PREMATURE DISCONTINUATION OF LONG ACTING REVERSIBLE CONTRACEPTIVES: A CROSS SECTIONAL STUDY IN HARARE

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ABSTRACT.

Introduction: Long acting reversible contraceptives (LARC) are very effective, with an unintended pregnancy rate of less than 1 per 100 women during the first year of use. Discontinuing contraception while still in need leaves a woman at risk of unwanted or ill-timed pregnancy. This study investigated reasons for premature discontinuation of LARC among women in Harare.

Objectives: To determine the reasons for premature discontinuation of the long acting reversible contraceptives. To identify gaps in the provision of LARC services.

Method: A cross sectional descriptive study was carried out at five major family planning clinics in Harare. Convenient sampling was used to identify 148 women who had prematurely discontinued the implants (Jadelle and Implanon) and intrauterine contraceptive devices (CuT380A and Mirena).

Results: LARC were discontinued by 46% of the women due to side effects while 36% desired pregnancy. Abnormal bleeding was the reason for discontinuation in 40.9%, 43.5% and 14.3% of Jadelle, Implanon and CuIUD users respectively. Desire for pregnancy was leading discontinuation reason in CuIUD and second for implants users. Partner discomfort at sexual intercourse, abdominal pain and vaginal discharge were the other side effects leading to CuIUD discontinuation. Half of the women who received medical treatment for side effects felt it was ineffective. The combined oral contraceptive pill was chosen by 62% of the women after discontinuing LARC.

Conclusion: Menstrual irregularities associated with LARC are the commonest reason for discontinuation of the contraceptive methods. Improving pre-insertion counselling and management of undesirable side effects will decrease premature discontinuation.

DEDICATION

To God Almighty, who is my refuge and my strength.

To my husband, Dr Tongai Chitsamatanga, my sons (Rufaro, Nashe and Mutsa) and all family members. Thank you for your support.

ACKNOWLEDGEMENTS

I would like to thank Professor Chipato and Dr Marere, my supervisors, for their professional guidance from the conception of the study idea to its completion.

I would like to acknowledge the study participants, the directors and staff of the family planning clinics for affording me the opportunity to carry out the study.

I extend my gratitude to Mr K Chimunda the statistician, for assisting with the statistical design and data analysis.

Last, but not least, I thank all the lectures and consultants in the department.

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LIST OF ABBREVIATIONS

LARC Long acting reversible contraceptive

CPR Contraceptive prevalence rate

IUD Intrauterine device

LNG levonorgestrel

ENG etonogestrel

ZDHS Zimbabwe Demographic Health Survey

WHO World Health Organisation

RCT Randomised controlled trial

SPSS Statistical package for social sciences

CuIUD Copper intrauterine device

WHO World Health Organisation

MEC Medical Eligibility Criteria

COC Combined oral contraceptive

PSZ Population Services Zimbabwe

ZNFPC Zimbabwe National Family Planning Council

PSI Population Services International

HIV Human immunodeficiency virus

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CHAPTER 1: BACKGROUND.

Introduction.

Family planning refers to a conscious effort by a couple to limit or space the number of children they want to have through use of contraceptive methods and treatment of infertility [1]. Contraception is the use of a drug, device or method to prevent pregnancy [1]. Freedom to plan and space births according to reproductive preferences ensures safety and well-being of both mother and children. The Safe Motherhood Initiative to reduce maternal deaths in developing countries has family planning as one of the four pillars that are key in its implementation [2]. It is estimated that in 2008, contraceptives use was responsible for a 44% reduction in maternal deaths globally [3].

Unintended pregnancy remains a global public health problem. About half of all the pregnancies per year in the world are unplanned or ill-timed, despite increased use of family planning [4]. An unintended pregnancy is a mistimed or an unwanted pregnancy [5]. The incidence of unintended pregnancy is among the most essential health status indicators of reproductive health. The rate of unintended pregnancies in Zimbabwe was 40% in 2016 and 25% of those ended up in abortion. [6]. Access to legal abortion is limited to special circumstances provided for in the constitution, that include rape, incest, to save the woman's life, or foetal impairment [7]. This results in clandestine abortions. A recent study in Zimbabwe estimated the rate of induced abortions to be 17.8 per 1000 women in the age group 15-49 years [6]. About 40% of Zimbabwean women experiencing abortion complications are classified as having moderate or more severe complications. Severe or near-miss morbidity constituted 21% of the complications [8].

In 2011, 45% of the 6.1 million pregnancies in the United States (US) were unintended. Of the 45%, 27% were ill-timed or "wanted later" and 18% were unwanted [5]. In 2008, more than half of unintended pregnancies in the US happened to women who reported current contraception use, and 90% of those were due to incorrect or inconsistent use [9]. Gaps in usage, switching between methods and discontinuing contraception while still in need puts women at an increased risk of unintended pregnancy.

The Government of Zimbabwe through the Ministry of Health and Child Care, with financial support from international partners has made a commitment to meeting Sustainable Development Goals SDG 3 and 5. The cost of contraceptives has been greatly subsidised to the extent that women may access services at affordable prices or free of charge. Family planning is used by 67% of married women in Zimbabwe [10]. Of these, 66% used modern methods and only 1% reported traditional method use. Modern contraceptive methods were used by 68% of unmarried women. The proportion of married women in the 15 to 49 years age group not using contraceptives decreased from 46.5% in 1999 to 41.5% in 2014 [10]. One of the goals in the Zimbabwe Family Planning Strategy is to increase Contraceptive Prevalence Rate (CPR), among married women from the 67% to 68% by 2020 [11]. The CPR increases with age, peaks to 73% at 35-39 years and drops to 56% among women 45-49 years. The CPR also increases with education and household wealth [10].

The extent to which the family planning programme is meeting the demand for services is reflected by the unmet need. Unmet need reflects an apparent discrepancy between one's reproductive preferences and behaviour [12]. Zimbabwe has the lowest unmet need in Sub-Saharan Africa [13]. Unmet need among women currently married or in union, whether for spacing or limiting births, declined from 12.8 % in 1999, to 10% in 2015 [10].

Long acting reversible contraceptives available in Zimbabwe are the levonorgestrel [LNG] releasing Jadelle, etonogestrel [ENG] releasing Implanon), the copper intrauterine device TCu380A (ParaGard) and the LNG IUD Mirena [10]. Other available modern contraceptive methods include, the combined oral contraceptive (COC) pill, the progesterone only pill (POP), Depo medroxyprogesterone acetate (Depo Provera), male & female condoms, diaphragm, male and female sterilisation and lactational amenorrhoea [10]. Knowledge of contraceptive methods is universal, with 99% of all women of reproductive age and 100% of all men age 15-49 knowing at least one method of contraception [10]. Emergency contraception is the least-known. Commonly used methods among married women are the pill at 41%, injectables 10%, and implants 10%. Sterilisation, IUCD and traditional method (mostly withdrawal) are 1% each [10]. The trend is different for unmarried women with 27% using condoms, 14% implants and 16% the pill. Implant use rose from 3% to 10% in 2010 and 2015 respectively [10]. Implants were preferred to IUD by Zimbabwean women because of their shorter duration, superficial and visible location [14].

LARCs are very effective with an unintended pregnancy rate of less than 1 per 100 women during the first year of use and are comparable to sterilization [15]. Pregnancy rate for Cu IUD is 0.6% with perfect use and up to 0.8% with typical use in the first year, while it is 0.1% with perfect use and up to 0.2% with typical use for Mirena [16]. Jadelle and Implanon each had the same 3-year cumulative pregnancy rate of 0.4 per 100 women years [17]. The IUD is the commonest method of reversible contraception worldwide, used by about 23% of women. The reported figure is a reflection of the high prevalence of IUD in China's vast population, which accounts for over 64% of worldwide use [18].

Long acting reversible contraceptives have high continuation rates and favourable cost–benefit profiles. While they have substantial initial costs, there are no further year-on year costs unless the method is prematurely discontinued, or side effects are encountered and managed. There

may be no need for re-supply or clinic visits once inserted, potentially conserving scarce healthcare resources. LARC have few contraindications and are appropriate in most demographics of women, even groups with increased risk of complications with other forms of contraception [19] [9].

The continuation rates for LARC are higher than those recorded for short-acting methods [20]. Discontinuation rates in less than 1 year are as high as 42%, have been reported [21]. Three months after discontinuing while still in need (DWSIN), 15 to 20 percent of LARC users are at risk of an unwanted pregnancy [22]. The main reasons for discontinuation of all the contraceptives among Zimbabwean women are the desire for pregnancy 37%, method- related health concerns or side effects 21%, and method failure 12% [10]. The reasons vary according to the method.

The dynamics of contraception discontinuation are complex, and the strength of a woman's fertility desires is key. High discontinuation rates for reasons other than desire to get pregnant are a major public health concern. Women who stopped using a method for any reason in the first year of use ranged from 20% in Zimbabwe to 48% in Bangladesh [22]. The proportion of discontinuation for the sake of falling pregnant ranged from 12% in Azerbaijan to 40% in Zimbabwe [22]. The proportion of pregnancies reported as unintentional following contraception discontinuation in developing countries has not been studied. Women aged 35 - 49 years were more likely to report a birth as intended following contraception discontinuation or failure than those younger than 25 years [23].

Problem statement.

According to the 2017 Annual Statistics Report for Parirenyatwa Group of Hospitals – Mbuya Nehanda family planning clinic, there were 159 Jadelle removals compared to 141 insertions [24]. Jadelle has been the most used long acting reversible contraceptive among Zimbabwean women. Information on whether these removals were premature or at the expected time of expiry of the contraceptive period of use was not reported.

Research question.

What are the reasons for premature discontinuation of the long acting reversible contraceptives among women presenting for removal of the methods in urban Harare?

Objectives.

Primary Objective.

To determine the reasons for premature discontinuation of the long acting reversible contraceptives.

Secondary Objective.

To identify gaps in the provision of LARC services.

CHAPTER 2: LITERATURE REVIEW.

A head to head, multicentre randomised controlled trial (RCT) of Implanon and Jadelle showed that the two had the same contraceptive effectiveness with a 3-year cumulative pregnancy rate of 0.4 per 100 women years [17]. This study includes data from Zimbabwe, where 140 women were randomised to each arm. Reasons for implants removal were similar. The continuation rate at 2.5 years of use was similar, 69.8% for ENG implant and 71.8% for LNG implant. This study also compared the IUD TCu380A versus the progestogen implants in an observational non RCT manner and noted that the continuation rates for the implants were higher than that of the IUD. Bleeding disturbances were the reason frequently given for stopping both implants and the IUD. This was more common in Implanon than Jadelle users, reaching 3-year cumulative rates of 16.7 per 100 woman-years and 12.5 per 100 woman-years respectively. Extended use of Implanon up to 5 years was also studied, and no pregnancy was recorded in the period [17].

Mrwebi et al, carried out a study in Buffalo City Metropolitan Municipality, Eastern Cape Province, South Africa, that sought to determine the reasons for discontinuation of Implanon among reproductive-age women. The results showed a mean duration of usage of 11.2 months among the participants. The study confirmed the assumption that most recipients of Implanon had it removed prematurely. Implanon was removed by 67.3% in the first year of use while 94.4% did so after the second year. The commonest reason for early discontinuation was attributed to the side effects (71.3%), particularly, excessive bleeding. Other reasons were desire for more pregnancies (4.3%), wrong positioning (3.2%), method failure (5.3%), and possible drug interactions [25]. Another study on factors associated with early LARC discontinuation, found that of 338 women who had a LARC inserted, 42% had removed it in less than 1 year [21].

The Contraceptive CHOICE Project in the United States aimed to introduce and promote LARC use by removing financial and knowledge barriers. A prospective cohort of 10,000 women aged 14-45 years seeking to initiate a reversible method of contraception for at least 1 year were followed up [26]. Information regarding long-acting reversible methods of contraception was availed to increase awareness of them. Contraceptive methods chosen were provided at no cost. The authors concluded that once financial barriers were removed and LARC methods were offered as a first-line family planning option, two-thirds of the women chose them [27]. Another analysis of the CHOICE project measured discontinuation within 6 months and identified baseline characteristics associated with early discontinuation among Mirena, CuIUD and Nexplanon users. Discontinuation rates at 6 months were 7.3%, 8.0%, and 6.9% for Mirena, CuIUD and Nexplanon, respectively [28]. The most common reasons for discontinuation were irregular or frequent bleeding among implant users and cramping among IUD users [28].

In a prospective study in the United Kingdom comparing Implanon and oral contraceptives in 493 women aged 13 to 48 years, Implanon was more cost-effective. Over a three-year period, the yearly cost per patient was £50.30 for Implanon and £83.02 for oral contraceptives [29]. Another study concluded that even if LARC methods are discontinued before their full durations of efficacy, they become cost-saving relative to short acting reversible methods within 3 years of use [30].

Women seen for placement or removal of an IUD or implant at a university clinic in South Carolina, United States were studied by Dickerson and colleagues. They analysed 132 respondents and early removal occurred in 24.2% of the women. Satisfaction with the contraceptive choice was reported by 72.7% [9]. Implants were preferred by younger and

nulliparous women while older and multiparous women preferred the IUD. There were no further differences in choice of LARC based on other patient demographics. Early removal occurred in 28.6% of IUDs and 18.2% of implants users [9]. There were no differences in rates of satisfaction or early removal with either method of LARC. Pain was reported in 48.0% of women using Levonorgestrel IUD. Implants users who reported increased bleeding and weight gain were 58.2% and 30.9% respectively. The authors concluded that perceptions about early removal of IUDs and implants may be misleading and continued use is much better than other methods [9].

Determinants of implant discontinuation within six months of insertion were examined by Kalmuss and colleagues among 786 low-income women attending family planning clinics in three U.S. cities. Implant discontinuation in this population was low with 7.6% of participants stopping by the end of six months. Menstrual side effects were the most common reasons given for early implant removal. Early removal versus continuation was significantly associated with the following: headaches (73% vs. 38%), hair loss (48% vs. 33%), weight gain (59% vs. 42%) and health problems feared would be long-term (37% vs. 2%) [31]. A partner desiring a child within the next two years, dissatisfaction with prior contraceptive methods, perceived influence from health care providers to choose the implant, negative media coverage and the number of implant side effects were significant predictors of early implant discontinuation. Social and demographic characteristics, motivation to avoid an unplanned pregnancy, and medical aid status were not significantly related to early removal) [31].

Unscheduled bleeding with progestin implants is a common side effect. Menstrual bleeding patterns are highly variable among users of implant contraception. A systematic review and meta-analysis involving 11 clinical trials revealed that the primary reason for discontinuation was unscheduled bleeding. It was responsible for 14.8% discontinuations in the United States and Europe in contrast to 3.7% in Southeast Asia, Russia, and Chile [32]. Women bleeding for

more days were more likely to discontinue, especially with prolonged bleeding. Those who discontinued implant in a 90-day reference period had average bleeding/spotting days of 45.2 while those who continued had 16.5 [32]. Menstrual bleeding disturbances were reported in 90% of women who discontinued the implant in contrast to 22% who continued its use [32].

While side effects are usually the reason for discontinuation, in some women they may prove to be favourable. A study was carried out at Turku University Hospital in Finland that aimed to determine continuation rates and symptoms associated with early removal of the levonorgestrel releasing intrauterine system. The risk of premature discontinuation was found to be significantly reduced in women who experienced total absence or reduced frequency of menstruation (RR 0.46, 0.43 – 0.50) [33]. Excessive bleeding and spotting on the other hand were associated with increased risk of discontinuation in the same study.

In a US study on continuation of the Cu IUD over a 40-month period, 6.9% had spontaneous expulsion, 1.3% fell pregnant, 11% removed the IUD within 6 months. The IUD was still in place in 72% at the end of the 40 months. Thirteen percent of the women who removed the IUD for reasons other than desire for pregnancy did fall pregnant during the study period. Pain and bleeding were the commonest reasons for removal [34].

The Copper intrauterine device is WHO MEC 1 within the first 48 hrs after delivery [19].. This period is critical because both mother and child need special care and will be in proximity to health care facilities. Post-partum intrauterine contraceptive device (PPIUCD) is an invaluable crisis-oriented service at a time when contraceptive options are limited. and can be inserted during caesarean section or after vaginal birth [35]. A study in India showed high continuation rates with CuIUD of 81.81% in the interval group and 88.23% in postpartum group [35]. Of the women who discontinued over a 12-month period, bleeding accounted for 88.89% in

interval IUCD group compared to 41.2% in the PPIUCD group. IUCDs were removed because of social factors in 58.8 % of women with PPIUCD [35].

Various factors including: history of negative publicity; misinformation on risks of ectopic pregnancy, infection, future fertility; eligible candidates; mechanism of action; lack of clinician training; initial cost and fears of litigation, have limited widespread use of the IUD in the US [36]. The media can be used for reproductive health promotion. Women with regular exposure to the mass media had lower unmet need especially if they had seen or heard about family planning in the media [12]. IUDs and implants have been shown to be safe for use by teenagers, nulliparous and younger women [19]. A study at an urban clinic in the US on discontinuation of LARCs in teenagers and young women concluded that the 6-month and 12-month discontinuation rates of 11.3% and 21.9% respectively, were low for that age group [37].

No studies in developing countries have examined the proportion of pregnancies reported as unintentional following contraception discontinuation. Women aged 35 - 49 were more likely than those younger than 25 to report a birth as unintended following contraception discontinuation or failure [23]. Such women do not sufficiently recognise the consequence of an unplanned pregnancy. A study was carried out by Bruckner and associates on 15-19-year-old females that sought to determine whether their attitudes toward pregnancy influenced their contraceptive consistency and their risk of pregnancy. Twenty percent of the adolescents were defined as having antipregnancy attitudes, 8% as having pro-pregnancy attitudes and 14% as being ambivalent toward pregnancy [38]. Teenagers who were ambivalent about pregnancy had reduced odds of using contraceptives consistently rather than not practicing contraception at all (odds ratios, 0.5 and 0.4, respectively) [38]. Antipregnancy respondents did not differ from pro-pregnancy respondents in terms of their contraceptive consistency.

Unscheduled bleeding secondary to progestogen releasing implants can be managed conservatively or COC, cyclical progestogen, non-steroidal anti-inflammatory drugs (NSAIDs), tranexamic acid, mifepristone, and doxycycline may be used [39] [40]. A Cochrane review concluded the available interventions offered a short-term effect on the current bleeding episode with no medium or long-term beneficial effects described in any of the studies [41]. Where IUD strings are causing discomfort to a sexual partner, directing them to the posterior vaginal fornix, cutting them shorter or even flush with the cervix can help. The latter has a high risk of an invasive procedure at removal [42].

Counselling before provision of contraception should increase awareness of anticipated side effects and prepare women better on their management. In a trial assessing effect of counselling on discontinuation of depo-medroxyprogesterone acetate in Mexican women, repeated, structured information about the injectable contraceptive was associated with a lesser risk of discontinuing by 12 months (O R 0.27; 95% CI 0.16 to 0.44) than were women who had routine counselling [43]. A Cochrane review however concluded that strategies to improve adherence and continuation, including intensive counselling, showed no benefit [44].

Sub-Saharan Africa has high HIV prevalence and maternal mortality rates. The recently updated WHO medical eligibility criteria, confirms LARC safety among high-risk and HIV-infected women [19]. Less than 5% of clinicians interviewed in surveys conducted in Zimbabwe and South Africa would provide IUDs in HIV-positive or at-risk women [45]. Clinicians in Zimbabwe (23%) would offer implants to women at risk of HIV, whilst 29% would offer to HIV-positive women [45]. Efavirenz-containing combination antiretroviral therapy has drug-drug interactions with hormonal contraceptives that may compromise their effectiveness [46]. Antiretroviral plasma concentrations and effectiveness are generally not affected. Despite such drug interactions, implants remain very effective and women taking

antiretrovirals should have full access to all hormonal contraceptives. Counselling on expected rates of unplanned pregnancy associated with all contraceptives should be given instead [46].

Justification of the study.

Global patterns of contraceptive use vary widely. No studies have focused on the reasons for premature discontinuation among LARC users in Zimbabwe. This study brings out information pertinent to our local setting and insight into discontinuation of LARC among Zimbabwean women. It also brings out gaps that may need to be improved in the service provision.

CHAPTER 3: METHODOLOGY.

Design.

A cross sectional descriptive study was carried out.

Setting.

The study was carried out in the city of Harare at the Parirenyatwa Hospital - Mbuya Nehanda family planning clinic, Harare Central Hospital family planning clinic, Population Services International -NewStart centre Kwame Nkruma Avenue, Population Services Zimbabwe clinic in Mbare, Population Services Zimbabwe clinic in Belvedere and the Zimbabwe National Family Planning Council - Spilhaus Centre. Women presenting at these clinics for removal of a LARC method during the period 1 October 2018 to 31 January 2019 were considered for the study.

Study Participants.

Study participants were consenting women between the ages 18 to 45 years who presented for removal of Jadelle, Implanon, TCu380A or Mirena, before its expected date of removal. They were identified by the clinic nurses, who directed them to the principal investigator for recruitment after removal of the LARC. Participants were recruited at the exit point, after being served and were about to leave the facility.

Inclusion Criteria.

Consenting women between the ages 18 to 45 years who presented for removal of a LARC before its expected date of removal.

Exclusion Criteria.

Women for whom contraception was no longer relevant (menopausal and post hysterectomy), whose period of use was not known and those who did not consent.

Sampling Method.

Convenient sampling method was used.

Sample Size.

The sample n = 143 was calculated using the Dobson formula: $n = Z\alpha^2 pq / d^2$

$Z\alpha^2 = 1.96$ for 95% confidence interval,

d =0.05 (level of significance)

p =0.24, according to a study by Dickerson L et al, carried out at the Medical University of South Carolina, USA, where early removal of LARC occurred in 24% of women who had discontinuation records.

q=0.76 (1-p)

The sample size calculated above is the minimum.

Data Collection.

A structured questionnaire in English was used. It was administered by the principal investigator who would translate it to participants preferred language where necessary. Data on patient demographics, reproductive history, LARC removed and reasons for removal, complications experienced, interventions sought, and contraceptive requirements after removal was collected.

Data Management.

The data was coded, and no participant identifiers were used. Questionnaires were checked for completeness by the principal investigator before data entry into the computer. The data was entered in Excel spread sheet before exporting to Statistical Package for Social Sciences.

Data analysis.

Study variables were analysed using the Statistical Package for Social Sciences version 22. Descriptive statistics used n (%) and mean (SD) for continuous variables. The Student T-test was used for continuous variables while the Chi-squared test was for categorical variables. Significance testing was set at P=0.05. The results were presented in written format, in graphs and in tables showing frequencies and percentages.

Ethical considerations.

Ethical clearance was sought and obtained from:

- Joint Research Ethics Committee for the University of Zimbabwe.
- Medical Research council of Zimbabwe – Approval number MRCZ/B/1555.
- Ethics committees for all the respective centres where the research took place: Parirenyatwa Hospital, Harare Central Hospital, ZNFPC Spilhaus Clinic, PSZ Belvedere and Mbare Clinics, PSI NewStart Clinic.

Informed consent in writing was sought before enrolling participants. The women received full disclosure of the nature of the study and an opportunity to ask questions. Participants were assured that no punitive implication or denial of service would be encountered in the event she declined to participate. Study participants were treated with respect and no coercion was used. All the information concerning the study was kept in privacy, and confidentiality was maintained. There was no material gain for the women.

CHAPTER 4: RESULTS.

Demograhics and reproductive history.

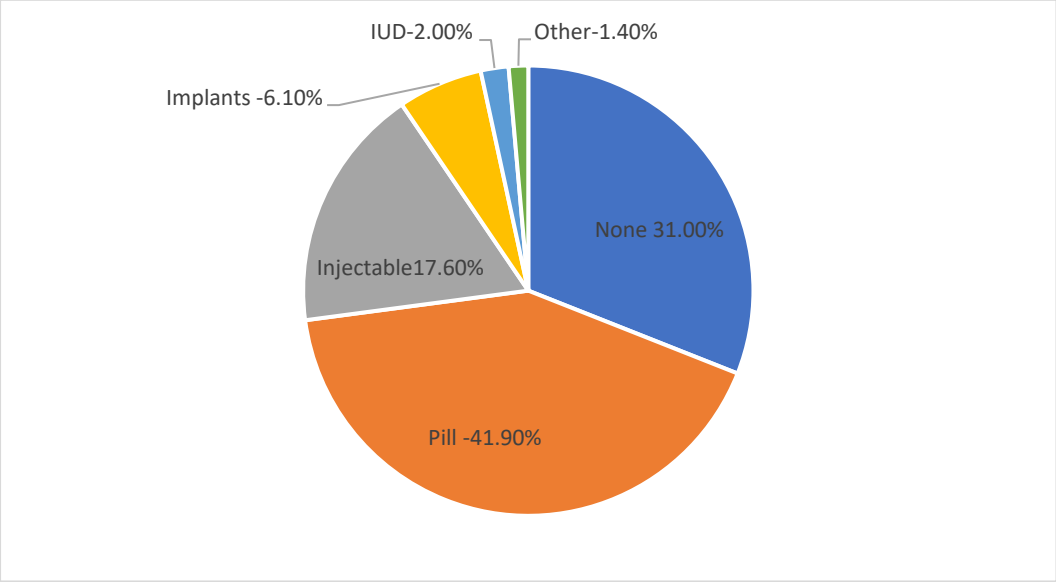
Table 1 : Demographic characteristics of the women who discontinued LARC.

		n (148)	% (100)
Age	18-24 years	49	33.1
	25-35 years	72	48.7
	36-45 years	27	18.2
Race	Black	134	90.5
	Mixed Race	14	9.5
Number of living Children	0	5	3.4
	1	54	36.5
	2	45	30.4
	3+	44	29.7
Marital status	Single/never married	19	12.8
	Married/ Living with partner	115	77.7
	Separated/Divorced/Widowed	14	9.5
Religion	Christianity	120	81.1
	Traditionalist	22	14.9
	Islam	3	2.0
	Other	3	2.0
Level of Education	Primary	26	17.6
	Secondary	85	57.4
	Tertiary	37	25.0
Employment Status	Formal employment	44	29.7
	Self employed	63	42.6
	Unemployed	41	27.7
Income	Adequate	69	46.6
	Inadequate	79	53.4
Age at first child	<16	21	14.2
	16-21	79	53.4
	21-29	48	32.4
	30+	0	0.0

The ages of the women analysed ranged from 18 to 45 years. The mean age was 29.53 years with a standard deviation of 6.61. Peak removals occurred in the age group 25-35 years (table 1). Most of the participants were of Black African race, married/living with a partner and Christians. Women with no living children constituted 3,4%. Secondary or tertiary level of

education was attained by 82.4% of the women and 72.3% were either formally or self-employed. The first child was born before the age of 16 years in 14,2% and between 16-21years in 53.4% of the women. None of the women gave birth for the first time after the age of 30 years (table 1).

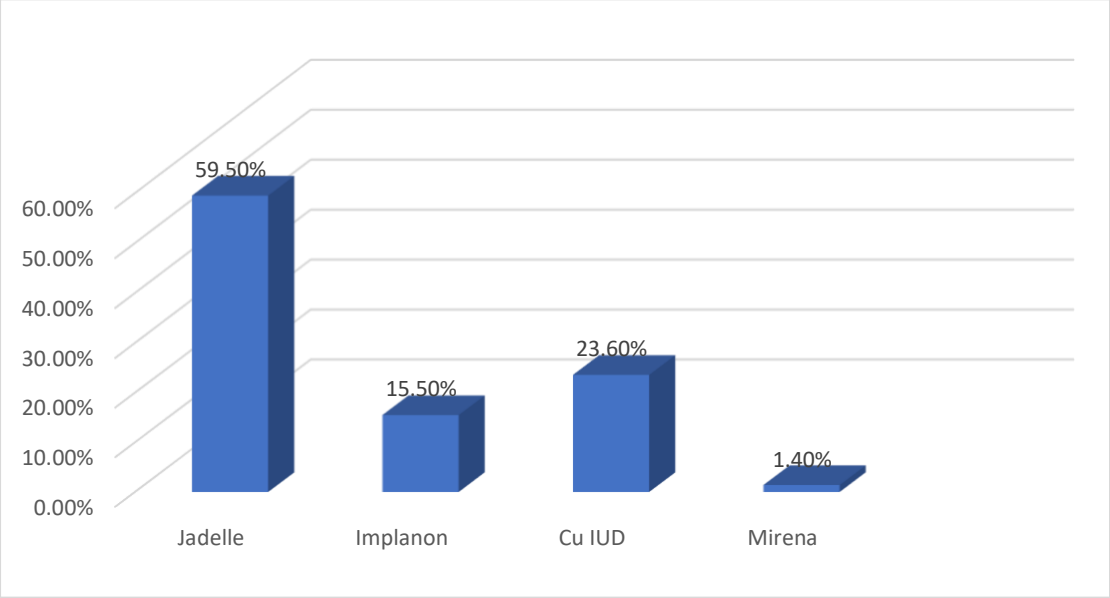
Figure 1: Contraceptive used prior to the LARC that was discontinued.



Thirty one percent of the women were not using a modern contraceptive method prior to the LARC they discontinued. The pill was used by 41.9% of women prior to using the LARC. Implants, IUDs and injectables were used by 6.1%, 2.0% and 17.6% of the women respectively prior to the LARC discontinued (figure 1). Women with a history of unintended pregnancies ever occurring in their lives were 37.2%, irrespective of any contraceptive use or not. Partner involvement in family planning decisions was present in 82.5%. Miscarriage, caesarean delivery, complications after vaginal delivery and sexually transmitted infections had occurred in 26.4%, 24.7%, 17.2% and 17.4% respectively.

Long acting reversible contraceptive discontinued.

Figure 2: LARC device discontinued prematurely.



Jadelle was discontinued by 59.5% of the women (figure 2). Implanon, CuIUD and Mirena were discontinued by 15.5%, 23.6% and 1.4% of the women respectively.

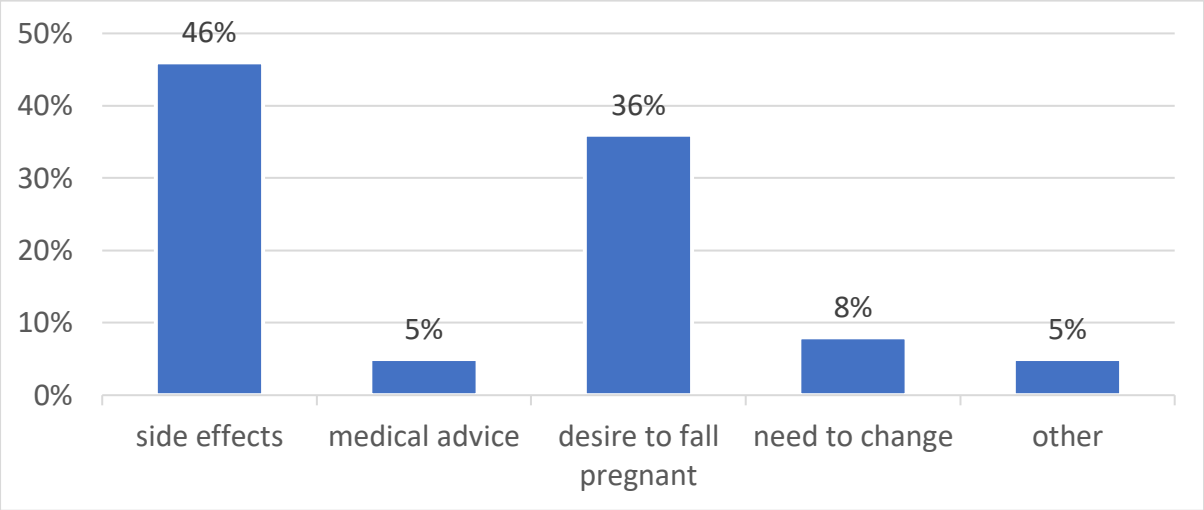
Table 2 : Number of months before premature discontinuation of each LARC device.

LARC method	Average number of months used	Standard deviation
Jadelle	28.56	15.86
Implanon	20.88	13.12
CuIUD	23.57	24.91
Mirena	8	_

The average number of months from insertion to discontinuation of the LARC were 28.56 for Jadelle, 20.88 for Implanon and 23.57 for CuIUD (table 2). Pre-insertion counselling was adequate for 68.5% of the women. Three quarters (75.3%) of the women chose LARC freely without any influence from the service providers while the remainder felt they were influenced

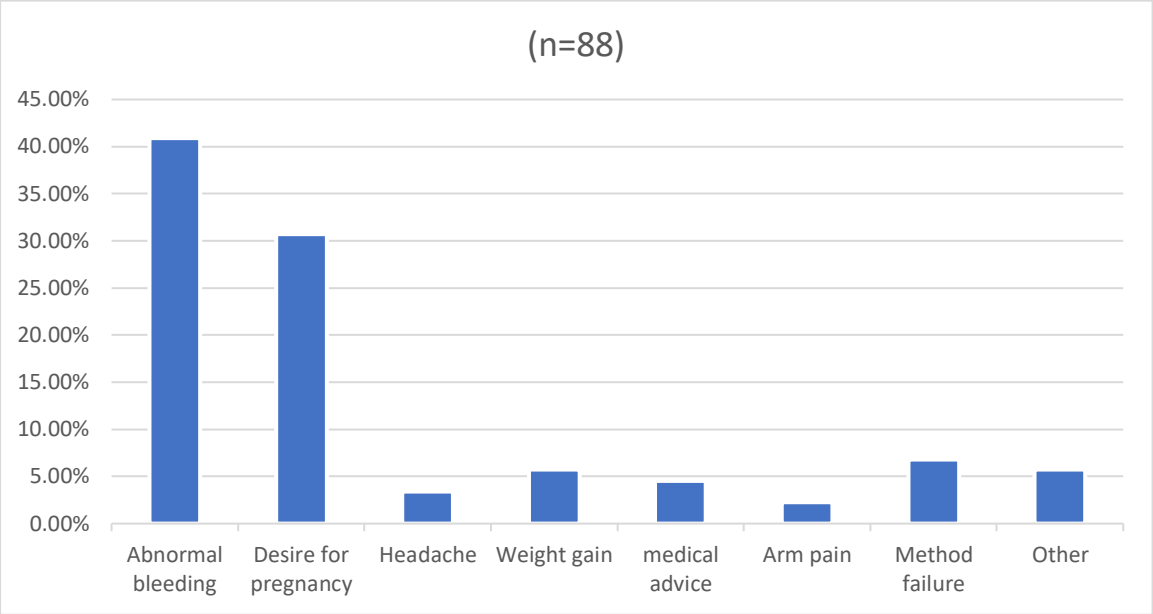
to some extent. Follow up visit after insertion occurred in 34.5% of the women. Women who would recommend the LARC they had discontinued to a friend were 64.8%.

Figure 3: Reasons for discontinuation of all LARC methods.



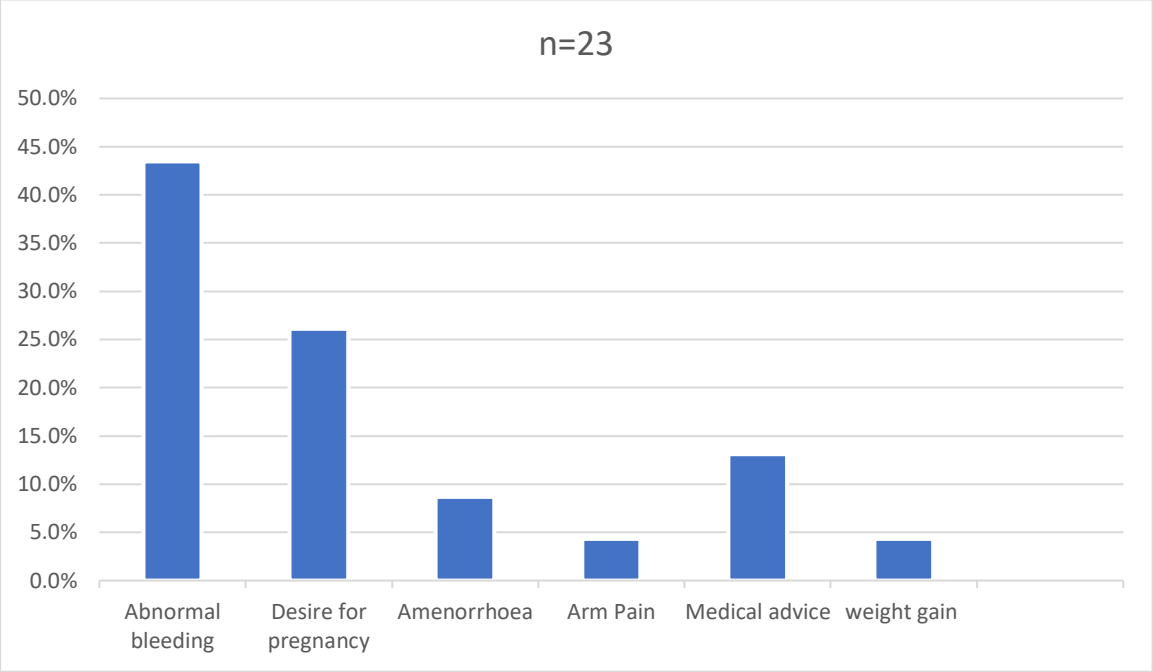
Side effects were the reason for LARC discontinuation in 46% and desire to fall pregnant in 36% of all the women. The need to change to another method and medical advice were contributory in 8% and 5% of the women respectively. (figure 3). Reasons that constituted the category ‘need to change’. included a woman who removed the implant because she was relocating to a rural area where services for removal might not be easily accessible if the need arose and those who did not give specific reasons for discontinuation but just wanted to switch to another method, to mention a few. In the category ‘other’ were reasons with small frequencies that could not be reported separately, including influence from family members, misconceptions about absence of side effects and religious reasons to name a few.

Figure 4: Reasons for discontinuing Jadelle.



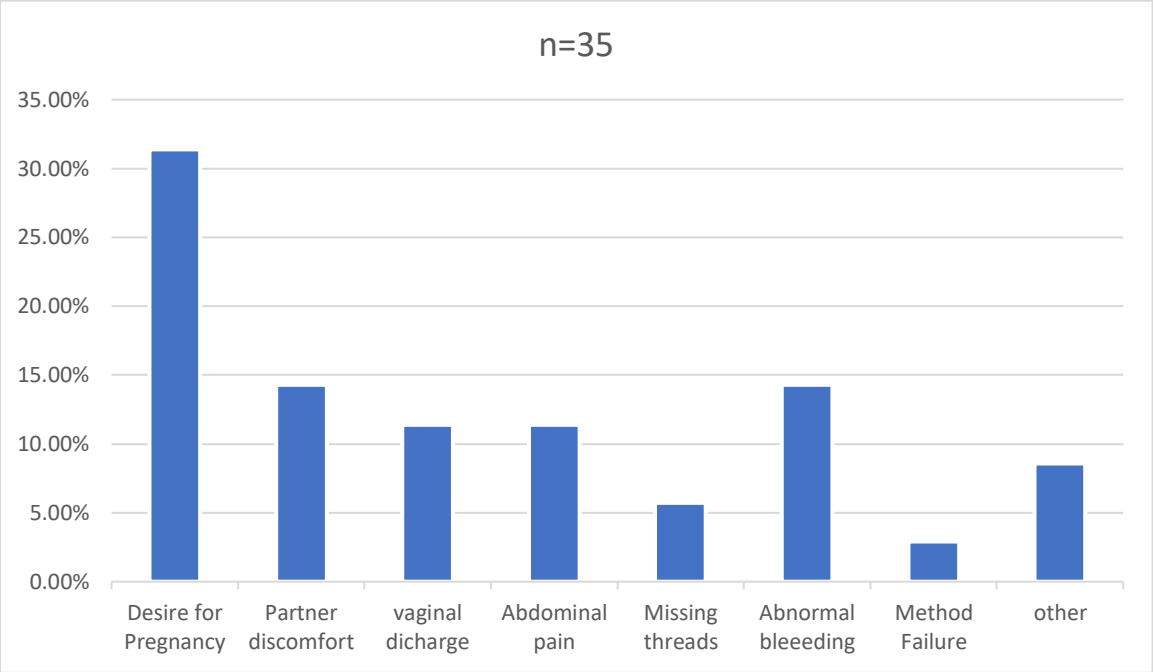
Abnormal (heavy/ prolonged/irregular) bleeding was reason for discontinuing Jadelle 40.9% and desire for pregnancy in 30.7% followed by desire for pregnancy. Method failure (falling pregnant whilst having the contraceptive device in situ) was reported by 6.8% of the women. Medical advice, weight gain, arm pain was reason for discontinuation in 4.5%, 5.7% and 2.3% of the women respectively.

Figure 5: Reasons for discontinuing Implanon.



Abnormal bleeding and desire for pregnancy resulted in premature discontinuation of Implanon in 43.5% and 21.6% of the participants respectively. Medical advice and amenorrhoea were discontinuation reasons in 13.1% and 8.7% respectively.

Figure 6: Reasons for discontinuing CuIUD.

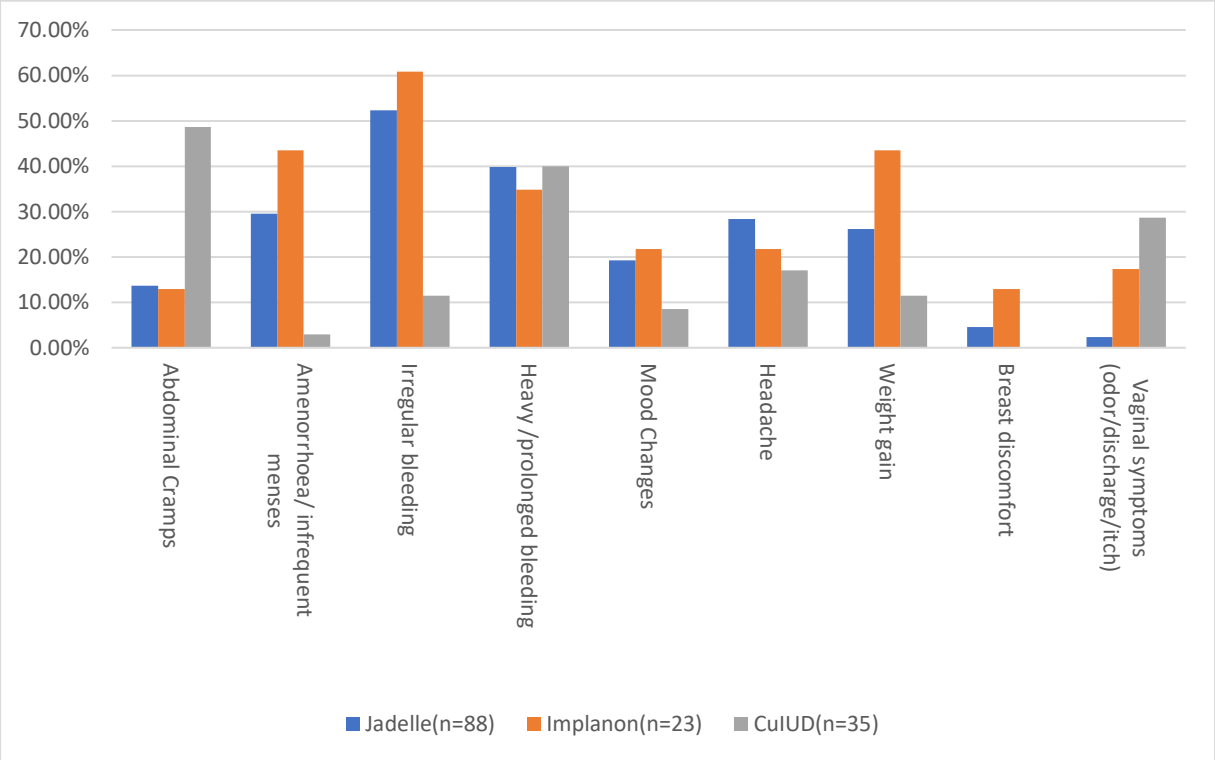


Desire for pregnancy was the reason for discontinuing CuIUD in 31.4% (figure 6). Partner discomfort at sexual intercourse caused 14.3% while vaginal discharge was responsible for 11.4% discontinuations. Abnormal bleeding and abdominal pain were discontinuation reasons in 14.3% and 11.4% of the women respectively. Missing threads and method failure were reasons in 5.7% and 2.9% of users respectively.

Two women discontinued Mirena. One discontinued due to abnormal uterine bleeding and the other due to loss of libido.

Common side effects experienced during LARC use.

Figure 7: Common side effects experienced at any time during use of the discontinued LARC



Irregular bleeding was reported by 52.3%, 60.9% and 11.4% of Jadelle, Implanon and CuIUD users respectively. Heavy/prolonged bleeding was experienced by 39.8%, 34.8% and 40% of the women using Jadelle, Implanon and CuIUD respectively. Amenorrhoea was reported by

29.5% of Jadelle and 43.5% of Implanon users. Abdominal cramps and vaginal symptoms were experienced by 48.6% and 28.6% of CuIUD users respectively. Weight gain was reported by 43,5% of implanon and 26.1% of Jadelle users.

Table 3: Outcomes of interventions received after seeking treatment for side effects experienced during use of LARC.

	Reassured only		**Received treatment/ drugs**	
	n	%	n	%
Intervention worked.	18	46.2	26	48.1
Intervention did not work.	21	53.8	28	51.9
Total	39	100	54	100

After experiencing side effects, 36.5% sought medical attention. After seeking help, 39.8% were either reassured or counselled only, while 55.1% received some form of treatment in addition to counselling. Among the women who received treatment/ drugs, 51.9% felt the intervention had not worked (table 3). For those who received counselling or reassurance only, 53.8% felt it had not worked.

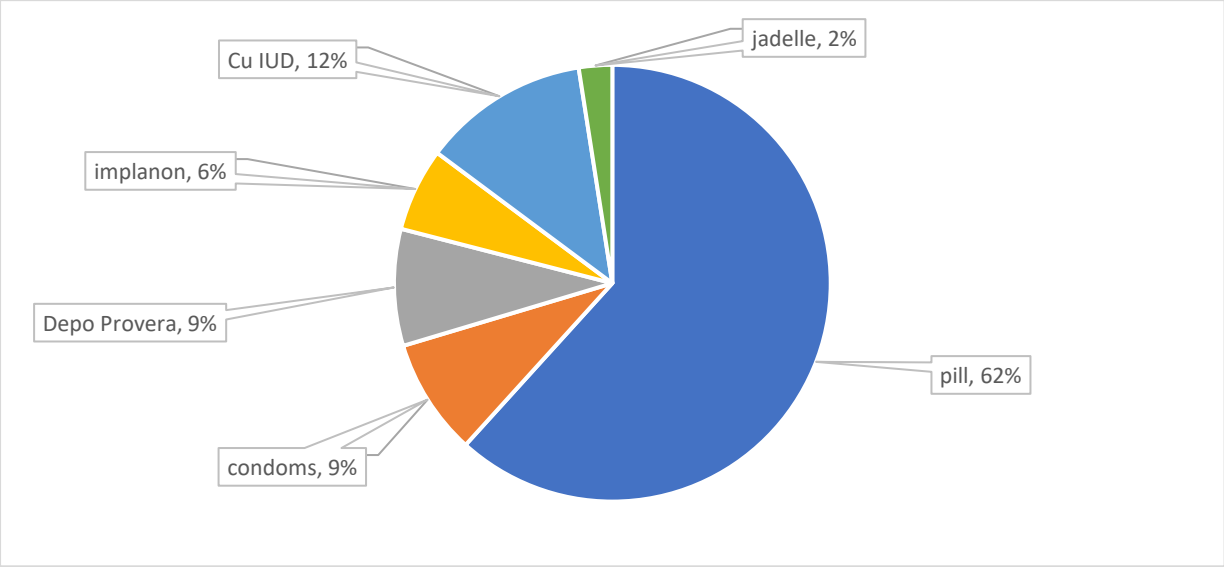
Table 4: Characteristics of women who discontinued LARC before 12 months compared to those who discontinued after 24 months.

		< 12 months n	%	**> 24 months** n	%	**p-value**
Age	18-24 years	11	37.9	9	20.5	0.086
	25-35 years	15	51.7	22	50.0	
	36-45 years	3	10.3	13	29.5	
Number of living children	0	3	10.3	0	0.0	0.071
	1	12	41.4	13	30.2	
	2	8	27.6	13	30.2	
	3+	6	20.7	17	39.5	
Reasons for removal	Side effects	16	55.2	14	31.8	**0.047**
	Medical advice	1	3.4	3	6.8	0.536
	Desire for pregnancy	8	27.6	20	45.5	0.124
	Need to change	3	10.3	3	6.8	0.591
	Other reasons	11	37.9	13	29.5	0.455

Table 4 compares different variables between the women who discontinued LARC before 12 months and those who discontinued after 24 months of use. Side effects were significant for discontinuation of LARC between the two groups (p=0.047). Age, number of living children and all the other reasons for removal were not significant.

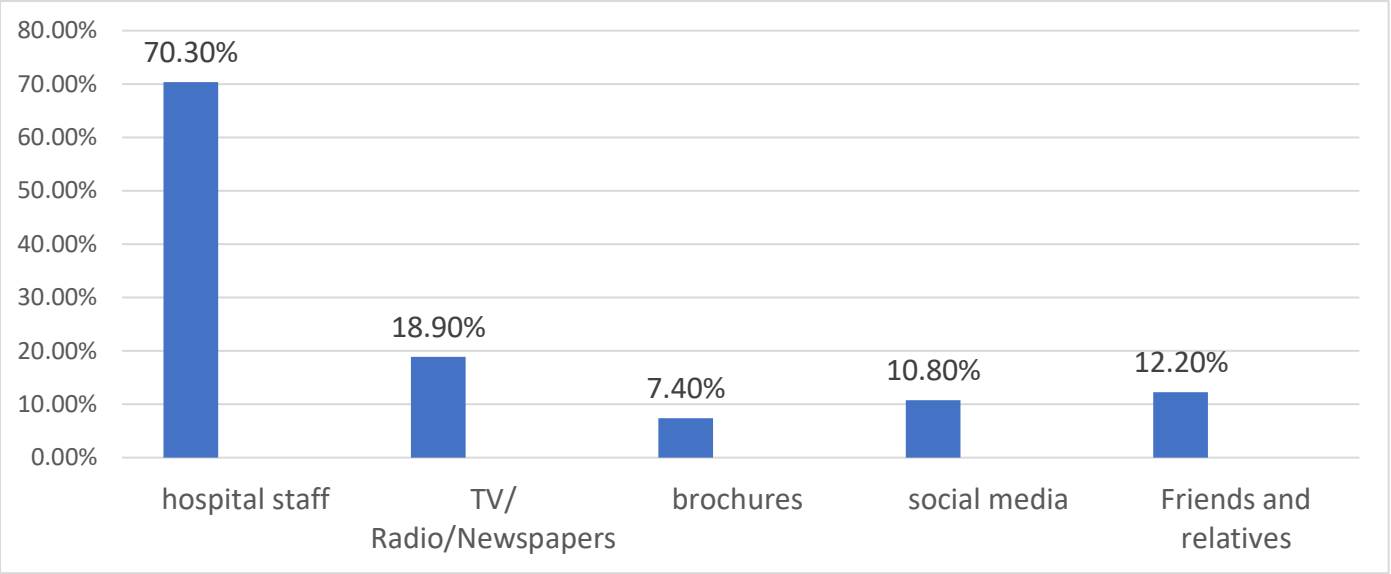
Future Contraception.

Figure 8 : Contraception chosen after discontinuing LARC.



After discontinuing LARC, 68% chose another modern method of contraception, 20% did not choose a new method and did not indicate a desire to fall pregnant, and 12% were planning a pregnancy. The pill was the contraceptive chosen after discontinuation in 62% of the women (figure 8). Copper intrauterine device, Depo Provera, and condoms were chosen by 12%, 9% and 9% respectively. The women who would be pleased if they had a baby in the next 12 months from discontinuing LARC were 42.2% while 32.7% felt they would be devastated. Twenty five percent would accept an unplanned pregnancy.

Figure 9: Sources of contraceptive information among the women.



Information on family planning was obtained from hospital staff 70.3% of the women. Television/newspapers/radio were sources of information in 18.9% of the women. Friends/relatives and social media were family planning information sources in 12.2% and 10.8% of the women respectively.

CHAPTER 5: DISCUSSION.

Women in this study discontinued long acting reversible contraceptives prematurely mostly because of undesirable side effects they experienced and desire for another child. Side effects led to premature discontinuation of all the four long acting reversible contraceptives in 46% of the women. Side effects were the commonest reasons for discontinuation of various LARC in other studies [25] [17] [47]. The occurrence of side effects differed according to contraceptive type.

Abnormal bleeding, which included heavy, prolonged and irregular bleeding, was the commonest reason for discontinuing Jadelle and Implanon. It was reported as the commonest reason for removal in other studies too [41] [31] [17] [28]. Among CuIUD users, the commonest reason for discontinuation was a desire to fall pregnant followed by abnormal bleeding and partner discomfort during intercourse. This is different to other studies where abdominal pain and irregular bleeding were main discontinuation reasons [34] [17] [28]. Abdominal pain and vaginal discharge symptoms were the most reported side effects in IUD users. This was a finding in other studies [9] [28].

Desire to fall pregnant was the second common reason for removal of all LARC, reported by 36% of the women. This is higher that the discontinuation rates for the same reason obtained in other studies [25] [48]. Contraceptive failure occurred in 6.8% and 2.9% of Jadelle and CuIUD users respectively. Contraceptive failure was also reported among Implanon users in Capetown, South Africa [25]. One woman in our study was on efavirenz based anti-retroviral therapy. Limited data on implants suggest drug to drug interactions with efavirenz that may compromise contraceptive effectiveness [46]. Despite this, implants remain very effective, even for women living with HIV and access to them should not be limited [19].

Women who sought help for side effects and received some form of treatment, went on to discontinue LARC prematurely despite reporting that the intervention had worked for them. The combined oral contraceptive pill was the treatment offered to most of the women with menstrual disturbances, according to our national family planning guidelines [49]. This is in keeping with a Cochrane review that showed that despite improving bleeding patterns in implants users, treatment with the pill did not alter discontinuation rates [41]. Discontinuation due to side effects should be reduced if undesirable effects are managed adequately.

LARC was freely chosen, without influence from service providers by most of the women who also reported that they had received adequate counselling at insertion. Adequate pre-insertion counselling should increase continuation of LARC by preparing women better for side effects and their management [25]. A Cochrane review however concluded that strategies to improve adherence and continuation, including intensive counselling, showed no benefit on discontinuation rates [44]. Counselling before insertion and in the follow up period still remains a key component of contraceptive use and adherence.

Younger women discontinued more than older women, which is expected as most would not have completed their families. This is a similar finding in other studies [25]. Age at first child was below sixteen years in 14.2% of the women and this constitutes statutory rape in Zimbabwe. The pill was the most popular method among the women both before LARC insertion and after discontinuation. It is usually associated with regular menstrual bleeding in most women. There is need to make available LARC with minimal menstrual bleeding disturbances as they are likely to be discontinued less. Information on contraception is mostly obtained from health services providers. The media and brochure are underutilised for information dissemination.

Conclusion.

Premature discontinuation of long acting reversible contraceptives occurred in women across all the reproductive age groups. Side effects were the commonest reason the women in this study discontinued LARC, followed by desire to fall pregnant. Bleeding disturbances, especially irregular and prolonged menstrual bleeding were the commonest reasons for discontinuation of Jadelle and Implanon. Women who experienced side effects and sought medical attention for them, still went ahead and discontinued the LARCs. Counselling on benefits and side effects of LARC, as well as management of undesirable effects should be improved at all health care centres.

Strength of the study.

The study was carried out at multiple centres in the city of Harare and the findings can be generalised for women in Harare.

Limitations of the study.

Our study did not have a comparison group of women who continued. The factors indicated as contributory to discontinuation cannot be conclusively deemed causal as they were not assessed in women who continued with the methods. The study design did not allow for calculation of discontinuation rates and thus we cannot determine the magnitude of premature discontinuation.

Recommendations.

There is need to develop and avail long acting reversible contraceptives with minimal side effects. There is need to focus care after LARC insertion and capacitation of clinics and health workers on effective management of side effects to improve continuation rates. We recommend a prospective study that investigates the prevalence of premature discontinuation and continuation rates, causes of discontinuation, outcomes of management of side effects experienced by women using LARC.

Conflict of Interest.

No conflicts of interest were declared.

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APPENDICES

Appendix 1; ENGLISH CONSENT FORM

P.O. Box A178

Avondale,
Harare
Zimbabwe
Telephone: **263-4-707707/731000**
Fax: **263-4-794272/621345**
***Telegrams*:** **UNIVERSITY**
Email: **obsgynpari@zol.co.zw**

UNIVERSITY OF ZIMBABWE Department Of Obstetrics & Gynaecology

TITLE: FACTORS ASSOCIATED WITH PREMATURE DISCONTINUATION OF LONG ACTING REVERSIBLE CONTRACEPTIVES.

RESEARCHER: DR MERCY GAZA

PHONE: 0772314147

PURPOSE OF STUDY

I am carrying out a study on Factors associated with premature discontinuation of long acting reversible contraceptives. The purpose of the study is to find out why a woman who would have chosen a family planning method that is meant to last for a long time would remove it before the time is up. I am requesting your participation because you were using a long acting family planning method and you had it removed before the recommended date of removal. I am hoping to speak to at least 143 women who have removed their family planning methods to get the information. The study is a project towards the attainment of a Master's degree with the University of Zimbabwe.

PROCEDURE AND DURATION

If you agree to participate I will ask you some questions about yourself, family planning and the method you were using. This will take about 10 minutes. I will be writing down your responses for further analysis. After the interview you will be free to go and that will be the end of your participation in the study.

RISKS AND DISCOMFORTS

Taking part in this study will not put you at risk of any harm. It will not change the management you will have received already and will not affect the care you will receive in future. Feel free to express your concerns if you feel any discomfort during the interview.

TITLE: FACTORS ASSOCIATED WITH PREMATURE DISCONTINUATION OF LONG ACTING REVERSIBLE CONTRACEPTIVES.

BENEFITS/COMPENSATION

There will be no monetary benefit or compensation for taking part in this study to you. The researcher is not receiving and financial benefit. The results of the study will hopefully help us understand why long acting methods are stopped before time and hopefully improve service delivery to increase continuation rates for those in need of family planning

CONFIDENTIALITY

There will be no use of names, the form on which your responses are recorded will be given a number that cannot be traced back to you. The information collected from the participants will be confidential, stored in a password locked computer. Data will be stored in an office accessible to the researcher only. Results of the study will be submitted to the University of Zimbabwe College of health sciences after analysis as the project write up.

VOLUNTARY PARTICIPATION

Participation in the study is voluntary and will not affect your future relations with the clinic. You are free to withdraw consent and participation at any point in the study and this will not affect you in any way today and in future.

QUESTIONS

You are free to ask any questions now and have any areas clarified before signing the consent. If you have any further questions or queries regarding this study, you are free to contact the principal investigator, Dr Mercy Gaza on 0772314147. You may also contact the Chairman of the Department of Obstetrics and Gynaecology on 04794272

AUTHORISATION

I have read / you have read to me and I understand the information given in this paper about the study. I agree to participate by signing the consent form.

SIGNATURE OF RESEARCH PARTICIPANT ……..……..…. DATE……

PARTICIPANT FINGER PRINT……
DATE…….

INTERVIEWER'S NAME ……. SIGNATURE ……..…. DATE……

Appendix 2: SHONA CONSENT FORM

GWARO RECHIBVUMIRANO

P.O. Box A178

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***Telegrams*:** **UNIVERSITY**
Email: **obsgynpari@zol.co.zw**

UNIVERSITY OF ZIMBABWE Department Of Obstetrics & Gynaecology

MUSORO WEONGORORO:

ZVINHU ZVINE CHEKUITA NEKUKURUMIDZA KUREGERWA KWENZIRA DZEKURONGA MHURI DZINOSHANDA KWENGUVA REFU, NGUVA YOKUREGERA ISATI YASVIKA.

MUONGORORI: CHIREMBA MERCY GAZA, 0772314147

DONZVO REONGORORO.

Ndiri kuita ongororo yekutsvaga zvinhu zvine chokuita nekukurumidza kuregerwa kwenzira dzekuronga mhuri dzinoshanda kwenguva refu, nguva yekuregera isati yasvika. Donzvo reongororo nderekutsvaga kunzwisisa zvikonzero zvingaita kuti munhukadzi anenge asarudza nzira yekuronga mhuri yake inofanira kushandiswa kwenguva refu airegere nguva yakatarwa kuti inge ichisevenzeswa isati yapera. Nzira dzatiri kuongorora dzinoti *Jadelle* ne *Implanon* dzeparuoko uye rupu dzemuchibereko dze kopa ne *Mirena*. Ndaona kuti imi maishandisa imwe yenzira dzokuronga mhuri idzi, uye masarudza kuiregera nguva yakatarwa kuishandisa isati yapera. Naizvozvo ndiri kukumbira kuita hurukuro nemi mutsvakurudzo yangu. Ndiri kutarisira kukurukura nemadzimai anosvika zana nemakumi mana nevatatu kuti ndive neruzivo rwakakwana. Zvichabuda muongororo iyi ndichazvishandisa pazvidzidzo zvangu zveuchiremba hwepamusoro zvandiri kuita ku Yunivhesiti ye Zimbabwe.

MAITIRO ETSVAKURUDZO

Muchinge mabvuma kupinda mutsvakurudzo ino ndichakubvunzai mibvunzo iri maererano nemi neupenyu hwenyu, zvekuronga mhuri uye nzira yekuronga mhuri yamanga muchisevenzesa. Ndichanyora pasi mhinduro dzenyu. Tichinge tapedza hurukuro yedu makasununguka kuenda nokuti ndipo panoperera kuvepo kwenyu muongororo iyi. Zvose izvi zvingatore maminitsi angangoita gumi.

NJODZI

Handitarisiri kuti mungava panjodzi nenzira ipi zvayo nokuda kwokuva mutsvakurudzo ino. Sunungukai kutaura kane muine kusagadzikana panguva yatinenge tirikuita hurukuro yedu.

MUSORO WEONGORORO: ZVINHU ZVINE CHEKUITA NEKUKURUMIDZA KUREGERWA KWENZIRA DZEKURONGA MHURI DZINOSHANDA KWENGUVA REFU, NGUVA YOKUREGERA ISATI YASVIKA.

ZVINGAWANIKA PAKUPINDA MUTSVAKIRIDZO

Tsvakurudzo ino ichatibatsira kunzwisisa zvikonzero zvinoita kuti nzira dzekuronga mhuri dzinoshanda kwenguva refu dziregerwe nguva yacho isati yakwana. Izvi ndinovimba zvinozobatsira vagadziri vezvirongwa zvekuronga mhuri kuti vasimudzire zvirongwa izvi zvichiwirirana nemadzimai akawanda. Hapana zvamunowana pamari kana zvimwewo pakuva muongororo iyi. Uye muongorori hapanawo chaanowana pamari kubva kuongororo iyi kunze kwekuwedzera njere.

ZVAKAVANZIKA

Zvinyorwa zvose zviri maererano netsvakiridzo ino zvichange zvisingashandise zita renyu. Zvatakurukurirana zvose hazvigoneke kuti zvigorondwa kusvika pamuri. Tichazvichengeta zvakavandika uye zvakavharirwa mukombiyuta isingagoneke kuverengwa neumwe munhu asiri muongorori uye zvakakiyirwa panzvimbo yakachengetedzeka. Zvichabuda mutsvakiridzo zvichazonyorwa se gwaro richaendeswa ku Yunivhesiti ye Zimbabwe kuzadzisa zvidzidzo zvemuongorori.

KUSARUDZA KUPINDA MUONGORORO.

Kupinda mutsvakurudzo ino kunobva musarudzo yenyu. Munekodzero yokunzwisisa nezveongororo musati maiata sarudzo yokupinda kana kusapinda muongororo. Sarudzo yenyu haishanduri marapirwo amunoitwa, muchapihwa rubatsiro runogara ruchipihwa pakiriniki kana pachipatara pano nhasi nemune ramangwana. Kana masarudza kupinda mutsvakurudzo, makasununguka kubuda mutsvakurudzo chero nguva ipi zvayo.

MIBVUNZO KANA ZVINETSWA

Makasununguka kubvunza mibvunzo kana zvimwe zvamusina kunyatsonzwisisa. Munogona kubvunza zvekare Chiremba Gaza parunhare 0772314147 panguva ipi zvayo. Munokwanisa zvekare kubata sachigaro veboka rezvekusunungutswa kwemadzimai nezvirwere zvesikarudzi zvemadzimai, kuYunivhesiti yeZimbabwe parunhare 04794272

MVUMO

Ndaverenga / mandiverengera ndikanzwisisa zvose zvakanyorwa muchinyorwa chino zviri maererano neongororo. Ndinoita sarudzo yekupinda muongoro iyi.

Sainecha yemudzimai ari kupinda muongororo ……..…… Zuva ……

Mucherechedzo we munwe wemudzimai arikupinda muongororo…….. Zuva……

Appendix 3: **DATA COLLECTION TOOL**

Record number				
Variable no	Questions	Responses		Code
SECTION A: DEMOGRAPHIC DATA				
1	Age	……..years		
		18-24 years		11
		25-35 years		12
		36-45 years		13
		unknown		99
2	Race	Black		11
		Mixed Race		12
		White		13
3	Number of Living Children	……..		
		0		11
		1		12
		2		13
		3+		14
4	Marital status	Single/never married		11
		Married/ living with partner		12
		Separated/divorced/widowed		13
5	Religion	Christianity		11
		Traditionalist		12
		Islam		13
		Other		14
6	Level of Education	Primary		11
		Secondary		12
		Tertiary		13
7	Employment status	Formal employment		11
		Self employed		12
		Unemployed		13
8	Income	Adequate		11
		Inadequate		12
SECTION B: REPRODUCTIVE HISTORY				
9	How old were you when you had your first child?	…….		
		<16		11
		16-21		12
		21-29		13
		30+		14
10	Have you ever had a miscarriage before?	Yes		11
		No		12
11	Have you ever had an unplanned or unwanted pregnancy?	Yes		11
		No		12
12	Have you ever had a sexually transmitted infection in your life?	Yes		11
		No		12
13	Have you ever had a caesarean delivery?	Yes		11
		no		12

14	Did you ever have serious complications following vaginal delivery?	Yes		11
		No		12
15	Have you ever discontinued a FP method due to dissatisfaction?	Yes		11
		No		12
16	What Family planning method did you use before using the method you just removed?	none		11
		pill		12
		injectable		13
		implant		14
		IUD		15
		other		16
17	Do you discuss contraception with your partner?	Yes		11
		No		12
SECTION C: FAMILY PLANNING METHOD REMOVED TODAY.				
18	What method was removed today?	Jadelle		11
		Implanon		12
		Cu IUD		13
		Mirena		14
19	Date of insertion	……		
20	Total number of months used	…….		
21	Reason of removal in patients own words	…….		
		Side effects		11
		Medical /doctors advice		12
		Desire to fall pregnant		13
		Need to change to another method		14
		Tired/ no reason		15
		Other		16
22	Did you ever experience any of the following during use?	Abdominal Cramps		11
		Amenorrhoea/ infrequent menses		12
		Irregular bleeding		13
		Heavy /prolonged bleeding		14
		Acne		15
		Mood Changes		16
		Headache		17
		Arm infection		18
		Weight gain		19
		Hair loss		20
		Pain with intercourse		21
		Sexual disinterest		22
		Breast discomfort		23

		Vaginal symptoms (odour/discharge/itching)		24
23	How did your experience compare to expectation before using the method?	Matched expectation		11
		Did not match expectation		12
24	Would you recommend it to a friend?	Yes		11
		No		12
SECTION D: SERVICE DELIVERY AT LARC INSERTION				
25	Do you think you were told all you needed to know about the method at the time of insertion?	Yes		11
		No		12
26	Did you feel influenced to choose the Family planning method by the service provider?	Yes		11
		No		12
27	Did you have a follow up visit after insertion?	Yes		11
		No		12
28	Did you seek help on any side effects or concerns you may have had?	Yes		11
		No		12
		N/A		13
29	What was done?	Reassured/counselled		11
		Received treatment/drugs		12
		N/A		13
30	Did it work?	Yes		11
		No		12
31	Where do you get most of your information on contraception?	Clinic/Hospital staff		11
		TV/Radio/Newspapers		12
		Social Media		13
		Friends/Relatives		14
		Brochures		15
SECTION E: FUTURE CONTRACEPTIVE PLAN				
32	Have you chosen another method of contraception today	Yes		11
		No		12
		NA		13
33	What Method did you choose?			
34	When do you start using it?			
35	How would you feel if you had a baby in the next 12 months?	Pleased		11
		Ambivalent		12
		Devastated		13
36	How would your partner feel if you had a baby in the next 12 months?	Pleased		11
		Ambivalent		14
		Devastated		15

Appendix 4: MRCZ Approval Letter.

Telephone: 791792/791193
Telefax: (263) - 4 - 790715
E-mail: mrcz@mrcz.org.zw
Website: http://www.mrcz.org.zw

Medical Research Council of Zimbabwe
Josiah Tongogara / Mazoe Street
P. O. Box CY 573
Causeway
Harare

APPROVAL LETTER

REF: MRCZ/B/1555

22 August, 2018

MEDICAL RESEARCH COUNCIL OF ZIMBABWE
2018 -08- 22
APPROVED
P.O. BOX CY 573 CAUSEWAY, HARARE

Dr.Mercy Gaza
University of Zimbabwe, College of Health Sciences
Department of Obstetrics and Gynaecology
Box A178
Avondale
Harare

RE: FACTRORS ASSOCIATED WITH PREMATURE DISCONTINUATION OF LONG ACTING REVERSIBLE CONTRACEPTIVE

Thank you for the above titled proposal that you submitted to the Medical Research Council of Zimbabwe (MRCZ) for review. Please be advised that the Medical Research Council of Zimbabwe has **reviewed** and **approved** your application to conduct the above titled study. This is based on the following documents that were submitted to the MRCZ for review:

a) Study proposal
b) Consent Forms (English & Shona versions)
c) Data collection tools

APPROVAL NUMBER : MRCZ/B/1555
This number should be used on all correspondence, consent forms and documents as appropriate.

- **APPROVAL DATE : 22 August, 2018**
- **TYPE OF MEETING : Expedited**
- **EXPIRATION DATE : 21 August, 2019**
  After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the MRCZ Offices should be submitted one month before the expiration date for continuing review.
- **SERIOUS ADVERSE EVENT REPORTING**: All serious problems having to do with subject safety must be reported to the Institutional Ethical Review Committee (IERC) as well as the MRCZ within 3 working days using standard forms obtainable from the MRCZ Offices.
- **MODIFICATIONS**: Prior MRCZ and IERC approval using standard forms obtainable from the MRCZ Offices is required before implementing any changes in the Protocol (including changes in the consent documents).
- **TERMINATION OF STUDY**: On termination of a study, a report has to be submitted to the MRCZ using standard forms obtainable from the MRCZ Offices.
- **QUESTIONS**: Please contact the MRCZ on Telephone No. (04) 791792, 791193 or by e-mail on mrcz@mrcz.org.zw.

Other

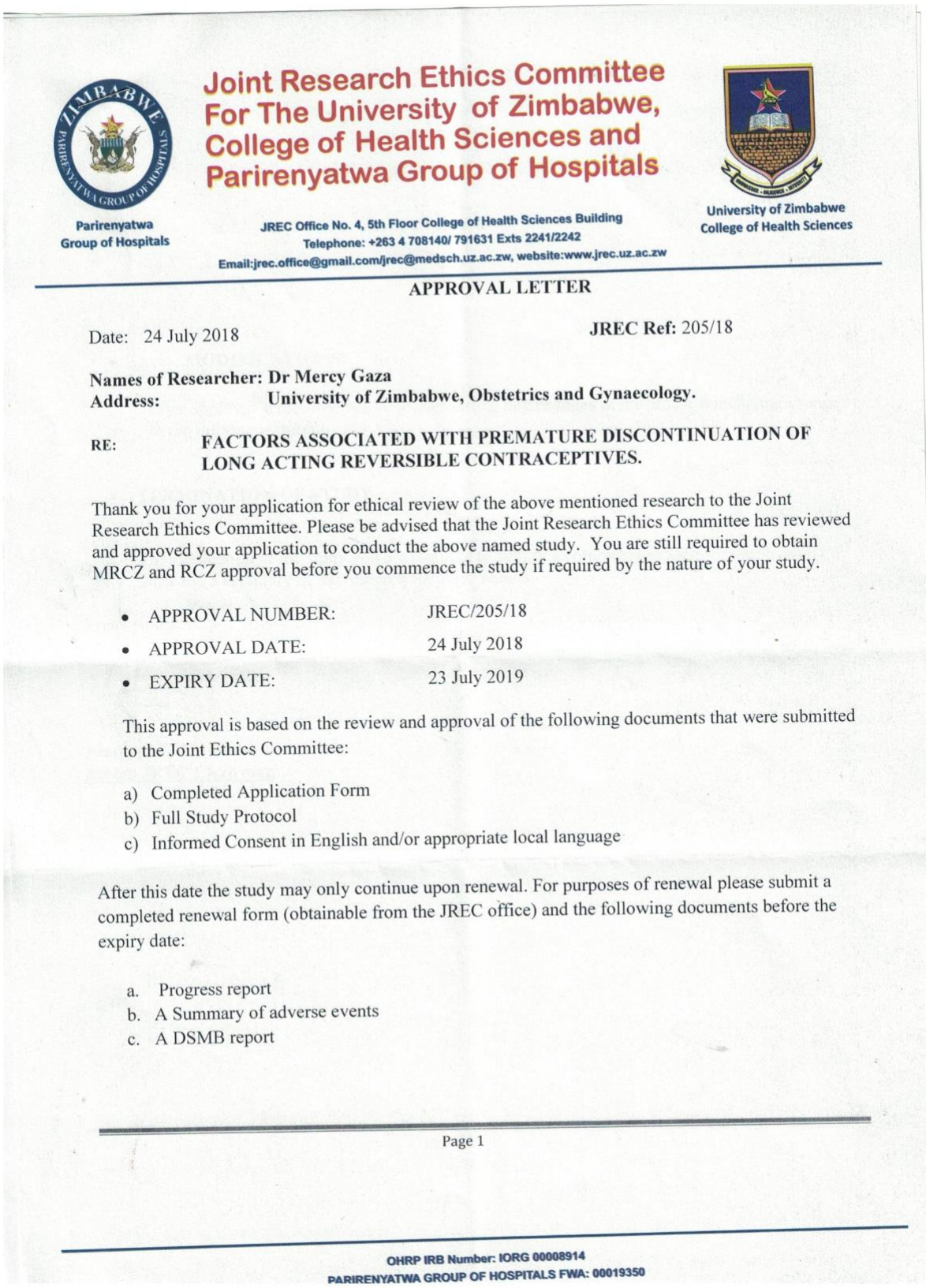
- Please be reminded to send in copies of your research results for our records as well as for Health Research Database.
- You're also encouraged to submit electronic copies of your publications in peer-reviewed journals that may emanate from this study.

Yours Faithfully

.....
MRCZ SECRETARIAT
FOR CHAIRPERSON
MEDICAL RESEARCH COUNCIL OF ZIMBABWE

PROMOTING THE ETHICAL CONDUCT OF HEALTH RESEARCH

Appendix 5: JREC Approval Letter



Joint Research Ethics Committee
For The University of Zimbabwe,
College of Health Sciences and
Parirenyatwa Group of Hospitals

Parirenyatwa
Group of Hospitals

University of Zimbabwe
College of Health Sciences

JREC Office No. 4, 5th Floor College of Health Sciences Building
Telephone: +263 4 708140/ 791631 Exts 2241/2242
Email:jrec.office@gmail.com/jrec@medsch.uz.ac.zw, website:www.jrec.uz.ac.zw

APPROVAL LETTER

Date: 24 July 2018 **JREC Ref:** 205/18

Names of Researcher: Dr Mercy Gaza
Address: University of Zimbabwe, Obstetrics and Gynaecology.

RE: FACTORS ASSOCIATED WITH PREMATURE DISCONTINUATION OF LONG ACTING REVERSIBLE CONTRACEPTIVES.

Thank you for your application for ethical review of the above mentioned research to the Joint Research Ethics Committee. Please be advised that the Joint Research Ethics Committee has reviewed and approved your application to conduct the above named study. You are still required to obtain MRCZ and RCZ approval before you commence the study if required by the nature of your study.

- APPROVAL NUMBER: JREC/205/18
- APPROVAL DATE: 24 July 2018
- EXPIRY DATE: 23 July 2019

This approval is based on the review and approval of the following documents that were submitted to the Joint Ethics Committee:

a) Completed Application Form
b) Full Study Protocol
c) Informed Consent in English and/or appropriate local language

After this date the study may only continue upon renewal. For purposes of renewal please submit a completed renewal form (obtainable from the JREC office) and the following documents before the expiry date:

a. Progress report
b. A Summary of adverse events
c. A DSMB report

Page 1

OHRP IRB Number: IORG 00008914
PARIRENYATWA GROUP OF HOSPITALS FWA: 00019350

- **MODIFICATIONS:**

  Prior approval is required before implementing any changes in the protocol including changes in the informed consent.

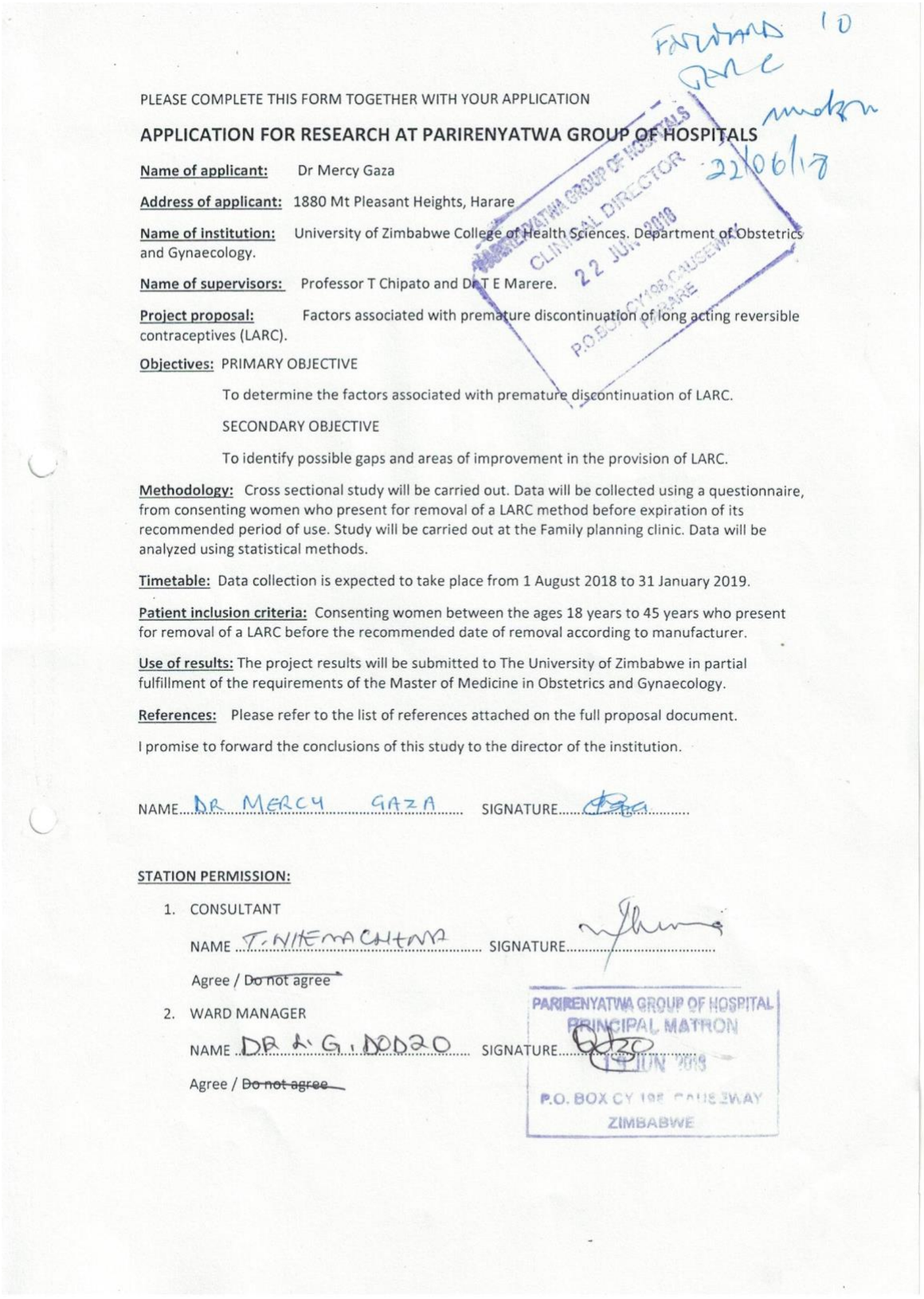
- **TERMINATION OF STUDY**:

  On termination of the study you are required to submit a completed request for termination form and a summary of the research findings/ results.

Yours sincerely,

Professor J Chifamba
Acting JREC Chairman

Appendix 6: Parirenyatwa Hospital Approval Letter.



PLEASE COMPLETE THIS FORM TOGETHER WITH YOUR APPLICATION

APPLICATION FOR RESEARCH AT PARIRENYATWA GROUP OF HOSPITALS

Name of applicant: Dr Mercy Gaza

Address of applicant: 1880 Mt Pleasant Heights, Harare

Name of institution: University of Zimbabwe College of Health Sciences. Department of Obstetrics and Gynaecology.

Name of supervisors: Professor T Chipato and Dr T E Marere.

Project proposal: Factors associated with premature discontinuation of long acting reversible contraceptives (LARC).

Objectives: PRIMARY OBJECTIVE

To determine the factors associated with premature discontinuation of LARC.

SECONDARY OBJECTIVE

To identify possible gaps and areas of improvement in the provision of LARC.

Methodology: Cross sectional study will be carried out. Data will be collected using a questionnaire, from consenting women who present for removal of a LARC method before expiration of its recommended period of use. Study will be carried out at the Family planning clinic. Data will be analyzed using statistical methods.

Timetable: Data collection is expected to take place from 1 August 2018 to 31 January 2019.

Patient inclusion criteria: Consenting women between the ages 18 years to 45 years who present for removal of a LARC before the recommended date of removal according to manufacturer.

Use of results: The project results will be submitted to The University of Zimbabwe in partial fulfillment of the requirements of the Master of Medicine in Obstetrics and Gynaecology.

References: Please refer to the list of references attached on the full proposal document.

I promise to forward the conclusions of this study to the director of the institution.

NAME DR MERCY GAZA SIGNATURE

STATION PERMISSION:

1. CONSULTANT

   NAME T. NHEMACHENA SIGNATURE

   Agree / ~~Do not agree~~

2. WARD MANAGER

   NAME DR A. G. NDOZO SIGNATURE

   Agree / ~~Do not agree~~

PARIRENYATWA GROUP OF HOSPITAL
PRINCIPAL MATRON
P.O. BOX CY 198 CAUSEWAY
ZIMBABWE

Appendix 7: Harare Hospital Approval Letter.

Telephone: 621100-19
Fax: 621157

ZIMBABWE

Reference: HCHEC 210618/67

HARARE CENTRAL HOSPITAL
P. O. Box ST 14
SOUTHERTON
Harare

09 July 2018

Dr. Mercy Gaza
1880 Mt. Pleasant Heights
HARARE

Dear Dr. Gaza,

REF: FACTORS ASSOCIATED WITH PREMATURE DISCONTINUATION OF LONG ACTING REVERSIBLE CONTRACEPTIVES

I am glad to advise you that your application to conduct a quality improvement project entitled: **Factors Associated with Premature Discontinuation of Long Acting Reversible Contraceptives (Ref: HCHEC 210618/67),** has been Approved by the Harare Hospital Ethics Committee.

This approval is premised on the submitted protocol. Should you decide to vary your protocol in any material way please submit these for further approval.

You are advised to avail the results of your project whether positive or negative to the hospital through the committee for our information.

Yours sincerely,

HARARE CENTRAL HOSPITAL
DEPARTMENT OF MEDICINE
09 JUL 2018
P. O. BOX ST14, SOUTHERTON
HARARE, ZIMBABWE

DR. C. Pasi
Chairman Harare Central Hospital Ethics Committee

Appendix 8: PSI Approval Letter

psi

Healthy lives. Measurable results.

To whom it may concern

Dear Sir/Madam

Ref: Approval Letter to conduct study

STUDY TITLE: FACTORS ASSOCIATED WITH PREMATURE DISCONTINUATION OF LONG ACTING REVERSIBLE CONTRACEPTIVES

This letter serves to inform you that the undersigned have granted permission to Dr Mercy Gaza to carry out the above-mentioned study. Dr Mercy Gaza will use a structured questionnaire to collect data from consenting women who would have had their LARC removed at the clinic supported by PSI/Zimbabwe.

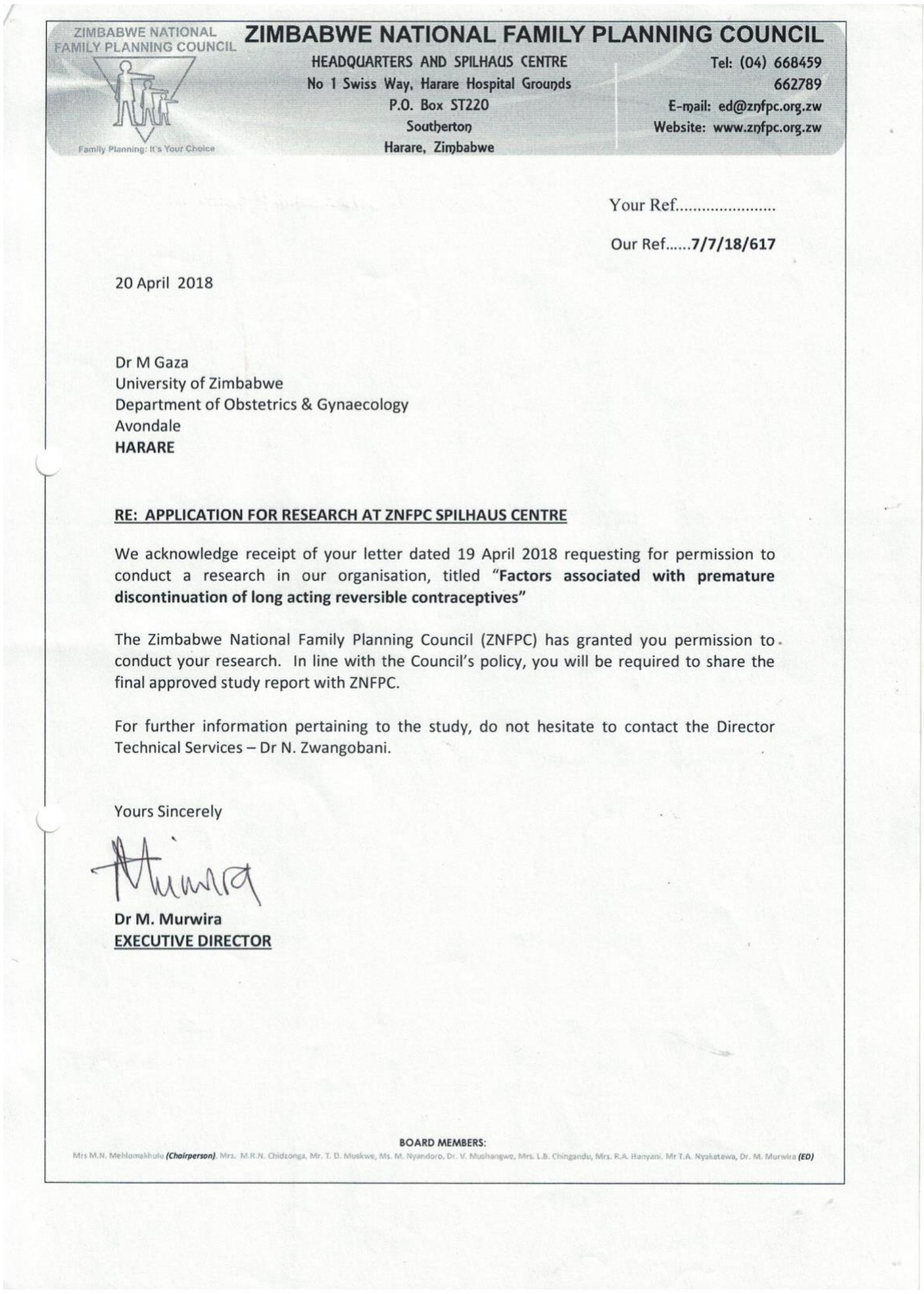
The investigator is mandated to observe ethical standards of the highest degree and will be required to acknowledge PSI and our major donors in the final project report. This includes but is not limited to submission of study protocol and all relevant study documentation to the local IRB – MRCZ for ethical clearance. The information gathered in the study should only be used for academic purposes and principal investigator will be obliged to share study findings with key program members at PSI, the donors and stakeholders locally and internationally. The principal investigator will also acknowledge PSI and its donors in all publications and presentations emanating from this study and subsequent findings.

Yours faithfully

Jabulani Mavudze
PSI/Zimbabwe Evidence Director

15/06/2018

Appendix 9: ZNFPC Approval Letter.



ZIMBABWE NATIONAL FAMILY PLANNING COUNCIL

Family Planning: It's Your Choice

ZIMBABWE NATIONAL FAMILY PLANNING COUNCIL

HEADQUARTERS AND SPILHAUS CENTRE
No 1 Swiss Way, Harare Hospital Grounds
P.O. Box ST220
Southerton
Harare, Zimbabwe

Tel: (04) 668459
662789
E-mail: ed@znfpc.org.zw
Website: www.znfpc.org.zw

Your Ref.....

Our Ref.....**7/7/18/617**

20 April 2018

Dr M Gaza
University of Zimbabwe
Department of Obstetrics & Gynaecology
Avondale
HARARE

RE: APPLICATION FOR RESEARCH AT ZNFPC SPILHAUS CENTRE

We acknowledge receipt of your letter dated 19 April 2018 requesting for permission to conduct a research in our organisation, titled "**Factors associated with premature discontinuation of long acting reversible contraceptives**"

The Zimbabwe National Family Planning Council (ZNFPC) has granted you permission to conduct your research. In line with the Council's policy, you will be required to share the final approved study report with ZNFPC.

For further information pertaining to the study, do not hesitate to contact the Director Technical Services – Dr N. Zwangobani.

Yours Sincerely

Dr M. Murwira
EXECUTIVE DIRECTOR

BOARD MEMBERS:
Mrs M.N. Mehlomakhulu ***(Chairperson)***, Mrs. M.R.N. Chidzonga, Mr. T. D. Muskwe, Ms. M. Nyandoro, Dr. V. Mushangwe, Mrs. L.B. Chingandu, Mrs. R.A. Hanyani, Mr T.A. Nyaketewa, Dr. M. Murwira ***(ED)***

Appendix 10: PSZ Approval Letter.

SUPPORT OFFICE
9 Bisley Circle
Belvedere
Harare

Phone: +263 4 740558, 740573
0772 145 223/4
Fax: +263 4 778224
Email: marketing@pszim.com

Registered Charity No. W/O 13/87

POPULATION SERVICES ZIMBABWE
Children by choice, not chance
An affiliate of Marie Stopes International

23 May 2018

Dear Dr Mercy Gaza

RE: APPLICATION FOR RESEARCH AT PSZ CLINICS IN MBARE AND BELVEDERE

I herewith notify you that your request to conduct a research study at PSZ Belvedere and Mbare clinics has been accepted. However, may you kindly provide the 3 documents herein under listed before commencement of the research study:

1. Confirmation of Ethical Approval of the protocol by the ethical review board (ERB);
2. Approved data collection tools;
3. Notice of Study to clients clearly stating the researcher's independence from PSZ;

In addition, you will be requested to sign a confidentiality statement with PSZ.

Yours Faithfully,

Abebe Shibru

(Country Director)