

**EVALUATING MANAGEMENT OF PATIENTS WITH ABNORMAL
UTERINE BLEEDING AT MOI TEACHING AND REFERRAL
HOSPITAL ELDORET KENYA**

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**A RESEARCH THESIS SUBMITTED IN PARTIAL FULFILLMENT
OF THE REQUIREMENT FOR THE AWARD OF THE DEGREE OF
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DECLARATION

Declaration by the Candidate

This research thesis is my original work and has not been presented for a degree or any academic credit in any other University or examining body. This thesis will help us know the clinical bleeding patterns of abnormal uterine bleeding, their causes, management and cost of treatment, it will be a source of information for a new protocol that will guide clinicians in treatment of abnormal uterine bleeding. No part of this thesis may be reproduced without the prior written permission of the author and/or Moi University.

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DEDICATION

This work is dedicated first of all to God, who has made all this possible. I would also like to dedicate this work to my loving family and my teachers who have continued to support and encourage me to excel in my studies.

ACKNOWLEDGEMENT

I would sincerely like to thank my supervisors, Dr. Mwaliko E. and Dr. Kirwa P. for their guidance and support during the development of this research thesis. I would also like to recognize my fellow residents for their encouragement and critique.

LIST OF ABBREVIATIONS AND ACRONYMS

| | |
|-------------------|---|
| AUB | Abnormal Uterine Bleeding |
| CBC | Complete Blood Count |
| CHC | Combined Hormonal Contraceptives |
| COCP | Combined Oral Contraceptive Pill |
| DMPA | Depot Medroxyprogesterone Acetate |
| FIGO | International Federation of Gynaecology and Obstetrics |
| GnRH | Gonadotropin Releasing Hormone |
| HPNCC | Hereditary Non-polyposis Colorectal Cancer |
| HRQoL | Health Related Quality of Life |
| IREC | Institutional Research and Ethics Committee |
| IUS | Intrauterine System |
| IV | Intravenous |
| LNG | Levonorgestrel |
| LNGIUS | Levonorgestrel Releasing Intrauterine System |
| MPA | Medroxyprogesterone Acetate |
| MTRH | Moi teaching and referral hospital |
| NET | Norethindrone (or Norethisterone) |
| NSAIDs | Non-Steroidal Anti-Inflammatory Drugs |
| OCs | Oral Contraceptives |
| PALM-COEIN | (P -polyps, A -Adenomyosis, L -leiomyoma, M -malignancy and hyperplasia C - Coagulopathy O ovulatory dysfunction, E -endometrial, I -iatrogenic, N -not yet classified) |

| | |
|-------------------|---|
| PCOS | Polycystic Ovary Syndrome |
| PTB | Pulmonary Tuberculosis |
| SIS | Saline Infusion Sonohysterography |
| TCRE | Trans Cervical Resection of Endometrium |
| VTE | Venous Thromboembolism |
| VWF | Von Willbrand's Factor |
| WHO | World Health Organization |
| B-HCG beta | Human Chorionic Gonadotropin |

OPERATIONAL DEFINITION OF KEY TERMS

Acute abnormal uterine bleeding is an episode of bleeding in a woman of reproductive age, who is not pregnant, that is of sufficient quantity to require immediate intervention to prevent further blood loss.

Chronic abnormal uterine bleeding that is abnormal in duration, volume, and/or frequency and has been present for most of the last 6 months.

An intangible cost is an unquantifiable cost relating to an identifiable source. Intangible costs represent a variety of expenses such as losses in productivity, customer goodwill or drops in employee morale

Breakthrough bleeding is vaginal bleeding usually referring to mid-cycle bleeding in users of combined oral contraceptives as attributed to insufficient oestrogens.

Heavy menstrual bleeding is excessive menstrual blood loss which interferes with the woman's physical, emotional, social, and quality of life.

Intermenstrual (metrorrhagia) bleeding is irregular episodes of bleeding, often light and short, occurring between menstrual periods

Oligomenorrhoea is infrequent bleeding at intervals > 38 days apart (1 or 2 episodes in a 90-day period).

Polymenorrhoea is frequent bleeding i.e. is at intervals <24 days apart (More than 4 episodes in a 90-day period).

Post coital bleeding is bleeding that occurs after intercourse.

Prolonged menstrual bleeding is menstrual blood loss that exceeds 8 days duration.

Shortened menstrual bleeding is menstrual bleeding less than 2 days in duration.

Withdrawal bleeding is predictable bleeding resulting from abrupt progestin cessation.

Saline Infusion Sonohysterogram (SIS) is a procedure in which fluid is instilled into uterine cavity transcervically to provide enhanced endometrial visualization during ultrasound scan.

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ABSTRACT

Background: Abnormal uterine bleeding (AUB) affects 3% to 30% of women in their reproductive age globally. The condition further interferes with the socioeconomic status and overall quality of life of the affected women. Despite this, there are limited studies evaluating the management of women with abnormal uterine bleeding in resource limited settings. PALM-COEIN (Polyp; Adenomyosis; Leiomyoma; Malignancy and Hyperplasia; Coagulopathy; Ovulatory dysfunction; Endometrial; Iatrogenic; and Not yet classified) guideline for structural and functional causes of AUB gives a consistent and universally accepted nomenclature as well standardises clinical care and research.

Objective: To evaluate proportion, patterns of presentation, management methods and cost of treatment of women with abnormal uterine bleeding at Moi Teaching and Referral Hospital (MTRH).

Methods: This was a cross sectional study conducted at the gynaecology department of MTRH between April 2nd, 2018 and April 1st, 2019. A census of 108 women aged between 18 to 45 years with confirmed abnormal uterine bleeding was done. Their sociodemographic and clinical characteristics were collected using a structured questionnaire through interviews and chart reviews. PALM COEIN was used to assess adherence to diagnosis. Data analysis was performed using SPSS version and variables with a p-value of <0.05 considered statistically significant.

Results: The participants median age was 30 (IQR: 22, 41) years. The proportion of women seeking gynecological care at MTRH with AUB was 3.96% (n=231) of whom 108 were enrolled into the study. Prolonged bleeding was the most predominant pattern at 41.7% (n=45), followed by heavy bleeding at 35.2% (n=38). Bleeding patterns were associated with age (p=0.04). PALM-COEIN diagnosis guidelines were adhered to among 16.7% (n=18) of all the participants. Initial laboratory evaluation included thyroid stimulating hormone, complete blood count and pregnancy tests; followed by hormonal profiling. Abdominopelvic ultrasound was done for 79.6% (n=86) while only 8.3% (n=3) of women older than 35 years had a biopsy. Leiomyoma was the common cause of AUB 48(44.5%), followed by endometrial causes (17.6%). PALM and COEIN accounted for 60% and 40% respectively. Medical management was provided for 78.7% of women. Cost for surgical management was higher than medical management with a cost difference of KSh.19, 000. Length of hospitalization was associated (p<0.001) with high cost of treatment.

Conclusion: Proportion of women with abnormal uterine bleeding was within known ranges but generally lower than those reported in previous studies. Prolonged bleeding was the commonest bleeding pattern. Less than one third of the women were diagnosed as per the PALM-COEIN criteria. Medical management was more commonly used due to its low cost in the short term.

Recommendation: Women presenting with prolonged uterine bleeding should be assessed for AUB. There is need for in-hospital algorithms to ensure AUB diagnosis in accordance to PALM-COEIN guidelines. Surgery should be recommended over medical management due to its long-term cost effectiveness.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

The global prevalence of abnormal uterine bleeding (AUB) among women is between 3 - 30% (Liu et al., 2007). This accounts for about one third of outpatient gynaecology visits. Abnormal uterine bleeding (AUB) affects quality of life leading to socioeconomic and psychological consequences (Liu et al., 2007). Normal menstrual flow is dependent on temporal and quantitative regulation of reproductive hormones (hypothalamic-pituitary-ovarian axis), mediated by prostaglandins following degeneration of the corpus luteum. Therefore the Use of PALM-COEIN classification reduces general inconsistency description of AUB in clinical and research settings.

The presenting complaints among patients with AUB are variable. They may be acute or chronic depending on their duration. This clinical pattern is determined by the heaviness, duration of flow, regularity and frequency.

The diagnosis of women with AUB involves laboratory and imaging techniques. In the laboratory, the most commonly ordered tests include: complete blood count, hormonal profile and histology of focal lesions of the endometrium (Kotdawala et al., 2013). Radiologically, transvaginal ultrasound, diagnostic hysteroscopy (discrete intrauterine abnormalities) and magnetic resonance imaging are the most ordered imaging techniques (Abdullahi et al., 2016).

The management for women with AUB is either medical or surgical. Medical management is the first line therapeutic option once malignancy and pelvic pathology have been ruled out (Walraven et al., 2001b). Medical management adopts hormonal (combined oral contraceptives, levonorgestrel intrauterine system, progesterone only pills, gonadotrophin releasing hormone agonists and antagonists) and non-hormonal (non-steroidal anti-inflammatory drugs, tranexamic acid) interventions. On the other hand, surgical Management includes both minimal invasive techniques such as endometrial ablation for heavy menstrual bleeding (Sioban D. Harlow & Campbell, 2004) and invasive techniques such as hysterectomy and myomectomy. Hysterectomy is the definitive solution with high rates of patient satisfaction (Weber, 1999).

The cost of management of women presenting with AUB are categorized as either direct or indirect costs. The direct costs include physician visits, investigations, hospitalization and medication costs (I. Fraser et al., 2007; Liu et al., 2007). The indirect costs associated with management increase the burden for those patients who pay out of their pockets and need longer follow-up.

1.2 Problem Statement

Although the PALM-COEIN classification guideline is the gold standard for abnormal uterine bleeding; it is not commonly used in many clinical settings leading to a lack of standardization and implementation in the diagnosis of women with abnormal uterine bleeding. There is limited documented studies on the bleeding patterns and management guidelines for women with abnormal uterine bleeding in Kenya. Management of

abnormal uterine bleeding has been reported to be costly by studies done in other settings, further complicating patient management and outcomes.

1.3 Justification

This study aimed at determining level of adherence to PALMCOEIN classification of abnormal uterine bleeding. This condition affects both the patient's quality of life and wellbeing. By determining the proportions of women presenting with abnormal uterine bleeding at MTRH, it will be possible to plan for various management options available. The knowledge of clinical presentation patterns of abnormal uterine bleeding will be used in putting in place control strategies. Evaluation of management strategies and their conformity to guidelines will create new knowledge on what aspects to be modified. Knowledge of management costs incurred by women presenting with abnormal uterine bleeding will inform policy makers on available care financing options.

1.4 Significance

The third sustainable development goal is to achieve good health and well-being by ensuring healthy lives and promote well-being at all ages. This study provided information that will expand existing knowledge on bleeding patterns, management and the cost incurred by women with abnormal uterine bleeding seeking care at Moi Teaching and Referral Hospital (MTRH) in Western Kenya.

1.5 Research Questions

What are the proportions, presentation patterns, management and costs of treatment of abnormal uterine bleeding at MTRH?

1.6 Objectives

1.6.1 Broad Objective

To evaluate the proportion, presentation patterns, management methods and costs of treatment among women presenting with abnormal uterine bleeding at MTRH.

1.6.2 Specific Objectives

1. To describe the proportion of women presenting with abnormal uterine bleeding among all gynaecology patients seen at MTRH.
2. To determine the clinical bleeding patterns among women presenting with abnormal uterine bleeding at MTRH.
3. To describe the management techniques and costs incurred by women presenting with abnormal uterine bleeding at MTRH.

CHAPTER TWO

2.1 LITERATURE REVIEW

2.1 Introduction

Abnormal uterine bleeding accounts for one third of outpatient gynaecology visits and the prevalence in reproductive age women is 9 to 30% (Liu et al., 2007). The incidence of heavy menstrual bleeding increases with age and peaks prior to menopause. Abnormal uterine bleeding account for up to two thirds of all hysterectomies performed worldwide (Kotdawala et al., 2013). The signs, symptoms and complications arising from abnormal uterine bleeding include fatigue and iron deficiency anaemia in up to 30% of cases.

Abnormal uterine bleeding results in social, economic and psychological consequences thereby diminishing the quality of life (Liu et al., 2007). The general process for evaluating patients who present with acute AUB can be approached in three stages by assessing rapidly the clinical picture to determine patient acuity, then determining most likely aetiology of the bleeding, and lastly choosing the most appropriate treatment for the patient.

2.2 Proportion of women presenting with AUB among all gynaecology patients.

Abnormal uterine bleeding affects up to 50% of menstruating women worldwide at some point in their life. Approximately 9 to 30% of reproductive age women suffer from heavy menstrual bleeding (Hurskainen et al., 2004) and prevalence increases with age and peaks prior to menopause due to hormonal imbalance. Menorrhagia and uterine fibroids account for up to 75% of all hysterectomies performed worldwide (Hurskainen

et al., 2004). A Study done in rural Gambia on reproductive organ morbidity revealed that menstrual dysfunction is quite common in women of reproductive age (Walraven et al., 2001a). In the Gambian study, the authors attributed the high frequencies reproductive-organ disorders to a high disease burden that could be partly silent in the rural settings (Walraven et al., 2001a). The target population of the current study is a mixture of women living in both the peri urban and rural settings. This study targeted adult women who are still having their menstrual cycles and aged between 18 to 45 years. The upper limit of 45 years was selected to avoid the hormonal imbalances associated with the perimenopausal period among women older than 45 years. This was to make it comparable with previous studies that targeted the same age group.

2.3 Clinical bleeding patterns among women presenting with AUB

2.3.1 Normal Menstrual Cycle

Generation of a cyclic, controlled pattern of menstrual bleeding requires a precise temporal and quantitative regulation of reproductive hormones (Dasharathy et al., 2012). The hypothalamic-pituitary-ovarian axis must be functional. The hypothalamus releases gonadotropin-releasing hormone (GnRH) to the anterior pituitary gland through the portal circulation in a pulsatile manner (Bradley & Gueye, 2016). GnRH stimulates the synthesis and release of gonadotropins: Luteinizing Hormone (LH) and Follicular Stimulating Hormone (FSH) by the gonadotropic cells of the anterior pituitary gland. Gonadotropins enter the peripheral circulation and act on the ovary to stimulate both follicular development and ovarian hormone production. Development of a mature follicle results in rapid rise of oestrogen levels, which acts positively on the anterior pituitary to cause an LH surge (Dasharathy et al., 2012). Circulating oestrogens also

stimulate development of a thickened, proliferative endometrial lining (Bradley & Gueye, 2016). Following ovulation, LH stimulates luteinisation of the follicular granulosa cells and surrounding theca with formation of the corpus luteum (Khrouf & Terras, 2014). The corpus luteum produces oestrogen and high levels of progesterone, which converts the endometrium to a secretory pattern. If pregnancy occurs, the corpus luteum is 'rescued' by human chorionic gonadotropin (HCG) from early trophoblastic cells (Sahai et al., 2013). If pregnancy does not occur, progesterone and oestrogen production ceases, the corpus luteum regresses and endometrial sloughing occurs. The pattern of this bleeding varies in duration and amount between women but should be relatively constant across cycles for everyone. Normal frequency of menstruation cycle is 24 to 38 days. It's a regular (cycle to cycle variation over 12 months) if variation is of within 2 to 20 days. Normal duration of menstrual flow is 4.5- 8days, while the normal Volume of monthly loss is between 5 and 80 ml.

2.3.2 Pathophysiology of AUB

Withdrawal of both oestrogen and progesterone following degeneration of the corpus luteum is believed to result in the menstrual blood flow through mechanisms mediated by prostaglandins (Munro et al., n.d.). Other multiple factors that are modulated by the sex hormones oestrogen and progesterone may result to different patterns of abnormal uterine bleeding (Hileeto et al., 2005). Abnormal uterine bleeding is believed to occur as a result of the derangement of the cyclical sex hormonal stimulation orchestrated by follicular development and formation of corpus luteum and its degeneration (Hartmann et al., 2013). The current study assessed abnormal bleeding patterns prospectively to

offer new knowledge in Western Kenya, as Hartman et al., 2013 reviewed previously published studies.

Menstrual bleeding occurs mostly from the upper two-thirds of the uterine cavity. This follows tissue necrosis of the endometrium associated with disruption of microvasculature, as well as the release of tissue necrosis factors released from migratory leukocytes with deposition of platelet/fibrin thrombi in small blood vessels (Silverberg, 2000). The molecular events underlying the endometrial tissue and vascular breakdown are related to the release of proteolytic enzymes from lysosomes of endometrial inflammatory cells. The cyclical hormonal stimulation of endometrial growth by oestrogen during the follicular phase of the menstrual cycle, followed by oestrogen and progesterone after ovulation, is the mainstay of normal development of the proliferative and secretory endometrium, respectively.

In abnormal uterine bleeding endometrial tissue breakdown located in the superficial layer (subsurface) of the endometrium occurs either focally in scattered areas of the endometrium (resulting in breakthrough spotting) or diffusely throughout the endometrial cavity (resulting in heavier withdrawal bleeding). Such derangements of endometrial tissue necrosis are believed to occur due to vascular alterations that are associated with continuous oestrogen stimulation unopposed by progesterone or irregular progesterone stimulation due to dysfunctional corpus luteum. Proliferative endometrium is encountered in anovulatory AUB (Mahapatra & Mishra, 2015a).

2.3.3 Clinical Patterns of women presenting with AUB

Thorough history and physical examination will often indicate the cause of AUB and therefore direct the need for further investigation and treatment. Abnormal uterine bleeding can present as heavy menstrual bleeding and or prolonged menstrual bleeding (Fairbanks & Sams, 2013). Presenting complaints are variable depending on timing of visit to the clinician (Betha et al., 2017). This is determined by occurrence of the presentation whether acute or chronic. Acute severe bleeding may lead to severe anaemia and hypovolemic shock unlike chronic bleeding. Severity of bleeding is greatly affected by factors like inability to timely access to health services in which leads to delay in management.

The causes of AUB according to the International Federation of Gynaecology and Obstetrics (FIGO) can be structural - PALM (Polyp; Adenomyosis; Leiomyoma; Malignancy and Hyperplasia;) or Non-structural-COEIN(Coagulopathy; Ovulatory dysfunction; Endometrial; Iatrogenic; and Not yet classified)(Fairbanks & Sams, 2013). The term DUB was used before as a diagnosis when there was no systemic or locally definable structural cause for AUB (Begum & Khanam, 2014). It is not included in the new system of classification and should be abandoned because these women usually have either a coagulopathy, ovulatory or primary endometrial disorder. The mnemonic PALM-COEIN classifies causes of abnormal uterine Bleeding (Qureshi & Yusuf, 2013)as **P**-polyps, **A**-Adenomyosis, **L**-leiomyoma, **M**-malignancy, and hyperplasia **C**-coagulopathy **O**-ovulatory dysfunction, **E**-endometrial, **I**-iatrogenic, **N**-not yet classified.

Family history of coagulation disorders, PCOS, endometrial and colon cancer may be present because these conditions have a genetically determined predisposition (Khrouf & Terras, 2014). Furthermore, drug history such as the use of over the counter drugs, herbal remedies that may interfere with ovulation or be associated with bleeding.

History may reveal symptoms of anaemia such as dizziness, light headedness, mood swings, fatigue and dyspnoea with activity. The sexual and reproductive history should explore the use of contraception, risk for pregnancy, desire for future pregnancy, infertility, cervix cancer screening and previous STIs. Impact on social and sexual functioning, quality of life should be evaluated. Symptoms suggesting systemic causes of bleeding e.g. hypothyroidism, coagulation disorders, PCOS, adrenal or hypothalamic disorders may be present. Other associated symptoms such as vaginal discharge, odour, pelvic pain or pressure may be present (I. S. Fraser et al., 2009).

General examination may reveal symptoms such as pallor resulting from anaemia and jaundice in liver disease. Abnormal weight/BMI and enlarged thyroid gland may be present. Pallor, bruising, hirsutism, petechial haemorrhage may occur on the skin. Palpable mass can be found on abdominal pelvic exam and rectal exam can reveal bleeding if there is concomitant recto anal pathology.

Other disease in the ovary, fallopian tube and vagina may affect the endometrial lining of uterine cavity that result in abnormal bleeding and should be sought for while evaluating women with AUB (Abdullahi et al., 2016).

2.4 Management techniques and costs incurred by women presenting with AUB at MTRH.

The society of obstetricians and gynaecologists of Canada (SOGC) developed guidelines for the management of abnormal uterine in pre-menopausal women in 2001. This guideline was reviewed by the Clinical Practice – Gynaecology Committee and updated in 2013 (Fairbanks & Sams, 2013). This current study premises its management guidelines on the SOGC recommendations.

2.4.1 Clinical Investigations for AUB

Several tests may be done to evaluate AUB but this may greatly be hampered by financial constraints, inadequate laboratory or imaging services or lack of proper infrastructure and inadequate health workers. At MTRH most if not all except hysteroscopy are done in evaluation of patients with AUB.

Endometrial biopsy is done in bleeding women over 35 years because of associated risk of endometrial hyperplasia and cancer or in those with bleeding unresponsive to medical therapy (Sahai et al., 2013). It's also done in younger women with risk factors from endometrial cancer. Endometrial sampling for biopsy can be done in any age group. Outpatient endometrial biopsy using pipelle endometrial suction curette or cannula should replace dilation and uterine curettage as the initial assessment of the endometrium for these women (Shubham & Kawthalkar, 2018). Focal lesions of the endometrium that require biopsy should be managed through hysteroscopy-guided evaluation (Kotdawala et al., 2013). Computed tomography scanning is used primarily

for evaluation of other causes of acute abdominal or pelvic pain. MRI is used primarily for cancer staging.

2.4.2 Medical and Surgical Management of women with AUB

Treatment encompasses several options depending on findings on history taking, examination, laboratory, imaging studies and definitive diagnosis of the patient (Fairbanks & Sams, 2013). Treatment can be medical or surgical. Medical management can be either non hormonal or hormonal (Fairbanks & Sams, 2013; Haththotuwa et al., 2011). Medical management is first line therapeutic option for AUB once malignancy and pelvic pathology have been ruled out (Walraven et al., 2001a). Management involves treating any complication first e.g. uses of Iron supplements for anaemia (de Vries et al., 2008). Regular heavy menstrual bleeding can be treated successfully by both hormonal and non-hormonal options (Walraven et al., 2001a). Irregular or prolonged bleeding is most effectively treated with hormonal options which regulate cycles, decreasing the likelihood of unscheduled and potentially heavy bleeding episodes. Medical treatment of heavy menstrual bleeding is effective for many women. Treatment with the LNG-IUS may be comparable to surgical options for improving quality of life (Hartmann et al., 2013). In sub Saharan Africa treatment is greatly hampered by financial constraints, unavailability of treatment options, inadequate health workers hence affecting quality of life of women with AUB.

Role of surgery in the treatment of AUB requires a thorough evaluation of the underlying pathology and patient factors (Hurskainen et al., 2004; Showstack et al., 2006). Endometrial ablation is a minimally invasive surgical option for heavy menstrual

bleeding (Singh et al., 2013). It may be considered in women who have failed medical treatment, have completed childbearing, or who may not be candidates for major surgery (Siobán D. Harlow & Campbell, 2000). There are two methods of endometrial ablation that may be offered at the present time. Either hysteroscopic or none hysteroscopic resection. None hysteroscopic encompasses the use of a heated balloon, a radiofrequency bipolar technology, and a microwave device (Fairbanks & Sams, 2013). Dilatation and curettage is no longer the standard of care for the initial assessment of the endometrium. It is a blind procedure, with sampling errors and risks of complications including uterine perforation, haemorrhage and endometrial adhesions (Kotdawala et al., 2013).

Myomectomy has been demonstrated as a safe procedure for the removal of submucosal fibroids. It is associated with a low complication rate and high patient satisfaction of between 71.4% and 94.0% and low surgical reintervention rates of less than 30% (Van Der Meulen et al., 2018). Polypectomy is a safe surgical treatment for the management of patients with abnormal uterine bleeding in the presence of endometrial polyps that has an acceptable level of satisfaction (De Los Ríos et al., 2015).

Hysterectomy is the definitive solution with high rates of patient satisfaction although less invasive options should initially be considered (Weber, 1999). Hysterectomy is indicated in the following reasons: when a patient has fails to respond to medical therapy or unable to utilize medical therapies due to side effects, or other contraindications. It's also indicated in patients with significant anaemia or concomitant uterine pathology like large uterine fibroids and endometrial hyperplasia. Surgery is

definitive for especially women who have achieved desire for fertility. On the other hand, Oophorectomy involves surgical removal of ovaries and may be performed with hysterectomy (Shahid et al., 2020). It is indicated for patients with abnormal uterine bleeding related to ovarian cancers (Abdullahi et al., 2016; Shahid et al., 2020). Endometrial radiation has a role only in women who have AUB and are found to have endometrial cancer (Silverberg, 2000).

2.5 Cost of Treatment for women with AUB

The likelihood of a patient choosing a given form of management- be it medical or surgical – for abnormal uterine bleeding is highly influenced by the cost of the said management option (I. S. Fraser et al., 2009). Furthermore, the higher the cost of management the more adverse the impact is on the patient's overall wellbeing.

There are many factors that determine direct costs. Disease severity increases direct costs due to complications associated with severe disease and need for possible admission to hospital. Compliance with medication is another factor as those who are not compliant with treatment tend to have relapses in abnormal uterine bleeding and this may need longer periods of treatment. The relative importance of the components which make up direct costs vary widely among the studies. Components include physician costs, cost of hospitalization, cost of drugs, other costs are due to laboratory investigations and radiological tests done (I. Fraser et al., 2007; Liu et al., 2007). For women with AUB we will take the costs incurred while at the hospital and this will help us compare costs as per bleeding pattern and diagnosis as per PALM-COIEN classification (I. S. Fraser et al., 2009).

Information on economic burden of AUB is limited although from systematic reviews suggest that economic costs are high (Singh et al., 2013). These figures do not account for intangible costs and productivity loss at work place due to people who are actually at work but because of complications associated with AUB they don't perform well at work (Liu et al., 2007).

Universal health coverage can help cover patients with abnormal uterine bleeding. Kenya still has a very large uninsured population. It's estimated that only 18% having any form of health insurance coverage in Kenya. Approximately four out of every five Kenyans lack access to medical insurance, meaning that most are just an accident or illness away from destitution (Olbara et al., 2020). Among the poorest, only 3% have health insurance, this provided by the government's National Hospital Insurance (Barasa et al., 2018) Fund (NHIF) . This rises to 42% in the wealthiest where private cover is used. Additionally, there are stark disparities between rural and urban populations, where rates of coverage are an average of 12% and 27% respectively. The aim of universal health coverage is to ensure everyone can use health services they need without risk of financial ruin or impoverishment, despite their socio-economic situation (Sahai et al., 2013). Financial risk protection is one element in the package of measures that provides overall social protection, as well as the protection against severe financial difficulties in the event of illness. This gives the peace of mind that is an integral part of well-being (Sahai et al., 2013).

With high burden of out of pocket payments for patients who may need longer follow-up use of health insurance may help lessen the financial burden for both out and in patient treatment. Current NHIF covers inpatient services and only a few of NHIF clients benefit from outpatient coverage. This Study will evaluate the cost to the patient of various treatment options and for different causes of AUB as to the PALM-COIEN classification. The variables that will determine cost are the aetiology of AUB and the process or type of management during the period of study.

2.6 Conceptual Framework

This study hypothesised that the abnormal uterine bleeding patterns as per the PALMCOEIN classification influences the management options selected. These could be broadly classified as either surgical or medical management of abnormal uterine bleeding. This relationship between the bleeding pattern and management option selected can be affected by the cost of treatment and the patients sociodemographic characteristics such as age, occupation, insurance status among others. Therefore, abnormal uterine bleeding pattern as per the PALMCOEIN classification is the independent variable while the management options are the dependent variables. Cost of treatment and sociodemographic characteristics are the intervening variables (figure 2.1).

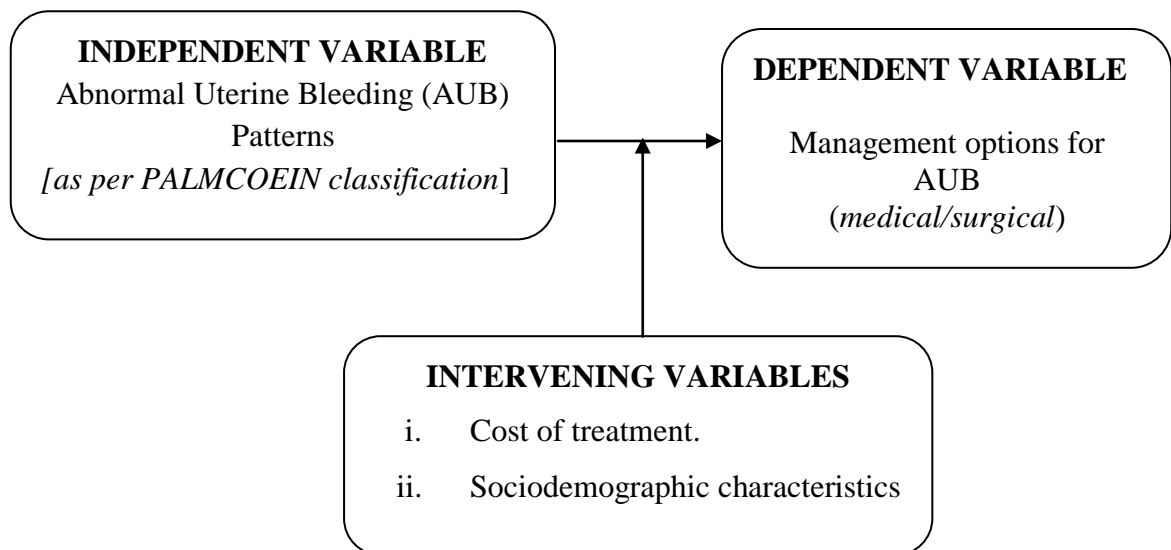


Figure 2. 1: Conceptual Framework

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study design

This study adopted a cross-sectional study design among women presenting with abnormal uterine bleeding from April 2018 to April 2019.

3.2 Study area

The study was conducted at the Moi Teaching and Referral Hospital (MTRH)'s gynaecology wards and outpatient clinics. The facility located in Eldoret, Kenya is the second largest referral hospital in the country and serves parts of the Great Rift Valley and Western regions in Kenya. It also serves parts of Uganda and Southern Sudan. The catchment area has 15 to 20 million people.

3.3 Study Population

This study population was made up of all women seeking gynaecological care at Moi and Teaching Referral Hospital

3.4 Sampling Technique

This was a clinical audit of all cases in study duration. Preliminary data from the MTRH records revealed that 155 and 180 women were confirmed to be having abnormal uterine bleeding (AUB) in 2016 and 2017 respectively. This numbers were too small for sampling to be done hence we recommended census study in that all women confirmed to be having AUB after speculum exam with vaginal and cervical causes ruled out, with negative pregnancy test be enrolled in the period of study. The total number of women seen at the gynaecology ward and gynaecology outpatient clinic of the hospital was compiled over one year to facilitate calculation of the proportion of women with AUB.

3.5 Eligibility Criteria

3.5.1 Inclusion Criteria

Women aged between 18 and 45 years with AUB seeking treatment at MTRH's gynaecology clinic and wards.

Willingness to participate in the study by giving an informed consent.

3.5.2 Exclusion Criteria

Pregnant women confirmed during the study period.

A positive VIA (visual inspection with acetic acid) test

Lower genital tract bleeding.

3.6 Study Procedure

Study population were all gynaecological women seen at MTRH gynaecology clinic and wards. Pregnant patients and those with other gynaecological causes of per vaginal bleeding were omitted. Those who tested positive for visual inspection with acetic acid (VIA) or were either below 18 or above 45 years were excluded. Those who were positive to VIA had lower genital tract bleeding which could have confounded the study findings. The study captured the demographic characteristics of all the women presenting with abnormal uterine bleeding who met the eligibility criteria. After which, further assessment to establish the abnormal uterine bleeding patterns was conducted. These assessments included: taking patient's history or responses from their caretakers and collecting clinical information from the hospital file. The diagnostic tests done, final diagnosis made and treatment given were recorded on the data collection tool. Management costs of treatment for each diagnosis according to PALM-COEIN classification and bleeding pattern were further noted.

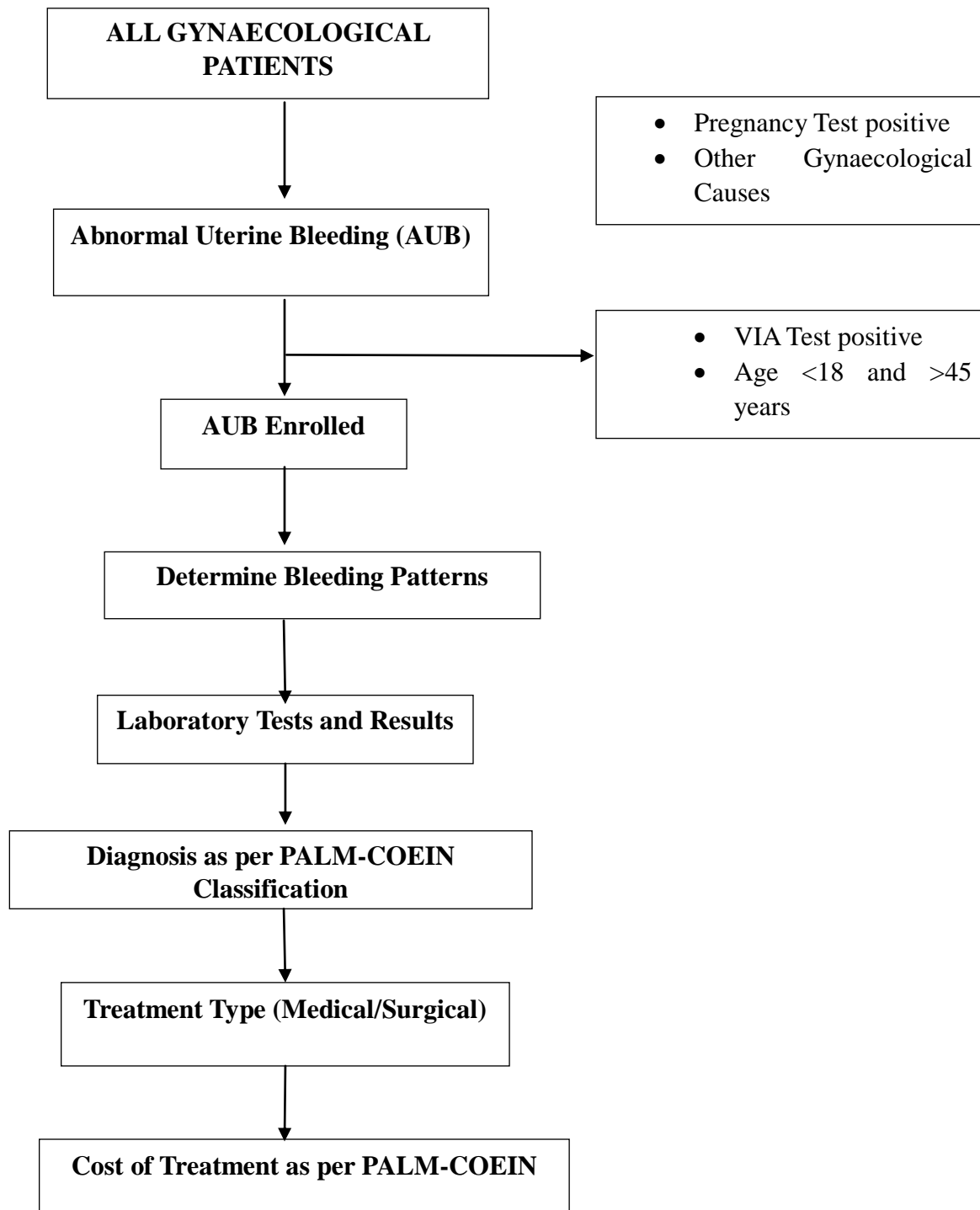


Figure 3.1: Study Flow Chart

3.7 Data Collection, Management and Analysis

3.7.1 Data Collection and Management

Data was collected between 2nd April 2018 and 1st April 2019 using structured questionnaire. The participants who met the eligibility criteria were consented and enrolled at the time of diagnosis by a trained research assistant. The structured questionnaires were administered by the research assistant while the sociodemographic data collection process was overseen by the principal investigator. Clinical data on laboratory, imaging and other clinical investigations was obtained through medical chart reviews by the principal investigator under the guidance of two gynaecologists (supervisors). The cost of treatment was stratified as either direct or indirect costs. The direct cost were those attributable to the treatment option adopted (such as cost of surgery, medical consultation, medication among others). Indirect cost were those not attributable to the patients' management but had to be incurred prior, during and after treatment. These indirect costs included transport costs, loss of worktime, meals and other personal use expenses.

The data collected was entered into a password protected electronic database accessible only to the study investigators. The questionnaires were kept in a safe cabinet under a lock, and the key held by the investigator alone once data entry was completed. Patient's identity was encrypted to prevent unauthorized access. Serial numbers were used in order to protect patients' identity. At the end of each day data collection forms were verified for completeness and coded appropriately. For quality assurance validity was ensured by pilot study of 12 participants with abnormal uterine bleeding done prior to

data collection. I also trained research assistant on abnormal uterine bleeding and the questionnaire layout and contents. Data cleaning was done on a daily basis.

Participants from the wards were enrolled at discharge to compute costs of treatment. Those enrolled from the gynaecology clinic as outpatients was after treatment had been offered.

Study variables (such as various forms of uterine bleeding) were measured based on the clinical diagnosis made by the attending clinician and compared to the PALMCOEIN classification guidelines for abnormal uterine bleeding.

3.7.2 Data Analysis

Data analysis was done using software for statistical package for social sciences (version 24). Descriptive statistics such as frequencies and the corresponding percentages were used to summarize categorical variables such as level of education and marital status. Continuous variables such as age, duration of bleeding among others were summarized using mean and the corresponding standard deviation if the Gaussian assumptions held. Otherwise, they were summarized using median and the corresponding inter quartile range (IQR). Gaussian assumptions were assessed using histograms and the normal probability plots.

The proportion of women with abnormal uterine bleeding was calculated based on the number of all the women who came to seek various gynaecological services at MTRH during the study period regardless of their diagnosis. This was the only way to determine the proportion of abnormal uterine bleeding out of all other gynaecological conditions seen at MTRH. Selection bias was mitigated since all these women came randomly from various facilities or geographical locations giving a snapshot of the burden of abnormal

uterine bleeding in comparison to other gynaecological disorders. This way, the findings can be reproducible in other clinical settings and generalized in the entire population of women seeking care at MTRH.

Inferential statistics such as Pearson Chi-square were conducted to determine the level of statistical significance between predictor and outcome variables (at a level of significance of ≤ 0.05).

3.8 Ethical Considerations

Approval to carry out the study was sought and obtained from the Institutional Research and Ethics Committee (IREC) of Moi University School of Medicine and Moi Teaching and Referral Hospital (approval number FAN: IREC 2051). Informed consent was sought for those above 18 years and guardians/relatives consent for those critically ill or have mental issues. Informed consent was taken in both English and Swahili language. All women were informed about the study and the procedures involved in the study.

Confidentiality was maintained throughout the study. The data collection forms used neither contained the names of the patients nor their personal identification numbers. Data collecting material was kept in a locked cabinet during the study period.

All participants were free to withdraw from the study at any point in time as they wish and without need to seek prior authorization to do so and without any consequences whatsoever for so doing. No inducements were given or care denied for discontinuity or failure to consent.

The results of the research will be presented to the Hospital's management and the University's Department of Reproductive Health for use as necessary. It will also be available for academic reference in the College of Health Sciences Resource Centre.

CHAPTER FOUR

4.0 RESULTS

4.1 Introduction

The results presented here are based on women of reproductive age with AUB who sought care at Moi Teaching and Referral Hospital between 1st April 2018 and 1st April 2019. Over the study period 5839 gynecological patients were seen at MTRH. Of these 231 were diagnosed with AUB and 108 of whom met study eligibility criteria were enrolled.

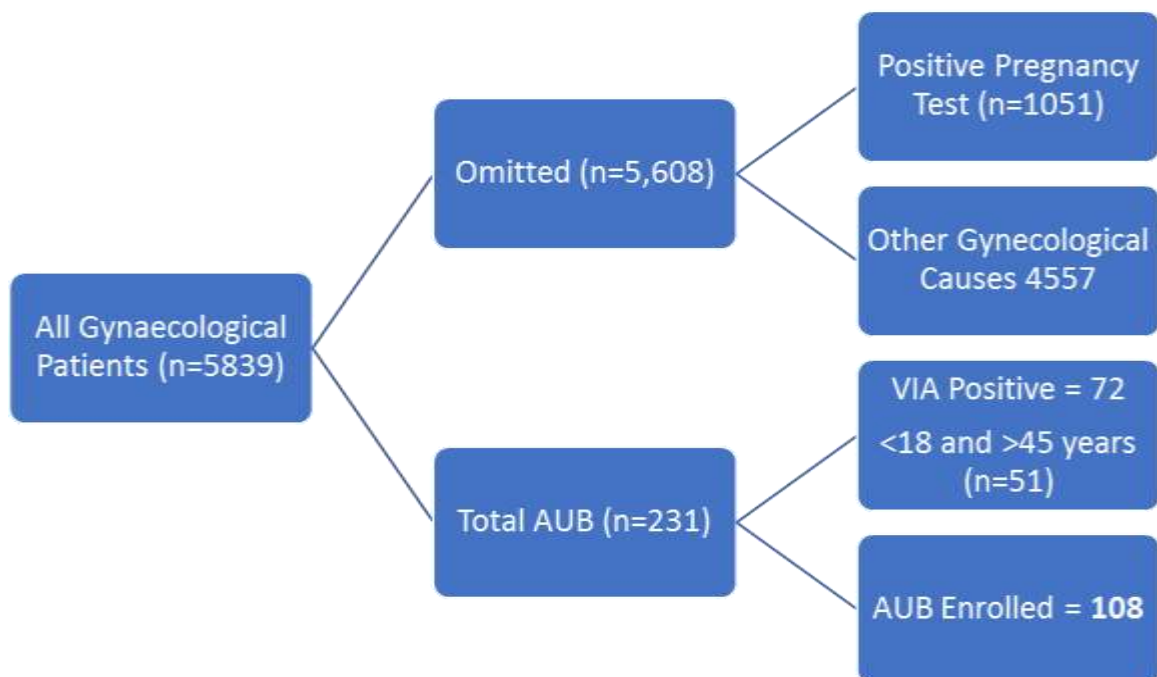


Figure 4.1: Participant Enrolment Chart

4.2 Proportion of AUB Seen at MTRH

Out of the 5839 gynecologic patients seen over the study period, 231(3.96%) were diagnosed with abnormal uterine bleeding.

4.2.1 Participants Sociodemographic Characteristics

The mean age of patient was 31.46 years (SD 11.17). Most 70 (64.8%) of the patients had attained secondary level of education with 26 (24.1%) having attended university/college level of education. Only 11 (10.2%) were formally employed and 62 (57.4%) of the patients lived outside Eldoret.

Table 4.1: Demographic characteristics (N=108)

| Variable` | Category | Frequency/ (IQR), | Median | Percentage (%) |
|------------------------|-----------------------|----------------------|--------|-------------------|
| Age | 18-45 | 30 (22, 41) | | |
| Education level | None | 1 | | 0.9 |
| | Primary | 11 | | 10.2 |
| | Secondary | 70 | | 64.8 |
| | Tertiary | 26 | | 24.1 |
| Employment | Student | 26 | | 24.1 |
| | Unemployed | 16 | | 14.8 |
| | Self-employed | 55 | | 50.9 |
| | Employed | 11 | | 10.2 |
| Residence | Uasin Gishu County | 46 | | 42.6 |
| | Any other County | 62 | | 57.4 |
| Marital status | Married | 56 | | 51.9 |
| | Separated | 4 | | 3.7 |
| | Single | 48 | | 44.4 |
| Parity | Nulliparous | 34 | | 31.5 |
| | Multiparous | 67 | | 62 |
| | Grand multiparous | 7 | | 6.5 |

4.3 Clinical Abnormal Uterine Bleeding Patterns seen at MTRH

Prolonged bleeding was the most common 45(41.7%) bleeding pattern followed by heavy 38 (35.2%), frequent 22(20.4%), intermenstrual 20(18.5%) and infrequent 9(8.3%) bleeding as shown in Table 4.2.

Table 4.2: Abnormal Uterine Bleeding Patterns seen at MTRH.

| Bleeding pattern | Frequency | Percentage |
|--------------------------------|------------------|-------------------|
| Prolonged bleeding | 45 | 41.7 |
| Heavy bleeding | 38 | 35.2 |
| Frequent bleeding | 22 | 20.4 |
| Intermenstrual bleeding | 20 | 18.5 |
| Infrequent bleeding | 9 | 8.3 |

The mixed abnormal uterine bleeding patterns were heavy and regular cycle 37 (64.9%), heavy and prolonged bleeding 12 (21.1%), heavy and intermenstrual bleeding 5 (8.7%), heavy and infrequent bleeding 2 (3.6%) as well as heavy and frequent bleeding 1 (1.7) as shown on Table 4.3.

Table 4.3: Mixed Abnormal Uterine Bleeding Patterns

| Bleeding pattern | Regular | Prolonged | Intermenstrual | Infrequent | Frequent |
|-------------------------|----------------|------------------|-----------------------|-------------------|-----------------|
| Heavy bleeding | 37 | 12 | 5 | 2 | 1 |
| (N=57) | | | | | |

4.4 Management of women with AUB

Management of women with AUB was categorized in terms of diagnosis and cost of management.

4.4.1 Diagnosis of women with AUB

4.4.1.1 Diagnosis as per the PALM-COEIN Criteria

Out of the 108 participants enrolled, only 18 (16.7%) were correctly diagnosed as per the PALM-COEIN criteria. However, there was no statistically significant (p-value =0.364) difference in abnormal uterine bleeding between the groups that were diagnosed as per the PALM-COEIN criteria versus those that were not (Table 4.4).

Table 4.4: Diagnosis as per the PALM-COEIN Criteria

| Diagnosis | Yes | No | Total | p-value |
|--------------------|-------------------|-------------------|-------------------|----------------|
| Polyp | 1 | 5 | 6 (5.5%) | |
| Adenomyosis | 1 | 8 | 9 (8.3%) | |
| Leiomyoma | 13 | 35 | 48 (44.4%) | |
| Malignancy | 1 | 12 | 13 (12.0%) | |
| Coagulopathy | 0 | 0 | 0 | |
| Ovulatory | 2 | 10 | 12 (11.1%) | p=0.364 |
| Endometrial | 0 | 7 | 7 (6.4%) | |
| Iatrogenic | 0 | 12 | 12 (11.1%) | |
| Not yet classified | 0 | 1 | 1 (0.9%) | |
| Total | 18 (16.7%) | 90 (83.3%) | 108 (100%) | |

4.4.1.2 Initial Laboratory Evaluation

All the study participants had a pregnancy test done. This was followed by a complete blood count (CBC) test among nearly half 49 (45.3%), coagulation profile 28 (25.9%) and Thyroid Stimulating Hormone (TSH) at 13 (12%). However, there was no statistically significant association between the type of test and evaluation status (Table 4.5).

Table 4.5: Initial Laboratory Evaluation

| Test | Yes | No | p-value |
|----------------------------|------------|------------|---------|
| TSH | 13 (12%) | 95 (88%) | 0.146 |
| CBC | 49 (45.3%) | 59 (54.7%) | 0.666 |
| Pregnancy | 108 (100%) | - | - |
| Coagulation Profile | 28 (25.9%) | 80 (74.1%) | - |

4.4.1.3 Additional Laboratory Evaluation

Additional hormonal profile laboratory tests were conducted based on menstrual cycle pattern (regular versus irregular). Overall, Follicle Stimulating Hormone (FSH) was the most commonly 14 (13%) ordered among all the study participants with 13.2% of the women with regular menstrual cycles being subjected to it. This was followed by a TSH test that was commonly ordered for women with irregular 6 (15%) compared to those with regular 7(10.3%) cycles. Prolactin hormone test was the least frequently ordered. Estradiol and progesterone hormone tests were not ordered at all. There were no statistically significant relationships reported between menstrual cycle patterns.

Table 4.6: Additional Laboratory Evaluation

| Test Ordered | Cycle Frequency | | Total | p-value |
|------------------|-----------------|-----------|----------|---------|
| | Regular | Irregular | | |
| TSH | 7 (10.3%) | 6 (15%) | 13 (12%) | 0.468 |
| Prolactin | 1 (1.5%) | 2 (5%) | 3 (2.8%) | 0.281 |
| FSH | 9 (13.2%) | 5 (12.5%) | 14 (13%) | 0.913 |

4.4.1.4 Ultrasound

As per the PALM-COEIN classification, all women presenting with polyps, endometrial causes and

Non-classified abnormal uterine bleeding had a pelvic ultrasound done. In total 86(79.6%) Leiomyoma was the most commonly presenting cause of endometrial bleeding, of which more than two thirds 33 (68.8%) of the women presenting with it had a pelvic ultrasound ordered. Higher proportions of pelvic ultrasound requests were reported among those with adenomyosis 7 (77.8%), malignancy/hyperplasia 11 (84.6%), ovulation dysfunction 10 (83.3%) and iatrogenic 11 (91.7%) causes of abnormal uterine bleeding (Figure 4.3).

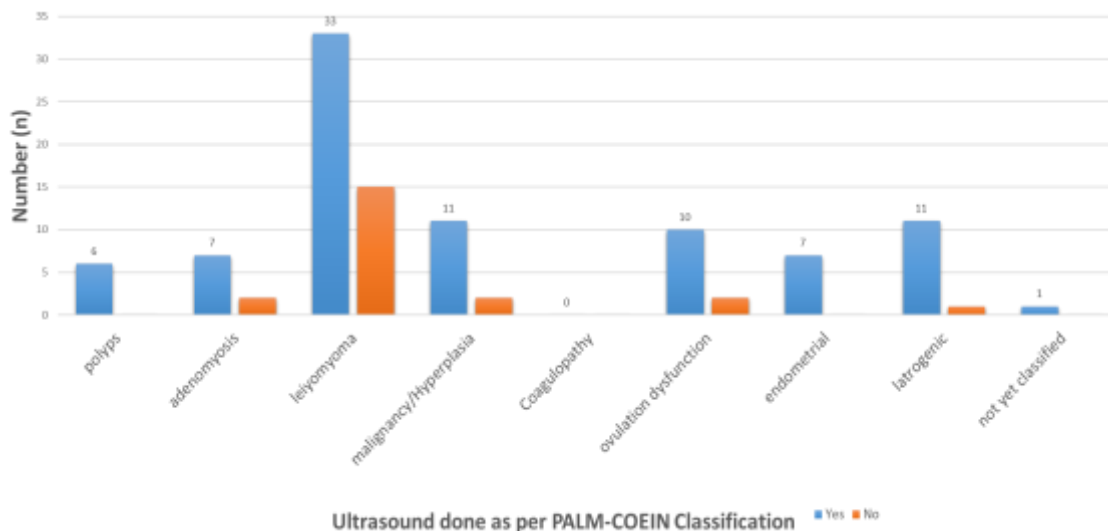


Figure 4.2: Ultrasound done as per PALM-COEIN Classification

4.4.1.5 Magnetic Resonance Imaging (MRI):

Even though 8.3% (n=9) of the participants presented with adenomyosis; none of them got an MRI scan done.

4.4.1.6 Biopsy

Biopsy sampling was categorized by the participants age and whether or not it was done. Among women aged 35 years or less (n=72), none of them had a biopsy specimen collected. On the other hand, those aged more than 35 years, only 8.3% (n=3) had biopsy sampling done (Figure 4.2).

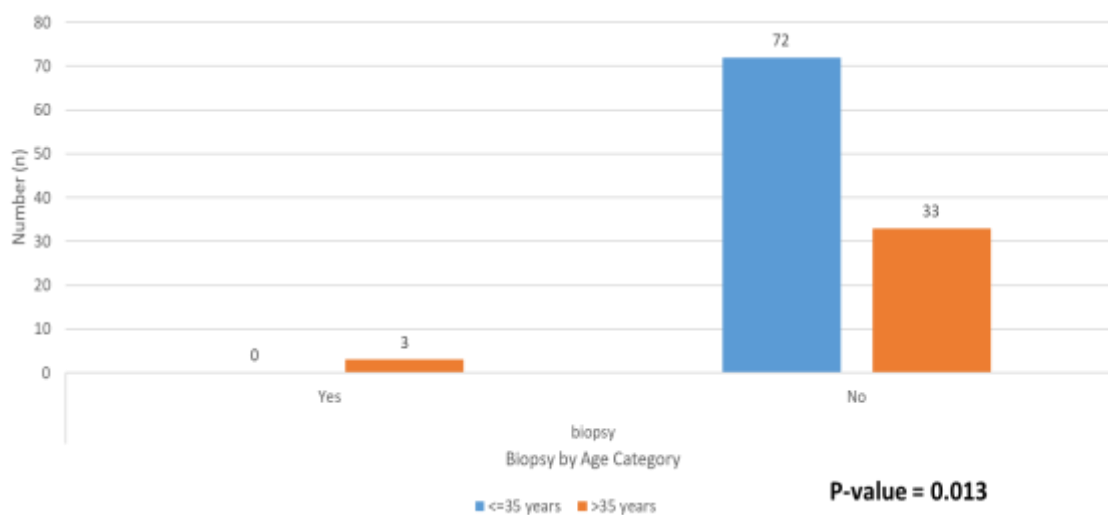


Figure 4.3: Biopsy test-results by age category

4.4.2 Medical Management of Women with AUB

More than three quarters 77 (78.7%) of all the women presenting with AUB were treated medically. Analgesics were given to all the study participants while tranexamic acid (TXM) was prescribed to more than half 66 (85.71%) of the study participants who received medical management, followed by haematinics 43 (55.84%) while blood transfusion and combined oral contraceptives (COCs) were given to 7 (9.1%) of all those enrolled. No participant was given levonorgestrel intrauterine system (LGIUS), Progesterone only Pills (POP), androgens and gonadotropin releasing hormone agonists (GnRH).

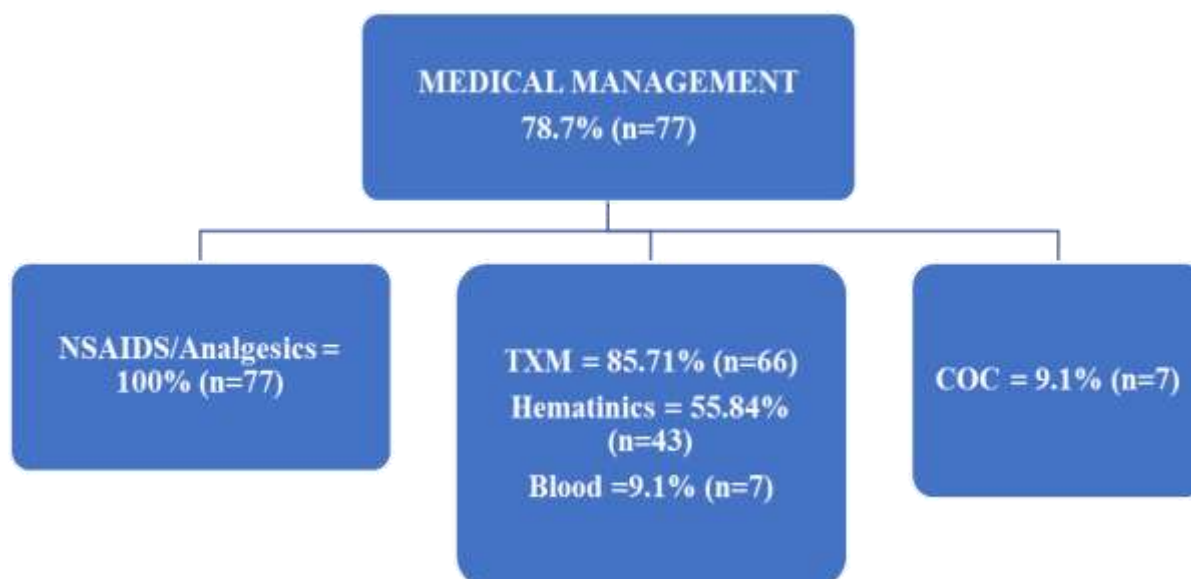


Figure 4.4: Medical Management of Women with AUB

4.4.3 Surgical Management of Women with AUB

Surgical management was offered to 21.3% (n=23) of all the study participants, majority 16 (69.6%) of whom got myomectomy done. This was followed by abdominal hysterectomy at 17.5% (n=4). The less frequent procedures were dilatation and curettage

(D&C), polypectomy and oophorectomy at 1 (4.3%) each. No participant got uterine artery embolization (UAE), Endometrial Ablation and vaginal or laparoscopic hysterectomy.

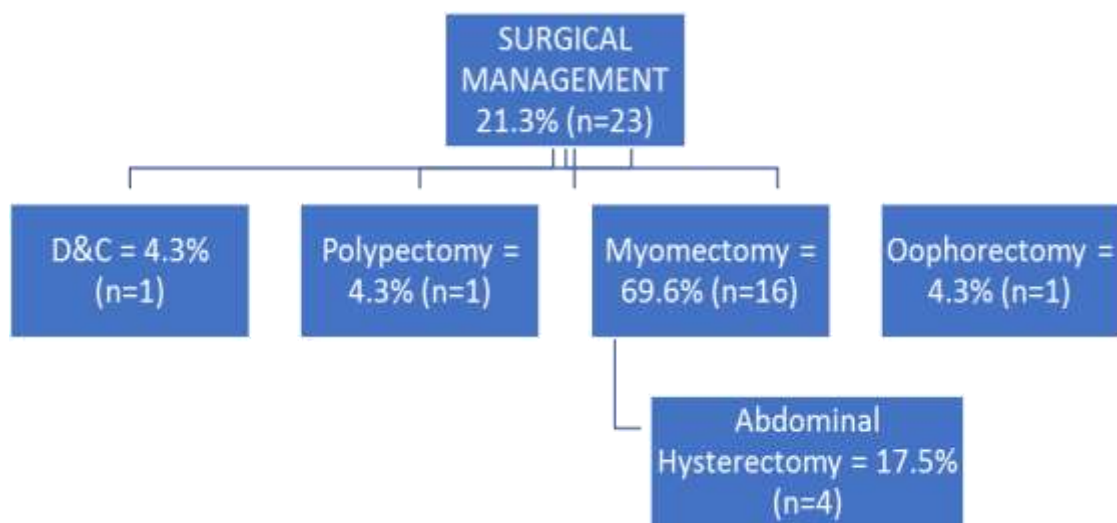


Figure 4.5: Surgical Management of Women with AUB

4.4.4 Cost of management by Place and Mode of Treatment

The median cost of treatment among those who attended in-patient facilities was KSh. 25,200 (IQR: 15890, 36785) while those in out-patient facilities was KSh. 16,581 (IQR: 9190, 23425). This study reported that it was cheaper attending an outpatient compared to inpatient facility among women with AUB; with a median cost difference of KSh. 8,619.

Medical treatment (21,000 IQR: 13379, 27500) was cheaper than surgical interventions (40,000 IQR: 31070, 57900) with a median difference of KSh. 19,000. Majority of the study participants opted for medical interventions compared to surgery.

Table 4.7: Cost of Management by Place and Mode of Treatment

| Variable | Category | Median (IQR) | Total |
|--|-----------------------|------------------------------|--------------|
| Place of Treatment (8619) | Inpatient (n=92) | 25,200 (15890, 36785) | 2,885,316 |
| | Outpatient (n=16) | 16,581 (9190, 23425) | 382,710 |
| Mode of Treatment (19000) | Surgical (n=23) | 40,000 (31070, 57900) | 1,162,022 |
| | Medical (n=85) | 21,000 (13379, 27500) | 2,106,005 |

4.4.5 Cost of management as per PALM-COEIN classification

The combined (medical and surgical) cost of managing women with polyps was the highest with a median management cost of KSh. 33,235 (IQR: 21149, 38700) compared to all other causes of abnormal uterine bleeding. The median cost of managing women with adenomyosis (KSh 29,594; IQR: 23600, 38500), endometrial (KSh 28,500 IQR: 25600, 34100) and iatrogenic (KSh 29,050; IQR: 23525, 63641) causes of abnormal uterine bleeding was nearly equal (Table 4.8).

Table 4.8: Cost of Treatment stratified by the PALM-COEIN classification

| Category | Median (IQR) | Total (KSh) |
|-----------------------|-----------------------|--------------------|
| Polyps | 33,235 (21149, 38700) | 170,997 |
| Adenomyosis | 29,594 (23600, 38500) | 271,657 |
| Leiomyoma | 20,860(11925, 33450) | 1,400,377 |
| Malignancy | 16,474 (11200, 41000) | 378,969 |
| Ovulation dysfunction | 19,900 (15248, 25924) | 248,913 |
| Endometrial | 28,500 (25600, 34100) | 221,753 |
| Iatrogenic | 29,050 (23525, 63641) | 559,178 |
| Not classified | - | 16,180 |

CHAPTER FIVE

5.0 DISCUSSION

5.1 Introduction

The study was undertaken to help us know the proportion of women with abnormal uterine bleeding, stratify the causes of AUB based on PALM COEIN classification, to describe how AUB is managed at MTRH and to correlate the Sociodemographic features with its patterns of presentation and cost of treatment.

5.2 Proportion of Women with AUB

This study reported that a small proportion (3.96%; n=108) of all the women seeking gynecological care at Moi Teaching and Referral hospital had abnormal uterine bleeding. This proportion was closer to another African study conducted in South West Nigeria where 10% of all the women seeking gynecological care had AUB (Abdullahi et al., 2016). The variance in proportions could be attributed to difference in study design and duration. In the Nigerian study (Abdullahi et al., 2016), it was conducted over a 10-year period (January 1999 to December 2008) and adopted a retrospective study design. This differs from the current study which was a one-year cross-sectional study between April 2018 to April 2019. Higher proportions are often reported when the study enrollment period is longer, bringing in more participants with the condition of interest. However, the proportions of AUB in Gambia West Africa 34.1% was way higher than the current study findings (Walraven et al., 2001a). The difference could be attributed to the target population, study design, setting and duration. The Gambian study was a retrospective study of the demographic medical surveillance system between the years 1981 and 1999 among rural women aged between 15 to 54 years. This contrasts the

current study that adopted a one-year prospective design among peri-urban women aged 18 to 45 years. Peri-urban women have better health seeking behaviour and may be diagnosed and managed earlier at the preclinical stage, leading to a lower likelihood of advancing to the disease stage.

5.3 Patterns of AUB

This study reported that prolonged bleeding was the most common bleeding pattern seen among nearly half (41.7%; n=45) of all the women enrolled into the study. This finding was higher than an Indian study (Anuradha et al., 2015) with one-third (33.6%) of all the study participants presenting with prolonged bleeding. The Indian study adopted a retrospective study design over a six-month period among 250 patients aged between 25 to 65 years. This variance in study design, period and target population could explain the variance in proportions of study participants. Prolonged bleeding was defined as more than eight (8) days of bleeding. It could have been easier to count more than 8 days than quantify other forms of AUB such as heavy bleeding.

Heavy Bleeding was the second most common AUB pattern among more than one-third (35.2%; n=38) of all enrolled study participants. This finding matched a Brazilian study that reported a proportion of women with heavy bleeding at 35.3% (Santos et al., 2011). Both studies adopted cross-sectional study designs among women aged 18-45 years and this could explain the similarity in proportions. Heavy bleeding was defined by the participants when they used more than five sanitary towels within 24 hours.

Frequent bleeding was the third most frequent AUB pattern among nearly one-fifth (18%; n=22) of all the study participants. This proportion is similar to the findings in another Indian study where 17% of all the women enrolled complained of frequent

bleeding (Mahapatra & Mishra, 2015b). This similarity could be attributed to the fact that both studies targeted women in their reproductive years and were both conducted in teaching hospitals.

5.4 Diagnosis and Management of Women with AUB

5.4.1 Diagnosis of AUB as per PALM COEIN guidelines

Less than one-fifth (16.7%; n=18) of all the study participants were diagnosed as per the PALM-COEIN criteria. Preoperative classification of AUB as per PALM-COEIN classification system was correctly done among 130 (65.0%) of the 200 women in a study in a low resource setting (Shubham & Kawthalkar, 2018). However, the overall proportion of participants who met the PALM and COEIN criteria accounted for 60% (n=64) and 40% (n=44) respectively. This matched an Indian study (Betha et al., 2017) where 60.4% and 39.6% were diagnosed as per the PALM and COEIN criteria respectively. This similarity could be attributed to the fact that both studies were done in a tertiary teaching hospital among non-pregnant women over a period of one year. There has been an increasing adoption of PALM-COEIN classification among clinicians managing women with abnormal uterine bleeding as evidenced in both the current and Indian (Betha et al., 2017) study.

In a retrospective analysis of women who underwent a planned abdominal hysterectomy for AUB, leiomyoma was most common cause at 44.2% (Mohammed & Prejisha, 2014). This finding is comparable to the current study's finding of nearly half (44.4%) of all study participants presenting with leiomyoma as the most common cause of abnormal uterine bleeding.

Malignancy and hyperplasia were the second most common abnormalities with a proportion of 12% (n=13). There were equal proportions iatrogenic and ovulation dysfunction among the women sampled at 11.1% (n=12). This matched an Indian study (Mishra et al, 2017) where 13.6% of the study participants presented with malignancy and hyperplasia. Malignancy is an advanced stage of abnormal uterine bleeding while hyperplasia is a precursor of endometrial malignancy. The malignancy of interest was both the ovarian and endometrial carcinoma.

The most frequent laboratory tests conducted among the enrolled women with abnormal uterine bleeding were pregnancy tests (100%). A sensitive urine or serum pregnancy test should be performed to rule out any pregnancy (I. S. Fraser et al., 2009) as the aetiology of the abnormal uterine bleeding. Complete blood counts and coagulation profile tests were ordered for 45.3% 25.9% of the women respectively. It is recommended that a complete blood count be done for women with heavy or prolonged bleeding. For those with a a history of heavy menstrual bleeding beginning at menarche or who have a personal or family history of abnormal bleeding should undergo coagulation profile testing (Singh et al., 2013).

Follicle stimulating hormone and thyroid stimulating hormone tests were done for 13% and 12% of the study participants respectively. This low proportion of thyroid function testing could be attributed to the fact that it is not routinely done unless clinical findings suggest thyroid disease or when other causes of abnormal uterine bleeding are excluded (Fairbanks & Sams, 2013).

There were low proportions of and prolactin hormone (2.8%) tests. However, no participant got laboratory requests for estradiol, progesterone and luteinising hormone.

Only 3 (2.7%) participants had a biopsy sample taken. This was done only among women aged above 35 years.

Abdominopelvic ultrasound was done 86 (79.6%) of all the study participants to rule out structural causes of AUB. Those (20%) who did not have the ultrasound scans done were due to lack of funds or clinicians not requesting. This finding compares to a Pakistani study (Khan et al., 2011) in which all the study participants had an abdominopelvic ultrasound done. However, the findings contrast those in the Netherlands where only 10% of the women presenting with AUB had an abdominopelvic ultrasound conducted (de Vries et al., 2008).

5.4.2 Management Options of women with AUB

Medical and surgical management was offered to 78.7% (n=85) and 21.3% (n=23) respectively. Analgesics were prescribed to nearly all (92.6%) of the study participants followed by antibiotics (78.7%) and antifibrinolytics (61.1%). This finding contrasted a Dutch study (de Vries et al., 2008) where nearly two thirds (62%) of the study participants did not receive any medication. Analgesics were prescribed among 5% of the study participants who presented with excessive bleeding. This could be due to the fact that majority of the women were initially seen by General Practitioners and only a few referred to gynecologists. A systematic review (Hartmann et al., 2013) by the Vanderbilt Evidenced based practice center of six studies on non-steroidal anti-inflammatory drugs (NSAIDS) among women with AUB; reported that NSAIDS reduced bleeding in the participants enrolled in all the six studies. The study further reported that TXA was more effective in reducing bleeding than NSAIDS in three out of four studies reviewed.

Hematinics used at 43(39.8%) while blood transfusion done in 7(6.5%) although more than 56 % needed either blood transfusion or haematinics. Combined oral contraceptives were prescribed among 5.5% of the study participants enrolled in this study. This was lower than the 35% of women who received hormonal treatment in the Netherlands (de Vries et al., 2008). A treatment algorithm for AUB (Ely et al., 2006) recommended that abnormal bleeding persists after three months, a higher dose of oral contraceptives can be used.

5.5 Cost of AUB management

This study determined that inpatients with AUB paid an average of KSh. 8,619 higher than outpatients for management. Surgery cost KSh. 19,000 more than medical management averagely. This finding is similar to those of an American study (Showstack et al., 2006) where surgery cost USD 191.5 (KSh. 19, 150) more than medical management.

Early treatment may prevent the chance of admission and further reduce the cost of inpatient care. Conservative treatment also reduces the probability of high costs of surgical management in the short term. However, overall long-term management is cheaper when surgery is opted for. Treatment of polyps and adenomyosis costs more than other forms of abnormal uterine bleeding.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

Proportion of AUB among women seen in MTRH is lower than those reported in other studies.

Prolonged bleeding was the most common bleeding pattern seen at MTRH followed by heavy bleeding.

Women who were correctly diagnosed as per the PALM-COEIN classification guidelines were 16.7%.

Medical management was a cheaper way than surgical management in the short-term, however, surgery was more cost-effective when it was projected annually.

6.2 Recommendation

There is need the development of a standardized algorithm for diagnosing various patterns of abnormal uterine bleeding at MTRH using the PALM-COEIN criteria.

More training and development of in-hospital algorithms should be done to ensure adherence to PALM-COEIN guidelines in the diagnosis of AUB.

Surgery, unless desire for fertility; should be recommended over medical management for women with AUB due to its long-term cost-effectiveness.

More studies using hysteroscopy in the diagnosis of the causes and management of abnormal uterine bleeding should be considered.

6.3 Limitations

To properly compare adherence to PALM-COEIN classification of abnormal uterine bleeding and the cost of management, it would have been better to conduct the study in multiple centers including private hospitals.

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APPENDICES

Appendix I: Questionnaire

Dear Sir/ Madam

This is a study on management of women with abnormal uterine bleeding at Moi teaching and referral hospital. The results of this study will help in the development and formulation of policies and programs that will facilitate and help know clinical patterns, outcome and management of abnormal uterine bleeding. There is no right or wrong answer. You will remain anonymous. Your participation is highly appreciated

Patient's Demographic Data: Reg. No...

Date of birth of patient

Level of Education

A). Not Attended Education

b). Primary education

c). Secondary education

d). University/college

3. Employment Status: Are you currently...?

A). Employed b) Self-employed c) Student d) Unemployed

Place of Residence: within Eldoret.....Outside Eldoret.....

What is your current marital status?

| Divorced | Married | Separated | Single | Widowed |
|-----------------------|---------|-----------|--------|---------|
| Would rather not say? | | | | |
| | | | | |

Phone number.....

Other phone number (Eg next of kin).....

SECTION B: HISTORY

a) What's your Bleeding Pattern?

Heavy bleeding (excessive menstrual bleeding > 5 pads per day).....

Prolonged bleeding (bleeding more than 8 days).....

Frequent bleeding (more than 4 episodes in 90 day period).....

IV) Infrequent bleeding (1 or 2 episodes in 90 day period).....

v). Intermenstrual bleeding (bleeding in between menstrual periods).....

Other.....

Specify.....

b. Have you taken any drugs before onset of the bleeding pattern?

SECTION C: DIAGNOSTIC TESTING:

| Diagnostic test | Date | Results |
|---------------------|------|---------|
| Pregnancy test | | |
| VIA | | |
| TSH | | |
| Estradiol | | |
| Prolactin | | |
| Progesterone | | |
| FSH | | |
| Hysterosalpingogram | | |
| Hysteroscopy | | |

CT scan

MRI

CBC

Ultrasound

Coagulation profile

Endometrial biopsy

Other:

SECTION C Current diagnosis.....

SECTION D Management

i) What treatment (if any) have you received for per vaginal bleeding so far?

No treatment Surgery Medications

Please describe your prior treatments
here.....

Treated as outpatient and discharged yes no

Admitted yes no

IV) admitted to ICU yes no

V) Ward

Medical treatment

Treated by surgery

VI) Died

At Casualty on Arrival

In Ward

Intra-Op

Discharged: Condition at time of discharge-a) Fully recovered

b) For clinic follow-up

SECTION E – QUESTIONS ON DIRECT COSTS

Question on indirect cost

| | COST OF CARE | (Confirm with receipt) |
|----------------------------|--------------|------------------------|
| | | |
| Consultation fee | | |
| | | |
| Laboratory tests (specify) | | |
| | | |
| Imaging services (specify) | | |
| | | |
| Drugs | | |
| (Specify) | | |
| | | |
| Cost of drugs (specify) | | |
| | | |
| Biopsy (Specify) | | |
| | | |
| Surgery (specify) | | |
| | | |
| Cost of inpatient care | | |
| | | |
| | | |
| Cost of outpatient care | | |
| TOTAL COST | | |

THANK YOU FOR YOUR TIME AND PARTICIPATION!

FOMU YA IDHINI

**MADA YA UTAFITI: EVALUATING MANAGEMENT OF
PATIENTS WITH
ABNORMAL UTERINE BLEEDING AT MOI TEACHING AND
REFERRAL**

HOSPITAL ELDORET KENYA

MTAFITI - DR MUTAKHA GODFREY SHICHENJE

RUNUNU: 0721818754

Mimi _____ was Sanduku la Posta
_____, nambari ya simu _____ najitolea
kwa hiari yangu mwenyewe kutoa kibali cha kujihusisha katika utafiti uliotajwa hapo
juu unaendelezwa katika MTRH. Nimepokea maelezo ya tafsili kuhusu utafiti huu
kutoka kwa Daktari Godfrey Mutakha (au mtafiti msaidizi wake) katika lugha, kanuni
na masharti ninayoelewa vyema.

Nimehakikishiwa kuwa, sitadhurika kamwe kutokana na kujihusisha kwangu katika
utafiti huu ilibainishwa kuwa kujihusisha katika utafiti huu ni kwa hiari na nina uhuru
wa kujiondoa wakati wowote ule bila ya kuhujumiwa hasa kuhusu haki yangu ya
kupokea matibabu katika MTRH. Zaidi ya hayo, nilihakikishiwa kuwa, kanuni zote za
maadili ya utabibu, uhuru, haki, na manufaa zitazingatiwa katika utafiti huu.

Natoa hii idhini kwa hiari bila kushurutishwa.

Mshiriki: Signature: _____ Date: _____

Mtafiti mkuu: Signature: _____ Date: _____

Appendix III: Introductory Letter

I am Dr Mutakha Godfrey Shichenje, a medical doctor currently pursuing my Master's Degree in reproductive health at Moi University, College of Health Sciences. I am conducting a study entitled: **EVALUATING MANAGEMENT OF PATIENTS WITH ABNORMAL UTERINE BLEEDING AT MOI TEACHING AND REFERRAL HOSPITAL ELDORET KENYA**

You are being asked to take part in the research study. Information on the study and your participation is detailed below. Please read this form carefully. You are free to ask any question during any time of the study. If you decide to participate in the study, you will be given a copy of this introductory letter and the consent form for your records.

Taking part in the study is voluntary. Choosing not to participate in the study will not, in any way, affect the care you receive at MTRH. If you accept to enroll in the study, you will be free to terminate your participation at any time. Any new information concerning the risks and benefits

Of the study will be communicated to you promptly after whom you will be free to opt out or continue with the study.

The purpose of this study is to characterize clinical presentation, and also management women with AUB at Moi Teaching and Referral Hospital. The process of your participation will involve clinical examination to evaluate the clinical presentation and answering of questions related to management. Your involvement in the study will be from admission into the gynaecology wards up to time of discharge. There will be

follow-up from the outpatient clinic required for the purpose of the study if treated as an outpatient.

The information you provide will be kept confidential at all times and there will be no use of identifiers that may trace back to you.

For more information concerning your rights as a research participant, you may contact the Moi University/MTRH Institutional Research Ethics Committee (IREC) on telephone number 053 – 33471 ext. 3008.

Yours faithfully,

Dr Mutakha Godfrey Shichenje

P.O.Box 626

Kakamega.

Mobile No: 0721818754

Barua Ya Utangulizi

Mimi ni daktari Mutakha Godfrey Shichenje. Nimehitimu kama daktari na nimesajiliwa na bodi ya madaktari ya kenya. kwa sasa, ninasomea shahada ya juu (masters) ya udaktari wa REPRODUCTIVE HEALTH katika Chuo Kikuu cha Moi. Ninafanya utafiti kuhusu: Assessment of the clinical presentation, management and outcome of women with AUB at Moi Teaching and Referral Hospital

Ninaomba ujiunge na utafiti huu. Maelezo yafuatayo yanahusu utafiti wangu. Ningependa usomee na iwapo unamaswali yoyote kwa sasa au baadaye kuwa huru kuuliza.

Appendix IV: Budget used

| Code | Item | Quantity | Unit Price@ | Total cost |
|------|--|----------|-------------|---------------|
| 1 | Laptop | 1 | 60000 | 65000 |
| 2 | Reams of plain paper | 8 | 500 | 4000 |
| 3 | Stationary (Pens, Pencils, Files etc.) | | | 25000 |
| 4 | Internet Services and Communication | | | 40000 |
| 5 | Computer Flash discs | 4 | 1500 | 6000 |
| 6 | Research Assistant | 1 | | 60000 |
| 7 | Photocopy, Printing and Binding | | | 35000 |
| 8 | Irec fees | | | 2000 |
| 9 | Statistical Consultation | 1 | | 35000 |
| 10 | Miscellaneous | | | 30000 |
| 11 | 10% Contingency | | | 29795 |
| | TOTAL | | | 328745 |

Appendix V: Work Schedule

| DATE | ACTIVITY | DURATION | RESPONSIBLE PERSON |
|---------------------------------|---------------------------------|--------------------|---|
| JANUARY-FEB 2016 | Selection of topic | 2 Months | Researcher |
| FEB 2016-MAY 2016 | Literature Review | 4 Months | Researcher |
| MAY 2016 - SEPTEMBER 2017 | Writing Proposal | 1 year 4 months | Researcher and Supervisors |
| SEPTEMBER 2017 | Submission to IREC | 1 Month | Researcher |
| MARCH 2018 | IREC approval | 5 Months | IREC |
| APRIL 2018 - APRIL 2019 | Data Collection and analysis | 1 year | Researcher and Assistant Researcher |
| APRIL 2019-JULY 2019 | Thesis writing | 3 Months | Researcher and Supervisors |
| JULY 2019 | Submission of thesis | - | Researcher |