FINDINGS IN SUBFERTILE WOMEN UTILIZING HYSTEROSALPINGOGRAPHY SERVICES AT THE MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA.

BY

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A research thesis presented to Moi University School of Medicine in partial fulfilment for the award of the degree of

Master of Medicine in Radiology and Imaging

Findings in subfertile women utilizing hysterosalpingography services at the Moi Teaching and Referral Hospital, Kenya.

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DECLARATION

Student's Declaration:

I declare that this thesis is my original work. It has not been presented elsewhere for academic purposes or otherwise. This research work was carried out in pursuant of a degree in Master of Medicine in Radiology and Imaging course at the Moi University, School of Medicine. No part of this work may be reproduced without permission of the author.

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DEDICATION

I dedicate this thesis to all those who are afflicted by this condition. May this serve as a reminder of our commitment as the medical fraternity to help you deal with this affliction.

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LIST OF ABBREVIATIONS

GOPC	Gynaecology Out-Patient Clinic
HSG	Hystero-salpingography
IREC	Institutional Research and Ethics Committee
MMed	Masters of Medicine
MOH	Ministry of Health
MSCT-HSG	Multi Slice Computed Tomography –Hystero-SalpingoGraphy
MTRH	Moi Teaching and Referral Hospital
R&I	Radiology and imaging
SoM	School of Medicine
SPSS	Statistical Package for Social Sciences.
STATA	Statistics/Data Analysis program
STI	Sexually Transmitted Infection
W.H.O	World Health Organization

OPERATIONAL DEFINITION OF TERMS

Female subfertility	any form of reduced fertility with prolonged time of unwanted non conception in 12 consecutive unsuccessful cycles after unprotected coitus in non-lactating females
Primary subfertility	Describes couples who have never been able to become pregnant after at least 1 year of unprotected sexual intercourse.
Secondary subfertility	Secondary infertility describes couples who have been pregnant at least once, but have not been able to become pregnant again
Hysterosalpingography	Common radiological contrast media based investigation of the female reproductive tract.

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ABSTRACT

HYSTEROSALPINGOGRAPHY FINDINGS IN SUBFERTILE WOMEN AT MTRH, ELDORET.

Background:
Subfertility is an important condition with widespread socio-cultural implications. Its prevalence has been increasing with structural anomalies of the female genital tracts being one of the biggest contributors. HSG studies are quintessential in diagnosing these and so invaluable in radiological work up of subfertile females. Few studies that are radiologically based have been done in Kenya hence such patterns as seen on HSG are not well known at MTRH.

Objective: To determine patterns of structural defects as seen on HSG and its association with demographic characteristics and subfertility sub types.

Research design & Methodology: This was a cross-sectional study done in the Radiology and Imaging department of MTRH. The study population was subfertile females. A sample size of 141 subfertile females was determined using fishers formula. Consecutive sampling was done. Non consenting or females with contra indications to HSG were not included. Data was analyzed using STATA version 12. Fischer's exact and chi-square tests to determine associations.

Results: Median age was 31 (IQR: 23-40) years. Most respondents, 131(93%) were married. Majority, 125(88.6%) had minimum level of secondary education. Primary subfertility seen in 40(28%) while secondary subfertility in 101(72%). Participants with primary subfertility presented at a mean duration of 4 years. Older participants had longer subfertility duration. A minority, 8(6%) had previous pelvic surgery; this wasn't statistically significant as an associated factor for subfertility (p 0.616). Contraceptives had been used by 78(52%), with no significance noted toward having utero-tubal defects (P=0.078). Normal uterine findings were seen in 122(87%). Filling defects were the commonest uterine abnormality. Tubal blockage was common, present unilaterally in 18% and bilaterally in 27%. No risk of increased tubal defects was seen in either primary or secondary subfertility over the other. Older age was linked to presence of uterine abnormalities. There was no significant associations between education level, employment and type of subfertility or between contraceptive use and previous pelvic infection with occurrence of utero-tubal defects.

Conclusions. Most patients were married and literate. Secondary subfertility was the commonest type. Tumors were the commonest uterine pathology and distal tubal occlusion the commonest tubal defect. There is a positive relationship between age and development of uterine defects.

Recommendations There's need for similar but larger studies to help determine associations of these patterns with a view of establishing proper interventions.

CHAPTER ONE: INTRODUCTION

1.1 Background

Subfertility is a multidimensional problem with social, economic and cultural implications. The impact of subfertility to a couple and the community depends on the prevalence of subfertility in that area and the regional socio-cultural values attached to childbearing. World-wide, there is an increasing number of women presenting in medical fertility centres with subfertility or other consequential morbidities.

The global prevalence of subfertility has been estimated by WHO to be between 5%-15% based mostly on hospital based data(Mascarenhas, Flaxman, Boerma, Vanderpoel, & Stevens, 2012). A downward trend in global prevalence rates has been noted but with significant rise in absolute numbers of subfertile people because of population increase.

In Kenya, prevalence rates for subfertility are about 8%with most cases identified among women in rural area (Mati et al., 1989). This again are figures derived from females who sought medical attention.For most couples, the inability to bear children is a tragedy and the psychological stigma associated with it prevents a vast majority from seeking conventional medical care. The conflict of personal, interpersonal, socio-cultural and religious expectations brings a sense of failure, loss and exclusion to those who are affected.

In most of the African continent a woman's social status, economic achievement, well-being and the very meaning marital life hinges around her ability to beget and rear children, seen as a true mark of womanhood and pride of a man. A childless marriage is plagued by tensions resulting from numerous man-made problems, social stigma, economics exploitations, and psychological torture from within and without her marriage.

Hysterosalpingography (HSG) is the most commonly used technique in the evaluation of subfertility. It has traditionally been considered the gold standard for assessment of the fallopian tubes, giving reliable information about their patency and morphology. It is also recommended for the study of the uterine cavity in the diagnosis of and treatment planning for other gynaecologic problems such as intrauterine adhesions and congenital anomalies(Horwitz, Morton, Shaff, & Hugo, 1979).

HSG is an important diagnostic test in the evaluation of intrauterine abnormalities and tubal patency in the infertility workup of female patients(Bustamante & Pacheco, 2000). It is available and affordable to most of the local population and hence the most commonly used investigation.

HSG is invaluable in the initial diagnostic work-up of subfertility patients, but its disadvantages include pelvic irradiation, adverse reactions to iodinated contrast medium, post procedure infection, bleeding and lower abdominal discomfort(Horwitz et al., 1979). It's recommended that one should consider other diagnostic modalities, such as hysteroscopy and/or laparoscopy, if no improvements are seen in about six months after

initiation of subfertility treatments with demonstrated normal HSG findings(Horwitz et al., 1979).

The aim of the study is to help identify what are the commonest structural abnormalities of the female reproductive tract as seen on HSGs, and assist clinicians on proper management of subfertility that is due to mainly structural defects since they will be more aware of the prevalence of various causes as identified by this study done in their own setting.

1.2 Problem Statement

Subfertility is a common condition globally. It has been classified as a re-emerging non communicable Disease with significant physical and psycho-social morbidity (Mascarenhas et al., 2012). Appropriate and timely management of patients is difficult in low resource settings sinceavailability and affordability of the key imaging modalities is an issue yet HSG plays a key role in diagnosis and planning of management of this condition.

There is also the need to fill the obvious gap in subfertility knowledge particularly on imaging findings locally which has contributed to poor diagnostic work up of subfertile women. This will greatly improve the utilization of HSG in investigating the major structural causes of subfertility.

1.3 Research Questions

This study aimed to answer the following questions: Amongst the patients seen at MTRH, Eldoret, Kenya:

1. What are the common demographic characteristics of women with subfertility done for HSG at MTRH?
2. What are the common utero-tubal structural defects as seen on HSG and their relationship to demographics and subfertility subtypes?

1.4 Justification

Subfertility is a critical factor in health care. In our setting, it bears widespread socio-cultural implications. Previous assumptions on causes of subfertility are being abandoned with the advent of science and so better diagnostic possibilities.

Most studies concerning subfertility in Africa have focused on its prevalence while fewer have looked into subfertility from the radiological work up view point. There is no study in this setting that aims to determine possible non-functional structural pathology causes as evidenced on HSG which remains an important diagnostic tool.

This study helps pinpoint specific structural lesions as seen commonly on HSG in MTRH. This will provide guidance for establishment of treatment protocols especially as far as management of these patients is concerned by giving information on most common gynaecological structural abnormalities that result in subfertility.

1.5 Objectives

1.5.1 Main Objective:

Main study objective was;-

To determine the patterns of hysterosalpingography findings in subfertile women seeking diagnostic and therapeutic services for subfertility at MTRH.

1.5.2 Specific Objectives:

1. To describe demographic profiles of women with subfertility who underwent HSG at MTRH.

2. To determine proportions of primary and secondary subfertility among subfertile women who underwent HSG at MTRH.

3. To determine patterns of common structural abnormalities as seen on HSG and their relationship to demographics and subfertility subtypes of subfertile women sent for HSG at MTRH

CHAPTER TWO: LITERATURE REVIEW

Sub fertility can be defined variously including clinical; epidemiological or demographic definitions. The agreed clinical definition is “any form or grade of reduced fertility in couples unsuccessfully trying to conceive for a period of 1year or after 12 unsuccessful cycles with unprotected coitus within the fertile phase of the cycles or inability to conceive within one year of exposure to high risk of pregnancy i.e. Unprotected regular coitus, in a woman of reproductive age who is not on contraceptives and is non-lactating (Jenkins et al., 2004).

Primary subfertility is defined as the inability to become pregnant after one year of unprotected normal intercourse or despite actively trying for a certain number of years.

Secondary subfertility is defined as the inability to become pregnant despite actively trying for years and having been pregnant (or had a child) in the past(World Health Organization (WHO), 1987).

Epidemiologic definition states 2 years as the cut off with the demographic definition using a childlessness definition after.

2.1 Prevalence of subfertility

Subfertility is one of the most prevalent but most ignored gynecological conditions worldwide. Prevalence estimates are not accurate as they are obtained mostly from hospital-based data and vary from region to region. About 8% of couples experience subfertility during their reproductive lives translating to 70-80 million subfertile couples globally .

Current estimates show that the prevalence rate of subfertility globally is 8%-15%. The 'childlessness' demographic definition was often used in reports from less developed countries[1].There is evidence that prevalence rates vary in regard to various factors like developed or developing world, urban or rural population, poverty status, educational background(Bustamante & Pacheco, 2000). In a decade long study Mascharenas et al subfertility prevalence changes showed significant downward trend in Asia and Sub Saharan Africa .A much recent study by Zhang et al shows a slight increase in prevalence in China (Zhang HX, 2014). In Canada, North America estimates on the prevalence of subfertility have shown an upward trend, according to Bushnik et al prevalence among women aged 18-44 was 8.5% in 1982 and 7.4% in 1992 and 11.5-15.7% in 2012[(Bushnik, Cook, Yuzpe, Tough, & Collins, 2012)

A report from the USA showed that the prevalence of 12-month subfertility stayed more or less the same in the USA from 8.5% in 1982 to 7.4% in 2002[(Jacky Boivin, Laura Bunting, John A Collins, & Karl G Nygren, 2007). In contrast, in some African countries the prevalence has dropped dramatically from an exceptionally high level reaching 30–40% in the 1950s and 1960s to an average national estimate of only 6% in 1994[9]. This decline may be due to significant decreases of 30–40% in the prevalence of some STDs in African nations (World Health Organization (WHO), 1987). Another study that sampled 25 population surveys of 172 413 found the 12-month prevalence rate ranging from 3.5 - 16.7% in more developed nations and from 6.9 - 9.3% in less-developed nations, with an estimated overall median prevalence of 9%(J. Boivin, L. Bunting, J. A. Collins, & K. G. Nygren, 2007).

Based on these estimates and on the current world population, 72.4 million women are currently subfertile; of these, only 40.5 million (56%) are currently seeking medical care(J. Boivin et al., 2007). These estimates are lower than those typically cited and are remarkably similar between more and less developed countries.

In Africa, the exact magnitude and significance of subfertility as a public health problem is poorly understood or even unknown. However, in most referral hospitals there are large numbers of patients due for investigative and/or treatment procedures such as HSG.

2.2 Causes of female subfertility

Aetiological factors include ovulatory disorders, tubal abnormalities, uterine abnormalities, endometriosis and advancing age. Unexplained subfertility after thorough evaluation occurs in about 5-10%(Adamson & Baker, 2003). Other associations to occurrence of subfertility include a past history of ectopic pregnancy, previous tubal surgery; infections from ruptured appendix, pelvic tuberculosis, septic abortion and sexually transmitted infections (STIs).Less frequent causes of infertility include tumours causing pituitary dysfunction, ovarian dysfunction and metabolic diseases.

According to Larsen U et al ,in study done in Tanzania and Ibekwe PC et al in a study in Nigeria, primary subfertility accounts for 20% and secondary sub fertility 80% of all cases [(Larsen, 2000),(Ibekwe, Udensi, & Imo, 2010). A study by Mati et al showed that primary subfertility contributed 58% and secondary subfertility 4% of all cases of subfertility in Kenyatta National Hospital Gynaecology outpatient clinic(Mati et al.,

1989). In the same study, using tubal insufflation, tubal occlusion was diagnosed in 49% of all cases of secondary subfertility.

There was a history of exposure to STIs in 5.7% of females. Of all females evaluated, 13.3% gave a history of pelvic inflammatory disease in the past. The leading causes of subfertility in the female were pelvic adhesions (61.3%), anovulatory problems (15.9%), hyperprolactinemia (9.9%) and ovulatory oligomenorrhea (5.6%). There was no demonstrable cause of subfertility in 20% of females and 68.6% in males. Other findings were: that the females seeking for subfertility management were younger with the age peak of 20-29 years.

2.3 Role of radiology and imaging in management of subfertility

Any evaluation of a subfertile couple should include search for an abnormality of the uterine cavity. Intrauterine abnormalities, especially congenital abnormalities of the mullerian ducts, are relatively common and contribute to the problems of subfertility, recurrent pregnancy loss and poor outcome in pregnancy[(Coleman et al., 1988). There are various methods for evaluating the uterine cavity.

Hysterosalpingography (HSG) is a widely used diagnostic tool. It demonstrates the luminal outline of the tubes, mapping out the site of obstruction and also may detect intrauterine defects. The uterine cavity and the lumen of the fallopian tubes are outlined by aseptic instillation of contrast medium through the cervix. The contrast medium is injected slowly under fluoroscopic observation and spot films are taken.

Assessment of the uterine cavity — In addition to assessment of tubal patency, HSG may identify developmental or acquired abnormalities of the uterine cavity with potential

effects on fertility, such as sub mucous fibroids, polyps, synechiae, and congenital mullerian anomalies.

Abnormalities found on HSG generally require further evaluation by other imaging modalities ultrasonography, magnetic resonance imaging or laparoscopy.

Trans-abdominal ultrasonography is used for monitoring follicular development and ovulation. However, the trans-vaginal probe is preferred for evaluating pelvic structures because of its better resolution capacity[14]. Sono-hysterography, in which the uterine cavity is scanned while it is infused with sterile saline, was shown to be able to detect 90.3% of abnormalities of the uterine cavity, compared with other diagnostic methods (Cengiz A, 1997). Tubal and uterine factors are usually examined simultaneously.

Hysterosalpingo-contrast sonography (HyCoSy); uses ultrasound to view the uterus, tubes, and adnexa before and after trans-cervical injection of echogenic contrast media. It is a safe, well tolerated, quick and easy method for obtaining information on tubal status, the uterine cavity, the ovaries, and the myometrium using conventional ultrasound.Shahid et al found it to be a good screening test and an effective alternative for laparoscopy(Shahid, Ahluwalia, Briggs, & Gupta, 2005)

Hysteroscopy is the ‘gold standard’ in the diagnosis of intrauterine pathologies. It’s the definitive method for evaluation of abnormalities of the endometrial cavity, and also offers the opportunity for treatment at time of diagnosis(Gillespie & Nichols, 1994). In patients undergoing laparoscopy, performing hysteroscopy at the same time and omitting HSG is efficient too.

Laparoscopy has a significant role in evaluation of subfertility. It's invasive and expensive. Laparoscopy with chromo-tubation may be more appropriate in women suspected of having endometriosis. Methylene blue or Indigo carmine can be used as the chromo-tubation dye.

Dye laparoscopy is performed in theatre under general anaesthesia following the method described by Steptoe. Laparoscopy gives an idea of the state of the pelvic organs, the presence or absence of extra-tubal adhesions, masses, and endometriosis and gives the feasibility of tubal surgery.

Gichuhi showed that laparoscopy was as good as HSG in diagnosis of tubal occlusion. In 140 subfertile women attending the gynaecology clinic at Kenyatta National Hospital, 44.7% had some degree of patency by HSG and 47% by laparoscopy. Similarly, 26.2% had some degree of cornual occlusion by HSG while 31.9% by laparoscopy. Some degree of intratubal occlusion was diagnosed in 10.6% of women by HSG and 10.1% by laparoscopy, giving a substantial agreement between the two tests at the intrauterine segment of the tube. Forty six percent had some degree of fimbrial occlusion by HSG and 51% by laparoscopy(L.N, 1985).

Nderi reviewed 485 cases that underwent diagnostic laparoscopy at Kenyatta National Hospital in the period 1976-1979. He found that 39.6% had primary infertility, 42.1% had secondary infertility while the rest 18.3% had such indications as primary amenorrhea, secondary amenorrhea, oligomenorrhea, possible ectopic pregnancy and

dyspareunia. 309 patients (63.7%) had tubal occlusion most of whom (75%) had fimbrial occlusion(Nderi, 1981)

Trans-vaginal hydro laparoscopy (THL) - It's a new culdoscopic technique for exploration of the pelvic cavity using micro-endoscopic technology and aqua flotation for inspection of the tubo-ovarian structures. It's combined with mini-hysteroscopy, chromo-tubation, fimbrioscopy and/or salpingoscopy. THL is better tolerated than HSG, less invasive than standard laparoscopy, and can be used safely as a first line investigation of the female partner in subfertility clinics(Carrascosa et al., 2008).

Magnetic resonance imaging (MRI) is the study of choice in subfertile women with suspected uterine anomalies because of its high accuracy and detailed elaboration of utero-vaginal anatomy. It is however not as good for depicting tubal pathology.

2.4 Hystero-Salpingo-Graphy (HSG)

HSG is a safe simple important and rapid diagnostic test in the evaluation of tubal patency in the workup of female subfertile patients(Cengiz A, 1997) HSG techniques include conventional HSG, multi slice CT – HSG, MR-HSG and radionuclide HSG which have 100per cent sensitivity for utero-tubal structural lesions and functional tubal activity respectively(Kuohung, Hornstein, Barbieri, & Barss, 2013)

The test is done between the 7-10th days of the menstrual cycle during the follicular phase when the endometrium is thin and its friability is at its minimum.

A preliminary scout film of the pelvis is taken then using a syringe contrast media is injected using a cannula into the uterus under fluoroscopic control. Three films are then

taken one once contrast fills the uterine cavity, the second as it passes through the tubes and spills and the third, a delayed one, at about 10 minutes later to check for peritoneal spillage (Horwitz et al., 1979).

It is widely used and has advantages including the lack of need for anaesthesia, faster speed at which procedure is done and the potential therapeutic impact with oil soluble contrast media(Horwitz et al., 1979). The complications of HSG include pain, infection, urticaria, syncope, haemorrhage, shock and pulmonary embolism(Horwitz et al., 1979).

Although somewhat insensitive, the high specificity of HSG makes it very helpful for ruling out tubal disease, even where endoscopic evaluation is available. Bustamante studied the diagnostic value of HSG in the basic study of subfertility in developing countries and concluded it had a great positive predictive value (92.4%) and high sensitivity (95%)(Bustamante & Pacheco, 2000).

Diagnostic HSG also appears to have therapeutic effects. A systematic review of 12 randomized trials found that pregnancy rates were significantly higher in subfertile women who underwent tubal flushing with oil soluble media than in those who did not undergo HSG (OR 3.30, 95% CI 2.00-5.43), and that pregnancy rates were similar whether oil or water soluble media were used (OR 1.21, 95%CI 0.95-1.54). Additionally there is evidence that a substantial number of pregnancies occur following an HSG, suggesting the test has therapeutic and diagnostic benefits (Kuohun W.et al, 2011)

2.5 Common structural findings on HSG

Common assumptions, and especially in the developing world, are that most cases of subfertility are due to structural tubal pathologies(Bukar, Takai, Mustapha, & Tahir, 2011).

Uterine abnormalities causing subfertility were also investigated with uterine septum by far the most common major congenital anomaly of the female reproductive tract with an incidence of 80-90% of all major malformations in women with recurrent pregnancy loss or general population (National Collaborating Centre for Women's and Children's Health, 2003).

Tubal factor infertility is the main reason for infertility in resource-poor countries Sub Saharan countries mostly due to sexually transmitted infections and pregnancy related complications. Bello reported secondary subfertility as more common with anatomical defects being commoner in those with secondary infertility and hydrosalpinx as being the commonest tubal pathology, as well as spasm of the tubes; which was also seen though noted to be difficult to differentiate from mechanical obstruction.

Findings in women investigated for subfertility by HSG in a tertiary centre in north eastern Nigeria found that 71% had abnormal findings. The most common pathology revealed among the subfertile women was tubo-peritoneal factor in 196 (72.1%) followed by uterine synechiae in 35(12.9%), 6.3% had bilateral tubal block and 5 (1.8%) had bicornuate uterus. (Bello, 2007) Horwitz described spasms as having smooth rounded cornual spasm while obstruction is seen as sharp cornual edges(Horwitz et al., 1979)

Al Subhi et al showed equal occurrence of bilateral tubal obstruction in both primary and secondary subfertility groups and that previous history of pelvic infection was significant as a potential cause (Al Subhi, Al Jashnmi, Al Khaduri, & Gowri, 2013) .Tubal blockage site and extent also depended on causative mechanism, Sinawat et al in a review of 740 patients showed tubal pathology in 27.3% of them. 46.04% had cornual blockage, distal tubal 8.42% and combined in 30.20 % (Sinawat S, 2005)

CHAPTER THREE: METHODOLOGY

3.1 Design

A cross-sectional study design was used. Women presenting to MTRH R&I department following referral from GOPC were interviewed and their HSG images and reports recorded over a study period of 12 months.

3.2 Study site

The study was carried out in the radiology unit of MTRH Radiology and Imaging department. The hospital is located in Uasin Gishu County. It is the second largest public referral hospital in Kenya and provides curative, preventive and rehabilitative health services. MTRH also serves as a Teaching hospital for Moi University, College of Health Sciences, Eldoret Medical Training College (MTC) and Baraton School of Nursing.

The total population that uses the health facility is about 400,000 inhabitants, and an indigent referral population of 13 million from northern and western Kenya. The national hospital bed capacity in Kenya is 14 beds per 10,000 population (Hospital, 2014). Most patients are seen as outpatients in the specialized clinics though there are a total of 800 beds available distributed in various specialities in the hospital, and in two of the hospitals Private Wings namely; Private Wing I and the Private Wing II.

3.3 Study population

This study was carried out among women with subfertility utilizing HSG services at MTRH based on their clinical history. According to records of the past two years 2010 and 2011 about 290 HSGs were carried out in the general radiology wing.

3.4 Sampling Technique

Consecutive sampling technique was used in recruitment of patients. Patients with subfertility referred to MTRH radiology unit who met the study's inclusion criteria were sampled as they presented themselves.

3.5 Eligibility Criteria

3.5.1 Inclusion criteria

1. Must have been diagnosed with clinical subfertility by a gynaecologist then referred for HSG.

2. Adults over 18years old.

3.5.2 Exclusion criteria

1. Women with contra indications to HSG e.g. pelvic infections, history of allergy to contrast material or with vaginal bleeding.

2. Patients who did not provide informed consent were not studied

3.6 Sample size

To get the desired sample size, Fishers formula was used as below

$$n = \frac{z^2 pq}{d^2}$$

Where:

n = the desired sample size

z = the coefficient of the level of significance that corresponds to 95% confidence interval (1.96)

p = estimated prevalence of endometrial polyps appearing as filling defects = 8%

q = 1 – p

d = margin of error/ precision

Alpha =significance level (5%)

$$n = \frac{1.96^2 \text{x } 0.08\text{x}0.92}{(0.05)^2} = \text{approximately } 113$$

By factoring in a response rate of 80% the sample size is computed to 113/0.8=141

The total sample size was 141 (The estimated sample size used).

3.7 Data Management and Analysis

3.7.1 Activities

After participant enrolment, HSG was done under fluoroscopic guidance assisted by a qualified and experienced radiographer.

3.7.2 Quality control

The images were then interpreted by the Researcher along with two other qualified senior Radiologists to increase inter-reader reliability. Preliminary reports were then sent to the referring Clinician and the reports also entered in the data collection forms by Research Assistants for later analysis.

3.7.3 Data collection

Data was collected using interviewer administered questionnaires with structured questions and through fluoroscopic images which provided the radiological findings.The forms were filled by the investigator and later transferred to a computer database. Variables collected included patients demographic measures, relevant gynaecological history and HSG outcomes. Collected data was only available to the Investigator and the Supervisors.

3.7.4 Data analysis

To facilitate analysis, data collected was converted to numerical codes and de-identified for privacy of the patient. The variables were defined and the coded responses were reflected in the STATA spreadsheet where data was entered. Before analysis the data

was cleaned by the Principal Researcher and an Independent Researcher to correct errors and mistakes made during entry.

Data analysis was done using STATA version 12 special edition. Categorical variables were summarized as frequencies and the corresponding percentages. Continuous variables that assumed Gaussian (bell shaped or normal) distribution were summarized as mean and the corresponding standard deviation (SD) while the continuous variables that (were skewed) violated the assumptions for Gaussian distribution were summarized as the median and the corresponding inter quartile range (IQR). The test for the assumption of normality or Gaussian distribution was done using Shapiro-Wilks test for normality. Association between the categorical variables was assessed using the Fisher's exact test if the expected value (cell count) in at least one of the cells was less than 5 otherwise Pearson's Chi square test would be used.

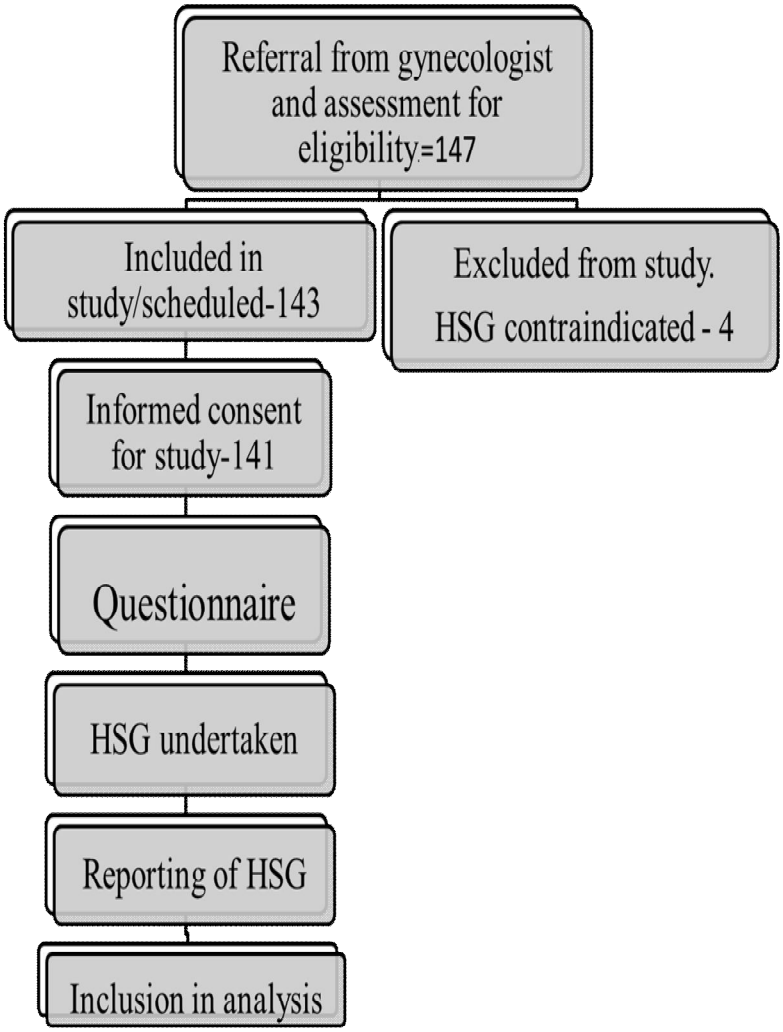
Participants' age was determined by subtracting the year of birth from the year of imaging. Age was categorized at five years interval just to help investigate the relationship between the HSG patterns and the said interval. The test for association between the continuous and the categorical variables was done using two-sample Wilcoxon rank sum test. The relationship between ordinal variables was assessed using Spearman's rank correlation coefficient. The results were presented using table and charts.

3.8 Ethical considerations

Approval to carry out the study was sought from the Institutional Research and Ethics Committee (IREC). Permission to access patient records in MTRH was sought from the

administration. All patient reports were kept confidential and the data obtained was password coded. Informed consent was sought from the patients and they were assured of their confidentiality. Collected data was only available to the investigator and the supervisors.

3.9 Study recruitment Schema



CHAPTER FOUR: RESULTS

4.1 Demographics of the participants

There were a total of 141 participants who met the inclusion criteria and were included in the study and whose data were subsequently analysed. The average age was 31(SD: 4) years with a minimum of 23 and a maximum of 40. Majority of the participants were aged 26-30 years then those aged 31-35 years (Figure 1). Of the total number of participants, 140 (99%) were Kenyans while the other one was a Sudanese.

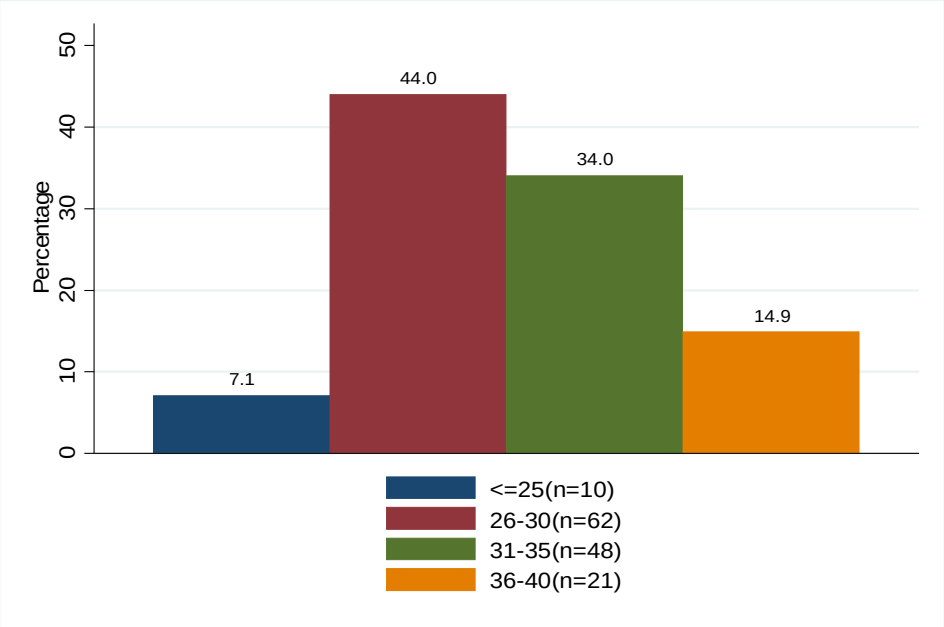


Figure 1: Distribution of participants by age groups

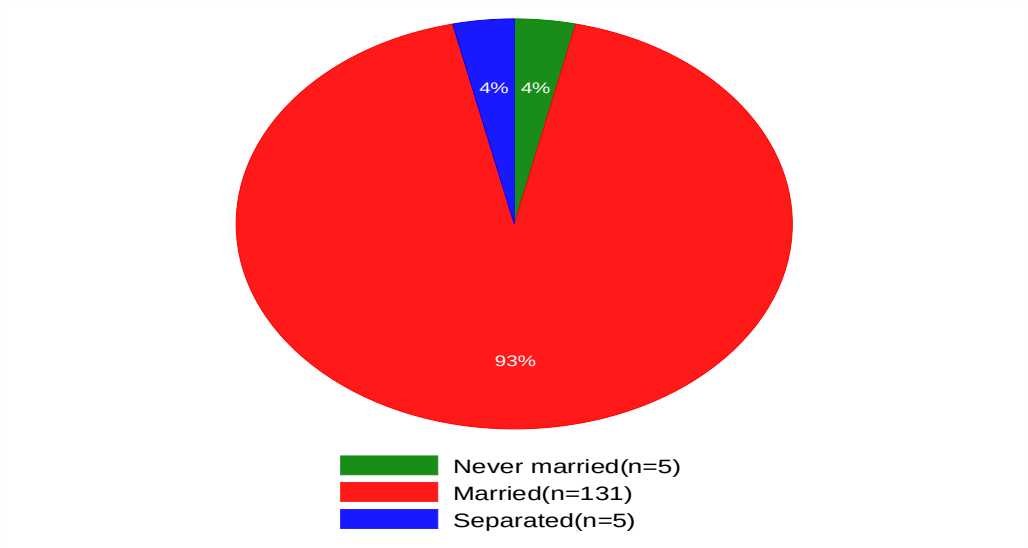


Figure 2: Distribution of participants by marital status

Majority of the participants, 131(93%) were married. There were 5(4%) who had never been married. The others were separated (Figure 2).

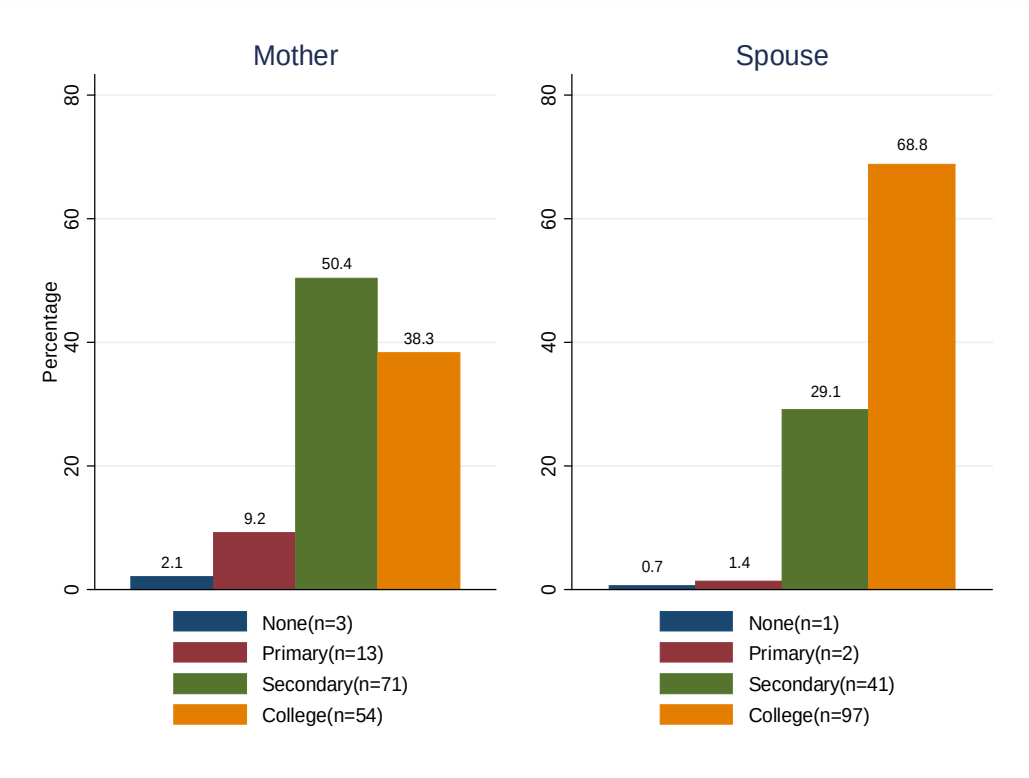


Figure 3: Distribution of participants and their spouses by the level of education

Majority of the participants had a secondary level of education while the spouses of the majority of the participants had a college education (Figure 3).

Table 1: Relationship between mother's education level and that of the spouse

		Spouse education				
		None	Primary	Secondary	College	Total
participants Education	None	0	1(33%)	2(67%)	0	3(100%)
	Primary	0	0	11(85%)	2(15%)	13(100%)
	Secondary	1(1.4%)	1(1.4%)	28(39.4%)	41(57.8%)	71(100%)
	College	0	0	0	54(100%)	54(100%)
	Total	1(0.7%)	2(1.4%)	41(29.1%)	97(68.8%)	141(100%)

Close to one third of the participants were unemployed with almost one half who were working in an informal sector (Figure 4). One fifth of the participants worked in a formal sector.

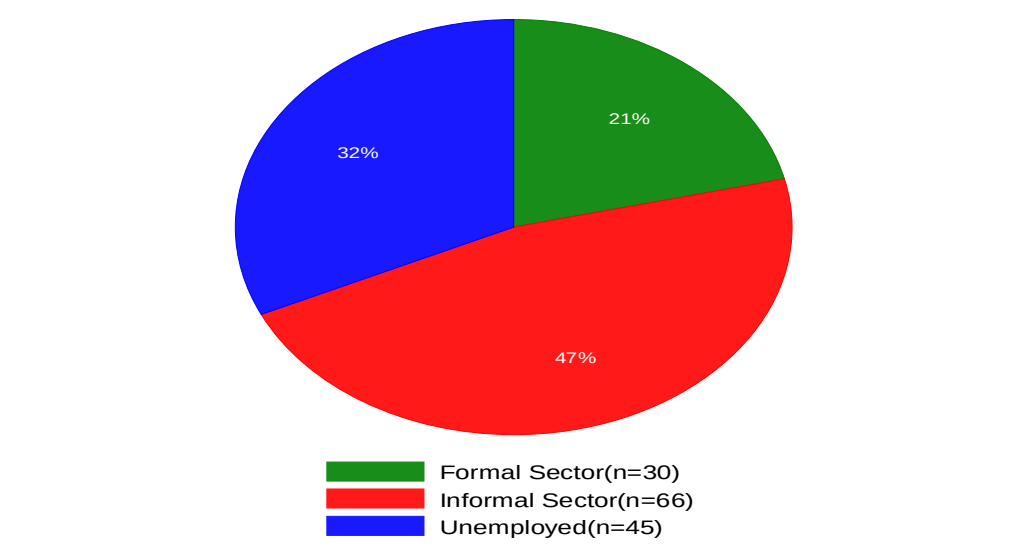


Figure 4: Distribution of the participants by the employment status

Table 2: Sub fertility types, duration and presumed risk factors

Characteristic	**N**	**Levels**	**n(%)**
Subfertility	141	Primary	40(28%)
		Secondary	101(72%)
Duration of sub-fertility	141	1 year	32(23%)
		2-3 years	67(48%)
		4-5 years	20(14%)
		>5 years	22(16%)
Contraceptive use	141	Yes	73(52%)
History of previous pelvic surgery	141	Yes	8(6%)
History of previous pelvic infection/STI	141	Yes	41(29%)

Of all subfertile participants, 101(72%) had a secondary sub-fertility while the rest (n=40) had primary subfertility. Majority of the participants had been subfertile for the past 2-3 years (Table 1).

The median duration since of subfertility among those who have at least one child was 4(IQR: 3-5) years with a minimum of 1 and maximum of 14 years.

Slightly over half of the participants were using contraceptives, 73(52%). The median duration on contraceptive use was 1(IQR: 0-2) years with a minimum of 0 and a maximum of 5 years.

Less than 10% of the participants reported history of previous gynaecological surgery, and 41(29%) reported history of previous pelvic infection/STI.

Table 3: Radiological/Imaging history and HSG structural findings

Characteristic	**N**	**Levels**	**n(%)**
Number of times HSG was done	141	Once	136(96%)
		More than once	5(4%)
Uterus	141	Normal	122(87%)
		Uterine filling defects	13(9%)
		Others	6(4%)
Fallopian tube	141	Normal	65(46%)
		Bilateral hydrosalpinx	8(6%)
		Left tube normal right tube blocked	14(10%)
		Unilateral hydrosalpinx	5(4%)
		Right tube normal left tube blocked	11(8%)
		Bilateral tube blockage	38(27%)
	65	Cornual	12(18.46%)
		Isthmus	7(9%)
		Ampulla	36(55.38%)
		Fimbria	10(15.38%)
Adnexal pathology	141	Nil	137(97.2%)
		Ovarian mass	2(2.8%)

The participants have had at least one investigation with only 5(6%) having had two investigations. There were 19(13%) participants who had abnormal uterus. Among them

were 13(9%) with filling defects/ tumours in the uterus and 6(4%) having other types of complications.

The fallopian tube was normal in 65(46%), with bilateral hydrosalpinx in 8(6%), with left tube normal but right blocked in 14(10%), with unilateral hydrosalpinx in 5(4%), right tube normal and left blocked in 11(8%), and with bilateral tube blocked in 38(27%) of the participants.

The tubal blockage occurred at the cornua in 12(8%), isthmus in 7(5%), ampulla in 36(26%), and fimbria in 10(7%). There were 76(54%) who had no tubal blockage.

Table 4: Relationship between sub-fertility types and demographic characteristics

Characteristic		**Primary Sub-fertility (n=40) n(%) or mean(SD) or Median(IQR)**	**Secondary Sub-fertility (n=101) n(%) or mean(SD) or Median(IQR)**	**P**
Mean Age (years)		31(4)	31(4)	0.954
Age groups	<=25	3(8%)	7(7%)	0.915[f]
	26-30	19(48%)	43(43%)	
	31-35	12(30%)	36(36%)	
	36-40	6(15%)	15(15%)	
Marital status	Never married	4(10%)	1(1%)	0.029
	Married	34(85%)	97(96%)	
	Separated	2(5%)	3(3%)	
Mother's education	None	0	3(3%)	0.616[f]
	Primary	4(10)	9(9%)	
	Secondary	23(57.5%)	48(48%)	
	College	13(32.5%)	41(41%)	
Spouse education	None	1(2.5%)	0	0.078[f]
	Primary	0	2(2%)	
	Secondary	16(40%)	25(25%)	
	College	23(57.5%)	74(73%)	
Employment	Formal	8(20%)	22(22%)	0.651[f]
	Informal	17(42.5%)	49(49%)	
	Unemployed	15(37.5%)	30(30%)	

The mean age of the participants with primary sub-fertility was similar to that of the participants with secondary sub-fertility (P=0.954). Similarly, there was no significant association between the age groups and the type of sub-fertility (P=0.915).

Marital status was significantly associated with sub-fertility. From the results in Table 4, it is evident that the proportion of married couples with secondary sub-fertility was significantly higher that of the participants who had primary sub-fertility, P=0.029.

The level of education among the participants with primary sub-fertility was similar to that of the participants with secondary sub-fertility (P=0.616). Similarly, the level of education of the spouses did not vary across the sub-fertility types (P=0.078).There was no association between the type of sub-fertility and the employment status (P=0.651).

Table 5: Relationship between sub-fertility types and clinical characteristics

Characteristic		**Primary Sub-fertility (n=40)**	**Secondary Sub-fertility (n=101)**	**P**
Duration of subfertility	2-3 years	19(47.5%)	48(47.5%)	0.067
	4-5 years	10(25%)	10(9.9%)	
	>5 years	6(15%)	16(15.8%)	
History of surgery	Yes vs. No	0	8(8%)	0.067[f]
Contraceptive use	Yes vs. No	16(40%)	57(56%)	0.078
Duration on contraceptives		2(1-2)	1(1-2)	0.277
History of pelvic infection/STI	Yes vs. No	13(32.5%)	28(27.7%)	0.573

Statistically there was no significant association between the duration of sub-fertility and the type of sub-fertility. However, examining the risks across the duration shows that majority of the participants with primary sub-fertility have had the condition for more than 4 years. Compared to those who had secondary sub-fertility this proportion is high, 40% vs. 25.7%.

None of the participants with primary sub-fertility had undergone a surgery. However, 8(8%) participants with secondary sub-fertility had undergone pelvic surgery for reasons

other than subfertility. This difference was however, not statistically significant (P=0.067).

There was no association between contraceptive use and the types of subfertility (0.078). However, the proportion of participants who were using contraceptives was higher among those with secondary sub-fertility.

The median duration of contraceptive use among the participants with primary sub-fertility using contraceptives was 2(IQR: 1-2) while the median duration of contraceptive use among the participants who had secondary type of sub-fertility and were using contraceptives was 1(IQR: 1-2). The two groups had similar durations of contraceptive use, P=0.277.

There was no association between reported histories of previous pelvic infection or STI (P=0.573). However, the results indicated a higher risk among the participants who had primary sub-fertility compared to those who had secondary sub-fertility, 13(32.5%) vs. 28(27.7%).

Table 6: Association between duration of subfertility and utero-tubal defects.

	Duration of sub-fertility					
	1 year (n=32)	2-3 years(n=67)	4-5 years(n=20)	>5 years(n=22)	Total (n=141)	P
Abnormal vs. Normal uterus	4(12.5%)	8(11.9%)	5(25%)	2(9%)	19(13%)	0.436[f]
abnormal vs. normal fallopian tubes	12(37.5%)	36(53.7%)	13(65%)	15(68%)	76(53.4%)	0.100

From Table 6, there was no statistically significant association between duration of sub-fertility and uterine defects (P=0.436). The results indicate that uterine defects, tumours in this case, occur among the participants at any duration of sub-fertility. There is no sufficient evidence to associate some length of duration with the development or emergence of tumours.

Similarly, there is no sufficient evidence from the data to associate some duration of sub-fertility with the fallopian tubes deformities or defects (P=0.100). The results, however, tends to suggest some increase in the risk as the duration becomes longer.

Table 7: Association between duration of subfertility and age.

Age(years)	Duration of sub-fertility						
	1 year (n=32)	2-3 years (n=67)	4-5 years (n=20)	>5 years (n=22)	Total (n=141)	P value	P
<=25	2(6.2%)	7(10.5%)	1(5%)	0	10(7%)		
26-30	12(37.5%)	38(56.7%)	8(40%)	4(18%)	62(44%)	0.004[f]	
31-35	14(43.8%)	18(26.9%)	6(30%)	10(45%)	48(34%)		
36-40	4(12.5%)	4(6%)	5(25%)	8(36%)	21(15%)		

The association between age and duration of sub-fertility was assessed (Table 7). From the results, there is an indication that older participants are more likely to have a longer duration of sub-fertility. This relationship is however, not strong (Spearman rank correlation coefficient (r_{sp}) = 0.2) with a P=0.02. Indeed, a linear relationship would be expected, but this relationship is weak demonstrating that the problem is distributed equally across all age groups.

Table 8; Association between patterns of HSG findings and subfertility subtypes

Characteristic	**Levels**	**Uterine defects n=19(%)**	**Tubal defects n=76(%)**	**Pathology =76**
Age group	**<25**	0(0%)	6(8%)	0.203
	26-30	7(36%)	38(50%)	0.274
	31-35	6(32%)	26(34%)	0.869
	>36	6(32%)	6(8%)	0.005
Education level	**Primary**	0(0%)	8(11%)	0.151
	Secondary	12(63%)	37(49%)	0.274
	College	7(36%)	31(40%)	0.749
Employment	**Formal**	5(26%)	23(30%)	0.732
	Informal	9(47%)	26(34%)	0.293
	Unemployed	5(26%)	27(36%)	0.411

Table 9: Relationship between patterns of HSG findings and type of subfertility

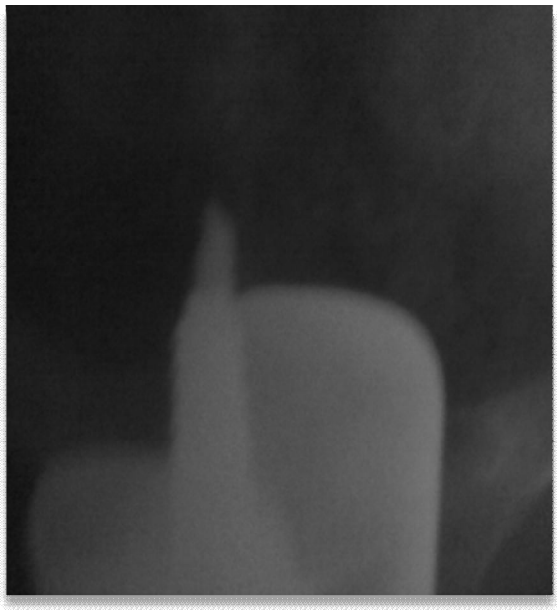
Patterns of Tubal HSG finding	**Primary subfertility**	**Secondary subfertility**	**P-values**
Normal	16(40%)	49(48%	0.284
Unilateral hydrosalpinx	1(2.5%)	4(4%)	0.777
Bilateral hydrosalpinx	4(10%)	4(4%)	0.166
Unilateral tubal blockage	4(10%)	11(11%)	0.863
Bilateral tubal blockage	13(32.5%)	25(25%)	0.544
Paratubal collections	2(5%)	8(8%)	0.533
Patterns of uterine HSG finding	**Primary subfertility**	**Secondary subfertility**	**P values**
Normal	28(70%)	94(94%)	0.001
Uterine filling defects	10(25%)	3(3%)	0.001
Irregular mucosal outline	1(2.5%)	2(2%)	0.853
Cervical lesions	1(2.5%)	2(2%)	0.853

There was a significantly higher risk of having filling defects in the uterus among the participants with primary sub-fertility compared to those who had secondary sub-fertility, 10(25%) vs. 3(3%), P=0.001. However, there was no statistically significant differences in the risks of having defective fallopian tubes among the participants with primary sub-fertility compared to those with secondary sub-fertility, 24(60%) vs. 52(51.5%).

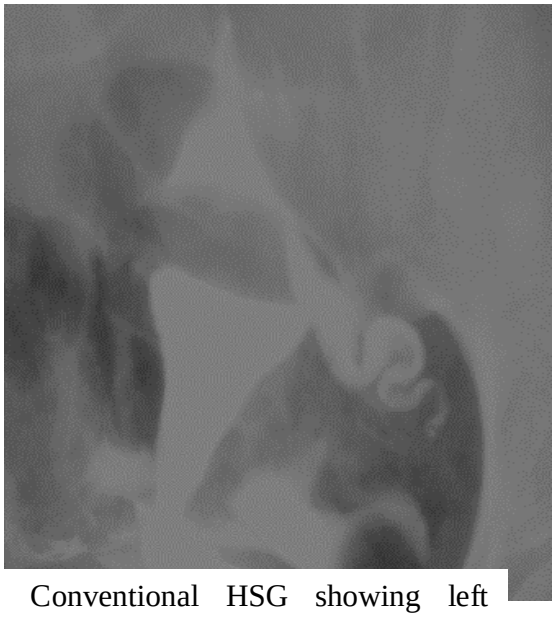
Radiological images

Normal

Conventional HSG showing unilateral left sided tubal occlusion in a 33year old with primary subfertility



Ashermann's syndrome in a 28year old
para 0+1 with history of previous



Conventional HSG showing left sided unilateral hydro-salpinx
in a 31year old with secondary subfertility

CHAPTER FIVE: DISCUSSION

5.1 Socio-Demographic characteristics

The sample in this study mainly constituted Kenyan women from the county of Uasin Gishu in which MTRH is locatedwho attended MTRH Radiology department with a reasonable sample size that offers credence in the results obtained.

The participants included in this study were of mean age of 31(SD: 4) years with most of them being 26-30years, this was similar to the mean age of subfertile women as found by Mathews T et al in Kenya (Matthews T, 1981) ; Kiguli-Malwadde[1] et al in Uganda(Kiguli-Malwadde & Byanyima, 2005) and Ramadhanin Tanzania (Kabala, 2011). It's also in tandem with what Zhanget al found in china that increased subfertility prevalence was higher in similar age groups and women who were of older age in their first marriages.

Most participants were married and this explains the reason why they sought treatment as maybe related to pressure from their spouses. It also depicts the psychosocial aspects of subfertility where women seek children to salvage their marriages. Sekadde-kigonduet al also depicted the social aspects of subfertility in Kenyan communities as a delicate issue(Sekadde-Kigondu, 2005). 3% who were separated actually attributed their marital woes to subfertility. This was also noted among Danish women by Kjaer TKwho established subfertility as a cause of social stress leading to suicide and psychiatric morbidity in these women(Kjaer et al., 2011)

A majority of participants had achieved a higher level of education and hence had presumably better awareness of the diagnostic and therapeutic options for subfertility.

The test for association between the level of education between the participants and their spouses was done. The test was statistically significant revealing that participants with higher level of education were more likely to be married to spouses who had a higher level of education P<0.0001 and in formal employment which explained their health seeking behavior.

This could also be attributed to the fact that the more learned tend to delay childbearing due to other socioeconomic priorities which could lead to subfertility due to their advancement in age. Zhang also found out in china that higher education and adverse occupational conditions were associated with higher subfertility rates.

The lower number of poorly educated participants could be explained by the fact that most of them seek traditional forms of treatment as Kaadaaga found out in a Ugandan study (n=260) that 76.2% subfertile females sought herbal treatment majority being from a rural population.(Kaadaaga et al., 2014)

Ainsworth et al in her study in multiple sub Saharan countries found that only secondary schooling contributed to declining fertility levels. Husband schooling levels however had an indirect relationship via higher contraceptive use in their partners, a fact that was evident in our study.(Ainsworth, Beegle, & Nyamete, 1996; Kitilla, 2010)

5.2 Prevalence of subfertility

The study showed that 28% of the participants had primary subfertility and those with secondary subfertility were 72% which is almost similar to what was found by Mati in Kenya and Ramadhan in Tanzania and by Kiguli-Malwadde et al in Uganda. This

illustrates unchanging proportions over what have been shown previously. However this differs from other studies where primary subfertility is commoner like in China where rates of primary subfertility were double secondary despite overall increasing prevalence of subfertility. Though China has a one child policy that would explain this, persisting trends over time would point to the possibility of untamed risk or causative factors in our own setting. It's also concordant with what was reported by the International Epidemiological Association that secondary subfertility is more common in Sub Saharan countries (Association)

The mean duration of subfertility was 4 years which is similar to other studies done in Nigeria and Tanzania (Bello, 2007)[30]. Most of patients in this study had 2-3 years of subfertility. Kitilla T found in Ethiopia of 5years. Older participants are more likely to have a longer duration of sub-fertility(Kitilla, 2010). Notably patients with primary subfertility took slightly longer to seek care. This long duration could be due to fear of patients in seeking early medical advice fearing for marital disharmony or unawareness of the importance of early treatment among the sub-fertile couple.

The availability of alternative traditional healing practices could be an important contributory factor for the delay in coming earlier to health facilities especially with poorly educated patients. Fatemeh R et al in Iran found out that psychological stress resulting in anxiety disorders and depression peaked at between 4 – 6 years subfertility duration and spur seeking of treatment in this groups (Fatemeh R, 2004)

There was minimal or no association as per this study among the 10% of participants who had previously undergone surgery ($p=0.067$) unlike in Nigeria where Famurewa et al

found significant association(Famurewa, Adeyemi, Ibitoye, & Ogunsemoyin, 2013). This relationship could beartefactual in view of the low number of participants who had history of surgeries done and so the study was not sufficiently powered to determine association. It was notable that all the patients with previous pelvic surgical experience presented among the secondary subfertility group.

Contraceptives were used by more than half of the participants. This would probably mean there's increased uptake of contraceptives and mostly non barrier forms among urban married women. There was no association noted between use of contraceptives for whatever period of time and development of anatomical abnormalities of the uterus and fallopian tubes potentially because of the small sample size.Ainsworth et alfound out that in sub-Saharan Africa a positive correlation existed between secondary level of schooling leading to increased contraceptive use and reduced fertility levels.

STI history wasn't shown to have any association with the defects unlike what Famorewa found in Nigeria; again this could be a result of biased history from participants who came from a rather conservative background [38]

5.3 Radiological findings on HSG

A minority5 (6%) had repeat HSGs after initial abnormal HSG report with better expectations. All except one got similar interpretations showing minimal variability among interpreters as Glatstein IZ et al found that inter-observer variability deferred according to pathology. It also demonstrates the psychological stresses that women undergo leading to denial of initial negative results leading to them seeking second opinion[(Glatstein et al., 1997).

Most participants (85%) had normal uterine findings while congenital abnormalities of the uterine were not identified among the study group with the commonest uterine pathology showed by this study being presence of uterine filling defects mostly due fibroids, polyps and probably endometriosis (13%) detected by the HSG.

Other abnormal findings like irregular uterine mucosal detail and synechiae was seen in 2% of respondents and in all cases in patients who had undergone interventional gynecological procedures.

HSG has a high specificity of 80% and low sensitivity of 65% for detecting tubal patency(Lim, Hasafa, Bhattacharya, & Maheshwari, 2011) Another study showed that MSCT-HSG is as accurate as laparoscopy in the diagnosis of tubal patency or blockage . Therefore due to its high specificity, HSG is a useful test for ruling out tubal obstruction. When patency is demonstrated in HSG, there is little chance that the tube to be actually occluded and should be first line investigation in female subfertility.

Most patients in this study (54%) were found to have tubal pathology which is similar to what was reported in Uganda, Tanzania, and Nigeria. Unilateral and/or bilateral tubal blockage accounted for 46%. This could be attributed to the previously assumed causative factors that led to mechanical tubal occlusion e.g. pelvic infections, surgeries. Women with increased durations of subfertility were more likely to suffer from tubal pathology than the ones with short lasting subfertility.

In our study majority of patients with tubal blockage were of older age (31-45years) in both types of infertility. This same result was reported in the literature previously in

Tanzania and Nigeria. This could be due to the increased risk of acquiring pelvic infection with age.

No statistically significant association between duration of sub-fertility and structural defects indicating occurrence among the participants at any duration of sub-fertility with no sufficient evidence to associate some length of duration with the development or emergence of tumours. However, risk for tubal pathology increases with longer durations of subfertility.

There was a significantly higher risk of having tumours in the uterus among the participants with primary sub-fertility compared to those who had secondary sub-fertility. However, there was no statistically significant differences in the risks of having defective fallopian tubes between the two Al Subhi et al found out that whereas there were aetiological differences there was no significant difference in prevalence of tubal pathology in both groups.

CHAPTER SIX: CONCLUSIONS, RECOMMENDATIONS AND LIMITATIONS

6.1 Conclusions

- Most subfertile women presenting in MTRH were married literate and with a mean age of 31years.
- Secondary subfertility was commoner than primary among the subfertile women
- The commonest uterine pathology was uterine masses presenting as filling defects and were more common in those with primary subfertility
- Bilateral distal tubal occlusion was the commonest tubal defect with similar frequency of occurrence in both subfertility subtypes.
- Older age above 30 years was linked with presence of uterine structural abnormality.

6.2Recommendations

1.There is need to do larger scale studies in the area of subfertility and more so associations with previously known risk factors e.g. pelvic surgery ,sexually transmitted infections and hence help curtail the incidence of subfertility.

2. Increase awareness on reproductive health and subfertility and importance of early intervention

6.3 Limitations

1. Due to the study design and information bias because the respondents may not have given accurate information .The study was only able to ascertain the prevalence based on women who seek services only from MTRH and so would not be representative .
2. Inadequate MTRH hospital records
3. Inability of HSG to conclusively determine all uterine structural abnormalities

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APPENDICES

APPENDIX I: DATA COLLECTION FORM

You are invited to participate in a study that seeks to determine the Pattern of findings at Hysterosalpingography (HSG) among infertile women at MTRH-ELDORET. The research is purely for learning purposes and any information given will be confidential. The findings of this study will be disseminated through Continuous Medical Education to the MTRH administration and various stakeholders with specific recommendations for ways of improving health care. While the Thesis that will result from this research will help the principal researcher to fulfil the requirements for the Awards of Master of medicine (MMed) of Moi University, Eldoret and for publication or reference purposes

PART I: DEMOGRAPHIC DATA

1. Date of birth ----------
2. Residence ----------
3. Nationality ----------
4. Marital Status of mother

   Single (never married) [ ] Married [ ] Divorced [ ] Widowed [ ] Separated [ ] other specify-------

5. Level of Education of mother

   None [ ] Primary [ ] Secondary [ ] College/University [

6. Level of education of spouse

   None [ ] Primary [ ] Secondary [ ] College/University

7. Form of employment of mother

   Formal sector employee [ ] informal sector employee [ ] unemployed [ ]

B.GYNAECOLOGICAL HISTORY

Last menstrual period…….

Parity……

Gravida……..

Duration in years since last delivery…….

Contraceptive use……duration……..

Known co-morbidities……

8. Subfertility type primary [ ] secondary [ ]

9 Duration of subfertility 1yr [ ] 2-3yr [ ] 4-5yr [ ] >5 yr [ ]

9b.Previus history of pelvic surgery Yes [ ] No [ ]

9c. previous history of pelvic infection Yes [ ] No [ ]

C.RADIOLOGICAL/IMAGING HISTORY AND FINDINGS

10. Number of times investigations done once [ ] more than once [ ]

If more results of initial exam……

11. Results of examination……

- Uterus

Normal [ ]

Congenital abnormality [ ]

Filling Defects [ ]

Others [ ]

- Fallopian tubes

  Normal [ ]

  Unilateral hydro-salpinx [ ]

  Bilateral hydro-salpinx [ ]

  Right tube normal left blocked [ ]

  Left tube normal left blocked [ ]

  Bilateral tube blockage [ ]

  Extra-uterine/adnexal pathology [ ]

The questionnaire has come to an end Thank you very much for your participation

APPENDIX II: CONSENT FORMS

Study Title: PATTERNS OF FINDINGS OF HYSTEROSALPINGOGRAPHY (HSG) AMONG SUBFERTILE WOMEN IN MTRH

Name of Principal Investigator(s): VICTOR OUMA (MMED STUDENT) MOI UNIVERSITY, SCHOOL OF MEDICINE, BOX 4606, ELDORET.

Part I: Information Sheet

Introduction: You are being asked to take part in a research study voluntarily. This information is provided to tell you about the study. Please read this carefully and ask questions. Saying no will not affect your rights to health services. You are also free to withdraw at any time. You will be notified if new information becomes available about the risks or benefits of this research.

Are there benefits to taking part in the study?

There will be no direct benefits from participating in the study. However, the findings and recommendations of the study will benefit the hospital by create a local database on patterns of subfertility causes based on radiological / hysterosalpingography findings and also help in coming up with new intervention protocols based on findings from the local setting to be used in management of patients with subfertility.

Purpose of the study: This study is purely meant for academic purposes. The aim is to give evidence based information on most common gynaecological structural abnormalities that result in either primary or secondary infertility

Procedure: The research entails registration of patients with subfertility and who have been sent for HSG. The investigation will be done by qualified personnel in radiology department. The results will be then recorded using coded numbers for later analysis.

Information confidentiality

All reasonable efforts will be made to keep your protected information (private and confidential. As part of the study, Dr.Ouma and the study team may share the results of your HSG. These may be study or non-study related. They may also share portions of your medical record, with the groups named below:

- The National Bioethics. Committee,
- The Institutional Review and Ethics Committee.

Part II: Consent of Subject:

I have read or have had read to me the description of the research study. The investigator or his/her representative has explained the study to me and has answered all of the questions I have at this time. I have been told of the potential risks, discomforts and side effects as well as the possible benefits (if any) of the study. I freely volunteer to take part in this study.

_____	_____	
Name of Participant	Signature of subject/thumbprint	Date & Time
_____	_____	___
Name of Representative/Witness	Relationship to Subject	
_____	_____	
Printed name of Investigator or Investigator	RA Date	Signature of

APPENDIX III: FOMU YA KUKUBALI KUSHIRIKI UTAFITI

Study Title: "matokeo ya kipimo cha HSG kuonyesha Magonjwa yaletayo utasa Kwa wanawake katika chumba cha uzazi Na mirija yaKupitisha mbegu"

JINA LA MTAFITI MKUU: VICTOR OUMA CHUO KIKUU CHA MOI , SLP 4606, ELDORET.

Sababu ya utafiti ; utafiti sababu zinazo sababisha ugumba kwa kutumia kipimo Kinaitwa HSG kwa wagonjwa wenye matatizo ya kupata mimba wanaotibiwa katika Hospitali ya MTRH kuonyesha magonjwa mbalimbali katika chumba cha uzazi na mirija ya kupitisha mbegu za uzazi ambayo yanasababisha tatizo hili la ugumba

Mtindo wa utafiti;Kama unakubali kushiriki kwenye utafiti huu kwa hiari yako, utaulizwa maswali, utapimwa chumba cha uzazi na mirija yakupitisha mbegu za uzazi kwa kuingiza dawa uke nina kasha kupiga picha kwa kutumia mionzi inayoitwa x-rays. Majibu ya picha zako yataingizwa kwenye kompyuta na nambari ya utambulisho; jina lako halitatumika kwenye maelezo ya utafiti.

Madhara; Tunategemea kwamba hakuna madhara yoyote makubwa yatokanayo na utafiti huu,Zaidi yakusikia maumivu kiasi wakati wa kufanya kipimo na matone kidogo ya damu baada ya kumaliza kipimo. Kipimo hiki hakina athari yoyote kwa afya yako Tunatumaini kwamba taarifa zitakazo patikana zitawanufaisha wengine pia.

Kama una Maswali au maelezo kuhusu utafiti huu wasiliana na mtafiti –

Dr. Victor Ouma,

MTRH, P.O. Box 3,Eldoret

Je,umekubali kushiriki?

NDIYO [ ]

HAPANA [ ]

Mimi……..nimesoma maelezo na Maswali yangu yamejibiwa na nimekubali kushiriki kwenye utafiti huu.

Sahihi ya Mshiriki……

Sahihi ya mtafiti …….

APPENDIX IV: HYSTEROSALPINGOGRAPHY PROCEDURE PROTOCOL

- Eligible patients scheduled day 7-10 of cycle, not pregnant or PDT negative
- Procedure quality control; patient preparation/education advised; infection control protocols adhered to.
- History on adverse contrast reactions sought and equipment and medications for treating emergencies availed
- Antispasmodics given within 8 hours of procedure.
- Antibiotics where pelvic infection possible

Procedure

- Phillips diagnost 15 plus conventional fluoroscopy machine.
- Conducted by qualified personnel only and interpreted by qualified radiologist
- 15-20mls of water soluble contrast by use of Leech-Wilkinson cannula injected under fluoroscopic control after elimination of air.
- 3 images:
  - Uterine
  - Tubal and
  - Peritoneal spillage
- Proper documentation of findings privately and confidentially

APPENDIX V: BUDGET

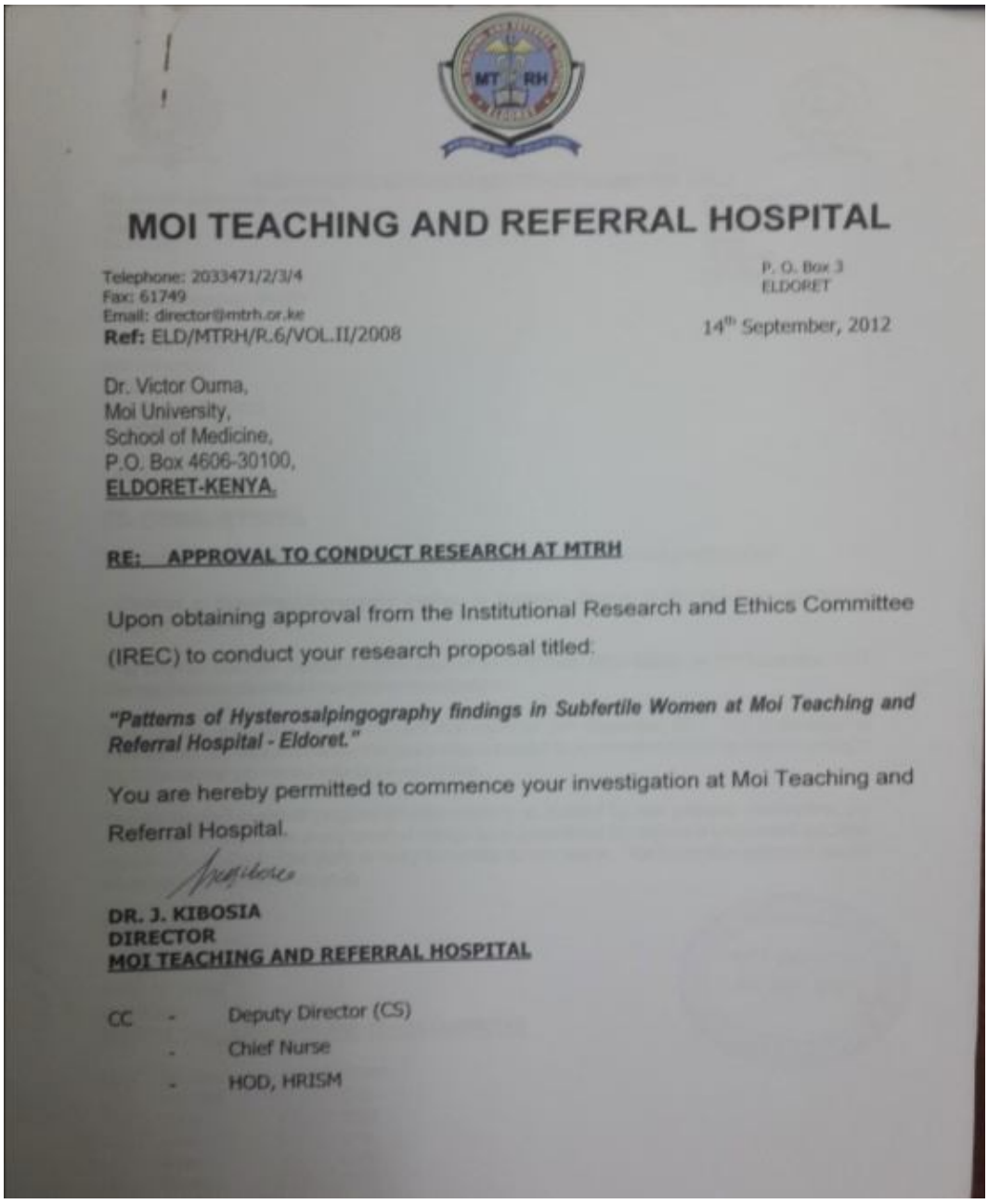
Item	**Quantity**	**Unit cost in KSh**	**Totals in KSh**
Personnel Subsistence			
Radiologists (141 Films)	2	1,000	282000
Radiographers	1	500	70,500
Research assistants	2	500	70,500
Sub-Total			**423,000**
Data Handling			
Printing	2,000	10	20,000
Photocopying	4,000	2	8,000
CDs (CT Images Storage)	141	20	3,000
Printing/ Photocopying Paper	10 reams	500	5,000
Flash Disk 4Gb	1	2,500	2,500
File folders	10	50	500
Biro Pens	25	20	500
Pencils & Rubbers	10	20	200
Rulers	10	30	300
Cartridges	2	2000	4000
Sub-Total			**44,000**
Data processing			
Statistician	1		20,000
Secretarial Services	1		10,000
Data Entry Clerks	1		7,500
Sub total			**37,500**

Equipment		
Digital Camera	1	15,000
Computer (Laptop)	1	50,000
Printer	1	5000
Sub-total		**70, 000**
Communication		10,000
Publication		50,000
Sub-total		**60,000**
Contingencies – 10%	**Misc.**	**63450**
GRAND TOTAL		**697,500**

APPENDIX VI; TIME SCHEDULE

Activity	Time period	Duration
Consultation with Supervisors, **-Literature review/search** **- Review of proposal by supervisors** **-Submission of proposal to IREC**	**APRIL2012-AUGUST2012**	**4months**
- Recruitment of research assistants **-Testing of data collection tools** **- Training of research assistants** **-pilot study**	**SEPTEMBER, 2012**	**1month**
- Restructuring of data collection tools **- Printing of data collection tools** **- Debriefing of research assistants**	**OCTOBER, 2012**	**1month**
- Actual study; recruitment of study participants performing HSGs, Interviewing subjects/ data collection	**NOVEMBER2012-OCTOBER 2013**	**12months**
Data entry and analysis	**NOVEMBER2013**	**1month**
- Draft report writing and Consultation with supervisors	**DEC,2013-JANUARY 2014**	**2months**
Report writing and submission	**FEBRUARY-MARCH,2014**	**2months**

APPENDIX VI1: MTRH APPROVAL LETTER



MOI TEACHING AND REFERRAL HOSPITAL

Telephone: 2033471/2/3/4
Fax: 61749
Email: director@mtrh.or.ke
Ref: ELD/MTRH/R.6/VOL.II/2008

P. O. Box 3
ELDORET

14th September, 2012

Dr. Victor Ouma,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

RE: APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:

"Patterns of Hysterosalpingography findings in Subfertile Women at Moi Teaching and Referral Hospital - Eldoret."

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

DR. J. KIBOSIA
DIRECTOR
MOI TEACHING AND REFERRAL HOSPITAL

CC - Deputy Director (CS)
- Chief Nurse
- HOD, HRISM