THE UNIVERSITY OF ZAMBIA
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FACTORS ASSOCIATED WITH INFERTILITY AMONG WOMEN ATTENDING THE GYNAECOLOGY CLINIC AT UNIVERSITY TEACHING HOSPITAL

by

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Abstract

Objectives: Infertility is a public health problem which in Africa south of the Sahara affects up to 40 percent of women. As such, infertility has devastating psychosocial consequences on affected couples. The World Health Organization estimates that there are 60-80 million infertile couples worldwide and the majority of whom are in developing countries. The objective of this study was to investigate and determine the factors associated with infertility in women attending the gynaecology clinic at the University Teaching Hospital (UTH) in Lusaka, Zambia.

Methods: Women attending the gynaecology clinic for infertility were enrolled using an unmatched case-control study design. Controls were randomly selected from women in the labour ward. A preformed investigator administered questionnaire was used to collect data. Bivariate analysis was used to determine association between infertility and demographic and previous gynaecological history. Odds ratios were used to determine statistical significance. Associations with a $p<0.05$ or those with clinical significance were further analysed by multivariate logistic regression.

Results: One hundred and thirty women were selected as cases and 260 as controls. Overall, primary infertility was found to affect 50/130 (38.5 percent) of the women while secondary infertility was found in 80/130 (61.5 percent). In multivariate logistic regression analysis, the following factors were independently associated with infertility: marital status, age at menarche, frequency of menses, ever use of contraception, ever had a manual vacuum aspiration and past pelvic procedure or infection. Though on bivariate analysis, age >35 years and partner alcohol use were associated with infertility, this was not the case in the multivariate logistic regression analysis when potential confounders were considered. The odds of a married woman having infertility was 9 times that of an unmarried woman (OR 9.09, 95% confidence interval 2.22 to 37.29). Irregular menses, was over 20 times that of a woman with regular cycles to be associated with infertility (OR 20.72, 95% CI 2.52-170.56). Past ever use of contraception was associated with 83 percent less odds of infertility (OR 0.27, 95 CI 0.14-0.57). Investigations were ordered for infertility were hormonal, HSG, ultrasound and semen analysis though in most cases the investigation was not done or results were not available.

Conclusion: There was a higher proportion of secondary infertility than primary infertility in this study. Marital status, age at menarche, frequency of menses, ever use of contraception, ever had a manual vacuum evacuation and past pelvic procedure or infection were independently associated with infertility though other factors, like behavioural and weight, were not considered. It appeared that ovulation problems as manifest by irregular menses could be amenable to ovulation induction agents though suspected tubal damage (after MVA and pelvic surgery) could be problematic in treating. Few of the couples were investigated and fewer still had results available for assessment at review reflecting a need to strengthen the health system to manage couples with infertility.

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Contents

Table of Contents

List of Tables and Figures

Abbreviations

95% CI	95% confidence interval
D&C	Dilatation and Curettage
HSG	Hysterosalpingogram or hysterosalpingograph(y)
IVF	*In vitro* Fertilisation
MVA	Manual Vacuum Aspiration
PID	Pelvic Inflammatory Disease
USS	Ultrasound Scan
UTH	University Teaching Hospital
WHO	World Health Organization

Dedication

This work is dedicated to the memory of my dearest mother Julia Mutibo Kalima who above anyone else, believed that I was a doctor in everything.

Chapter 1: Introduction

Infertility is a public health problem which affects millions of couples worldwide and has devastating psychosocial consequences on affected couples. The majority of infertile couples are found in developing countries. It has been estimated that approximately 15 percent of the population in industrially developed countries are affected. The highest incidence is in some areas of sub-Saharan Africa, where rates of up to 50 percent have been recorded. In eastern Mediterranean, this rate is about 20 percent (Mokthar et al., 2006). Developing countries experience negative consequences of childlessness to a greater degree than western societies. In most developing countries, reproductive health is almost equalled to decreasing the number of births but infertility is given little or no attention. (Esmaeilzadeh, 2013). Clinical infertility is defined as the inability to become pregnant after 12 months of unprotected intercourse. Fertility is affected by many factors, including cultural, environmental, and socioeconomic. The causes of infertility are wide ranging including diagnoses such as ovulatory disorders, fallopian tubal disease, endometriosis, chromosomal abnormalities, sperm-related factors and unexplained infertility (Homan et al., 2007).

The prevalence of infertility varies between countries mainly due to variations in lifestyle factors causing or contributing to the infertility status, dominantly the time interval between the age when sexuality is initiated and the age where first pregnancy is desired, and of course, the prevalence of sexually transmitted diseases (STDs) (Leke et al., 1993). In a study conducted in Nigeria, it was found that pelvic infection, unsafe abortion and previous laparotomy were recognised risk factors for the development of tubal infertility (Famurewa, et al., 2013). Other researchers in Oman found that tubal obstruction was a cause of infertility in women studied (Al Subhi et al., 2013). They also reported that previous pelvic surgery may be the cause of tubal obstruction in patients with secondary infertility (Al Subhi, et al., 2013). In Pakistan, investigators found that educating women on hygiene during menstruation and delivery decreased the incidence of secondary infertility (Sami, et al., 2012). Changes such as bathing during menses, washing hands between deliveries and use of clean sanitary clothes all helped to reduce pelvic infection and, subsequently, secondary infertility.

In Zambia, fertility trends have been studied by some workers (Fylkenes, et al., 1998). However, the prevalence of infertility has not been well-documented. The University Teaching Hospital (UTH) serves as a tertiary referral hospital not only for the surrounding clinics in Lusaka, but also the whole Lusaka province, and also the whole country. It serves a diverse population from a wide socioeconomic spectrum. In 2012 a total of 6,993 patients were seen in the gynaecology clinic at UTH. These were seen for conditions including menstrual problems, gynaecological malignancies, pelvic infections and chronic pelvic pain and infertility and others. Of these patients, 1,243 (17.8 percent) were seen for infertility. This current study was undertaken to determine factors associated with infertility among patients attending the gynaecology clinic at the University Teaching Hospital in Lusaka, Zambia.

Chapter 2: Literature Review

Epidemiological studies have revealed that in a normal population of heterosexually active women who are not using birth control, 25 percent will become pregnant in the first month, 63 percent within 6 months, and 80 percent within one year of having intercourse. By the end of the second year, 85-90 percent will have conceived. Because some couples, who are not infertile may not be able to conceive within the first year, the WHO recommends the epidemiological definition of infertility to be the inability to conceive within two years of exposure to pregnancy (Tabong & Adongo, 2013) though practically, after12 months initial assessments and investigations are generally initiated.

There is a growing interest in the impact of infertility on the reproductive health of men and women in Africa. Prevalence rates are among the highest and the underlying causes contribute to the high burden of disease in African countries. The high demand for fertility is fuelled by social, economic, and religious imperatives to reproduce. Thus, childlessness carries profound negative psychosocial implications (Dyer et al., 2005). Infertility as a public health problem varies widely in different communities according to the prevalence of the condition and the importance ascribed to it by society. Some of the documented consequences of infertility can include marital instability, abuse, neglect, social stigma, discrimination, banishment from religious ceremonies and poverty (Barden-O'Fallon, 2005). In some cultures, childless couples are excluded from taking leading roles in important family functions and events (Rutsein & Shah, 2004).

In sub-Saharan Africa, the elevated levels of secondary infertility—affecting as many as one-quarter of all women in some societies—are commonly due to infection-induced tubal infertility (Inhorn 2003). Rates of secondary infertility in Latin America are also high (40 percent of all infertility cases, as compared to 23 percent in Asia and 16 percent in North Africa). Most secondary infertility among women is due to four sets of factors: (1) sexually transmitted infections; (2) postpartum complications; (3) post abortive complications; and (4) other unhygienic health care practices carried out in either the biomedical or traditional health care sectors (Inhorn, 2003). Larsen found that infertility was prevalent in sizeable areas of southern Africa. Larsen also found that if a relatively large proportion of couples became infertile after they had their first child, then this would suggest that poor access to health care during the first pregnancy and delivery, poor resources for midwifery care, possible poor midwifery practices, and a

high incidence of complications that cannot be remedied or prevented may be important causes of secondary infertility (Larsen 2000). In both men and women, sexually transmitted disease-associated genital infections may cause permanent damage to the reproductive tract resulting in sub- or infertility. This type of infertility is acquired and thus, treatable (Westrom 1994).

A number of factors associated with infertility have been identified. These include demographic characteristics such as age, marital status, ethnicity and religion. Female factors have been more thoroughly studied because it is commonly assumed that the woman is primarily responsible for infertility. However, studies have shown that the male factor contribution to infertility ranges between 20-40 percent. Male factor infertility is usually associated with primary infertility and not secondary infertility (Araoye, 2003). Health factors include sexually transmitted infections (STIs) that include gonorrhoea, chlamydia, trichomoniasis and syphilis. Sexual behaviours such as having multiple sexual partners, sexual debut at an early age increase the risk of acquiring infections including HIV and have been found to be associated with fertility problems (Barden-O'Fallon, 2005).

In a study comparing the regional variations, it was found that the most cost-effective way of reducing the burden of infertility in Africa was prevention and education as the most common causes were infections. Further, workers found that in Mexico detrimental factors are pregnancy in adolescents, sexually transmitted diseases and prevalence of congenital malformations (Leke et al., 1993). Infertility prevalence is shown to be highest in South Asia, sub-Saharan Africa, North Africa/Middle East, Central/Eastern Europe and Central Asia (Mascarenhas et al., 2010).

Most reports on the prevalence of infertility are derived from census data or clinical centres, rather than from total community centres. This problem was noted to be particularly acute in sub-Saharan Africa, including Zambia, where involuntary infertility affects about 5 percent of couples (Homan et al., 2007). These reports cite prevalence rates of 30-50 percent. In a study done in Malawi the total fertility rate was estimated at 6.3 live births per woman, which is high, and yet the estimate of primary infertility (where pregnancy had never occurred before) in women aged 20-44 years was 2 percent. Secondary infertility (infertility after having previously conceived) was

found to be much higher for women aged 40-44 years (60 percent), and those between 20-24 years (17 percent) (Leke et al., 1993). The prevalence of primary infertility in sub-Saharan Africa is less than that of secondary infertility. This is due mainly to the high prevalence of infections and medical interventions under unhygienic conditions. Secondary infertility, although not life-threatening, can have severe consequences for the couple involved. Very few of these women also have access to effective infertility treatment. Reproductive technologies are either not available or prohibitively expensive in most sub-Saharan countries (Dhont et al., 2011). Templeton found that the main diagnostic groups of the causes of infertility were those relating to male partners (25 percent), problems relating to ovulation (25 percent), tubal factors (20 percent), unexplained (25 percent) and endometriosis (5 percent) (Templeton, 1995).

Infertility due to tubal factor was the most common cause in a study conducted in South Africa (Stewart-Smith & van Iddekinge, 2003). Investigators in India found that current *Chlamydia trachomatis* infection was found to be significantly low in a group of women with children when compared with infected infertile women (9.4 *vs* 18.6 percent) (Mania-Pramanik et al., 2012). Average infection rate was 12.1 percent, highest in women with infertility (18.6 percent) or with ectopic pregnancy (25 percent). In Uganda, Kiguli-Malwadde and Byanyima using hysterosalpingogram (HSG) found that tubal blockage possibly secondary to chronic pelvic inflammation was the commonest pathology in women presenting with infertility in Kampala (Kiguli-Malwadde & Byanyima, 2004). The fact that secondary infertility is common points to pelvic infection complicating mismanaged pregnancies, septic abortions or sexually transmitted infections. The use of the copper intrauterine device was found not to be a risk factor for tubal infertility in nulligravid women (Hubacher et al., 2001).

In a study of secondary infertility done among women in Pakistan, the authors made the following recommendations: “health education and awareness messages for safe practices during menstruation, delivery, and the postpartum period for women in general should be encouraged” (Sami et al., 2012). Additionally, sanitary napkins should be made available at an affordable cost, and safe delivery kits should contain educational/pictorial brochures for appropriate hand washing skills. In Gambia, workers studying the prevalence of infertility found that tubal pathology was the most prevalent (Mabey et al., 1985). Further, the results indicated that infertile Gambian

women with tubal pathology had a higher prevalence and higher levels of circulating IgG antibody against *C. trachomatis* and *Neisseria gonorrhoeae* (*N. gonorrhoeae)* than did pregnant controls and that these differences were statistically highly significant. This suggests that these women had suffered more frequent, more prolonged, or more severe infections than have the pregnant controls. They therefore concluded that *C. trachomatis* and/or *N. gonorrhoeae* are likely to have caused the tubal pathology in a high proportion of cases. Other investigators in India found that consequences of *C. trachomatis* infection were more damaging to the reproductive health of women than to men (Mania-Pramanik et al., 2012). A number of clinical conditions like mucopurulent endocervicitis, endometritis or salpingitis have been attributed to this infection. The potentially serious sequelae of cervical infection with *C. trachomatis* include infertility, ectopic pregnancy, pelvic pain and recurrent pelvic inflammatory diseases (PID). Women who had tubal infertility were found to have a higher prevalence of *C. trachomatis* antibody than did women with non-tubal causes of infertility (Brunham et al., 1985). They also were more likely to have begun coitus earlier and more likely to have more sexual partners.

In a study to determine the epidemiology of infertility in Africa, Belsey concluded that infertility and pregnancy wastage represent only a small proportion of the health problems related to human reproduction (Belsey 1976). They may be a consequence of infection following unskilled obstetrical practices or septic illegal abortion. Other consequences include incompetence of the cervix, vesicovaginal fistula, birth trauma with injury to the infant, etc. Tubal occlusion is but one consequence of gonorrhoea; others include partial occlusion with resultant ectopic pregnancy, ophthalmia neonatorum, and arthritis. Repeated gonorrhoeal infection in the male may lead to urethral stricture, chronic obstructive changes in the ureter, or chronic renal disease. This finding is similar to that found by Odile who determined that the single major cause of infertility in 18 sub-Saharan countries was gonorrhoea through infection and tubal occlusion (Odile, 1983). In a multicentre collaborative study sponsored by the WHO, African couples were found to be more likely to have secondary infertility than those from other places (Cates, et al., 1985). They were also more likely to have the infertility for a longer duration, a history of sexually transmitted infections or pregnancy complications and infertility diagnoses suggestive of previous genital infections.

Fertility has also been known to decrease with age both in men and women. The percentage of infertility was estimated as 8 percent in women aged 19-26 years, 13-14 percent in those 27-34 years and 18 percent in 35-39 year olds. Starting in the late 30s male age was an important factor with failing to conceive within 12 cycles increasing from an estimated 18-28 percent in age 35-40 (Dunson et al., 2004). Other authors have found that there is strong evidence that age, weight and smoking impact on general health. Other factors that affect fertility include psychological stress, caffeine consumption, alcohol consumption and exposure to environmental pollutants (Homan 2007). Other causes of infertility include submucosal fibroids. Those women with subserosal uterine fibroids were found to have no difference in their fertility outcomes compared with infertile controls with no myomas, and myomectomy did not change their outcomes (Pritts et al., 2009).

Infertility is therefore, a common public health problem with varied biomedical male and female causes and consequences ranging from social stigmatisation and loss of income, to physical abuse and violence and also psychological problems. This study was undertaken to attempt to investigate and determine the factors associated with infertility in the Zambian context.

Chapter 3: Study Justification and Objectives

3.1 Statement of the Problem

On average, 104 women with infertility attend the gynaecology clinics at UTH monthly. This attendance is for either primary or secondary infertility. The actual prevalence is however, not known for this clinic. Information is lacking as to what factors are prevalent in these women. It is also not very clear what correlates associated with infertility in Zambia in general and, at UTH in particular, are involved. The study was undertaken to investigate and determine the factors associated with infertility in women attending clinic at UTH.

3.2 Rationale for the Study

Little is known about the factors associated with infertility among couples in Zambia and specifically at UTH. Some information is available regarding the prevalence of STIs, but how these may be associated with infertility is not known. Studies have shown that the major cause of infertility in Africa is infection and/or pelvic surgery. Studies have also shown that the most cost effective way of dealing with infertility in Africa is by prevention of these infections and education of women (Sami et al., 2012). The gynaecology clinic at UTH attended to women with a diverse range of problems during 2012. The average monthly attendance was 593 and of these an average 104 monthly were for infertility. Over the year, 617 women were seen for abortions, tubo-ovarian masses, ectopic pregnancies, pelvic abscesses and PID. These 617 clients potentially could have either primary or secondary infertility as a result of these infections/conditions.

3.3 Research Question

What are the factors associated with infertility at UTH?

3.4 Objective

The study objective was to determine factors associated with primary and secondary infertility among women attending the gynaecology clinics at UTH.

3.5 Specific Objectives

1. To describe sociodemographic and past medical and gynaecological history of women presenting with infertility.
2. To determine the factors associated with infertility among these women.

Chapter 4: Methodology

This was an unmatched case control study.

4.1 Study Site

The study was conducted at the UTH and focused on patients attending the gynaecology clinics.

4.2 Target Population

The target population was women living in Lusaka who attended the gynaecology clinic with fertility related complaints.

4.3 Study Population

The study population included women who attended the clinics during the study period and met the inclusion criteria for infertility as described. Similarly, controls were women in the labour ward that met the inclusion criteria.

4.3 Study Duration

The study was conducted between February and December 2015.

4.4 Inclusion/ Exclusion Criteria

- Women aged below 45 years and attending the clinic for infertility.
- Married (or co-habiting) for a duration of 1 year or more for women less than 35 years with unprotected intercourse for the duration.
- Married (or co-habiting) for a duration of 6 months or more for women 35 years or older.
- Giving informed consent to participate in the study.
- Women not meeting the above were not included.

4.5 Sample size calculation

The prevalence of infertility was assumed to be 18 percent. The confidence interval selected was 95 percent and the power 80 percent. The sample size, to be able to demonstrate an association with OR >2 or more was therefore calculated using Open Epi as follows:

Sample Size for Unmatched Case-Control Study
For:

Two-sided confidence level:(1-alpha)	95
Power (percent chance of detecting)	80
Ratio of Controls to Cases	2
Hypothetical proportion of controls with exposure	18
Hypothetical proportion of cases with exposure:	30.51
Least extreme Odds Ratio to be detected:	2.00

	Kelsey
Sample Size – Cases	**130**
Sample Size – Controls	**260**
Total sample size:	**390**

(Dean, et al., 2014)

4.6 Participant Recruitment

Participants were selected by random convenience sampling until the sample size was reached. The controls were also randomly selected from women coming to the labour ward. The study collected data from a sample of 130 women consecutively enrolled who attended the gynaecology clinic at UTH. The 230 unmatched controls were sampled from women who were in the labour ward. Data was collected from participants with an investigator administered interview using a structured questionnaire (Appendix I).

4.7 Data Analysis Plan

4.7.1 Variables

Dependent variable

Infertility

Independent variables

Age
Level of education
Age at menarche
Frequency of menses
Duration of menses

Employment status of partner
Alcohol consumption by the woman and partner
Ever been pregnant
Ever had pelvic surgery
Treatment received in the event of pelvic surgery
Number of children
Number of partner's children
Pregnancy losses
MVAs done
Use of traditional or herbal (non-conventional) medicine
Willingness to undergo in-vitro fertilisation (IVF).

4.7.2 Data analysis

Statistical analysis was performed using the software package STATA (StataCorp. 2007. *Stata Statistical Software: Release 10. College Station, TX: StataCorp LP*). Descriptive analyses of the study were performed with determination of frequencies and means of the discrete variables. Bivariate analysis with chi-square was used to examine the relationship between infertility and other covariates. Multivariate logistic regression analysis was performed to examine the association of infertility with the covariates that were statistically significant in the bivariate analysis. A p-value of less than 0.05 was used to indicate statistical significance.

4.8 Ethical considerations

Ethical approval for the study was obtained from ERES Converge IRB (Appendix II). Permission to conduct the study was provided by the UTH management (Appendix III). All participants provided written informed consent to take part in the study (Appendix IV). None of the questionnaires had identifiable data and these were stored in a locked cabinet only accessible by the investigator. The electronic data was stored in a password protected file.

Chapter 5: Results

A total of 390 women participated in the study comprising 130 infertile (cases), and 260 fertile (controls). The general characteristics of the study population are shown in Table 1. The average age of the respondents (both cases and controls) was 25.4 years with a range of 12-43 years. Most women were between the ages of 20-29 (8.5 percent). The majority of the women were married (50.6 percent) and 5 (1.29 percent) were divorced. However, 89 (22.9 percent) were single.

Table 1: Distribution of socio-demographic characteristics of infertility cases and controls (N=390)

Variable	Category	Total	%
Age groups	<20	33	8.5
	20-29	196	50.3
	30-39	147	37.7
	40+	8	2.1
	Unreported	6	1.5
Age in years:	Mean (SD)	25.4 (6.2)	
Marital status	Not Reported	2	0.5
	Married	294	75.3
	Divorced	5	1.2
	Single	89	22.8
Employment status of women	Not Reported	5	1.2
	Unemployed	269	68.9
	Employee	91	23.3
	Still at School	25	6.4
Employment status of partners	Not Reported	57	14.6
	Unemployed	322	82.6
	Employee	11	2.8
	Still at School	0	
Highest level of education	Not Reported	9	2.3
	Primary	97	24.9
	Secondary	232	59.5
	College/Uni	52	13.3
Partners level of education	Not Reported	94	24.1
	Primary	21	5.4
	Secondary	209	53.6
	College/University	66	16.9
Age menarche	Not Reported	103	26.4
	09-Dec	120	30.7
	13-15	149	37.9
	16-19	14	3.6
	19+	4	1
Alcohol Use	Unreported	1	0.3
	Yes	234	60
	No	155	39.7
Partner's alcohol use	Unreported	1	0.3
	Yes	162	41.5
	No	227	58.2
Age at sexual debut	Unreported	110	28.2
	<15	37	9.5
	16-19	174	44.6
	20+	69	17.7

Table 2 shows the reproductive characteristics in relation to pregnancy state and prior use of contraceptives. In all characteristics there were statistically significant differences in the two groups (p value of chi square test shown below).

Table 2. Bivariate Analysis of variables in infertile and fertile women

Variable	Category	Cases (Infertile) N (%)	Controls (Fertile) N (%)	P value Pearson chi^2
Marital status	Divorced	2 (1.5)	3 (1.2)	
	Married	128 (99.2)	166 (63.8)	<0.0001
	Single	1(0.8)	88 (33.7)	
Employment	Employed	43 (33.1)	48 (18.5)	
	Unemployed	87 (66.9)	181 (71.2)	<0.0001
	Student	0	25 (9.6)	
Partner consumes alcohol	Yes	34 (26.2)	128 (49.2)	<0.0001
	No	96 (73.8)	130 (50)	
Age at menarche	9-12y	21 (16.2)	99 (38.1)	
	13-15y	64 (49.2)	85 (32.7)	<0.0001
	16-18y	14 (10.7)	0	
	19y+	3 (2.3)	1(0.4)	
Frequency of menses	Amenorrhoea	6 (4.6)	0	
	Irregular	28 (21.5)	12 (4.6)	<0.0001
	Regular	96 (73.8)	245 (94.2)	
Contraceptive use	Unreported		33 (12.7)	
	Yes	62 (47.7)	194 (74.6)	<0.0001
	No	68 (52.3)	63 (24.2)	
Contraceptive type	Hormonal	18 (13.8)	26 (10)	
	Barrier	25 (19.2)	134 (51.5)	
	IUCD	1 (0.8)	3 (1.2)	0.001
	Mixed	18 (13.8)	31 (11.9)	
	None	68 (52.3)	63 (24.2)	
Pregnancy	Unreported			
	Yes	80 (61.5)	260 (100)	<0.0001
	No	50 (38.5)		
Pregnancy outcome	Baby	46 (35.4)	260 (100)	
	Miscarriage	33 (25.4)	1 (0.4)	<0.0001
	Ectopic	3 (2.3)	0	
	Unreported	48 (36.9)	0	
MVA previously	Unreported	0	2 (0.8)	
	Yes	28 (21.5)	16 (6.2)	<0.0001
	No	102 (78.5)	242 (93.1)	
Pelvic process	Unreported	0	2 (0.2)	
	Yes	36 (27.7)	17 (6.5)	<0.0001
	No	94 (72.3)	241 (92.7)	
Treatment received	Yes	30 (23.1)	0	
	No	99 (76.5)	260 (100)	<0.0001

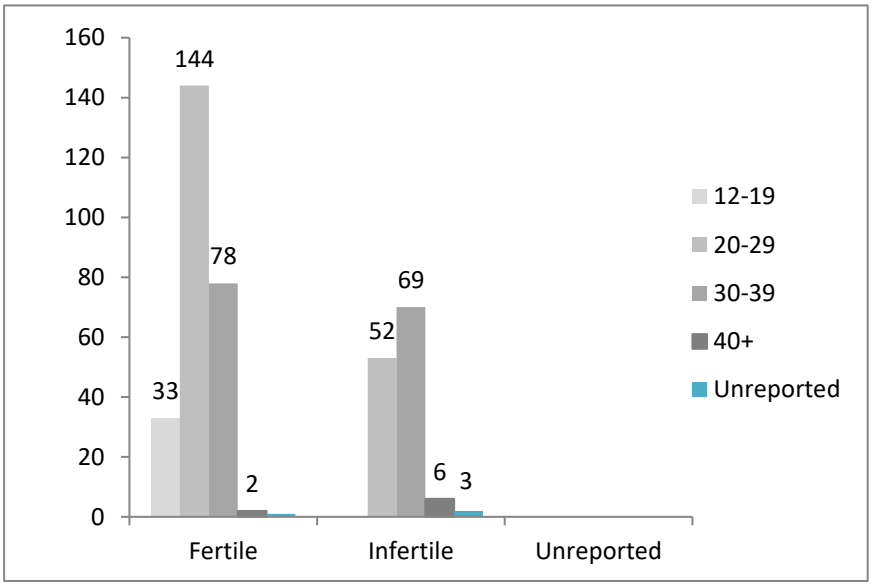
Of the 130 infertile women (cases), 50 (38.5 percent) had primary infertility, whereas 80 (61.5 percent) had secondary infertility. Table 3 specifically shows the type of infertility by age group. In the age group 20-29 years, a greater percentage of women reported having primary infertility than secondary infertility (64 vs 25 percent). In the 30-39 age group, a greater percentage of women had secondary infertility than primary infertility (67.5 vs 30 percent). Above 40 years, though numbers were small, there was a greater percent of women with secondary infertility (6.25 vs 2 percent). The age group categories were significantly different in cases and controls (chi square, $p<0.0001$).

Table 3. Infertility Type by Age Group

	Infertility Type				
Age Group	**Primary n (%)**	**Secondary n (%)**	**Any infertility N (%)**	**No infertility N (%)**	**All N (%)**
12-19	0 (0)	0 (0)	0 (0)	33 (12.7)	33
20-29	32 (64)	20 (25)	52 (40)	144 (56.5)	196
30-39	15 (30)	54 (67.5)	69 (53.1)	78 (30)	147
40+	1 (2)	5 (6.25)	6 (4.6)	2 (0.8)	8
Unreported	2 (4)	1 (1.25)	3 (2.3)	3 (1.3)	6
Grand Total	**50 (100)**	**80 (100)**	**130 (100)**	**260 (100)**	**390**

P value of Pearson chi^2 <0.001

Figure 1: Distribution of Fertility Status by Age Group



Tables 4 show the investigations that were done for the 130 cases with infertility. Most tests were not done or not reported though ultrasound (USS) was more commonly done (60 percent).

Table 4. Status of Investigations for infertility

	Primary n (%)	**Secondary n (%)**	**Total N (%)**
Hormone test			
Done	13 (26)	18 (22.5)	31 (23.8)
Not done	24 (48)	28 (35)	52 (40)
Unreported	13 (26)	34 (42.5)	47 (36.2)
USS			
Done	36 (72)	42 (52.5)	78 (60)
Not done	3 (6)	5 (6.2)	8 (6.2)
Unreported	11 (22)	33 (41.3)	44 (33.8)
Semen analysis			
Done	8 (16)	7 (8.8)	15 (11.5)
Not done	28 (56)	38 (47.5)	67 (29.1)
Unreported	14 (28)	34 (42.5)	48 (36.9)
HSG			
Done	8 (16)	8 (10)	16 (12.3)
Not done	30 (60)	37 (46.3)	67 (51.5)
Unreported	12 (24)	35 (43.7)	46 (57.5)

As shown in Table 5, just under half the women with infertility (45.4 percent) had no ultrasound report during assessment either because it was not done or not reported. Hormone results were not available for 84.6 percent and over 90 percent for the semen analysis and hysterosalpingograph (HSG).

Table 5. Results for investigation for infertility

	Primary		**Secondary**		**Any infertility**	
	n	**%**	**n**	**%**	**N**	**%**
Hormones						
Normal	12	24	11	13.8	33	25.4
Abnormal	1	2	5	6.3	6	4.6
Unreported/ not done	37	74	64	80.0	110	84.6
USS						
Normal	21	42	25	31.3	46	35.4
Abnormal	13	26	12	15.0	25	19.2
Unreported/ not done	16	32	43	53.8	59	45.4
Semen analysis						
Normal	2	4	1	1.3	3	2.3
Abnormal	5	10	3	3.8	8	6.2
Unreported/ not done	43	86	76	95.0	119	91.5
HSG						
Normal	3	6	1	1.3	4	3.1
Abnormal	2	4	5	6.3	7	5.4
Unreported/ not done	45	90	74	92.5	119	91.5

Multivariate logistic regression

The logistic regression analysis showed that the following factors were independently associated with infertility: marital status, age at menarche, frequency of menses, ever use of contraception, ever had a manual vacuum evacuation and past pelvic procedure or infection. Though on bivariate analysis, age >35 years and partner alcohol use were associated with infertility, this was not the case in the multivariate logistic regression analysis when potential confounders were considered.

The odds of a married woman having infertility was 9 times that of an unmarried woman (OR 9.09, 95% confidence interval 2.22 to 37.29). Similarly, irregular menses, was over 20 times that of a woman with regular cycles to be associated with infertility (OR 20.72, 95% CI 2.52-170.56). Past ever use of contraception was associated with 83 percent less odds of infertility (OR 0.27, 95 CI 0.14-0.57).

Table 6. Logistic regression model of characteristics associated with infertility

Characteristic	Unadjusted Odds Ratio	(95% Conf. Int.)	Adjusted Odds Ratio	(95% Conf. Int.)	P value
age >35	18.84	(2.06-17.35)	2.19	(0.59-8.18)	P = 0.2421
married	0.89	(6.63-53.51)	9.09	(2.22-37.29)	P = 0.0022
Partner alcohol use yes	5.33	(0.53-1.49)	1.84	(0.75-4.53)	P = 0.1821
Age at menarche >13	4.08	(2.94-9.66)	2.58	(1.17-5.67)	P = 0.0183
Menses irregular	51.71	(2.30-7.27)	20.72	(2.52-170.56)	P = 0.0048
Ever Contraceptive use	0.17	(6.81-392.67)	0.27	(0.14-0.57)	P = 0.0006
Ever had MVA	4.60	(0.10-0.31)	3.15	(1.12-8.83)	P = 0.0294
Pelvic procedures/infection	10.34	(2.04-10.39)	11.13	(3.83-32.29)	P < 0.0001

Chapter 6: Discussion

This study showed that that the following factors were independently associated with infertility: marital status, age at menarche, frequency of menses, ever use of contraception, ever had a manual vacuum evacuation and past pelvic procedure or infection. The odds of a married woman having infertility was 9 times that of an unmarried woman (OR 9.09, 95% confidence interval 2.22 to 37.29). Similarly, irregular menses, was over 20 times that of a woman with regular cycles to be associated with infertility (OR 20.72, 95% CI 2.52-170.56). Past ever use of contraception was associated with 83 percent less odds of infertility (OR 0.27, 95 CI 0.14-0.57). The most commonly ordered investigations were hormonal, HSG, USS and semen analysis though the frequency of ordering varied and few results were available for assessment.

Overall, of the cases of infertility, 38.5 percent were primary and 61.5 percent secondary. Women aged 20-29 years were more likely to have primary infertility than secondary infertility (64 vs 25 percent respectively). In the age group 30-39 secondary infertility was more common than primary infertility (67.5 vs 30 percent). This was also the case for the few women that were 40 or more years of age. These results are similar to those reported by Larsen who found that primary infertility was relatively low in 28 African countries studied. Secondary infertility for women aged 20-44 years ranged from 5 to 23 percent (Larsen, 2000). Secondary infertility was also found to be higher in Latin America, Asia and North Africa (Inhorn, 2003; Leke et al, 1993; Dhont, et al 2011).

Married women were observed to have over nine times odds of being infertile (OR 9.09, 95% CI 2.22-37.29). These findings were unlike those reported by Dhont et al who found that of 177 infertile women, 83 (47 percent) were married, 94 (53 percent) single, and none separated, widowed or divorced (Dhont, et al., 2011). Married women are those more likely to be intending to get pregnant and those that do not attend for services in a fertility clinic like that at UTH.

Infertile women were found to be less likely to have used contraceptives than women who were fertile. This finding was similar to that found in Malawi where women who reported difficulty getting pregnant were 38/133 (28.6 percent) (Barden-O'Fallon,

2005). This may be because use of contraceptives would be seen to compound their problem of infertility.

There were higher odds of women with infertility that had a previous manual vacuum evacuation after miscarriage (OR 3.15, 95% CI 1.12-8.83). These women would be experiencing secondary infertility. Those women that had a previous pelvic infection or surgery in the pelvis (e.g. an ectopic pregnancy) also had very high odds of infertility (OR 11.13, 95% CI 3.83-32.29). This could be a result of tubal blockage which could be diagnosed by a hysterosalpingograph (HSG).

Neither the woman's nor partner's consumption of alcohol had any effect on her fertility status. Nevertheless, other authors have found that social factors such as weight, smoking, alcohol consumption and caffeine consumption affect fertility (Anon., 2004).

Irregular menses (including amenorrhea) was strongly associated with infertility (OR 20.72, 95% CI 2.52-170.56, p value 0.0048). This could be a marker of ovulation problems that could be amenable to ovulating inducing drugs like clomifene.

The number of women who had any investigations done at UTH was relatively low. In a study conducted in Oman, the prevalence of fallopian tubal obstruction was 19.1 percent in primary infertility and 28.7 percent in secondary infertility (Subhi, et al., 2013). The study also found that surgery for ectopic pregnancy, myomectomy, caesarean section, appendectomy, cystectomy etc., were significantly higher for women with secondary infertility compared to those with primary infertility. In this UTH study There were low levels of investigations done making interpretation of female or male factors or both difficult. Male factor contribution to infertility has been reported to be 20-40 percent (Araoye, 2003). The absence of results also meant that it was not possible to analyse which of the female factors were more prevalent, hormonal, tubal or both. Pritts found that infertility was not associated with subserosal fibroids whereas those with submucosal fibroids may have associated infertility (Pritts, et al., 2009). It is noted that ultrasound appeared to be a commoner investigation at UTH, though 45.4 percent had not had imaging done.

Chapter 7: Conclusion, Study Limitations and Recommendations

Conclusion

There was a higher proportion of secondary infertility than primary infertility (61.5 percent and 38.5 percent, respectively). Marital status, age at menarche, frequency of menses, ever use of contraception, ever had a manual vacuum evacuation and past pelvic procedure or infection were independently associated with infertility. The most common investigations that were ordered for infertility were hormonal profiles, pelvic ultrasound, semen analysis and hysterosalpingography (HSG). However, few of the women were investigated and fewer still had results available for assessment at review.

Study limitations

It was not possible to follow up patients who participated in the study therefore it was not possible to determine the full extent to which factors like abnormal test results were contributing to the couples' infertility. Further, some of the participants were attending the gynaecology clinic for the first time and had no tests ordered or results available.
An unmatched study design was used as certain factors (like previous MVA or pelvic procedure) would have been difficult to match for in controls. Certain factors like weight, smoking, alcohol consumption and caffeine consumption affect fertility though were not considered in this study.

Recommendations

1. Prevention of pelvic infection due to pelvic inflammatory disease or after manual vacuum aspiration after miscarriage should be vigorously prevented using aseptic techniques and antibiotics.
2. Investigations should be ordered early during the management of patients and results followed up.

Future studies should explore:

1. Optimizing management of infertility couples within the health system
2. Determining what other factors affect infertility

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Appendix I: Questionnaire

Serial No ……of 390

1	Age at last birthday in years							
2	Marital status	Married			Single			
3	If married, no of years							
4	Level of education	Primary		Secondary		tertiary		
5	Partner's level of education	Primary		Secondary		tertiary		
6	Employment status							
7	Partner's employment status							
8	Do they use alcohol?			Yes		No		
9	Does partner use alcohol?			Yes		No		
10	Age when Menarche attained							
11	Frequency of menses							
12	Duration of menses in days							
13	Sanitary method used	Cloth		Tampons		Pads		Other
14	Age at sexual debut							
15	Any use of contraceptives?					Yes		No
16	What type of contraceptive used	IUD		Injectable		Pill Condoms		Implants Chinese medicine
17	Is the infertility	Primary		Secondary				
18	Have you ever been pregnant?					Yes		No
19	If yes	Child		Miscarriage		Ectopic		
20	If they had a miscarriage was an MVA done?					Yes		No
21	Does the partner have any children?					Yes		No
22	Have you ever had pelvic surgery or infection? E.g. appendicitis, PID					Yes		No
23	How many times have you attended this clinic?							
24	Does your partner attend with you?			Yes (no. of times)		No		Never
25	If no, why not	Unwilling		Busy		Lives/works out of town		Other
26	Whom did they see? (from file)			JRMO		Registrar		Consultant
27	What investigations have been done?			Female				Male
28	Results of investigations	……		……..				
29	Have they received any treatment?					Yes		No

30	If yes	Surgical		Medical					
31	If medical what drugs and for how long?								
32	Have you used any traditional medicine for your condition?				Yes			No	
33	If yes, what traditional medicine								
34	Have you suffered any physical violence as a result of not having children?				Yes			No	
35	Have you suffered any verbal abuse as a result of not having children?				Yes			No	
36	If yes, from whom?	Partner			In-laws		Other		
37	Have you heard of In-Vitro Fertilisation? (Explain what this is)				Yes		No		
38	Would you be willing to try it in order to have a child?				Yes		No		
39	If no, why not?	Religious belief		Cost		Not know enough about it			

Thank you for your time.

Appendix II. Ethics Approval

ERES CONVERGE

33 Joseph Mwilwa Road
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I.R.B. No. 00005948
F.W.A. No. 00011697

10th February, 2015

Ref. No. 2014-Dec-007

The Principal Investigator
Dr. Mukatimui Namangale Kalima-Munalula
Department of Obstetrics and Gynaecology
University Teaching Hospital
P/Bag RW 1X,
LUSAKA.

Dear Dr. Munalula,

RE: PREVALENCE AND CORRELATES OF INFERTILITY AMONG WOMEN ATTENDING THE GYNAECOLOGY CLINIC AT UNIVERSITY TEACHING HOSPITAL

Reference is made to your corrections dated 1st February, 2015. The IRB resolved to approve this study and your participation as principal investigator for a period of one year.

Review Type	Ordinary	Approval No. **2015-Dec-007**
Approval and Expiry Date	Approval Date: 10th February, 2015	Expiry Date: 9th February, 2016
Protocol Version and Date	Version-Nil	9th February, 2016
Information Sheet, Consent Forms and Dates	• English, Nyanja.	9th February, 2016
Consent form ID and Date	Version-Nil	9th February, 2016
Recruitment Materials	Nil	9th February, 2016
Other Study Documents	Questionnaires.	9th February, 2016
Number of participants approved for study	390	9th February, 2016

Specific conditions will apply to this approval. As Principal Investigator it is your responsibility to ensure that the contents of this letter are adhered to. If these are not adhered to, the approval may be suspended. Should the study be suspended, study sponsors and other regulatory authorities will be informed.

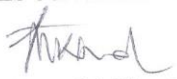
Conditions of Approval

- No participant may be involved in any study procedure prior to the study approval or after the expiration date.
- All unanticipated or Serious Adverse Events (SAEs) must be reported to the IRB within 5 days.
- All protocol modifications must be IRB approved prior to implementation unless they are intended to reduce risk (but must still be reported for approval). Modifications will include any change of investigator/s or site address.
- All protocol deviations must be reported to the IRB within 5 working days.
- All recruitment materials must be approved by the IRB prior to being used.
- Principal investigators are responsible for initiating Continuing Review proceedings. Documents must be received by the IRB at least 30 days before the expiry date. This is for the purpose of facilitating the review process. Any documents received less than 30 days before expiry will be labelled "late submissions" and will incur a penalty.
- Every 6 (six) months a progress report form supplied by ERES IRB must be filled in and submitted to us.
- ERES Converge IRB does not "stamp" approval letters, consent forms or study documents unless requested for in writing. This is because the approval letter clearly indicates the documents approved by the IRB as well as other elements and conditions of approval.

Should you have any questions regarding anything indicated in this letter, please do not hesitate to get in touch with us at the above indicated address.

On behalf of ERES Converge IRB, we would like to wish you all the success as you carry out your study.

Yours faithfully,
ERES CONVERGE IRB



Dr. E. Munalula-Nkandu
BSc (Hons), MSc, MA Bioethics, PgD R/Ethics, PhD
CHAIRPERSON

Appendix III. UTH Approval

REPUBLIC OF ZAMBIA

MINISTRY OF HEALTH

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OFFICE OF THE SENIOR MEDICAL SUPERINTENDENT

Our Ref:
Your Ref:

Dr. Mukatimui N. Kalima Munalula
Department of Obs/Gynae
University Teaching Hospital
Private Bag RW IX
LUSAKA

2nd December 2014

Dear Sir/Madam

RE: RESEARCH PROJECT – DR. MUKATIMUI N. KALIMA MUNALULA

Reference is made to your letter of 27th November 2014.

I wish to inform you that permission has been granted to you to conduct research at University Teaching Hospital entitled Prevalence and Correlates of infertility among women attending the Gynaecology clinic at University Teaching Hospital, Lusaka, Zambia. You are advised to liaise with the Head of Department – Obs/Gynae.

Yours faithfully

Dr. P. Tembo
AG/HEAD- CLINIC CARE
for/SENIOR MEDICAL SUPERINTENDENT
UNIVERSITY TEACHIN G HOSPITAL

cc: Senior Medical Superintendent

Appendix IV. Information and Consent Sheet

Dear participant,

Many women in our country desire to have children for various reasons. However, some are not able to have children at the time they wish to.

This is a study to determine factors that may result in women failing to have children. We will ask you questions about your reproductive life, your work and the care you have received here at UTH. You do not have to answer any question that you find uncomfortable or intrusive. Your participation in this study will help us better understand what may contribute to couples being unable to have children. The study does not mean, however, that we will be able to help you achieve your desire to have children at this time.

Participating in the study may have no direct benefit for you at this time. However, there also is no risk to you if you do choose to participate.

You are free to decide not to participate in the study and your subsequent treatment in our clinic will not be affected. If you do agree to participate, we will ensure that confidentiality will be maintained at all times and your name will not be entered on the data form. All information obtained from you will only be used for research purposes.

The information we collect from you will be used to determine the different factors that may cause women not to have children. It will help us know how to provide appropriate interventions and design public health messages that may help women avoid some of these factors.

The interview will take about 10 minutes and will be conducted in a private place where no one will be able to hear what is discussed.

If you have any questions or complaints regarding this study please contact the following:

Dr Mukatimui Kalima-Munalula
Department of Obstetrics & Gynaecology
University Teaching Hospital
0979-882 537

Or, The Chairperson
ERES Converge IRB
33 Joseph Mwilwa Road
Rhodes Park, Lusaka
0955-155633; 0955155634; 0966766503

Information Sheet in local language

Adzimai ambiri mu Zambia afuna kunkala ndi ana. Koma bina bache alepela kunkandi ana chifukwa cha zinthu zo siyanasiyana.

Iyi study ifuna ku sakira chifukwa chiani azmai ena alepela kunkala di ana. Ti samifunasa palimankalidwe yanu, umoyo wanu na mwamene ba dotolo kuno kuchipatala ba mi onela. Ngati simufuna kuyankha mafunso yenangu, chilitelo. Mayankidwe yanu azatitandiza ku ziba zambiri. Koma si kuti kingamitandize kunkala ndi mwana pantwi ino.

Ku vumela kuti munkale mu study iyi si chifotokoza kuti muza pezapo chilichonse, or ku luza chilichonse. Muzatitandiza kuti ti ziwe zamene zilikuchitika.

Ngati simufuna kunkala mu study iyi, tizamisamallila chabe mwamene uenela ngati mwabwera ku chipatala. Si tiza uza aliyense zamene muzatifotokozela. Dzina lanusiizalembedwa pa ma paper aliense ndipo nso zones zamene tizakamba zi zankala chabe mu research.

Mafunso yonse yazatenga ma minute yali 10. Tizankala mu office mwamene kulibe wina azamvela vamene tilikukamba.

Ngati mulina mafunso, kapena madandaulo, munga lankule ndi a

Dr Mukatimui Kalima-Munalula
Department of Obstetrics & Gynaecology
University Teaching Hospital
0979-882 537

Or, The Chairperson
ERES Converge IRB
33 Joseph Mwilwa Road
Rhodes Park, Lusaka
0955-155633; 0955155634;
0966766503

Consent Form

I wish to confirm that the interviewer has explained to me the purpose and nature of this study. I understand that the information that is being collected will only be used for research purposes.
I also understand that I am free to withdraw from the study at any time. My participation in the study or refusal will not change the way I will be managed and treated in the gynaecology clinic.
I have not been pressured into participating.

Signed……

Thumb print……

Na vumela kuti ofunsa atantauza chamene bafuna kupunzila mu study iyi. Ndipo nso na vumela kuti bazasebenzesa chabe mu research.
Ni ngate kuchoka mu study iyi pantawi iliyonse. Ba doctor bazaniona bwino nikavomela olo iyi.
Sinina patikizwe kuyanka mafunso, olo kun kala mustudy.

Signed……

Thumb print……