high of 8.1 births per woman in the 1977-78 Kenya Fertility Survey to the current figure of 4.6 (KDHS 2008-09). Although fertility rates are declining and contraceptive prevalence is rising there is a notable decline in the utilisation of the long term(IUCD) and permanent methods (female and male sterilisation). The provision of these methods suffers most from deterioration in standards in clinical services, provider attitudes and skills (7). The Ministry of Health is currently working with several organizations to improve contraceptive prevalence rates especially since the KDHS 2008-09 estimated an unmet need of 26% for family planning services. Revitalization of long acting and permanent methods and postpartum contraception is one of the ongoing priority projects.

LITERATURE REVIEW

The postpartum period is recognized as an appropriate time for contraceptive initiation. A Turkish study conducted in the early 1990s found that 95% of postpartum and 88% of postabortal women were willing to use a contraceptive method immediately after termination of pregnancy. However, more than 70% of the women who were admitted for delivery or termination of pregnancy left the institution without receiving a contraceptive method (8).

In resource limited settings where postpartum follow up visits are poorly attended, postpartum contraception may prove to be of great value. Women are highly motivated to use a contraceptive method in the postpartum period (9). The woman is also known not to be pregnant therefore avoiding the need for questioning, delay to wait for menses or a pregnancy test. Furthermore delivery may be the only time a woman, especially those who have a vaginal delivery, visits a

health facility prov iding an opportune time to counsel and initiate contraception. The setting is also appropriate for both patient and provider.

The methods available for use in the postpartum period are limited and appropriate counselling must be carried out. Combined hormonal contraceptives are not recommended in the post-partum period, for their inhibiting effect on lactation (10). Some authorities do not consider progestin-only methods, the first choice during lactation, because small amounts of steroids are present in the milk and there is not sufficient information regarding the long-term effects on the neonate (ll).This leaves the choice of lactational amenorrhea method (LAM), barriers methods (condoms), surgical sterilization (bilateral tubal ligation and vasectomy), and the non hormonal IUCDs.

The Intrauterine contraceptive device has been in use since 1929 though its discovery was first described by a German publication in 1909 (12). Time has seen the evolution of the devise from the outdated silk suture IUCD. the infamous Dalkon Shield to the latest improved models of hormone releasing lUCD's (Mirena. Lingus) with minimal side effects and higher efficacy levels. The Copper T 380A model still remains the most widely used model in resource limited countries as it is inexpensive, readily available and efficacious for at least 12 years. The IUCD is well tolerated by most women and ranks second as a family planning method worldwide, probably due to its widespread use in China, representing about two thirds of women using IUCD worldwide (2.13). In Kenya IUCD prevalence rates have declined from 2.7 in the 1998 KDHS to 1.6 in 2008-09 K.DHS. A study conducted in New Mexico concluded the two most common reasons for failure to obtain an IUCD were provider bias and that the woman failed to return to the postnatal clinic (14). The immediate postpartum IUCD method would overcome the second obstacle.

Postpartum IUCD insertion encompasses postplacental, transceserean, immediate postpartum and postabortal timings. PPIUCD was recommended more than 4 decades ago in 1967(15). However, the uptake of this method has been rather slow except in countries such as Egypt, China and Mexico where it is widely used. In October 1990. Kenya and Mali became the first countries in Sub Saharan Africa to initiate postpartum IUCD insertion programs (16.) Almost 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, EngenderHealth, 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.

Postpartum IUCD insertion has been shown to be a safe and feasible method of contraception (17). Insertion immediately after delivery (postplacental) provides a time when there is minimal discomfort to the patient as the cervix is still open, unlike in interval insertion. The demand on hospital resources and expense to the patient is limited to the cost of the IUCD. as the device is inserted using the same equipment and by the same professional attending to the delivery. The mother leaves hospital with a contraceptive method that provides immediate protection from future pregnancy without interfering with lactation or causing concern about hormonal transfer to the infant (18). Previous studies had reported an increase in postpartum blood loss (19). This has long been disputed with most studies showing no or minimal increase (20). In addition the IUCD is a safe method that doesn't increase the incidence of ST1 / STD acquisition (21), PID in HIV positive women (22), ectopic pregnancy (23), or shedding of the HIV virus (24) as earlier thought. The IUCD is also a perfect method for use in PLWHA; as long as those with clinical AIDS are on HAART. dual methods are advocated and there is access to ongoing medical care.

The most recognized limiting feature of postplacental IUCD insertion is the high expulsion rates. This method lost favour in the 1980"s after a WHO multicentre trial concluded that it resulted in "unacceptably high pregnancy and expulsion rates (up to 35%)" (25). Studies done later have dispelled this and shown that this method is generally safe and effective (26), with expulsion rates varying from 6% to 19% and minimal pregnancy rates at 2% (16, 17). Transcesarean insertion is also known to be safe (27) with lower rates of expulsion than vaginal delivery at 1.2% to 9.6 %. (28). There has been debate on whether rates of expulsion differ with providers training and experience, time (and technique) of insertion and type of IUCD used. Clinical personnel with limited training and experience in postpartum insertion contributed to greater expulsion rates than their counterparts (16. 29. 30).The postplacental IUCD insertion also showed better clinical performance than early postpartum insertions (16, 28, 31).The technique of insertion whether manual or with forceps has been shown to have no association with expulsion rates (16, 29, 32). 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 (33, 34). The type of IUCD models studied earlier are now outdated however copper bearing IUCDs generally had lower expulsion rates (35) 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 per 1000 women (36). Studies have shown that uterine perforation following postplacental IUCD insertion is almost unheard of with most studies having no complication of perforation (16,17,31.33).This is probably due to the thickness of the endometrium in the postpartum period in comparison to in the peuperium. Displacement is another known complication of IUCD insertion however, this subject has been poorly reported in most studies and there seems to be no consensus as to whether the differences in length of strings mean displacement or not (37).

No known contraceptive method has an efficacy of 100%. The IUCD however 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 (38) with cumulative pregnancy rates of 2 % (39). The pregnancy rates of postplacental IUCD insertion has shown a rate varying from 0% to 2% (16.17,31,33).This compares to the rates at interval insertion thereby verifying the efficacy of this method.

One fact that cannot be disputed is that the IUCD even after postplacental insertion is a method that is favoured by the women using it. This is evidenced by its high continuation rates of greater than 75% (16,17,31.33). Studies have found that most women stop using the IUCD because of personal, not medical, reasons. For example, a study of 2,748 users in 14 countries found that the most common reasons given for discontinuation were planned pregnancy (32 percent) and a husband or family opinion against IUCD use (26 percent) (40).

Provider bias and potential user misconceptions remain a major obstacle to IUCD use (41). Health care workers providing the service rarely go for pre-service training, updates and in-service training leaving them ill prepared to offer the IUCD as a method. Furthermore, those who were trained have lost their skill due to a decline in use of the method. Time constraints factor in as the method takes long to insert and they therefore opt to counsel and provide other quicker methods like the male condom and injectables. This is evidenced by the fact that the most common methods used in our country are the male condom (18%) and injectables (16.8%) (2008-09 KDHS). Misinformed providers as well as potential clients have misconceptions about the IUCD. Many still think the IUCD is harmful and can cause infections including HIV, ectopic pregnancy and abortions. The image of the IUCD also scares many women who perceive it to be able to move around the body or hurt their partner during intercourse (41).

Kenya, like other developing countries, has limitations within the health system making it poorly prepared to offer sufficient IUCD services. A survey done in 2004 showed that despite 50% of health facilities reporting they had adequate tools and conditions to provide IUCD services only 11% had the method, all the basic items, and all the conditions necessary for quality IUCD insertion and removal (41). Another serious obstacle in our country is a lack of trained providers to handle IUCD insertion and its management. This may have changed with the recent revitalization of PPIUCD.

Awareness of available contraceptive methods is a prerequisite for making a decision to initiate contraception. Counselling is a key component of family planning services and has been used to improve the care clients receive in family planning programmes and help ensure clients make voluntary, informed and well considered choices (42). Studies have shown that women demand improved privacy, a wider choice of contraceptive methods and accurate and more comprehensive information about methods and side effects (43). Women must be empowered to make an informed choice on the contraceptive method that best suits them as an individual.

Adequate time, careful listening and encouragement to raise concerns and questions are necessary to facilitate the woman to make an appropriate contraceptive choice (43). This can only be done by providing sufficient time and more visits for comprehensive counselling beginning in the antenatal period and extending beyond the puerperium even in women who already have a method in place. Women who attend more antenatal visits are significantly more likely to document a breastfeeding and contraceptive plan (44). The integration of family planning services in antenatal care and postnatal care packages by the MOH should impact on adequate time.

The use of counselling tools and reading material may improve counselling standards and facilitate decision making. Job and decision making aids have the potential to improve health communication even and especially when the clients have limited education and providers have limited training and supervision (45). There is a need for reading materials and take home pamphlets to take home to partners as requested by women in a study on women's perspectives on family planning (43).

Educating the woman is not enough. Male involvement has been shown to increase contraceptive practice (46). A study done in Iran showed that women wished their husbands were more involved in family planning to help make a decision in agreement (43). Couple counselling on family planning improves counselling quality. A study done in Kenya showed that couple counselling sessions resulted into longer, more interactive sessions (than did individual women's sessions) and the couple acquired more overall information on family planning (47). The overall required effect is to improve couple harmony and contraceptive initiation and continuation rates.

In conclusion, the postpartum period offers an opportunity for women to acquire a contraceptive method. The methods available may be limited but the IUCD is one of the safest and most effective methods and can be inserted at various times postpartum. An improvement in the quality of counselling may lead to increased uptake of these methods, especially postplacental and early postpartum methods, bridging the 26% unmet need for family planning among our Kenyan women.

STUDY JUSTIFICATION

In Kenya the overall contraceptive prevalence rate is low at 46% (KDHS 2008-09) with a notable decline in use of the IUCD and an unmet need for family planning of 26% (KDHS 2008-09).

The postpartum period provides a convenient and appropriate time for contraceptive initiation. Postpartum contraceptive initiation exploits missed opportunities. In Kenya, a large number of women (53%) do not receive postpartum care after delivery (KDHS 2008-09). The postplacental IUCD method allows the woman to go home after delivery protected from unwanted pregnancy.

Since the introduction of the postpartum IUCD in 1990 there has been no significant increase in the uptake of this method and the trend has been downwards. The MOH in conjunction with some NGO's are in the process of revitalizing this method. In Embu PGH the revitalization has been ongoing for nearly two years and yet no study has been done to assess the acceptability and uptake of this method in this setting. A study was carried out in the early 1990's to assess the outcomes of postplacental IUCD in Nyeri PGH (16). Despite this it is important to know whether the outcomes remain the same, with the introduction of highly trained personnel through intensive re-training of this method in Eastern Province.

Few studies have focused on contraceptive counselling and no experimental or observation literature reliably answers questions on the effectiveness on counselling on increasing contraceptive prevalence and reducing unwanted pregnancy (47). This study evaluated the effect of two levels of counselling on acceptance, uptake and early outcomes at 6 weeks of postplacental IUCD use. It also assessed barriers to acceptance and uptake of the postplacental IUCD.

The study sought to provide important information to policy makers on ways to enhance the uptake of this method and bridge the unmet needs for contraception.

OBJECTIVES

Broad Objective

To determine the effect of two levels of counselling on the acceptance, uptake and outcomes of expulsion, pelvic infection, couple satisfaction and continuation rates at 6 weeks postpartum of the postplacental intrauterine device

Specific Objectives

1. To determine acceptance rates of postplacental IUCD insertion.
2. To determine uptake rates of postplacental IUCD insertion.
3. To determine the factors and barriers influencing acceptance and uptake of the postplacental IUCD.
4. To determine the rates of continuation, expulsion, pelvic infection and satisfaction among acceptors of postplacental IUCD insertion at 6 weeks postpartum.

STUDY QUESTION

Does intensive family planning counselling on contraceptive methods and the postplacental IUCD during the antenatal period influence the acceptance, uptake and early outcomes of this method?

Hypothesis

Intensive antenatal family planning counselling will increase uptake rates of the postplacental IUCD in comparison to routine antenatal family planning counselling.

Null Hypothesis

Intensive family planning counselling will have no impact on uptake rate of the postplacental IUCD when compared to routine family planning counselling.

STUDY METHODOLOGY

Study Site

The study site was Embu Provincial General Hospital which is the biggest referral hospital in Eastern Province conducting on average 5021 deliveries per year. The hospital has a bed capacity of 78 in the antenatal and postnatal wards. The hospital is located 2kms from the town centre along the Nairobi -Meru Highway.

The study site has a busy antenatal clinic with an average of 120 new patients and a total of 400 clients per month. Comprehensive serv ices are provided at the site encompassing all antenatal and postnatal care services and adjuvant health talks and family planning. .

Postnatal services at the study site are booked for postpartum clinics at intervals of 2 weeks and 6 weeks. At the 6 weeks postpartum visit counselling on appropriate family planning is carried out and a method given..

Embu PGH has been an important site for training on postpartum IUCD insertion by the Ministries of Health in conjunction with JHPIEGO.

Study Population

The study population consisted of pregnant women between the gestational ages of

36 weeks and term, who attended antenatal clinic at Embu PGH and were followed up at labour ward, pre-discharge in the wards and at 6 weeks postpartum.

Inclusion Criteria

All pregnant women who attended antenatal care clinic at Embu PGH. between the gestational age of 36 weeks to term and were:

(1) 18 years and above:

(2) able to give informed written consent;

(3) meet the Medical Eligibility Criteria for IUCD Use (WHO, Third Edition. 2004);

(4) willing to use IUCD for contraception;

(5) scheduled for vaginal delivery:

(6) had the same partner for at least 1 year:

(7) had a mobile phone.

Exclusion Criteria

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

(1) ruptured membranes for greater than 8 hours;

(2) prolonged labour (> 12 hours);

(3) history of fever or of clinical symptoms of infection;

(4) history of pelvic inflammatory disease, ectopic pregnancy or complications of IUCD use;

(5) underwent emergency or elective caesarean section;

(6) previous history of postpartum haemorrhage;

(7) HIV/AIDS Stage 4 disease:

(8) the male partner had opposed the method;

(9) opted out after enrolment;

(10) extensive genital trauma post delivery, including cervical tears and laceration;

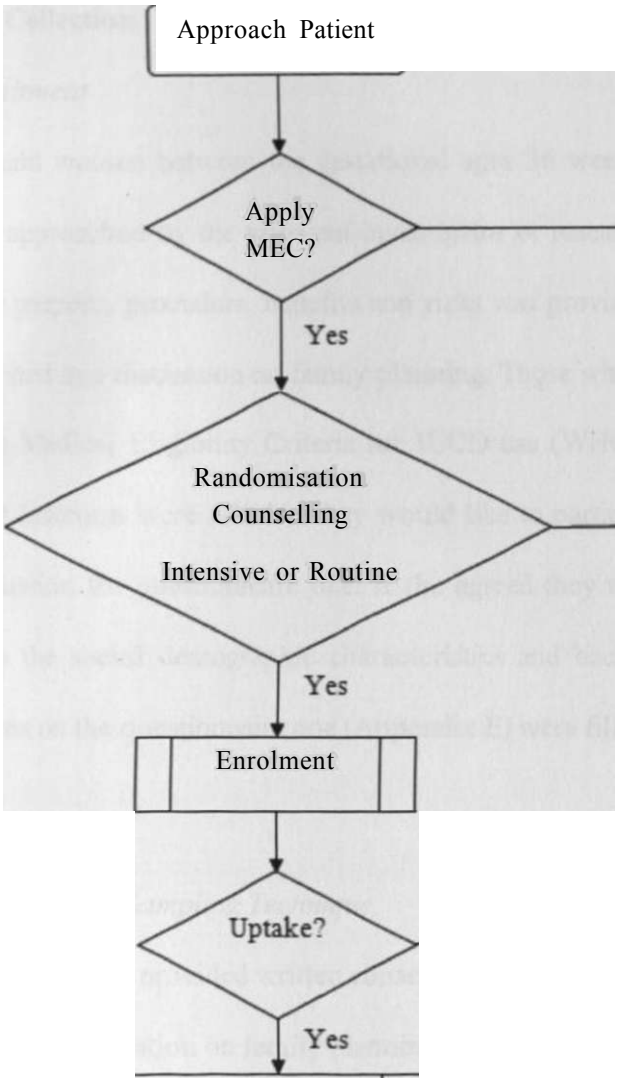
(11) postpartum haemorrhage at delivery.

Study Design

This was a randomized "open-label" clinical trial. The trial was non-blinded and sought to determine the effect of two levels of counselling on the acceptance, uptake and early outcomes of postplacental IUCD insertion in clients who received intensive family planning counselling as compared to clients who received routine counselling. Routine family planning counselling was the norm given to patients at the antenatal clinics at Embu PGH while intensive counselling was an extra effort in order to enhance informed decision making.

The overall study design is shown below:

Overall Study Design



KEY

	Decision
	Start or End Process
	Pre-defined process
MEC	Medical Eligibility Criteria (for contraceptive use)

Data Collection

Recruitment

Pregnant women between the gestational ages 36 weeks and term who attended the ANC clinic were approached by the principal investigator or research assistant. A detailed explanation of the study purpose, procedure, benefits and risks was provided. The patient was then asked if they are interested in a discussion on family planning. Those who accepted to the discussion were subjected to the Medical Eligibility Criteria for IUCD use (WHO 2004) (Appendix B). Clients eligible for IUCD insertion were asked if they would like to participate in the initial counselling and provide information for questionnaire one. If the agreed they were asked to provide written consent after which the social demographic characteristics and background contraceptive knowledge and use sections on the questionnaire one (Appendix E) were filled.

Intervention

Randomization Sampling Technique

Clients who had provided written consent were randomized to the two counselling levels: routine or intensive information on family planning methods. Simple randomization sequence was determined manually by indicating either routine or intensive on alternate sheets of paper. The notes were then sealed in opaque envelopes. The principle investigator mixed the sealed envelopes in a box that was placed in the counselling room. Once the patient had been recruited, given written consent and initial social demographic data obtained by the study nurse, the counsellor picked an envelope form the box, opened the envelope and counselled according to the instructions within.

Antenatal Family Planning Counselling

Patients were randomized to two different levels of counselling, routine or intensive family planning counselling. The sessions were facilitated by nurses specifically trained in family planning counselling. The nurse who provided the intervention was different from the one who had recruited and filled the first sections of Questionnaire 1. Counselling ensured the patient made an informed choice.

The main differences between the two levels of counselling were as follows:

1. A study protocol (Appendix C) on steps of family planning counselling was used for the intensive FP counselled group. The routine family planning counselled group followed the normal steps of the FP counselling given at antenatal clinic at Embu PGH.
2. The intensive FP counselled group had longer (at least 30 minutes) more interactive sessions as compared to the routine FP counselled group which followed the timings (usually less than 15 minutes) for individual FP counselling given at the antenatal clinic at the hospital.
3. A decision making Hip chart tool (48) was used in the intensive family planning counselled group to enhance knowledge and understanding. The tool is available at the hospital but is not routinely used to aid in antenatal family planning counselling.
4. Samples of all methods were made available for the individual clients who underwent intensive family planning counselling. The routine FP counselled group were not exposed to the sample methods during the one to one session but they had been exposed to the methods briefly during the group family planning talks.
5. The intensive FP counselled group were scheduled for up to three antenatal follow up visits (depending on gestational age) on family planning counselling whereas the routine group was restricted to one session.

6. Provision for partner involvement during counselling sessions was given for the intensive family planning counselled group whereas for the routine FP counselled group this was not provided as this was not routine in the hospital.
7. A take home pamphlet (Appendix D) was provided to the intensive FP counselled group to recap and share information with her partner. The routine group was not offered any additional reading materials as this was not carried out during antenatal visits in the hospital.

All other procedures remained the same for the two counselling groups. The patient was greeted, questions were entertained and adequate interaction was ensured during the session.

A. Routine Family Planning Counselling

Routine family planning counselling was done in accordance to the normal antenatal counselling at Embu PGH with exception to the additional emphasizes on PPIUCD. In Embu PGH PPIUCD emphasize occurs intrapartum at labour ward and more comprehensive family planning counselling occurs during the 6 week postpartum visit.

Routine family planning counselling began with a brief session of group counselling on all available contraceptive method which formed part of the scheduled health education talks.

This was followed by a one to one counselling session in a private room which took place for no more than 15 minutes where the steps were:

1. The patient was greeted and asked to take a seat.
2. The counsellor introduced themselves and created rapport. The client was asked about previous contraceptive use, knowledge on methods available and in particular any knowledge on PPIUCD.
3. A brief explanation on the different methods (with mention to those ideal for postpartum use), advantages and disadvantages was offered. The depth of this discussion depended on the

clients' individual prior knowledge and interest on the different methods. No decision making flip chart was used.

4. Exploration of future reproductive goals and history was sought as was the plan for method of infant feeding in relation to LAM.
5. The client was asked about their circumstances and relationships while exploring the client's history and risk of HIV/STI and PMTCT was explained.
6. Focus was then shifted to the IUCD and its insertion postpartum where the counsellor explored what the client knew about the PPIUCD and corrected misconceptions. A brief explanation of advantages, disadvantages and practicability was offered. The verification that the IUCD does not protect against STI/STDs was emphasized.
7. At the end of the session the client was encouraged to ask questions on any method of interest.

B. Intensive Family Planning Counselling

The Intensive family planning counselling protocol used the GATHER (Greet, Ask. Tell, Help, Explain and Return) and REDI (Rapport. Exploration, Decision making and Implementation of Decision) approaches of family planning counselling. The counsellor had a guide (Appendix C) that was to be followed to ensure uniformity of the intervention.

The session began with a brief group session on all available contraceptive methods.

The following steps were carried out during the individual (plus partner if available) counselling session in a private room which took place for not less than 30 minutes:

1. The patient was greeted and asked to take a seat.
2. The counsellor introduced themselves and created rapport.
3. The client was asked about previous contraceptive use. knowledge on methods available and in particular any knowledge on PPIUCD.

4. An in depth explanation on the different methods (with mention to those ideal for postpartum use), advantages and disadvantages was offered using the decision making flipchart tool (48).
5. Questions were entertained at this point.
6. Exploration of future reproductive goals and history was sought as was the plan for method of infant feeding in relation to LAM.
7. The client was asked about their circumstances and relationships while exploring the client's history and risk of HIV/STI and PMTCT was explained.
8. Focus was then shifted to the IUCD where the counsellor explored what the client knew about the IUCD and corrected misconceptions. The verification that the IUCD does not protect against STI/STDs was emphasized.
9. The client was shown the IUCD and encouraged to hold it and have a close look.
10. The hand held uterine model was shown and an explanation on the insertion techniques for both postplacental and interval timing were given.
11. Questions were encouraged at this point.
12. A recap on advantages, disadvantages and practicability of the PPIUCD methods was given and emphasize was made on the need for a postpartum method.
13. Clients were issued with a take home pamphlet (Appendix D) to read and share with their partner. The importance of male participation in decision making was imparted.
14. An appointment for a follow up FP counselling visit was made and the client was requested to bring her partner for the session.
15. At the end of the session the client was encouraged to ask questions on any method of interest.

Enrolment

After counselling the clients were asked to fill the selection part of Questionnaire 1.

A recap of the study purpose, procedures, benefits and risks was availed to the patient and questions were entertained. The client was asked whether she would like to have the 1UCD inserted after delivery in the postplacental timing. Enrolment consent was taken immediately if the patient was willing or could be taken on the return visit, at a later date.

Women in both family planning counselling groups were allowed to consult their partner before consenting. Consent could be taken later for women who wanted to consult their partners.

Those who did not consent for the method were asked to fill in their reasons for decline and this was the exit point for them. They were advised on the need to use any other contraceptive method suitable for them.

Postplacental IUCD Insertion

Intrapartum Assessment

Women who had been enrolled and presented to labour ward in labour were requested to fill the first section of the Questionnaire 2. Women who opted out of the study were allowed to do so. They were also advised on the need for postpartum contraception. Those who accepted underwent a clinical assessment to determine progression of labour and eligibility.

Progress of labour was monitored by way of partogragh. If complications arose during labour that were contraindications to postplacental IUCD insertion the method was not administered and the patient was counselled after delivery on other alternative timings for IUCD insertion such as early or interval and other methods suitable.

Postplacental Assessment

Women who had an uncomplicated vaginal delivery had the IUCD inserted within 10 minutes of postplacental delivery. In anticipation of delivery all medical records were counter checked to ensure the patient opted for the method and was still eligible.

The IUCD was inserted by the "champion" midwifes trained in postplacental IUCD insertion.

Before any IUCD was inserted, active management of third stage of labour was performed. If excessive bleeding occurred tears were first repaired and the insertion done in the immediate postpartum if the patient wished.

Patients were not given prophylactic antibiotics or additional analgesia beyond that given at labour.

Manual Postplacental IUCD Insertion Technique.

The Copper T 380A intrauterine device was used for insertion by manual insertion method. The following guidelines used are in accordance to the EngenderHealth Training Course Manual (49).

The uterus was palpated to evaluate the height of the fundus and its contraction. This step was important to assess the uterine size in order to estimate length of strings post procedure.

1. The external genitalia was cleaned with a clean cloth.
2. A clean drape was placed over the client's abdomen and beneath her buttocks.
3. The cervix was visualized with the aid of a retractor.
4. The cervix and vagina were prepped with a liberal application of an antiseptic solution and time was allowed for the antiseptic to work.
5. The IUCD was held by gripping the vertical rod between the index and middle fingers of the predominant hand.

6. The IUCD was slowly inserted into the vagina and through the cervix into the uterus, in the direction of the abdominal hand that held on firmly to the uterus through the relaxed abdominal wall. The abdomen was palpated with the external hand to ensure placement at the fundus had been reached.
7. Care was taken not to dislodge the IUCD as the hand was slowly removed from the uterus.
8. The cervix was examined.

After the insertion procedure the patient was helped into bed and reviewed for postpartum haemorrhage and abdominal pain over the next two hours.

The patient was sensitized to pay attention to an increase in vaginal blood How and abdominal pain. If this occurred the patient was managed appropriately for postpartum haemorrhage and a pelvic exam done to check for IUCD expulsion.

Sterilization of equipment and disposal of waste was carried out as per guidelines for infection prevention. (1)

The study nurse then filled the IUCD insertion section on Questionnaire 2.

Follow up

Pre-Dischargc Review

Recipients were seen before hospital discharge and evaluated for fever, pelvic tenderness, excessive vaginal bleeding, unusual vaginal discharge and IUCD expulsion.

Appropriate medical attention was given to any of the patients experiencing the above. Those who have IUCD expulsion exited from the study. Appropriate information on interval insertion of IUCD

insertion or alternative methods were given to the study participants. Women who chose alternative postpartum methods were given a prescription and those who choose interval methods were advised to come back to family planning clinic in 6 weeks.

All study participants who had postplacental insertion of the IUCD without complications were given a return note (Appendix H) with details of date and place of return for the follow up visit, warning signs and post insertion instructions. They were re-educated using the study protocol post-insertion instructions (Appendix G) on warning signs, reminded to check undergarments and pads for expulsion and trained to assess for the location of strings. The patient was requested to keep and bring the IUCD if she noticed its expulsion. The patient was also allowed to ask any questions pertaining to her new contraceptive method.

It was made clear to the study participants that they could return to the clinic without an appointment if any complications or queries arose. On weekends they were advised to go to the casualty or call the contact number that was provided on the return note.

Sixth week postpartum visit

The follow up visit was held at 6 weeks postpartum. The visits were scheduled at the family planning clinic on Mondays.

During the follow up visit the follow up section of Questionnaire 2 was filled to obtain data on the outcomes. Physical and pelvic examination were performed by the principal investigator or research assistant to verify the presence of the IUCD and check for signs of infection. Expulsion was verified physically by visual inspection. IUCD strings which were too long were cut but not to less than 3cm from the external cervical os.

Patients who had no complications were re-educated on assessment of IUCD stings and proper hygiene. This was the final exit point from the study; however, they were advised to return to the family planning clinic at 3 months postpartum for a follow up visit or before then if any complications arose.

Patients who had complications were treated accordingly. If the string were missing, and the patient was unsure of expulsion the study doctor followed the EngenderHealth Protocol (49) for missing strings which involved:

1. Pregnancy was ruled out.
2. The strings were located by probing the cervical canal with narrow forceps and gently drawn out if felt.
3. If the strings were located but could not be retrieved and the client wanted the IUCD removed, the IUCD was removed with alligator forceps.
4. If the strings could not be located a sound was used to check whether the IUCD was in place.
5. If the strings could not be located an X-ray or ultrasound was carried out to determine whether the IUCD had been expelled. Back up contraception was provided if the procedure was not done immediately.

If the results showed expulsion the patient was offered information on reinsertion and alternative methods.

Patients who wished to discontinue use of this method due to any side effects or dissatisfaction were allowed to do so. Proper and adequate information was given to ensure the client left with a contraceptive method.

Study participants who had had the postplacental IUCD and failed to return for the follow up visit were called via telephone and advised to return. Those who were unable to return were interviewed via telephone and the data entered. They were however advised on the importance of the return visit and asked to telephone the contact person or come to the family planning clinic if any complications or queries arose. The importance of the 3 month postnatal visit was also emphasised. This was the final point of the study.

Sample Size

To have detected a 25% difference in the prevalence of postplacental IUCD use between the intensive and routine FP counselled women, the prevalence of IUCD use was taken to be the baseline 2.4% (KDHS 2003), we estimated using the sample size formula below:

$$N = \frac{2\left(z_{1-\alpha_2}\sqrt{2\bar{p}(1-\bar{p})} + z_{1-\beta}\sqrt{p_c(1-p_c)+p_a(1-p_a)}\right)^2}{(Pc\text{-}Pj^2}$$

Where, a two sided alpha—0.05. z_{t_a} —1.960 and for an 80% power, z,^—0.842. p_c was the estimated prevalence of IUCD use among the routine FP counselled women; in this case 2.4%. $\boldsymbol{p_a}$ was the estimated prevalence of IUCD use among the intensively counselled women; in this case (2.4 + 25) 27.4%.

The result was that a minimum of 78 women in total (39 per group) were required to achieve an 80% power to detect the stated difference of 25% in postplacental IUCD use prevalence between the two groups of women (alpha=0.05 two-sided).

The sample size was adjusted for loss to follow-up by adding 20% of the estimated sample size which resulted to 94 study subjects. 47 clients in each randomization arm. The estimated 20% was calculated by overestimating results from a study done in Kenya (16) that showed 2-10% loss to follow up at 6 weeks.

A total number of 127 clients were recruited (63 clients in the intensive FP counselled group and 64 clients in the routine FP counselled group. The power therefore increased to 98% to detect the stated 25% difference in postplacental IUCD use prevalence between the intensive FP counselled and routine FP counselled randomization groups.

Study Period

The study was conducted between the months of October, 2009 and February. 2010.

Data Management

The data was collected using two structured questionnaires.

Questionnaire One (Appendix E) contained information derived from the index visit of the clients interviewed in the antenatal clinic. The questionnaire comprised of social demographic data, obstetric characteristics, medical history, contraceptive knowledge and previous use, IUCD misconceptions and acceptance status.

Questionnaire Two (Appendix F) contained information from clients who had enrolled for IUCD insertion. The questionnaire consisted of three parts: entry at labour ward, pre discharge visit and follow-up visit. The data collected comprised of type and adequacy of counselling, method acceptance, medical history and physical exams carried out intrapartum, on discharge review and follow up visit.

The questionnaires were stored safely in a locked drawer awaiting data entry.

Data Analysis and Presentation

Data from the questionnaire forms was transferred to a specifically designed database on Microsoft Access. SPSS version 17.0 was then used for data processing and analysis. The data was validated and analysed with assistance from a biostatistician.

Descriptive statistics were presented for the two groups of women: means for age and counts together with percentages for categorical variables such as socio-demographic and background contraceptive use. Socio-demographic and background contraceptive use variables were tested for associations with type of counselling, acceptance and uptake of IUCD using Chi-square test. Univariate analysis was used to evaluate the predictors of acceptance and uptake of postplacental IUCD.

All statistical tests were performed at a 0.05 level of significance (95% confidence interval).

Ethical Considerations

The study was reviewed and approved by the Kenyatta National Hospital Research Ethics Review Board and the Embu PGH Review Board. (Appendix I)

The principal investigator or research assistant ascertained that the method was suitable for the patient in accordance to Medical Eligibility Criteria for IUCD Contraceptive Use (WHO, 2004).This ensured the postplacental IUCD was only inserted in IUCD eligible patients.

Each patient enrolled gave written consent only after a detailed explanation of the study purpose, procedure, benefits and risks was provided to them by the interviewer.

Routine family planning counselling information is the norm provided at the antenatal clinics. Failure to use the interv entions of the intensive counselled group for all study subjects did not constitute an ethical injustice as the intervention was an extra effort.

The information the patient availed was confidential and counselling was carried out privately. The questionnaires were kept safe and the information was only available to the study nurse and principal investigator.

Those who did not accept to take part in the study were allowed to continue with appropriate care within the hospital without discrimination.

There was no financial inducement to participate in the study.

Only trained professionals were allowed to insert the postplacental IUCD. This ensured minimal complications such as expulsion and displacement.

Patients found to have missing IUCD were informed and sent for X-rays or pelvic ultrasound to ascertain position. Expulsion of the IUCD was a chief complaint and sign sought. The woman who had expulsion were informed and advised on alternative suitable methods. In cases where expulsion was suspected and investigation could not be done immediately, an additional suitable contraceptive method was provided.

Study Limitations

Displacement was an important outcome of measure, attained by carrying out an ultrasound on each patient. However due to financial constraints this could not be assessed.

RESULTS

This was a randomized clinical trial to compare the acceptance, uptake and early outcomes at 6 weeks of the postplacental IUCD in women who received antenatal intensive compared to routine counselling on family planning methods and the postplacental IUCD.

Figure 1: Flow Chart of the Study Events

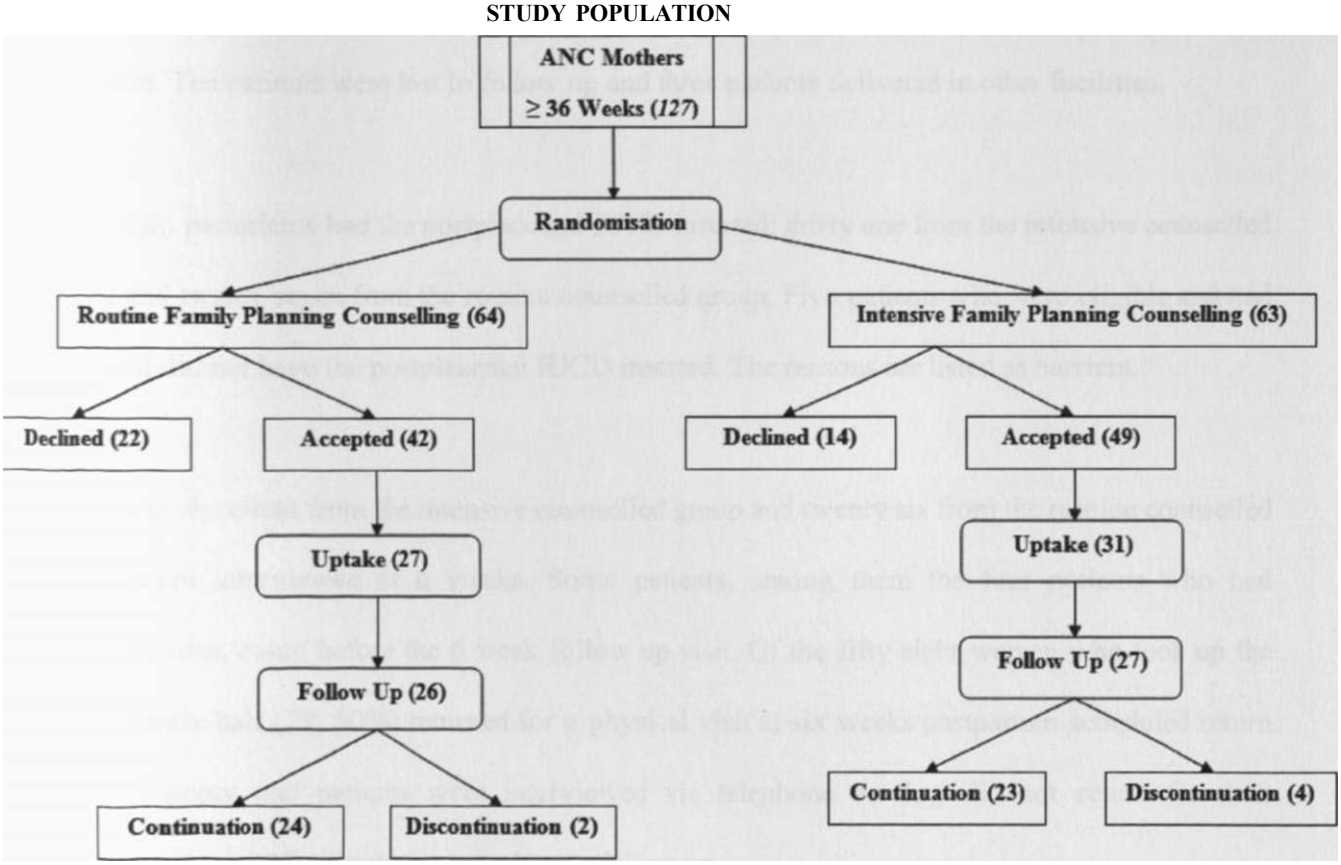


Figure 1 above represents the flow chart of the study groups. In this study one hundred and twenty seven eligible antenatal mothers were approached and all accepted to participate in the study. Randomization yielded two groups: Sixty three women received intensive family planning counselling and sixty four women received routine family planning counselling. Of these women forty nine women in the intensive family planning counselled group and forty two women in the routine family planning counselled group accepted to have the postplacental IUCD inserted.

Seventy eight women delivered at Embu PGH labour ward. Sixty eight women accepted intrapartum to have the method inserted: thirty five in the intensive FP counselled group and thirty three in the routine counselled group. Thirteen women of the ninety one clients who had accepted at antenatal clinic declined to have the method inserted. One patient who had accepted postplacental IUCD insertion did not qualify for insertion as physical examination revealed intrauterine fetal demise. Four clients who had accepted postplacental IUCD insertion underwent emergency caesarean sections and lost eligibility form the study, however the postplacental IUCD was inserted for some. Ten patients were lost to follow up and three patients delivered in other facilities.

Fifty eight parturients had the postplacental IUCD inserted: thirty one from the intensive counselled group and twenty seven from the routine counselled group. Five patients who were eligible and had accepted did not have the postplacental IUCD inserted. The reasons are listed as barriers.

Twenty seven client from the intensive counselled group and twenty six from the routine counselled group were interviewed at 6 weeks. Some patients, among them the four patients who had complications, came before the 6 week follow up visit. Of the fifty eight women who took up the method only half (29, 50%) returned for a physical visit at six weeks postpartum scheduled return date. Twenty one patients were interviewed via telephone as they did not return for their appointment visit. Four patients were lost to follow up.

Twenty three women in the intensive family planning counselled group and twenty four women in the routine family planning counselled group at the 6 week visit decided to continue to use the postplacental IUCD as their contraceptive method.

Table 1: Social Demographic Characteristics of the Study Population.

	Level of Counselling		
	Intensive	Routine	
Characteristic	N = 63 (%)	N = 64 (%)	P-value
Age			
<30 years	48 (76.2%)	38 (60.3%)	0.056
>=30 years	15(23.8%)	25 (39.7%)	
Marital Status			
Married	55 (87.3%)	62 (98.4%)	0.033*
Others	8(12.7%)	1 (1.6%)	
Educational Attainment			
Primary	24 (38.1%)	26 (41.3%)	0.304
Secondary	33 (52.4%)	26 (41.3%)	
College/University	6 (9.5%)	11 (17.5%)	
Employment			
Unemployed	45 (71.4%)	35 (55.6%)	0.064
Employed	18(28.6%)	28 (44.4%)	
Parity			
0+0	34 (54.8%)	24(38.1%)	0.166
1+	16(25.8%)	21 (33.3%)	
>=2+	12(19.4%)	18(28.6%)	
Number of additional children wanted			
None	19(30.2%)	29 (45.3%)	0.288
One	14(22.2%)	12(18.8%)	
Two and more	28 (44.4%)	20(31.3%)	
Not sure	2 (3.2%)	3 (4.7%)	
Duration before next pregnancy			
<=3	6(13.3%)	4(10.8%)	0.728
>3	39 (86.7%)	33 (89.2%)	

*Fishers exact test

Table 1 above shows the social demographic characteristic of the study population. The routine FP counselled group were more likely .than the intensive FP counselled group, to be over 30 years of age and employed but being married (98%; p-value 0.03) was the only variable that showed statistically significant difference. There was no statistical significant difference in parity, required additional children and intended duration before next pregnancy between the two randomization arms.

Table 2: Background contraceptive knowledge and use of the study population

Characteristic	Level of Counselling: Intensive N = 63 (%)	Level of Counselling: Routine N = 64 (%)	p-value
Would leave after delivery with an FP method	59 (93.7%)	64(100%)	0.058
Prior contraceptive use	33 (53.2%)	47 (75.8%)	0.009
Prior IUCD use	2 (3.2%)	5 (7.8%)	0.440
HavelUCD misconceptions			
Lost inside the body	21 (33.3%)	16(25.0%)	0.301
Move to the heart	7(11.1%)	16(25.0%)	0.042
Fail and will be in babies head	25 (39.7%)	24 (37.5%)	0.801
Be felt by partner (pinching)	20(31.7%)	22(34.4%)	0.753
Fall out	12(19.0%)	18(28.1%)	0.229
Causes cancer	8(12.7%)	13(20.3%)	0.248
Causes abortion	3 (4.8%)	6(9.4%)	0.492
Knowledge on IUCD			
IUCD is more than 97% effective	22 (34.9%)	26(40.6%)	0.507
IUCD functions by preventing implantation	11 (17.5%)	5(7.8%)	0.101
Copper T IUCD protects for 10 years	18(28.6)	17(26.6%)	0.800
IUCD side effects	22 (34.9%)	28(43.8%)	0.309
Painful periods	3 (4.8%)	6(9.4%)	0.492*
Heavy bleeding	18(28.6%)	23(35.9%)	0.375
Expulsion	1 (1.6%)	0	0.496
Pregnancy	3 (4.8%)	6(9.4%)	0.492
Know benefits of IUCD	36(57.1%)	41(64.1%)	0.496
Protects against pregnancy	28 (44.4%)	38(59.4%)	0.092
Long duration of protection	18(28.6%)	14(21.9%)	0.385
Safe	4 (6.3%)	5(7.8%)	1.000*
Easily reverses fertility	1 (1.6%)	2(3.1%)	1.000*
Minimal side effects	5 (7.9%)	1(1.6%)	0.115
IUCD protects against STI/STDs	61 (98.4%)	58(96.7%)	0.616*
Prior knowledge on PPIUCD			
Yes	21 (33.3%)	18(28.1%)	0.525
No	44 (67.7%)	47(72.3%)	

'Fishers exact test

Table 2 above shows the background contraceptive knowledge and use of the study population. The utine family planning counselled group were more likely to accept an immediate postpartum method md had more previous contraceptive use (75.8%; p-value 0.009). Only seven (5.5%) out of the one mndred and twenty seven participants had used an IUCD before

the majority of women had at least one misconception about the IUCD. More women in the routine FP .ounselled group thought it could move to the heart (25%; p-value 0.042).

Ikre was no statistically significant difference in IUCD knowledge before counselling between the two zroups. Both groups also had similar prior knowledge on postplacental IUCD (p-value 0.525) with only 30.7% having heard of the method prior to this intervention.

Table 3: Antenatal Acceptance Rates of Postplacental IUCD insertion by Level of Counselling

Acceptance Rates			
	Postplacental IUCD insertion chosen		
Level of counselling	N = 91 (%)	OR (95% CI)	p-value
Intensive	49(77.8)	0.6 (0.2-1.2)	0.129
Routine	42 (65.6)		

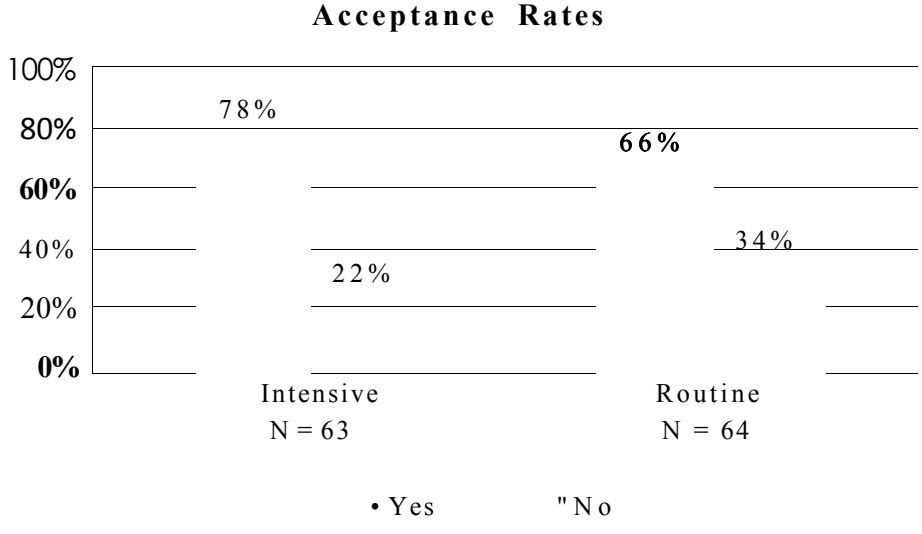


Figure 2: Antenatal Acceptance Rates of the Postplacental IUCD by Level of Counselling

Table 3 and Figure 2 above, show the antenatal acceptance rates of the postplacental IUCD by level of counselling. Of these ninety one women who accepted postplacental IUCD insertion, forty nine women were from the intensive family planning counselled group and forty two women from the routine family planning counselled group. There was no statistically significant difference in acceptance rates between the two randomization arms (p-value 0.129)

Table 4: Social Demographic Characteristics by Acceptance of Postplacental IUCD insertion

	Outcome of Counselling		
	Accepted	Declined	
Characteristic	N = 91 (%)	N = 36 (%)	p- value
Age			
<30 years	59 (65.6%)	27 (75.0%)	0.304
>=30 years	31 (34.4%)	9 (25.0%)	
Marital Status			
Married	84 (93.3%)	33(91.7%)	0.714*
Others	6(6.7%)	3 (8.3%)	
Educational Attainment			
Primary	33 (36.7%)	17(47.2%)	0.135
Secondary	47 (52.2%)	12(33.3%)	
College/University	10(11.1%)	7(19.4%)	
Employment			
Unemployed	59 (65.6%)	21 (58.3%)	0.447
Employed	31 (34.4%)	15(41.7%)	
Parity			
(HO	41 (46.1%)	17(47.2%)	0.394
1+	24 (27.0%)	13(36.1%)	
>=2+	24 (27.0%)	6(16.7%)	
Number of additional children wanted			
None	35 (38.5%)	13(36.1%)	0.819
One	20 (22.0%)	6(16.7%)	
Two and more	33 (36.3%)	15(41.7%)	
Not sure	3 (3.3%)	2 (5.6%)	
Duration before next pregnancy			
<=3	9(15.5%)	1 (4.2%)	0.267*
>3	49 (84.5%)	23 (95.8%)	

*** Fishers exact test**

Table 4 above shows the social demographic characteristics of those who accepted postplacental IUCD insertion. Cross tabulation was carried out to determine factors associated with acceptance. From the table we observe that there was no statistically significant difference in social demographic characteristics between the women who accepted and those who did not accept to use the postplacental IUCD.

Table 5: Background Contraceptive Knowledge by Acceptance of Postplacental IUCD Insertion

	Outcome of Counselling		
	Accepted	Declined	
Characteristic	N = 91 (%)	N = 36 (%)	p- value
Would leave after delivery with FP method	87 (95.6%)	36(100.0%)	0.577
Prior contraceptive use	52 (59.1%)	28 (77.8%)	0.048
Prior IUCD use	5 (5.5%)	2 (5.6%)	1.000*
Have IUCD misconceptions			
Lost inside the body	27 (29.7%)	10(27.8%)	0.832
Move to the heart	15(16.5%)	**8 (22.2%)**	0.449
Fail and will be in babies head	39 (42.9%)	10(27.8%)	0.116
Be felt by partner (pinching)	31 (34.1%)	11 (30.6%)	0.705
Fall out	22 (24.2%)	**8 (22.2%)**	0.815
Causes cancer	11 (12.1%)	10(27.8%)	0.032
Causes abortion	4.4 (4.8%)	5(13.9%)	0.117*
Knowledge on IUCD			
IUCD is more than 97% effective	34 (37.4%)	14(38.9%)	0.873
IUCD functions by preventing implantation	13 (14.3%)	3 (8.3%)	0.554*
Copper T IUCD protects for 10 years	30 (33.0%)	5(13.9%)	0.030
IUCD side effects	38 (41.8%)	12(33.3%)	0.381
Painful periods	7 (7.7%)	2 (5.6%)	1.000*
Heavy bleeding	31 (34.1%)	10(27.8%)	0.495
Expulsion	1(1.1%)	0 (0.0%)	1.000*
Pregnancy	4 (4.4%)	5(13.9%)	0.117*
Know benefits of IUCD	51(56.0%)	26 (72.2%)	0.158
Protects against pregnancy	42 (46.2%)	24 (66.7%)	0.037
Long duration of protection	27 (29.7%)	5(13.9%)	0.065
Safe	9 (9.9%)	0 (0.0%)	0.060*
Easily reverses fertility	2 (2.2%)	1 (2.8%)	1.000*
Minimal side effects	4 (4.4%)	2 (5.6%)	1.000*
IUCD protects against STI/STDs	1(1.1%)	2 (5.7%)	0.097
Prior knowledge on PPIUCD	28 (30.8%)	11 (30.6%)	0.981

* Fishers exact test

Table 5 above shows background contraceptive knowledge and use in women who accepted postplacental Il'CD insertion. Cross tabulation was carried out to determine factors influencing acceptance.

The table shows that women who accepted postplacental IUCD insertion were more likely to be naive to contraception (58%: p-value 0.048).

Women who had the misconception that the IUCD may cause cancer were less likely to accept the method (p- value 0.032).

Women who knew the method was a long term method were more likely to accept the method (p-value 0.030).

Table 6: Univariate Analysis for Predictors of Acceptance

Variable	OR	CI 95%	p - value
Prior contraceptive use	0.4	0.2 - 1.0	0.058
IUCD causes cancer	0.4	0.1-1.1	0.079
Copper T IUCD protects for 10 years	4.2	1.4 - 12.6	0.01
Protects against pregnancy	0.6	0.2 - 1.4	0.244

Table 6 above shows the univariate analysis to verify for statistically significant predictors of acceptance. The only true statistically significant predictor of acceptance was the knowledge that the IUCD is a long terni method. Women who knew, prior to counselling, that the IUCD is a long term method were 4.2 times more likely to accept the method, (p-value 0.01)

Figure 3: Barriers to Acceptance of Postplacental IUCD insertion.

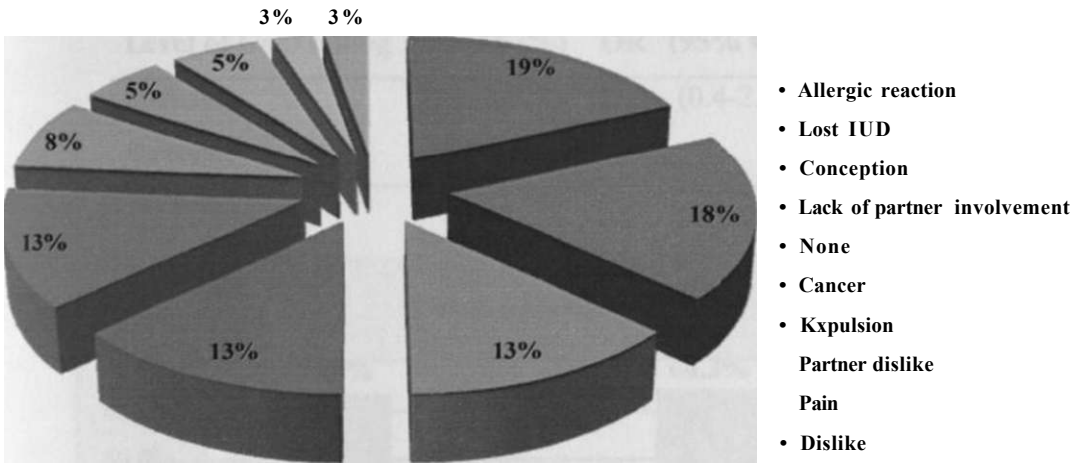


Figure 3 above shows reasons why women did not accept the postplacental IUCD method. The most common reasons why women did not accept to use the method were fear of foreign body causing an allergic reaction (19%) and fear of lost IUCD (18%).

A large number of women (13%) also reported lack of partner involvement in decision making a reason to decline acceptance.

Table 8: Uptake Rates of Postplacental IUCD insertion by Level of Counselling

Uptake Rates				
	Postplacental IUCD inserted			
Level of Counselling	N = 58 (%)	OR	(95% CI)	p-value
Intensive	31 (63.3)	1.0	(0.4-2.5)	0.920
Routine	27 (64.3)			

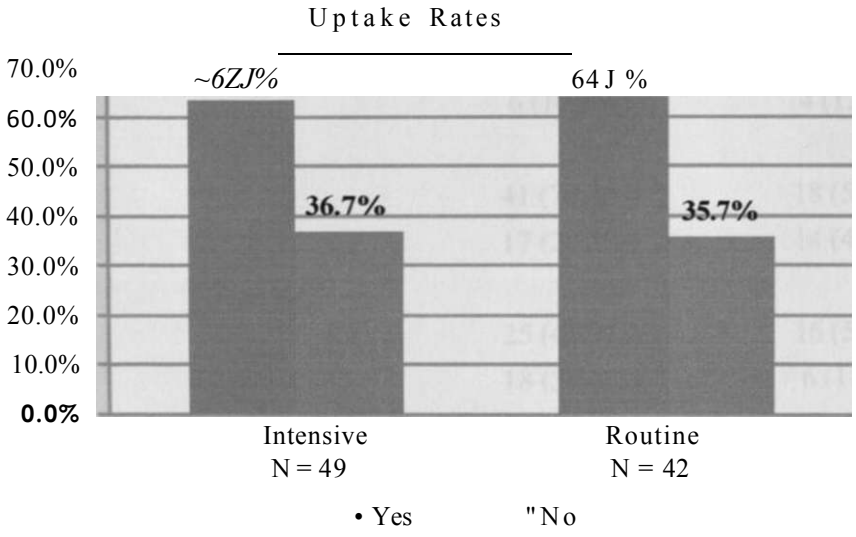


Figure 4: Uptake rates of the postplacental IUCD by level of counselling.

lable 8 and Figure 4 above show the uptake rates of postplacental IUCD insertion by level of counselling. Fifty eight parturients (44% of study subjects) out of the ninety one antenatal acceptors had tie IUCD inserted postplacental. This consisted of 31 (63.3%) women in the intensive FP counselled group and 27 (64.3%) women in the routine FP counselled group. There was no statistically significant difference in uptake between the two randomization arms (p-value 0.232)

Table 9: Uptake of Postplacental IUCD by Social Demographic Characteristics

Characteristic	Uptake of Postplacental IUCD Yes N = 58 (%)	No N = 33 (%)	p -value
Age			
<30 years	40 (69.0%)	19(59.4%)	0.359
>=30 years	18(31.0%)	13(40.6%)	
Marital Status			
Married	58(100.0%)	26(81.3%)	0.001*
Others	0 (0.0%)	6(18.8%)	
Educational Attainment			
Primary	18(31.0%)	15(46.9%)	0.250
Secondary	34 (58.6%)	13 (40.6%)	
College/University	6(10.3%)	4(12.5%)	
Employment			
Unemployed	41 (70.7%)	18(56.3%)	0.168
Employed	17(29.3%)	14(43.8%)	
Parity			
(HO	25 (43.9%)	16(50.0%)	0.415
1+	18(31.6%)	6(18.8%)	
>=2+	14(24.6%)	10(31.2%)	
Number of additional children wanted			
None	23 (39.7%)	12(36.4%)	0.318
One	10(17.2%)	10(30.3%)	
Two and more	22 (37.9%)	11 (33.3%)	
Not sure	3 (5.2%)	0(0.0%)	
Duration before next pregnancy			
<=3	7 (20.0%)	2 (8.7%)	0.295*
>3	28 (80.0%)	21 (91.3%)	

*Fishers exact test

Table 9 shows the social demographic characteristics of those who took up the postplacental IUCD. Cross tabulation was carried out to determine factors associated with uptake. The only statistically significant variable was that the women who took up the method were more likely to be married (p- value 0.001). There was no statistically significant difference in age. educational level, employment, number of additional children or intended duration before next pregnancy.

Table 10: Uptake of Postplacental IUCD by Background Contraceptive Knowledge And Use

Characteristic	Uptake of Postplacental IUCD		p-value
	Yes	No	
	N = 58 (%)	N = 33 (%)	
Would leave after delivery with FP method	55 (94.8%)	32 (97.0%)	1.000*
Prior contraceptive use	34(61.8%)	18(54.5%)	0.502
Prior IUCD use	2 (3.4%)	3(9.1%)	0.349
Ha\eIUCD misconceptions			
Lost inside the body	16(27.6%)	11 (33.3%)	0.564
Move to the heart	14(24.1%)	1 (3.0%)	0.009
Fail and will be in babies head	28 (48.3%)	11 (33.3%)	0.166
Be felt by partner (pinching)	22 (37.9%)	9 (27.3%)	0.302
Fall out	16(27.6%)	6(18.2%)	0.314
Causes cancer	4 (6.9%)	7(21.2%)	0.090*
Causes abortion	3 (5.2%)	1 (3.0%)	1.000*
Knowledge on IUCD			
IUCD is more than 97% effective	16(27.6%)	18(54.5%)	0.011
IUCD functions by preventing implantation	7(12.1%)	6(18.2%)	0.535*
Copper T IUCD protects for 10 years	17(29.3%)	13(39.4%)	0.325
IUCD side effects	27 (46.6%)	11 (33.3%)	0.219
Painful periods	3 (5.2%)	4(12.1%)	0.250*
Heavy bleeding	22 (37.9%)	9 (27.3%)	0.302
Expulsion	0 (0.0%)	1 (3.0%)	0.363*
Pregnancy	4 (6.9%)	0 (0.0%)	0.292*
Know benefits of IUCD	23 (39.7%)	28 (84.8%)	<0.001
Protects against pregnancy	16(27.6%)	26 (78.8%)	<0.001
Long duration of protection	16(27.6%)	11 (33.3%)	0.564
Safe	5 (8.6%)	4(12.2%)	0.718*
Easily reverses fertility	1 (1.7%)	1 (3.0%)	1.000*
Minimal side effects	2 (3.4%)	2(6.1%)	0.619*
IUCD protects against STI/STDs	0 (0.0%)	1 (3.1%)	0.157
Prior knowledge on PPIUCD	19(32.8%)	9 (27.3%)	0.586

* Fishers exact test

Table 10 above shows background contraceptive knowledge and use in women who had the postplacental IUCD inserted. Cross tabulation was carried out to determine factors associated with uptake.

rhe results show that women who had prior knowledge that the IUCD protected against pregnancy (p-,alue 0.001), was 97% effective (p- value 0.01) and who reported knowing benefits of the IUCD (p-value).00l) were less likely to take up the method.

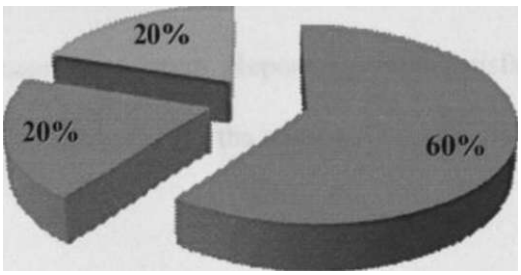
Aomen who had the misconception that the IUCD could move to the heart were more likely to take up he method (p-value 0.009).

fable 11: Univariate Analysis for Predictors of Uptake

Variable	OR	CI 95%	p - value
Move to the heart	5.7	0.6-51.2	0.118
IUCD is more than 97% effective	0.6	0.2- 1.5	0.26
Know benefits of IUCD	0.2	0.1 -0.6	0.005

able 11 above shows the univariate analysis to verify for statistically significant predictors of uptake, "he only true statistically significant predictor of uptake was that women who reported already knowing he benefits of the IUCD were less likely to take up the method (p-value 0.005).

rigure 5: Barriers to Uptake of the Postplacental IUCD



•gure 5 above shows barriers to uptake of the postplacental IUCD. Out of the sixty three women who Kcepted to use the postplacental IUCD intrapartum, five did not have the IUCD inserted.

The figure above shows that for 3 patients (60%), the unavailability of trained staff to insert the IUCD aas the barrier to uptake. The reasons the two other patients did not have the postplacental IUCD inserted .sere postpartum haemorrhage and the neonatal outcome of a fresh stillbirth,

fable 12: Outcomes of Postplacental IUCD insertion at 6 weeks by Level of Counselling

	Level of Counselling		
3utcomes	Intensive N = 31 (%)	Routine N = 27 (%)	p-value
Expulsion	2(4.1%)	-	-
[5]elvic Infection	-	1 (1.8%)	-
\Ilergic Reaction	-	1 (1.8%)	-
\bdominal Pain	1 (1.8%)	-	-
Discontinuation	1 (1.8%)	-	-
Continuation	23 (92%)	24 (89%)	0.235*
Client Satisfaction	23 (92%)	25 (93%)	1.00*
Partner Satisfaction	22 (85%)	23 (86%)	0.77

*Fishers exact test

Table 12 above shows the outcomes at 6 weeks of postplacental IUCD insertion by level of counselling. From the table we observe that only five parturients had complications that included expulsion (2; 3.7%), allergic reaction (1; 1.8%), pelvic infection (1; 1.8%) and abdominal pain (1; 1.8%).

The continuation rates were 92% (23) for the intensive FP counselled group and 89% (24) for the routine FP counselled group. Client satisfaction rates were 92% (23) for the intensive FP counselled group and 93% (25) for the routine FP counselled group. Reported partner satisfaction rates were 85% (22) in the intensive FP counselled group and 86% (23) in the routine FP counselled group.

DISCUSSION

The purpose of this study was to evaluate the impact of intensive counselling on acceptance, uptake and early outcomes (expulsion, pelvic infection, continuation and couple satisfaction rates at 6 weeks postpartum) of the postplacental IUCD. The results indicate that there is no difference in postplacental IUCD acceptance and uptake rates between women who received more detailed intensive family planning counselling compared to those who received routine information about contraception. These finding are similar to other studies that have found, that it is possible to increase the quality of family planning counselling but that such an intervention is not associated with higher contraceptive use. (50, 51)

The postplacental IUCD is an acceptable method among women in this region. Forty five percent of women had the IUCD inserted postplacental. Randomization to FP counselling whether intensive or routine did not have any impact on the acceptance (p- value 0.129) and uptake (p-value 0.92) rates of postplacental IUCD insertion.

Women in this region have a need for immediate postpartum methods and long acting methods. The only significant determinant for acceptance was that the IUCD was a long term method. Women who were aware of this were 4.2 times more likely to accept this method. Notably, the majority of women (97%) interviewed reported they would leave the hospital with an immediate postpartum method if it was offered to them.

•Oiowledge may not be the key determinant of contraceptive method use (46). The results show that, the only significant determinant for uptake was that women who reported knowing the benefits of the IUCD prior to the FP counselling intervention were less likely to take up the method (p- value 0.005). Studies have shown that women get information on contraception from their peers before the heath worker and most already have a postpartum method in mind during the antenatal period regardless of counselling, [ev]en those who are naive to contraception. (52) Choice of method is mainly based on a woman's prior

perception of effectiveness and convenience of use (50). Nonetheless adequate information on all methods available, benefits and side effects should be offered and misconceptions corrected.

Barriers of acceptance included misconceptions, lost IUCD. fear of a foreign body giving an allergic reaction and lack of partner involvement to assist in decision making. Barriers to uptake included lack of trained personal available to insert the postplacental IUCD in sixty percent and unforeseen complications such as postpartum haemorrhage. This highlights the need for training on PPIUCD insertion for all staff working in labour ward.

The postplacental IUCD is a safe method with few side effects. The rates of expulsion were low; only two patients (3.7%) had the IUCD expelled by 6 weeks. Expulsion rates are comparable to a similar study done inNyeri in 1990 which showed rates of 10% at 6 months (16). The other complications experienced were pelvic infection, severe abdominal pain and allergic reaction occurring in one patient each. The study had inadequate power to assess for statistical significant differences in the outcomes for the two randomization arms.

Ninety one percent of patients opted to continue with the IUCD as their choice of contraception. The continuation rates were 92% (23) in the intensive FP counselled group and 89% (24) in the routine FP counselled group. Client satisfaction rates were high at 88%; 23 (92%) clients in the intensive FP counselled group and 25 (93%) clients in the routine FP counselled group reported they were happy with the postplacental IUCD. Although partner involvement was low, only two men, most women (83%) reported that their partners were happy with their choice of contraception. Reported partner satisfaction rates were 85 %(22) in the intensive FP counselled group and 86 % (23) in the routine FP counselled group. The study had inadequate power to determine statistically significant differences in continuation, client and reported partner satisfaction rates between the two randomization arms. Most studies have

shown that the postplacental IUCD is a highly effective method that gives the couple satisfaction and thus affords high continuation rates. (16,31.33)

Despite Embu PGH being a centre for revitalization of the PPIUCD. few women were aware of the method (30.7%). only seven (5.5%) women had used an IUCD before and most had inadequate knowledge and several misconceptions about the IUCD. Knowledge on the method was similar in both randomization arms (p- value 0.52). This may suggest that inadequate information on the IUCD is given during antenatal visits. In Embu PGH more of the counselling for PPIUCD occurs at labour ward.

The social demographic and background difference between the two groups calls for caution in interpretation of the lack of effect because the randomization did not yield identical groups. More women in the routine FP counselled group were married, over 30yrs. employed and had used contraception before. This may have had an effect on acceptance rates as this group would be more likely to accept to a long term immediate postpartum contraceptive method. Another possible cause for bias was counselling of patients in the two randomization arms in the same building. There may have been some diffusion of information between clients after the intervention leading to bias. In spite of these two possible reasons for bias: the study provides similar finding, on effect of counselling, to other studies(46,50).

This study did not assess for uptake rate of other contraceptive methods despite counselling for all contraceptive methods. There may have been increased uptake of other methods at the 6 week visit by those who did not accept to use this method. The impact of the randomization arms may have yielded different results if this shortcoming was factored.

A longer duration of follow up would have been of interest to consolidate the outcome variables such as continuation and determine pregnancy rates.

There may have been counselling bias among the different counsellors despite a strict protocol. Use of a video camera within the counselling room may have reduced possible bias.

Due to financial constraints the study was unable to assess for displacement by performing an ultrasound on the client. Displacement as an outcome measure of postplacental IUCD use has not been adequately investigated. It is an important measure as displacement may lead to unwanted pregnancies (37).

One of the strengths of the study was adequate power to assess for the main objectives. Fortunately most patients (86%) who accepted the method delivered in the hospital and only 14 patients were lost to follow up. This was achieved by adjusting for loss to follow up by increasing the sample size, making reminder and interv iew calls to those who did not return for appointment visits and reimbursing patient transport costs to come for the follow up visit at 6 weeks.

The study followed up patients from antenatal visits to the end of puerperium in order to assess for early complications of the method. The study encouraged couple involvement and harmony by allowing the patients in both randomization groups to consult their partners on their decision and give an answer at a later visit.

Other strengths of the study include carrying out the study in a centre where PPIUCD is an ongoing project therefore adequate systems were in place to handle any complications that may have arose and further facilitate continual care. Similarly only medical personnel who had attended a course in PPIUCD were allowed to counsel the clients and only champions i.e. medical personal who had inserted several postplacental IUCD's were allowed to insert the postplacental IUCD. This ensured quality counselling and medical care were given to all study subjects.

CONCLUSION

Intensive FP counselling carried out on antenatal clients at Embu PGH did not result in a significant increase in acceptance and uptake rates of postplacental IUCD use in comparison to routine FP counselling.

Routine counselling provides adequate information to allow a woman to make an informed choice on a contraceptive method, without adding extra burden to staff who already have time constraints. We need to provide women with just enough information to make a decision and use the method safely and effectively.

The postplacental IUCD is an acceptable method among women in this region. Seventy two percent of women enrolled in the study accepted to have the postplacental IUCD inserted after counselling. Eventually forty five percent of women enrolled in the study had the postplacental IUCD inserted luptake) despite randomization to counselling (p - value 0.232).

Women have a need for immediate postpartum methods and long acting methods for women in this region. Ninety seven percent reported they would leave the hospital with a contraceptive method in place after delivery. The only true predictor for acceptance was that the IUCD was a long term method with the clients who reported this, 4.2 times more likely to accept the method.

The IUCD is still mystified: several misconceptions still exist and contribute as barriers to uptake of this method. Fear of lost IUCD (18%) and allergic reactions (18%) were the most common barriers to acceptance. Uack of partner involvement also played a significant role as a barrier to acceptance at 13%.

The most critical barrier to uptake was lack of trained medical personnel to insert the postplacental IUCD which occurred in 3 (60%) clients who had consented. Medical staff working in labour wards should be trained adequately to avoid missed opportunities.

Complications such as expulsion which had once become a barrier to PPIUCD insertion are minimal i4.1°o) at 6 weeks. Similarly other complications are minimal allergic reaction, pelvic infection and abdominal pain all at 1.8%.

The postplacental IUCD is a favourable method. Continuation rates (91%), client (88%) and reported partner (77%) satisfaction were notably high at 6 weeks.

RECOMMENDATIONS

Routine counselling provides adequate information on available contraceptive options and should be offered by healthcare workers during antenatal visits.

Women should be offered immediate postpartum contraceptive methods and long acting methods.

Information on the postplacental IUCD as a contraceptive method should be disseminated widely to both healthcare workers and women.

Adequate information on the IUCD should be provided to demystify this method. Family planning counsellors should ensure relevant information is given to reduce misconceptions.

Medical personal should be adequately trained on insertion the postplacental IUCD to reduce missed °Pportunities for women who choose this method. Similarly the IUCD should be made easily available in labour wards to enhance uptake of postplacental IUCD.

Male partner involvement in family planning is low. Strategies to encourage partner involvement should be sought.

Studies should be done to evaluate rates of displacement in users of the postplacental IUCD.

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STDDV **WRITTEN CONSENT FORM**

LEVELS OF COUNSELLING ON ACCEPTANCE. UPTAKE AND ^IP-GOF POSTPLACENTAL INTRAUTERINE CONTRACEPTIVE DEVICE.

itors:

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* Committee Chairperson: Professor K. M. Bhatt, 272-6300

Statement

" your time. You are being asked to kindly join this research study on the impact of two selling on acceptance, uptake and early outcomes of postplacental intrauterine contraceptive x you are above 18years . attend antenatal clinic at Embu Provincial General Hospital and 3 deliver at Embu Provincial General Hospital. You are being asked to undergo counselling tam,|y planning methods, answer a questionnaire, and should you find the method of 11 f D insertion agreeable sign consent to have one inserted immediately after delivery. O you win asked to fill a questionnaire and have a clinical evaluation. Once the intrauterine dcv,ce has been inserted you will be observed and further be asked to attend a follow up w,-cks where you will have a clinical evaluation and complete your questionnaire form.

' "11s c»nsent form is to give you the information you will need to help you decide whether Uci- or Hot. Please read the form carefully. You are free to ask questions about the purpose

of the of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer , and anything else about the research or about this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called informed consent". If you w ish: we will give you a copy of this form for your records. Deciding whether or not to be in the study will not affect your ability to receive medical care and treatment from Embu Provincial General Hospital in any way.

Purpose of the Study

The purpose of this study is to find out how acceptable the method of postplacental intrauterine device insertion is to the women attending our clinics and who choose to deliver at Embu Provincial General Hospital. We would also like to find out whether more women would be willing to use the method if more counselling was given. This will help our policy makers know whether we can advise on this method to more expectant mothers especially those who may only attend a health care unit at delivery and are in need of family planning.

Procedures

MEC Criteria

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

Questionnaire One

If you agree to be interviewed a written consent will be required of you to sign. Once you have signed this form you will be asked questions on general knowledge on your awareness of the method, what method of contraception you have used before this pregnancy, any problems experienced with contraceptives.

If you are eligible join this study the following will take place:

Counselling Session

A nurse will counsel you on the different methods of family planning. The method of immediate insertion of an IUCD after delivery will also be introduced to you and the all the advantages and disadvantages given. You will be free to ask questions where you do not understand. You will also be free to refuse to answer our questions with no consequences to your treatment.

Enrolment

Once you have understood you will then be asked whether you would like to participate in the study. You will be encouraged to speak to your partner about this method and make a decision together. You will be given time to speak to your partner before consenting. Once you are sure you want to use this method you will be asked to sign another form allowing us to insert the IUCD after birth of your baby

Questionnaire Two

You will be asked to alert us when you arrive at labour ward. In labour ward you will be asked a few questions on the choice you have chosen and how you are feeling. This questionnaire will be used for all following visits.

Physical Examination

A physical examination will be carried out on you once you arrive at labour ward to make sure you can still participate in the study. A doctor will examine your abdomen and your birth canal to check how far into labour you are and to ensure you have no infections.

Your labour will be monitored carefully and if any problem arises during labour that does not allow us to insert the IUCD we will not insert one. We will however counsel you on other methods still appropriate for you.

Insertion of the IUCD

Once you have delivered you baby with no complications a trained doctor or nurse will insert the IUCD after the placenta is removed. You will be observed to ensure you have no complications after delivery.

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.

Follow up visit

You will be advised on the importance of a follow up visit and will be given an appointment date after 6 weeks. A card will be given to you bearing all the information and where to attend.

During the visit you will be undergo a physical examination where we will check for infection and check that the IUCD is still in place. We will also ask a few questions on whether the IUCD has suited you.

You will then be given your clinic card and asked to return after 6weeks for a review by the nurses at the family planning clinic. Any other follow up will be done by them.

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.

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, previous contraceptives used 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.

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

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 Embu PGH. 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. You may also choose to seek medical treatment and testing from other doctors, local clinics, and hospitals in Embu. The study stafT will discuss all available options with you.

Benefits of the Study

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. You may also receive no direct benefit from this study. The study may help increase the use of this method by more women.

Other information

Information about your family planning choice and other maters arising will be confidential and we will keep your records in a locked office. Information about your participation in the research will be available to you and to the study team but not to anyone outside the study.

There is no cost for you to participate in the study.

You may refuse to participate or may withdraw from the study at any time without penalty or loss of benefit to which you were otherwise entitled.

Questions about the study or any adverse events should be addressed to this investigator. Do you have any questions? Do you agree to participate?

Signature of investigator_____Date

Printed name of investigator

Subject's statement

Selection Section

This study has been explained in detail to me. I willingly volunteer to take part in counselling and questionnaire one section of this study. I have agreed to give my telephone number and a contact number. I have had a chance to ask questions and I understand that if I have more questions about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject. I can call the Ethical Review Committee at Kenyatta National Hospital 272-6300. I will receive a copy of this consent form if I so wish.

Signature of subject_____Date_____

Printed name of subject_____

Finger print_____(If subject is unable to write)

Enrolment Group

This study has been explained in detail to me. I willingly volunteer to have the postplacental IUCD inserted as part of this research study. 1 have had a chance to ask questions and I understand that if I have more questions about the research. I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the Ethical Review Committee at Kenyatta National Hospital 272-6300. I will receive a copy of this consent form if 1 so wish.

Signature of subject_____Date_____

Printed name of subject_____

Finger print_____(If subject is unable to write)

KJSWAHILI V ERSION

FOMU YA MAKUBALIANO YA KUJIUNGA NA UTAFITI

THE EFFECT OF TWO LEV ELS OF COUNSELLING ON ACCEPTANCE. LPTAKE AND EARLY OUTCOMES OF POSTPLACENTAL INTRAUTERINE CONTRACEPTIVE DEVICE.

Watafiti:

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Nambari za simu za dharura saa 24 kwa siku: 020-6751136

Mwenyekiti wa kamati ya kuayaanagalia masilahi ya haki zako: Profesa K. M. Bhatt. 272-6300

Habari Za Watafiti

Shukrani sana kwa muda wako ulionipa. Unapoombwa kushiriki utafiti huu wa the impact of two levels of counselling on acceptance, uptake and early outcomes of postplacental intrauterine contraceptive device kwani umehitimu umri wa miaka 18. ukatembelea hospitali ya mkoa wa Embu na umechagua kupata mtoto wako katika hospitali huu. Unaombwa kumwona daktari ambaye atakuzungumzia kuhusu njia mbalimbali za kupanga uzazi. Utatakikana kujaza karatasi na kutoa maoni yako kuhusu njia hizo. Iwapo utapendezwa na njia ya kupanga uzazi ya kuingizwa IUCD. utatakiwa kujaza fomu ya kukubali kuwekwa moja baada tu ya kujifungua. Kabla ya kujifungua mwana. sharti utie sahihi fomu na kufanyiwa ukaguzi katika zahanati. Baada ya kuwekwa kifaa hicho cha kupanga uzazi. utafanyiwa ukaguzi zaidi na kutakikana kurejea hospitalini baada ya wiki sita ambapo utafanyiwa ukaguzi na kupewa maelezo zaidi na madaktari.

Nia ya fomu hii ya makubaliano ni kukuezesha kupata habari ambayo itakusaidia kukata kauli kama utajiunga na utafiti huu au la.Tunakuomba usome fomu hii kwa makini. Waweza kuuliza maswali kuhusu nia ya utafiti jambo ambalo tunakuuliza kufanya.nikujifahamisha na uwezekano wa adhari. faida. haki zako kama aliyejitolea, na kitu chochote kile ambacho hakieleweki.Tutakapojibu maswali yako yote.utaamua kama utajiunga na utafiti au la. Mwelekeo huu unajulikana kama " kielelezo sahihi". Ukipcnda tutakupa nakala ya fomu hii uweke kama thibitisho lako. (Jamuzi wako kama utajiunga na utafiti huu, au la , hautaathiri kwa njia yoyote ile utakavyotumikiwa au kupata matibabu katika Hospitali ya Mkuaya Embu.

Nia Ya Utafiti Huu

Madhumuni ya utafiti huu ni kutathamini ubora wa nia ya kupanga uzazi ya postplacental intrauterine devise insertion kwa wanawake wanaotembelea na kujifungua katika hospitali ya mkoa ya Embu. Aidha. tungependa kufahamu iwapo wanawake ambao wangependa kutumia njia hii wanahitaji ushauri. 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.

Taratibu

Kama umehitimu na ukubali kujiunga na utafiti huu, taratibu itakuwa kama ifuatavyo:

MEC Criteria

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

Orodha ya Maswali

Iwapo utakubali kufanya mahojiano, utalazimika kutia sahihi barua ya kueleza kuwa unakubali kuhojiwa. Baada ya kutia sahihi. utaulizwa maswali ya jumla kuhusu unachofahamu juu ya njia hii ya kupanga uzazi. Pia. utaulizwa iwapo unafahamu njia hii yakupanga uzazi na kama umeshawahi tumia njia zozote hapo awali za kupanga uzazi. Kisha utaulizwa iwapo ungependa kutumia njia hii ya kupanga uzazi. Iwapo utabainika kuweza kushiriki utafiti huu. yafuatayo yatatendeka:

Kikao cha 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 yakoya kutibiwa matalani.

Jinsi ya kuiiunua na utafiti

Baada ya kudhibitisha kuwa umcelewa. utaulizwa kujiunga na utafiti. Utaelezwa kuwa ni bora ikiwa utazungumza na mpenziwe ili mlanye uamuzi pamoja. Utapewa muda wa kujadiliana na mwenzako kabla ya kutupa uamuzi wako. Baada ya kutufahamisha uamuzi wako, utaulizwa kutia sahihi fomu nyinginc itakayotupa ruhusa ya kukuwekca kifaa cha IUCD baada ya kuzaliwa kwa mwana wako.

Fomu ya utafiti

Wakati utawasili hospitalini. itabidi utueleze. Katika wadi ya kujifungua. utaulizwa maswali kadhaa kuhusu chaguo lako na hisia zako. Maswali haya yatawasidia madaktari kila utakaporejea hospitalini.

Ukaguzi wa kiafya

Utafanyiwa ukaguzi wa kiafya ukiwasil katika wadi ya kujifungua kuhakikisha kuwa bado unaweza kushiriki utafiti huu. Daktari atakagua tumbo yako na eneo la uzazi kubaini kuwa huna magonjwa yoyotc.

Utakaguliwa sana saa chache kabla ya kujifungua na iwapo kutakuwa na tatizo lolote ambalo halitaturuhusu kukuwekea kifaa cha IUCD. hatutakiweka. Licha ya hivyo. utashauriwa kuhusu njia bora ya kupanga uzazi inayokufaa.

Kuwekewa kifaa cha IUCD

Baada ya kujifungua bila shida yoyote, daktari au muuguzi atakuwekea kifaa cha IUCD. Baadaye. utafanyiwa ukaguzi kuhakikisha kuwa hauna shida yoyote baada ya kujifungua.

Ukaauzi wa kabla va 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 hujarejca hospitalini kwa ukaguzi zaidi. Zaidi. utapewa ushauri kuhusu jinsi bora ya kuchunga eneo lako la uzazi na kuangalia ivvapo kifaa hicho kiko sawa.

Ukaguzi wa baadaye

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

Wakati wa ukaguzi huo. utafanyiwa uchunguzi wa kiafya ya kubaini iwapo una magonjwa yoyote kutokana na kifaa hicho. Aidha. tutaangalia iwapo kifaa cha IUCD kiko sawa. Utaulizwa maswali zadii kuhusu mema uliyoyapata kutokana na kifaa hicho cha IUCD.

Kisha utapewa kadi ya zahanati na kuulizwa kurcjea katika zahanati baada ya wiki sita kwa ukaguzi zaidi na wauguzi katika zahanti 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.

w

Hatari Na Usumhufu Katika Upelele/i

Utafiti huu utakuuliza maswali ya kibinafsi kuhusu hali yako ya ukimwi na pia iwapo umetumia njia za kupanga uzazi hapo awali. Si lazima uyajibu maswali haya iwapo hautaki.

Ukaguzi wa kiafya unaweza ukakupa maumivu.

Kifaacha 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.

Njia Zinginc Za kushiriki

Unaweza ukachagua kutoshiriki katika utafiti huu. Ukiamua kutoshiriki. utapata uuguzi wa kabla na baada ya kujifungua katika hospitali kuu ya mkoa wa Embu. 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. Unaweza kupokea matibabu kutoka kwa madaktari wengine, zahanati zingine na hospitali kadhaa mjini Embu.

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. Huenda pia usipokee faida yoyote kutokana na utafiti huu. Utafiti huu unaweza pia kuongeza matumizi ya njia hii na wanawake wengi.

Ujumbe Wa Ziada

Ujumbe kuhusu chaguo lako la kupanga uzazi na ujumbe mwingine utakuwa siri na tutaweka ujumbe wako katika allsi iliyofungwa. Ujumbe kuhusu ushiriki wako katika utafiti huu utawezekana kupatikana na wewe na wanaoandaa utafiti na wala si yeyote mwingine.

Hakuna gharama ya kushiriki katika utafiti huu.

Unaweza kukata kushiriki au kutoka kwa utafiti huu wakati wowote bila adhabu yoyote na pia kupoteza faida zako ambazo una haki kupewa.

Maswali kuhusu utafuti au matokeo yoyote yatatatuliwa na muuguzi. Je, unayo maswali yoyote? Je, umekubali kushiriki?

Sahihi Ya Mpelelezi_____Tarehe_

Jina La Mpelelezi_

Agizo La Mhusika

Nimeeleza kuhusu utafiti huu. Nimekubali kwa hiari yangu kujiunga na utafiti huu. Nimekuwa na fursa ya kuuliza maswali.Kama nitakuwa na maswali baadaye juu ya utafiti, ninaweza kuuliza mmoja wa watafiti walioorodheshwa hapo juu.Kama ninayo maswali juu ya haki zangu.katika utafiti kama mhusika.ninweza kupiga simu kwa kamati ya kushugulikia masilahi ya haki katika hospitali kuu ya Kenyatta kwa nambari 272-6300.Nitapewa nakala ya fomu hii nikihitaji.

Sahihi Ya Mhusika_____Tarehe_

Jina La Mhusika_

Alama ya Kidole_____(kwa wasioweza kusoma na kuadinka)

Agizo Ya Kuhali Kuingia Utafuti

Nimeelezewa utaflti huu kwa kina. Nakubali kushiriki utafiti huu kwa hiari yangu. Nimcpata wakati wa kuuliza maswali na nimeelewa kuwa iwapo nina maswali zaidi. ninaweza kumwuliza mtafiti mkuu au watafiti waliotajwa hapa juu. Iwapo nina maswali kuhusu haki zangu. ninaweza kupiga simu kwa kamati ya maswala ya maadili katika hospitali ya kitaifa ya Kenyatta kwa nambari 272-6300. Nitapokea nakala ya fomu hii ikiwa ninaitaka.

Sahihi Ya Mshiriki_____Tarehe

Jina La Mshiriki

Ishara ya Kidole_____(Iwapo mshiriki hawezi kuandika)

APPENDIX B: MEC FOR CONTRACEPTIVE USE

Quick Reference Chart for the **WHO Medical Eligibility Criteria for Contraceptive Use -**

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1 CONDITION		COC	DMPA	Implants	Cu-IUD
Pregnancy		NA	NA	NA	
Breastfeeding	less than 6 weeks postpartum				NC
	6 weeks to < 6 months postpartum				
	6 months postpartum or more				NC
Postpartum	less than 21 days, non-breastfeeding				
	< 48 hours including immediate post-placental	NC	NC	NC	
	2 48 hours to less than 4 weeks				
	Puerperal sepsis				
Postabortion	Immediate post-septic				
Smoking	Age *2* 35 years. < 15 cigaretteVday				
	Age t 35 years, z 15 cigarettes/day				
Multiple risk factors for cardiovascular disease					
Hypertension	History of (where **BP** cannot be evaluated)				
	BP is controlled and can be evaluated				
	Elevated BP (systolic 140 -159 or diastolic 90 - 99)				
	Elevated BP (systolic 2 160 or diastolic 2 100)				
	Vascular disease				
Deep venous thrombosis (DVT) and pulmonary embolism IPE)	History of DVT/PE				
	Acute DVT/PE				
	DVT/PE. established on anticoagulant therapy				
	Major surgery with prolonged immobilization				
Known thrombogenlc mutations					
Ischemic heart disease (current or history of) or stroke ihistory of)				I C	
Known hyperlipemias					
Complicated valvular heart disease					
Systemic lupus erythematosus	Positive or unknown antiphospholiptd antibodies				
	Severe thrombocytopenia		I C		I C
	Immunosuppressive treatment				I C
Headaches	Non-mlgralnous (mild or severe)	I C			
	Migraine without aura (age < 35 years)	I C			
	Migraine without aura (age * 35 years)	I C			
	Migraines with aura (at any age)		I C	I C	
Vaginal bleeding patterns	Irregular without heavy bleeding				
	Heavy or prolonged, regular and irregular				
	Unexplained bleeding (prior to evaluation)				I C

1 CONDITION		1 coc	DMPA	iiI^M<i	Cu-IUD
Gestational trophoblastic disease	Regressing or undetectable P-hCG levels				
	Persistently elevated (J-hCG levels or malignant disease				
Cancers	Cervical (awaiting treatment)				
	Endometrial				
	Ovarian				
Breast disease	Undiagnosed mast				
	Current cancer				
	Past w/ no evidence of current disease for 5 yrs				
Uterine distortion due to fibroids or anatomical abnorma					
STIs/PID	Current purulent cervicitis, chlamydia, gonorrhea				I C
	Vaginitis				
	Current pelvic inflammatory disease (PIP)				I C
	Other STIs (excluding HIV/hepatitis)				
	Increased risk of STIs				
	Very high individual risk of exposure to STIs				I C
Pelvic tuberculosis					I C
Diabetes	Non-vascular disease				
	Vascular disease or diabetes for > 20 years				
Symptomatic gall bladder disease (current or medically treated)					
Cholestasis (history of)	Related to pregnancy				
	Related to oral contraceptl\				
Hepatitis	Acute or flare	I C			
	Chronic or client Is a carrier				
Cirrhosis	Mild				
	Severe				
liver tumors (hepatocellular adenoma and malignant hepatoma)					
HIV	High risk of HIV or HIV-infected				
AIDS	No antlretroviral therapy (ARV)				I C
	Clinically well on ARV therapy	see drug interactions			
	Not clinically well on ARV therapy	see drug interactions			I C
Drug Interac-tions, including use of:	Nucleoside reverse transcriptase Inhibitors				
	Non-nucleosIde reverse transcriptase Inhibitors				
	Ritonavir, rItonavIr-boosted protease inhibitors				
	RIfampicln or rifabutin				
	Anticonvulsant therapy"				

Source: Adapted from *Medical Eligibility Criteria for Contraceptive Use*, Geneva: World Health Organization, updated 2008. Available at: http://www.who.int/reproductive-health/family_planning/guidelines.htm

•• Category 1 There are no restrictions for use

I ___ I Category 2 Generally use; some follow-up may be needed.

I ___ I Category 3 Usually not recommended; clinical Judgment and continuing access to clinical services are required for use.

^m Category 4 The method should not be used.

(£ ; U S A I D
WH1W IIW WIIWII

Unlike previous versions of the MEC Quick Reference Chart, this version Includes a complete list of all conditions classified as Category 3 and 4 by WHO. IX (Initiation/Continuation): A woman may fa) Into either one category or another, depending on whether she is Initiating or continuing to um a method For example. • cfcmt with current MO who wants to Initiate IUO us* would be considered » Category 4. and should not have an WO inserted. However * she develops PIO Wh4e using the IUO. she would be considered as Category 2 This m e m she could generally continue using the IUO and be treated for P® with the IUO in place Where I/C Is not marked, the category Is the same for Initiation and continuation.

NA (not applicable): Women who are pregnant do not require contraception

NC (not classified): The condition Is not part of the WHO classification for this method.

• Evaluation of an undiagnosed mass should be pursued as soon as possible

" Anticonvulsants include phenytoln. carbamaiepln.. barbiturates, primidone, toplramate. oxcarbaiepin. and lamotngme. lamotngtne Is a category 1 for implants.

' f | _
I i l l ^iTi^tw^l'
c JOOT

APPENDIX C: INTENSIVE FAMILY PLANNING COUNSELLING PROTOCOL

This material has been adapted from the Engenderhealth/Acquire learning guide for Copper T 380A PPIUCD counselling skills (50).

PRE INSERTION COUNSELLING

Rapport Building

1. Greet the client politely and offer a seat.
2. Ensure privacy without interruptions throughout the counselling session.
3. Explain the need to ask personal and sometimes sensitive questions to help select the proper method.

Exploration (As filling selection form, use tool to explain as you explore)

1. Ask client about prior FP use, knowledge on FP methods, satisfaction with methods and interest in IUCD/PPIUCD. Ensure the client knows about all the available options of FP for the postpartum period and the future.
2. Explore client's reproductive goals and history.
3. Explore client's circumstances and relationships.
4. Explore client's history of STI/HIV and explain PMTCT.
5. Explain that IUCD doesn't protect against STI/STDs.
6. Explore patients plan for breastfeeding baby, including LAM.
7. Focus on the IUCD: Explore what the client knows about IUCD and correct misconceptions. Ensure the client knows about the advantages, disadvantages and possible complications of the IUCD and PPIUCD.
8. Show a sample of the IUCD and encourage the client to touch it. Show the patient the hand held intrauterine model.

9. Explain postplacental and interval insertion techniques.
10. Allow for questions.
11. Provide reading material and entourage discussion with her partner.
12. Allow for questions.

Decision making

1. Explain all available methods of FP available during the postpartum period.
2. Readdress the PPIUCD with information on available timing, advantages, disadvantages, complications, and efficacy.
3. Ask the patient to consider how her partner would react.
4. Help client assess for possible risk of STI/STD.

IMPLEMENTATION

For those who agree discuss birth plan, transport to the facility and what she requires to do when she arrives at the hospital.

APPENDIX D: CLIENT TAKE HOME PAMPHLET

POSTPARTUM INTRAUTERINE DEVICE

Now you can go home after delivery protected from pregnancy.

What arc postpartum family planning methods?

Postpartum indicates the period after delivery. Postpartum family planning methods are therefore the methods one can use in this period to protect themselves from pregnancy.

What are the methods available for use in the postpartum period?

- Postpartum IUCD
- Male or female sterilization
- Condoms and Spermicides
- Lactational Amenorrhea Method

For women not breastfeeding other hormonal methods can also be used.

What is the postpartum IUCD?

This is a method that involves the insertion of the IUCD after delivery.

When can this method be used?

Immediately after delivery of the placenta or within 48 hours of delivery before the patient goes home.

Who can use this method?

Any woman who has given birth and has been informed about this method.

Who cannot use this method?

Women who have an STI/STD are not advised to use this method.

Women who have clinical AIDS and are not on medication.

Is this method safe?

Yes, this is a very safe method that protects against pregnancy.

What are the disadvantages of using this method?

- The IUCD may fall out but it can easily be replaced.
- Some women experience heavier bleeding with the IUCD.

What advantages do I get from using this method?

- You can get the IUCD inserted at delivery therefore no additional discomfort to you.
- You get to go home with a method already in place therefore you are protected from pregnancy.
- You require minimal checkups thereafter.
- It is an inexpensive method to use.
- The IUCD protects against pregnancy for at least 10 years.
- You can remove the IUCD when you want to get another baby with no difficulty and conceive almost immediately.

W ill my partner feel the strings?

No he will not. The strings will be trimmed at the follow-up clinic if seen to be too long.

How will I know if the IUCD is still in place?

You are advised to check for the IUCD on your undergarments and before you throw away used pads. You can also examine yourself to check for strings. At the follow-up visits we will also confirm presence of the strings.

How do I care for my IUCD?

There is nothing you really have to do with the IUCD just ensure good personal hygiene. If you think you could get an STD/STI please use condoms in addition to this.

KISWAHIL1 VERSION

CLIENT TAKE HOME PAMPHLET

KIFAA CHA POSTPARTUM INTRAUTERINE

kufikia hapa, unawcza ukacnda nyumbani haada ya kujiftingua ukiwa umekingwa dhidi ya kupata niimha.

Mbinu za kupanga uzazi baada ya kujifungua (postpartum) ni zipi?

Postpartum inamaanisha wakaii baada ya kujifungua mimba. Mbinu za kupanga uzazi baada ya kujifungua ni zilie ambazo unaweza kuzitumia kudhibiti uwezo wa kupata mimba.

Ni njia gani zinapatikana wakati huu (postpartum)?

- **Kifaa cha postpartum IUCD**
- **Kutolewa nguvu za kuzalisha**
- **Mipira ya condom**
- **Njia ya l actational Amenorrhea**

Kwa **wanawakc ambao hawa nyonycshi. wanaweza kupewa dawa za kusitisha nguv-u zao za kuzaa.**

Kifaa cha postpartum 11(1) ni nini?

Ilii ni njia ya kupanga uzazi inayojumuisha kuingizwa kwa kifaa cha IUCD baada ya kujifungua.

Njia hii ya kupanga uzazi inawcza ikatumika wakati ganl?

Inaweza kutumika baada ya kujifungua au katika muda wa saa 48 baada ya mwanamkc kujifungua.

Ni nani ambaye anaweza kutumia njia hii?

Mwanamke veyote ambaye amejifungua na amefahamishwa kuhusu njia hii ya kupanga uzazi.

Ni nani ambaye hawaezi kutumia njia hii?

W'anawake ambao wana magonjwa ya zinaa wanatahadharishwa wasitumie njia hii.

Wanawake ambao wana ukimwi na amabo hawatumii madawa ya kupunguza makali ya ugonjwa huo.

Njia hii ya kupanga uzazi ni salama kwa afya?

Ndio. Njia hii ni salama sana kwa kukinga mimba.

Kuna shida yoyote inayoneza kunikumba nikitumia njia hii ya kupanga uzazi?

- **Kifaa cha IUCD kinaweza kikaanguka lakini kinaweza kuregeshwa upesi na daktari.**
- **Baadhi ya wanawake ambao hutumia njia hii hutokwa na damu nyingi wakaii wa mwezi.**

Je. ninafaidika aje na kutumia njia hii >a kupanga uzazi?

- **Unaweza ukawekewa kifaa hiki wakaii ukijifungua na kupunguza uwezo wako wa kupata maumivu zaidi.**
- **nyumbani kwako na kifaa hiki kikiwa kimewekwa na kuwa umckingwa dhidi ya kupata mimba.**
- **Utahitaji ukaguzi kiasi tu baada ya kuwekcwa kifaa hiki.**
- **Njia hii si ya bei ghali.**
- **Kifaa cha IUCD kukinga dhidi ya uwezo wa kupata mimba kwa muda wa miaka 10.**
- **Unaweza ukatoa kifaa cha IUCD ikiwa unataka kupata mtoto bila shida yoyote na kupata mimba.**

Je, nipenzi wangu atazisikia nyuzi hizi?

La. Nyuzi hizi huwa zitatakwa wakati utarejea hospitalini baada ya wiki sita.

Nitafahantu aje iwapo kifaa hiki kiko sana?

Unahimizwa kuangalia kifaa kila wakati baada ya kutoa suruali ya ndani na pia kabla ya kutupa kifaa ulichotumia wakati wa mwezi. Mwenyewe unaweza kuchunguza nyuzi hizo. Wakati ukifika hospitalini. madaktari watahakikisha kuwepo kwa nyuzi hizo.

Ninatunza aje kifaa changu cha IUCD?

Hakuna jambo haswa unapaswa kufanya na kifaa chako lakini ni lazima uhakikikishe usafi. Ukishuku utapata magonjwa ya zinaa. tumia mipira ya condom pamoja na kifaa hiki.

APPENDIX E: QUESTIONNAIRE ONE

Serial number

Interviewers Name

Date of interview

A: Socio-demographic data

1. Age |

2. Marital Status (tick one)

1. Married (monogamous) O
2. Married (polygamous) O
3. Single O
4. Divorced / Separated O
5. Widowed O

3. Highest Education Level Attained

1. None O
2. Primary O
3. Secondary O
4. College / University O

4. Employment (tick one)

1. Unemployed	O	3. Housewife	O
2. Self-employed	O	4. Salaried job	O

5. Residence

6. How will you get to the hospital for delivery?

Private car O Public means O Taxi O Walk O

B: Obstetric Characteristics

7. Parity

8. Number of living children \

9. Date of last delivery

10. Mode of Last Delivery

1. Normal Vaginal Delivery O

2. Caesarean Section O

11. Date of last menstrual period

12. Estimated date of delivery

13. Anticipated Birth Plan

1. Normal Vaginal Delivery o

2. Elective Caesarean Section O

14. How many more children would you like to have?

1.None 2. One 3. Two 4. Three 5. More than three 6. Not sure

15. How soon would you like to have your next child?

I. Less than a year 2. One year 3.Two years 4. 3 years 5.More than 3 years

16. Would you leave the hospital after delivery with a family planning method if one was offered to you?

1. Yes 2.No

17. Have you had excessive bleeding after any of your previous pregnancies?

1. Yes 2.No

C: Gyaenecological History

18. Do you have regular menses? 1. Yes 2. No

19. Do you experience heavy bleeding during menses? 1. Yes 2.No

20. Do you experience pain during your menses? 1. Yes 2.No

21. Do you have bleeding between menstrual periods that is unusual for you, or bleeding after intercourse (sex)? 1.Yes 2.No

22. Have you been told you have any abnormality of your uterus? 1. Yes 2.No

23. Have you been told that you have any type of cancer in your genital organs, trophoblastic disease, or pelvic tuberculosis? 1. Yes 2.No

D: Medical & Surgical History

24. Do you have any of the following?

- O High blood pressure (dizziness, severe headache)
- O Heart problems (breathlessness, palpitations)
- O Respiratory problems (TB, cough, asthma)
- O Joint pains, jaundice (sickle cell)
- O Surgery or hospitalization
- O Allergies to food or medicine
- O Diabetes (weight loss, fatigue, thirst and frequent urination)
- O Migraines
- O Previous and current medication
- O Are you HIV-positive and have you developed AIDS?

E: Family History

25. Does anyone in your immediate family suffer from?

- O High blood pressure (dizziness, severe headache)
- O Heart problems (breathlessness, palpitations)
- O Diabetes

F: Sexual History

26. Within the last 3 months, have you had more than one sexual partner? 1. Yes 2.No

27. Within the last 3 months, do you think your partner has had another sexual partner?

1. Yes 2.No

28. Within the last 3 months, have you been told you have an STI? 1. Yes 2.No

29. Within the last 3 months have you had vaginal discharge, odour, itching, and pain?

1. Yes 2.No

30. Within the last 3 months, has your partner been told that he has an STI or has he had any symptoms - for example, penile discharge? 1. Yes 2.No

G: Contraceptive Knowledge & Use

31. Which contraceptive methods are you aware of? (Unprompted response)

Oral contraceptives	Q	Spermicides	O
Condoms	O	IUCD	O
Injectables	O	Tubal Ligation	O
Implants	O	Natural methods	O
Herbal remedies	O		

32. Have you ever used any family planning method? 1. Yes 2.No

33. If yes, which one/s and for how long?

34. Have you ever had any problems with the method you used? 1. Yes 2.No

35. If yes, which problem?

36. Have you ever used the IUCD? I. Yes 2.No

37. Have you ever had any problems with this method? 1. Yes 2.No

38. If yes which problem?

39. How effective is the IUCD?

- O a. More than **97%**
- O b. 80%
- O c. 50%

40. How does the IUCD work?

- O a. Kills the embryo
- O **b.** Prevents implantation
- O c. Prevents fertilization

41. How long does the copper T IUCD protect against pregnancy?

- O a. 2 years

O b. 5 years

O c. 10 years

42. Do you know of any side effects of the IUCD?

1. Yes 2.No

43. If yes which ones? (Unprompted response)

O Painful periods

o Heavy bleeding

O Expulsion

O Pregnancy

Q Doesn't protect against STI/STDs

Others

44. Do you know of any benefits of using the IUCD?

1. Yes 2.No

45. If yes which ones? (Unprompted response)

O Protects against pregnancy

O Long duration of protection

O Cheaper than most FP methods in the long run

O Safe

O Easily reverses fertility

O Minimal side effects

Others

46. Does the IUCD protect against STI/STDs?

1. Yes 2.No

H: IUCD Misconceptions

47. Do you think the IUCD can?

a. move and get lost inside the body	O
b. move to the heart	O
c. fail and will be in the baby's head	O
d. be felt by the partner (pinching)	O
e. fall out	O
f. causes cancer	O
g. causes abortion	O

h. Other (specify)

I: Knowledge on Immediate Postplacental IUCD insertion

48. Have you ever heard of the IUCD being placed for family planning immediately after delivery?

1. Yes 2.No

49. If you were offered this method would you consider using the IUCD just after delivery?

1. Yes 2.No

50. What would be your fears?

Selection

51. Does the client fit the medical eligibility criteria for IUCD insertion?

1. Yes 2.No

52. Where was the patient counselled?

Antenatal clinic o

Antenatal wards O

53. Which counselling option has the patient undergone?

Intensive O

Routine O

54. How many sessions of counselling did the client attend?

a. One b. Two c. Three d. Four

55. Did the partner attend any of the sessions?

1. Yes 2.No

56. Is the partner aware of the choice made?

I. Yes 2.No

57. Has the client made an informed choice to use postplacental IUCD insertion as her method of contraception?

1. Yes 2.No

58. If no, which method does the patient consider best for her use either now or later?

Oral contraceptives	O	Interval IUCD	O
Condoms	O	Tubal Ligation	O
Injectables	O	Natural methods	O
Implants	O	Herbal Remedies	O
Spermicides	O		

APPENDIX F: QUESTIONNAIRE TWO

Serial number

Interv iewers Name

Date of interv iew

Name of patient_____.

Telephone number of patient

Telephone number of contact

A: Counselling and Method Choice

1. Did the provider discuss with you a range of Family Planning methods available in clinic?

   1. Yes 2. No

2. Did the provider ask you which method you were interested in?

   1. Yes 2. No

3. Did the provider discuss the advantages and disadvantages of the IUCD?

   1. Yes 2. No

4. Did the provider discuss and clarify any rumours or mistaken ideas about the IUCD?

   1. Yes 2. No

5. Do you feel you were adequately counselled to make a decision?

1. Yes 2. No

6. Does your partner feel you made the right choice?

1. Yes 2. No

7. Do you feel you made the right choice?

1. Yes 2. No

If not, please specify

8. Do you still accept to use this method? 1. Yes 2. No

B: Medical History

9. Gestation Age (in weeks)

10. How long ago did you begin experiencing labour pains (in hours)?

11. Have you had your water broken? 1. Yes 2. No

12. If yes. how long ago?

13. Are you still feeling your baby kick normally? 1. Yes 2. No

14. Have you experienced fever in the last 24 hours? 1. Yes 2. No

15. Have you experience any vaginal discharge, foul smell or pain in the last 3 weeks?

1. Yes 2. No

C: Physical exam

16. General condition:

Pallor	O	Lymphadenopathy	O
Oedema	O	Cyanosis	O
Jaundice	O	Finger clubbing	O

17. Vital signs:

a) Pulse rate _____ c) Blood pressure

b) Temperature _____ d) Respiratory rate

18. Obstetric exam:

a) Fundal height

b) Fetal Lie

c) Fetal Presentation

d) Fetal Decent

19. Vaginal Exam

a) Dilatation (cm) [

b) Decent

c) Cervical consistency

D:lntrapartuni

20. Duration of labour (hours)

21. Duration of Caesarean section (hours)

22. Any complications during delivery/ theatre:

Obstructed labour o

Antepartum haemorrhage O

Delayed second stage **O**

Uterine rapture **O**

Excessive haemorrhage Q

Cervical tears **Q**

E: Postpartum

23. Did the patient get the IUCD inserted?

1. Yes 2. No

24. If not, why?

25. Was the IUCD inserted within lOminutes of placental removal?

1. Yes 2. No

26. Did the patient feel any pain or discomfort?

1. Yes 2. No

27. Was there excessive vaginal blood loss postpartum?

1. Yes 2. No

F: Inserter's Section

28. What method did you use to insert the IUCD?

1. Manual O

2. Forceps O

29. Did you use sterile methods for insertion? 1. Yes 2. No

30. Was the insertion difficult? 1. Yes 2. No

31. If so what was difficult about it.

32. How long did it take to insert the IUCD (minutes)?

33. How many IPP IUCD insertions have you done?

G: Discharge Review

34. Do you have any of the symptoms below?

Fever O

Excess abdominal pain O

Excessive bleeding O

Unusual vaginal discharge o

IUCD Expulsion O

Feels the hard plastic of the IUCD O

Perineal pain or discomfort O

35. Have you opted to exclusively breastfeed your baby?

I. Yes 2. No

H: Follow up Visit

36. Was the visit done via

1. Face to face interview O

2. Telephone conversation O

37. Did the patient return on the correct visit date?

1. Yes 2. No

38. If not why:

Lack of fare ^

Inadequate time

Didn't see the need to hurrv O

Too busy with the infant O

Partner's disapproval O

Others

39. Are you still practising exclusive breastfeeding (for mothers who had prior chosen this method)?

1. Yes 2. No

40. Have you resumed sexual relations with your partner? 1. Yes 2. No

41. If so when (weeks postpartum)

42. Have you changed sexual partners since delivery? 1. Yes 2. No

43. If yes are you using a condom? 1. Yes 2. No

44. Have you experienced any of the following?

Fever	O
Excess abdominal pain	o
Excessive bleeding	o
Irregular bleeding	o
Unusual vaginal discharge	o
IUCD Expulsion	o
Feels the hard plastic of the IUCD	o
Perineal pain or discomfort	o
Missed / Late period	o

45. Physical Exam

General condition

Pallor O

Lymphadenopathy O

Cyanosis O

Finger Clubbing Q

46. Vital signs:

a) Pulse rate

b) Temperature

c) Blood pressure

d) Respiratory rate

47. Abdominal exam:

a) Distension Yes 2- No

b) Palpation Light: Tenderness 1.Yes 2. No

Guarding LYes 2. No

Deep: Tenderness LYes 2. No

Guarding 1.Yes 2. No

Masses 1.Yes 2. No

Uterine involution 1.Yes 2. No

48. Pelvic exam:

a) Abnormal Vaginal Discharge I. Yes 2. No

b) Nature of cervix 1. Normal 2. Hyperaemic 3. Inflamed

c) Visible IUCD strings present 1. Yes 2. No

d) Adnexal tenderness 1. Yes 2. No

e) Cervical excitation present 1. Yes 2. No

49. Do you think you made the right decision? 1. Yes 2. No

If no, why?

50. Will you continue to use this method? 1. Yes 2. No

If no, why?

51. Would you use the same method again? 1. Yes 2. No

If no, why?

52. Is your partner happy with your choice? 1. Yes 2. No

If not, why?

APPENDIX G: 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 and 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.

APPENDIX H: FOLLOW IP VISIT RETURN NOTE

The named is a participant of the effect of two levels of counselling on acceptance, uptake and early outcomes of postplacental intrauterine contraceptive device study being held at Embu PGH. She is scheduled for a follow up visit at the family planning clinic as shown below.

Name of Patient

Study Number

Hospital IP Number

Date of Delivery

Date of Return

Warning signs that require return before the above date include:

- Cramping that does not decrease over time or with medications
- Severe pain in your belly
- Pain during intercourse
- Unusual vaginal discharge
- Excessive bleeding
- Strings missing or suddenly longer
- Feeling the IUCD when checking for strings
- Signs of pregnancy
- Pain in the birth canal
- Hotness of body

Please feel free to call the number below if you are have any problems.

PI number 0722-391821

Post-insertion instructions:

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

The IUCD may fall out. Please check on pads and undergarments before disposal. If you think it has come out please come back to clinic.

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.

NOTI YA KUREJEA KWA UKAGUZI ZAIDI

Aliyetajwa hapa chini ni mshiriki wa utafiti wa the impact of two levels of counselling on acceptance, uptake and early outcomes of postplacental intrauterine contraceptive device inayofanywa katika hospitali ya mkoa ya Embu. Anatarajiwa kurejea hospitalini kwa ukaguzi zaidi kama ilivyoashiriwa hapa chini.

Jina:

Nambari ya utafiti:

Nambari ya hospitali:

Siku ya kujifungua:

Siku ya kurejea:

Unatarajiwa kurudi hospitali iwapo utaona ishara zilizotajwa hapa chini:

- Kusokotwa na tumbo ambako hakukomi hata baada ya kunywa dawa
- Uchungu mwingi sana tumboni
- Kuhisi maumivu wakti ukishiriki ngono
- Kutokwa na damu kama isivyo kawaida
- Ukosefu wa nyuzi au kukosekana kwa nyuzi kabisa
- Kuhisi kifaa cha IUCD wakati ukitaftita nyuzi hizo
- Ujauzito
- Maumivu katika sehemu ya siri.
- Mwili kuwa na joto jingi

Usisite kupiga simu kwa nambari iliyo hapa chini ikiwa una shida yoyote.

Nambari: 0722-391821

Njia Ya kutumia Kifaa:

Hakikisha kuwa umejikinga kutokana na magonjwa ya zinaa. Iwapo unashuku kuwa una ugonjwa. rejea hospitalini kwa ukaguzi.

Kifaa cha IUCD kinaweza kikaanguka. Tafadhali chunguza suruali na vifaa unavyovitumia wakati wa mwezi kabla ya kuvitupa. Ukishuku kuwa imeanguka au kutoka rejea hospitalini.

Wakati unataka kuchunguza kifaa, fanya yafuatayo:

1. Osha mikono yako na maji na sabuni.
2. Simama na mguu mmoja ukiwa juu ya eneo lililo juu.
3. Kwa utaratibu. ingiza mkono wako katika sehemu yako ya siri. Chunguza na tafuta eneo lililo ngumu.
4. Tafuta nyuzi lakini usizivute.
5. Kama nyuzi hazijajitokeza, usiwe na shaka zinaweza kuongezwa urefu. Rejea kifaa katika zahanati.

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1* October 2009

Ref: KNH-ERC A318

Dr. Serah Wanjru Ndegwa
Dept. of Obslefrtes/Gynaecotogy
School of Medicine
University ol Nairobi

Dear Dr Ndegwa

RESEARCH PROPOSAL: "ACCEPTABILITY, **UPTAKE AND** CXTTCOMES *OF* POSTPLACSfTAL INTRAUTERINE CONTRACEPTIVE DEVICE INSERTION" |P242JBi2009;I

This is to inform you that the Kenyafla National HospitaWJON Ethics and Research Committee has reviewed and approved your above revised research proposal for the period 1" October 2009 • 30* September, 2010.

You wll be required to request for a renewal of the approval if you intend to continue with the study beyond Ihe deadtne given Clearance for export of btobgical specimen must also be obta ned from KNH-ERC for each bafch.

On behalf of the Committee. I wish you fruitful research and look forward to receiving a summary of the research findings upon completion of the study

This infomia»on will form part of dalabase that wH be consulted in future when processing related research study so as to minimize chances of study dupfcation

Yours sincerely

PR C (GONDII
AG SECRETARY. KNH/UON-ERC

c.c. Prof K M. 8hatt Chairperson, KNHAJON-ERC
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