

**MANAGEMENT OF SECOND TRIMESTER ABORTIONS AT  
KENYATTA NATIONAL HOSPITAL: A FIVE-YEAR CROSS-  
SECTIONAL STUDY**

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A research dissertation Submitted in partial fulfillment of a master of Medicine in Obstetrics  
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**2019**

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## **DEDICATION:**

I dedicate this book to my family for their efforts, motivation and belief in me during my training in Medicine.

## **ACKNOWLEDGEMENT:**

I would like to acknowledge my supervisors Professor Joseph G.Karanja, Dr. Alfred Osoi for their availability during my research study to develop and finalization of this research.

Also I would like to acknowledge the efforts of my research Assisitants, my statistician, Departmental Librarian Daniel Muasya and Nursing staff at Kenyatta National Hospital labour ward without them this would not have been achieved.

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## **LIST OF ABBREVIATIONS**

D&E	Dilatation and Evacuation
G.A	General Anaesthesia
K.N.H	Kenyatta National Hospital
MVA	Manual Vacuum Aspiration
NSAIDS	Non-steroidal Anti-inflammatory drugs
PI	Principal Investigator
POCs	Products of Conception
SPSS	Statistical Package for Social Sciences
UoN	University of Nairobi
WBC	White blood cells
WHO	World Health Organization

## ABSTRACT

### **Background**

Abortion is the spontaneous or induced termination of pregnancy before fetal viability. The World Health Organization (WHO) defines it as termination prior to 22 weeks gestation or a fetus weighing less than 500 gms. Abortions occurring in the second trimester account for 10-15% of all abortions but are responsible for two thirds of all complications and thus its management is key in preventing maternal morbidity and mortality. The purpose of this study is to evaluate the management practice of second trimester abortion at Kenyatta National Hospital, identify any potential pitfalls and address the same.

**Broad Objective:** To describe the management practice and associated outcomes of second trimester abortions at Kenyatta National Hospital.

**Study Design:** This was a descriptive cross-sectional study.

**Study setting and Site:** The study was conducted at Kenyatta National Hospital with data obtained from records of patients previously admitted at the acute gynecological ward.

**Study Population:** Women of childbearing age, above the age of 18 who sought abortion related care at Kenyatta National Hospital (KNH) from July 2013 to July 2018.

**Sample Size:** A **sample** of 139 patients, calculated using Fisher's formula of proportions was obtained. Systematic random sampling of patients' files and records was done and data **was collected using a structured questionnaire** administered by the principal investigator and analysis done by Stata version 12.

**Data analysis:** The study utilized univariate and bivariate analysis: Categorical variables were described using frequency tables and continuous variables using the median and mean. Fischer's exact test was used to evaluate the association between the method of management and outcomes. A p value of <0.05 and 95% confidence interval that doesn't include the null value were considered significant.

**Results:** Between July 2013 and July 2018, 573 patient records were screened and 372 were found to be eligible. 139 patient records were obtained from these by simple random sampling.

Methods used in the management of second trimester abortion were 34%, 32% and 31% respectively for surgical, medical and surgical plus medical interventions. The main surgical method was Manual Vacuum Aspiration while the main medical method was utilization of misoprostol

There were no statistically significant differences between method of management and outcome.

**Conclusion:** The prevalence of methods of management of second trimester abortion were similar among the 3 main categories at 34.5%, 32.3% and 31.6% for surgical, medical, surgical and medical management (MVA+Misoprostol) respectively.

The complication rate was 14% and did not vary by method of management.

## **CHAPTER ONE: INTRODUCTION AND LITERATURE REVIEW**

### **1.1: INTRODUCTION**

#### **1.1.0 Background**

Abortion is the spontaneous or induced termination of pregnancy before fetal viability(1) . The World Health Organization (WHO) defines it as termination prior to 22 weeks gestation or a fetus weighing less than 500gms(1). Abortions occurring in the second trimester account for 10-15% of all abortions but are responsible for two thirds of all complications and thus its management is key in preventing maternal morbidity and mortality.(1)

The United Nations through sustainable development goal 3 envisions the need to reduce global maternal mortality ratio to less than 70 per 100, 000 live births. The maternal mortality ratio in Kenya currently stands at 510 per 100,000 live births (WHO trends in MMR 2015). To bridge this gap, actions must be undertaken to reduce abortion related maternal deaths particularly in the second trimester where complications are more likely to occur (2).

#### **1.1.1 Epidemiology of Second Trimester Abortions**

During 2010–2014, an estimated 56 million induced abortions occurred each year worldwide(3). This number represents an increase from 50 million annually during 1990–1994, mainly because of population growth. Women in developing regions have a higher likelihood of having an abortion than those in developed countries with respective abortion rates at 37 per 1000 women and 27 per 1000 women. 25% of pregnancies globally ended in abortion in the period 2010-2014. The highest annual rate of abortion in 2010–2014 was in the Caribbean, estimated at 65 per 1,000 women of childbearing age, followed by South America, at 47. The lowest rates were in Northern America, at 17, and Western and Northern Europe—both at 18.(3)

In Africa/2010-4, the overall abortion rate was 34 per 1,000 women in 2010–2014. Sub-regional rates ranged from 31 in Western Africa to 38 in Northern Africa. There has been little if any change in abortion rates in these subregions since 1990–1994 (3).

A 2015 report by Guttmacher institute of New York and Africa population and Health Research Centre of Nairobi estimated the number of abortions in Kenya at 464,000 in 2012 or 48 procedures in every 1000 women. In this report, the most affected age group was 16-30 years (3).

### **1.1.2 Pathophysiology of Second Trimester Abortions**

Second trimester abortion may be attributable to chromosomal abnormalities such as aneuploidies; mosaicism and structural abnormalities. Advancing maternal age is one of the factors that predisposes to chromosomal abnormalities. The earlier the gestational age at abortion, the higher the incidence of cytogenetic defects: the incidence of abnormal fetal karyotype is 90 percent in anembryonic products of conception, 50 percent for abortuses at 8 to 11 weeks of gestation, but decreases to 30 percent of abortuses at 16 to 19 weeks(4).

Other causes include congenital anomalies due to genetic or extrinsic factors like teratogens (including drugs and chemicals for example mercury, alcohol, and smoking)(5).

Structural factors for example submucous leiomyoma, adhesions and incompetent cervix are also contributory as are maternal infection for example Herpes simplex, Toxoplasmosis, Listeria Monocytogenes, CMV, choriomeningitis(6).

Endocrine disorders such as Diabetes Mellitus, Thyroid disease, Cushing syndrome, Polycystic ovarian syndrome are also culpable(7) and Inherited or acquired thrombophilia and disorders of the immune system like SLE and antiphospholipid syndrome can lead to immunological rejection or placental damage.(8)

### **1.1.3 Clinical presentation of second trimester abortion**

A typical patient with second trimester abortion would present with a history of amenorrhea, pelvic pain and vaginal bleeding of variable duration. The amount of bleeding is variable and delayed presentation may lead to symptoms (for example light headedness and confusion) and signs (for example tachycardia, delayed capillary refill, hypotension, oliguria, altered mental status, cold clammy extremities) of hypovolemic shock. On pelvic examination, the cervix may be open and products of conception may be visualized at the vagina or cervical os. The uterine size compared to the gestational age is variable depending on the type of abortion(1).

#### **1.1.4 Management of second trimester abortion**

According to the WHO guidelines 2014,(9) second trimester abortion may be managed either surgically or medically. The protocol for medical management of second trimester abortion involves use of either misoprostol alone or a combination of mifepristone and misoprostol.

Misoprostol when used alone is administered as a 400-microgram dose either vaginally or sublingually every three hours up to five doses

The combination treatment involves administration of mifepristone 200 mgs as a single dose followed 36-48 hours later by misoprostol 800 micrograms vaginally then 400 micrograms vaginally or sublingually every 3 hours up to 5 doses. Alternatively, misoprostol 400 micrograms orally then 400 micrograms vaginally or sublingually every 3 hours up to 5 doses may be given following administration of 200 mgs of mifepristone 36-48 hours prior. Routine uterine curettage is not warranted in medical abortion (retained tissue is usually <10%). Aspiration or curettage should only be performed in women with heavy bleeding, fever or retained placenta beyond 3-4 hours.

Supportive care during medical management of second trimester abortion involves counselling the patient on the procedures to be undertaken, side effects, complications and pain management.

Antibiotic prophylaxis is not necessary during management of second trimester abortion(9)

Some of the complications encountered include pain, bleeding, fever, nausea/vomiting, diarrhea and pelvic infection. These may be managed by use of analgesics, intravenous fluids/transfusion, antipyretics, antiemetics, antidiarrheal medication and use of antibiotics and evacuation respectively.(9)

Abortion may be managed surgically either by MVA (up to 14 weeks) or by dilatation and evacuation for higher gestation(9). Cervical preparation either with laminaria, mifepristone (200 mgs 24-48 hours prior) or misoprostol (400 microgram 3-4 hours prior) is usually required before surgical management is performed. Use of antibiotics is also recommended perioperatively(9)

Routine follow up for surgical procedures is not necessary if the procedure was uncomplicated barring any further occurrences of complication. If requested, follow up should be between 7-14 days.

Following treatment, post abortion care is recommended and encompasses monitoring for complications and treating appropriately, offering contraceptive solutions, use of haematinics, analgesics and counselling as need may dictate. Sexual intercourse is only after heavy bleeding has ceased(9)

Complications encountered following surgical management of second trimester abortion include incomplete abortion, haemorrhage, infection and uterine perforation. These may be managed by re-evacuation and use of antibiotic drugs, antibiotic use and repair of rupture either via laparotomy or laparoscopically respectively.

## **1.2 LITERATURE REVIEW**

### **1.2.1 SURGICAL METHODS OF MANAGEMENT OF ABORTION**

#### **Vacuum aspiration**

This is the surgical method of choice in management of 1<sup>st</sup> trimester abortion and can be used early in the second trimester up to 15 weeks if done by experienced clinicians (10). However, after 8 weeks the risk of major complications rise by 15-30% for each week delay (Cates et al 1979)(11)

#### **Dilatation and evacuation**

This is the standard method at gestations above 13 weeks in many parts of the world. The method is comparatively faster and safer as compared to prostaglandins(12)). Preoperative cervical priming reduces risk of cervical injury and is therefore recommended (13,14)

### **1.2.2 MEDICAL METHODS OF MANAGEMENT OF ABORTION**

Refers to termination of pregnancy by stimulation of labor like contractions leading to eventual expulsion of fetus and placenta from the uterus (15).

### **Prostaglandins and their analogues:**

These drugs induce cervical ripening both by a direct effect on the cervix and concomitant stimulation of myometrial activity(16,17)

The naturally occurring PGs such as PGE1, PGE2 and PGF2 $\alpha$  have limited utility in termination of pregnancies due to the high rates of metabolism and high incidence of gastrointestinal adverse effects(18,19). The PG analogues have a longer duration of action and are more resistant to rapid metabolism due to introduction of a methyl group to their structure at positions C15 or C16.(20)

Misoprostol- PGE1 analogue- is the preferred prostaglandin used in the management of second trimester abortion due to a favorable adverse effect profile when compared to the other analogues such as carboprost (methyl PGF2 $\alpha$ ), sulprostone (PGE2 methylsulphonylamide) and gemeprost (PGE1 analogue) which have significant gastrointestinal or cardiac side effects in the case of sulprostone(21) .

### **Antiprogesterone**

The progesterone receptor antagonist mifepristone binds to uterine progesterone receptors inducing vascular damage, decidual necrosis and bleeding by disrupting the normal uterine quiescent state promoted by the hormone(22). Mifepristone may be utilized in doses of 600mgs (though 200 mgs is also efficient) or in combination with a prostaglandin analogue whereupon their actions are synergistic with a shorter interval of induction to abortion(23).

In a study by Tang et al(24), Hamoda et al(25) all women pretreated with mifepristone led to abortion within 24 hours of receiving the first misoprostol dose and induction to abortion interval was less than half with misoprostol alone.



### **1.2.3 OUTCOMES OF SECOND TRIMESTER ABORTIONS**

Studies have been done to compare outcomes between D&E and mifepristone–misoprostol medical abortion in the second trimester. In one of the study done by Grimes DA smith et al(26) (27) several pitfalls were encountered namely difficulty in randomizing subjects with most opting for D&E due to its perceived safety and low adverse effect profile and subsequent loss to follow up with the study stopped after one year with only 18 enrolled subjects. Women assigned to receive mifepristone – misoprostol reported significantly more pain than those undergoing D&E ( $p=0.03$ ).

Although there were no statistically significant differences in complications between the two groups, six of nine women randomized to mifepristone–misoprostol had one or more adverse events associated with the procedure, compared to one woman who underwent D&E. In the medical induction group, the complications included the following: three women had retained placental tissue that required instrumental removal; three had a fever greater than 38°C; and one woman delivered a fetus that showed signs of life. The woman in the D&E group who had complications aborted spontaneously after laminaria were placed;

Women undergoing medical abortion reported more symptoms such as nausea, vomiting, dizziness and headache compared to those who had D&E, although these differences were not statistically significant.

A retrospective cohort study by Autry am, Hayes Fc et al 2002(27) that compared complications of medical abortion (misoprostol regimen) and D&E found that after controlling for gestational age, gravidity and length of hospital stay, the odds ratio of experiencing an adverse event was significantly lower for surgically managed abortion compared to medically managed abortion (OR 0.1; 95% CI 0.0–0.3). The study compared the outcome of 139 women who underwent D&E to those of 158 women who underwent abortion by any medical method at two hospitals in the US in 1994-2001. 79% of the women undergoing medical induction, the misoprostol-alone regimen was used; none received mifepristone. The induction method used in the other 21% of cases was unspecified but were assumed to be an older method. Complications from D&E are generally dependent on the expertise of the surgeon (14).

The following complications are commonly encountered while conducting second trimester abortions:

### **Uterine perforation and uterine rupture**

This is of variable incidence globally depending on the methodology, theatre settings and time before surgery .A study in the US by Patel A, Talmont E et al 2006 (28) demonstrated a 0.2% incidence when done by experienced practitioners.

Factors associated with perforation in the study above include:

- Underestimation of pregnancy duration
- Inadequate cervical dilatation
- Failure to use ultrasound during the procedure
- Following failed medical induction when surgery is performed
- Previous C/S and subsequent misoprostol induction

Uterine rupture has been shown following induction with mifepristone-misoprostol regimen (Ashok P et al 2004 )(29) This study demonstrated a 0.1% incidence of uterine rupture with this regimen.

### **Haemorrhage**

Haemorrhage can occur with both D&E and medical induction. Blood loss with D&E is usually between 100 and 400 mls (30). In the D&E case series by Patel A, Talmont E et al-2006(28) from the US, 0.09% of women had haemorrhage requiring blood transfusion. Factors that have been associated with increased blood loss at the time of D&E include:

- increasing gestational age
- use of general anaesthesia
- prolonged operating time
- placenta praevia and placenta accreta.(31)

In the case series by Ashok P et al (29) 0.7% of women required blood transfusion. This incidence is higher than that of the D&E studies above.

### **Incomplete abortion**

This was found to be significantly more common among women undergoing medical induction than surgical abortion.(27)In a case series of medical induction with mifepristone–misoprostol, incomplete abortion was noted in 8% of women (29) In the retrospective cohort study, where misoprostol alone or other medical induction methods were used, 19% of women had a failed medical induction (27). These findings are consistent with other studies that have demonstrated that the combined mifepristone–misoprostol regimen results in significantly improved efficacy compared to misoprostol alone(15)

However, incomplete abortion after D&E is still far less likely than after medical induction with mifepristone-misoprostol. Following D&E Cases requiring a repeat surgical procedure for incomplete abortion varied from as low as 0.05%( Patel A, Talmont E et al-2006)- (28) in the most recent study to 0.3%,( Peterson WF, Berry FN et al-1983)- (32).

### **Cervical laceration**

Cervical laceration can occur after either D&E or medical induction. The study by Autry AM, et al-2002(27) found no significant difference in the incidence of cervical laceration needing repair among women who underwent D&E compared to those who underwent medical induction

### **Infection**

Antibiotic prophylaxis around the time of surgical abortion performed before 16 weeks of pregnancy was shown in 1996 in a meta-analysis of studies to result in a significant reduction in the relative risk of infection (RR 0.58, 95% CI 0.47–0.71) and is now standard practice (33). No such studies exist for medical induction in the second trimester, but most protocols do not involve routine use of antibiotic prophylaxis(9).

#### **1.2.4 Second trimester pregnancy termination in women with a prior Caesarean section**

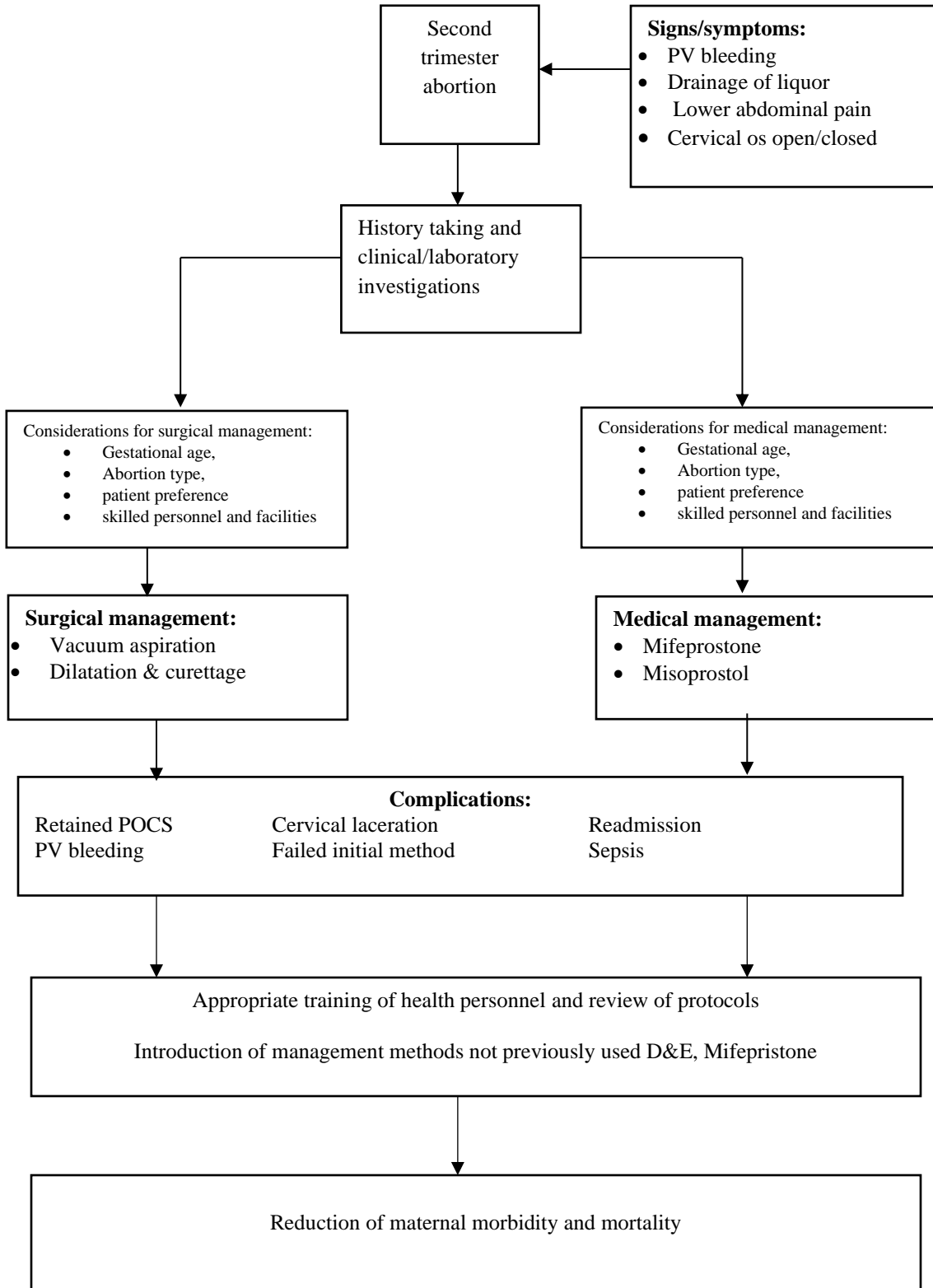
Studies on the above subject are scarce. In a study conducted by Gaskalakis et al (34), there was no evidence that a previous caesarean delivery affected the incidence of complications in women undergoing second trimester pregnancy termination with misoprostol (between gestation 17-24 weeks). The study was a retrospective analysis of case records between 1997 and 2002. and had 108 women with prior C/S (study group) and 216 women without such history (controls). The study group were given 400 mcgs of misoprostol vaginally and an additional 400 micrograms orally. Complications occurred in 16 out of 108 women of the study group (15%) and 26 out of 216 (12%) of the controls with only one case of ruptured uterus in the control group. The outcome measures were severe haemorrhage requiring transfusion, post abortal infection, retained placenta and uterine rupture.

Another study by Naguib AH, Morsi HM et al(35) conducted in Egypt (women in gestation 16-20 weeks) demonstrated doses of misoprostol 200mcgs given every four hours for a maximum 4 doses to be safe in a previously scarred uterus, with no complications reported. The regimen also proved to have a 90% success rate in the study subjects. This study was however limited by sample size and further larger studies need to be carried out.

Shamila Ijaz Munir(36) et al compared efficacy of misoprostol, PGF<sub>2</sub>& and intracervical foley catheter traction for second trimester pregnancy termination. The study found that misoprostol can safely be used in second-trimester pregnancy termination in a previously scarred uterus and was more efficacious than PGF<sub>2</sub>& and foley catheter traction.

### 1.3 Conceptual framework

#### Management of second Trimester Abortions



## **Narrative**

Women with second trimester abortion may present with either PV bleeding, lower abdominal pain or drainage of liquor. The cervix may either be open or closed. Upon presentation and subsequent clinical evaluation (history, physical examination, laboratory investigations/imaging) a decision is made to either manage the patient medically or surgically. Factors influencing the choice of management method include the gestational age, abortion type, patient preference and availability of skilled personnel and equipment.

Surgical management may either be done by MVA or by dilatation and curettage while medical management may be carried out with either mifepristone or misoprostol or a combination of both. Both have similar complications (Retained POCs, PV bleeding/hemorrhage, Cervical laceration, Failure of method and Sepsis).

With proper training of health personnel on management of second trimester abortions and complications and introduction of methods such as mifepristone and Dilatation and Evacuation, maternal morbidity and mortality can be mitigated.

### **1.4 Problem Statement**

There is currently a lack of a standardized protocol in the management of second trimester abortion in KNH with different clinicians utilizing different methods. The incidence and frequency of complications are also yet to be established and this can help infer the efficacy of the various methods available.

### **1.5 Justification**

Studies have shown that compared to first trimester abortion, second trimester abortion has a 13 times higher risk of complications and comorbidities (37). It is therefore imperative to have a set superior standard for management of second trimester abortions.

Management of second trimester abortion is primarily dependent on gestational age(9) with medical methods and vacuum aspiration preferred up to a gestation of 14 weeks. For gestations above this, the WHO recommends D&E(9). There are currently no local guidelines to inform the same and in spite of being available, mifepristone is currently not in clinical use. It is unknown whether the current management methods comply or adhere to international guidelines and

whether there is a need to develop appropriate guidelines for management of second trimester abortion.

The findings of this study will therefore inform policy and practice in the management of second trimester abortion.

### **1.6 Research Question**

What are the management practices of second trimester abortions at the KNH?

### **1.7 Broad Objective**

To describe the management practice of second trimester abortions at Kenyatta National Hospital from July 2013 to July 2018

### **1.8 Specific Objectives**

Among women with second trimester abortions managed at Kenyatta National Hospital,

1. To determine the prevalence of the methods (medical versus surgical) used in management of second trimester abortion.
2. To determine the complications of second trimester abortion
3. To determine the association between the method of management of second trimester abortion and complications

## **CHAPTER TWO: METHODOLOGY**

### **2.1 Introduction**

This chapter covers the research design and methodology, including sampling method, study population, data collection, data analysis and ethical considerations.

### **2.2 Study design**

This was a descriptive cross-sectional study whose participants had sought abortion related care at KNH between the year July 2013 and July 2018. The exposure/independent variable was a diagnosis of second trimester abortion and the outcome/independent variable were absence/presence of complications. Data obtained from files and records of these patients was used to determine prevalence of methods used in the management of second trimester abortion and the prevalence of complications that occurred during management,

### **2.3 Study site**

The study was conducted at Kenyatta National Hospital with data retrieved from records and files of patients previously admitted to the acute gynecology ward. Kenyatta National Hospital being a national referral hospital covers a wide geographical area and due to its high patient numbers offers a diverse sociodemographic study population.

It is located in Upper Hill area of Nairobi and has a bed capacity of 2500 inpatients. The hospital also serves as a teaching hospital for the University of Nairobi and the Kenya Medical Training College.

The acute gynecological ward (ward 1D) handles gynecological emergencies and is staffed and equipped to handle both medically and surgically managed cases of abortion. The ward has a procedure room where MVA procedures are carried out. However, other procedures such as suction curettage or dilatation and curettage are carried out at the main hospital theatre. The ward is staffed by a resident senior house officer assisted by a medical officer intern, clinical officer intern and highly qualified nurses. A consultant who is the overall head conducts ward rounds every day of the week.



Patients in need of specialized care such as intensive care (ICU) or high dependency care (HDU), dialysis from renal complications are managed accordingly as the above facilities are available with a multidisciplinary team at hand.

## **2.4 Study population**

The study population were women of childbearing age, above the age of 18 and over who had attended the KNH casualty and were admitted at the acute gynaecology ward between the year July 2013 and July 2018.

ICD-10 coded files of all patients who had presented in this time frame with a diagnosis of second trimester abortion were obtained by consecutive sampling from the records department at Kenyatta National Hospital. This included patients with a diagnosis of missed, incomplete and inevitable abortions within the gestational period of 13-22 weeks. A simple random sample of eligible files (those meeting the inclusion criteria) was then performed to obtain the study population.

The lower age limit of 18 was selected as an ethical precautionary measure.

## **2.5 Selection and enrolment of study participants**

### **2.5.1 Inclusion criteria**

- Women with second trimester abortion (13-22 weeks) in casualty and gynecology wards at KNH
- Women of minimum age 18 years.
- Gestation age 13-22 weeks

### **2.5.2 Exclusion criteria**

- Women with pre-existing comorbidities that may subsequently influence their management for example chronic illness like diabetes, hypertension.
- Women presenting with other types/forms of miscarriage that have a definitive management such as septic abortion.

## 2.6 Sampling method

A total of 573 files were identified as second trimester abortion between July 2013 and July 2018 from the records department at Kenyatta National Hospital. A total of 201 did not meet the inclusion criteria. From the remaining 372, a sample size of 139 as determined by Fischer's formula was obtained by simple random sampling.

## 2.7 Sample size calculation

The sample size for the study was calculated using Fishers formula as shown below, taking p, the proportion of patients with second trimester abortions admitted in a South African hospital during a similar study conducted by D Grossman et al. (38)

$$N = \frac{Z_{1-\alpha/2}^2 \times p(1-p)}{d^2} \text{ (Fisher's et al., 1998)}$$

$\alpha$ =Level of significance (0.05)

$Z_{1-\alpha/2}$  = Standard normal deviate at 95% confidence interval (1.96)

$p$ = Proportion in the target population with second trimester abortion = 23%(38)

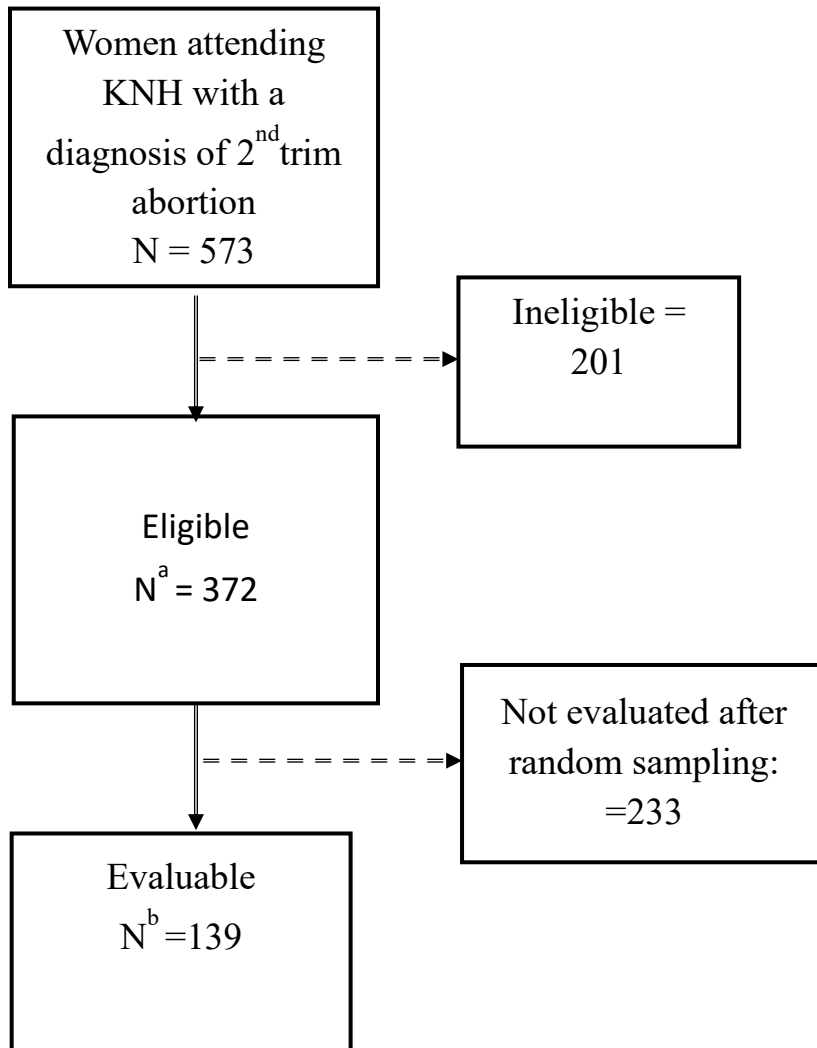
$d$ =margin of error allowed= 0.07

Therefore  $N = 139$

$$N = \frac{1.96^2 \times 0.23 \times 0.78}{0.07^2} = \frac{3.8 \times 0.23 \times 0.78}{0.0049}$$

Therefore  $N = 139$

## 2.8 Flow chart showing sample recruitment



## **2.9 Data collection**

A structured questionnaire (annex 3), was used to collect data. Data on demographics, length of stay in hospital, type of management and complications if any were obtained from the patient's file. Once collected, the data was entered in to excel computer software and transcribed into Stata version 12 software for cleaning and analysis.

## **2.10 Data management and analysis**

Quantitative data from questionnaires were checked daily for completeness and coded for appropriate computer entry. Equivalent responses were pooled to arrange the response in different categories. Data was entered into Stata version 12 software computer program for data cleaning and analysis. The study utilized univariate and bivariate analysis.

Prevalence of methods was determined as proportion of women with second trimester abortion managed either medically, surgically or both medically and surgically and displayed using frequency tables.

For the second objective, proportion of complications was determined and reported as frequencies and lastly fisher's exact test was used to determine association between the method of management and complication (objective three)

## **2.11 Control of biases and errors**

- Measurement bias: the data collection tool was pretested for validity and reliability
- Sampling bias: KNH was conveniently selected, being the largest hospital in the region; this may therefore not represent the management of abortion across the country.
- Errors during data entry were minimized by daily checking of collected data by the PI and verifying the collected information from the files

## **2.12 Study limitations**

- Incomplete patient records from the files: This refers to files that were missing clerkship details either in the history, physical examination or investigations as documented by the primary clinician
- Lack of clarity of patient records mostly due to illegibility of documented records.

Mechanisms of minimizing the limitations:

- Thoroughly checking for all patient information present in the files including the nursing cardex as this provided some details that were missing from the clerkship of the primary clinician. Some patients had 2 or more files and these had to be sought to ensure that complete records were obtained.
- A second person counterchecked illegible/unclear files and this also helped to ensure that complete records were obtained

### **2.13 Ethical considerations**

Permission was sought from the KNH and UON Ethics Research Committee to carry out this study as part of the UoN thesis dissertation. All information was handled with uttermost confidentiality throughout the tenure of the study, held in trust by the investigator, research assistants and the study institution. A password protected computer with access by the primary investigator and research assistant was used. No information concerning the study participants will be released to an unauthorized third party without prior written approval of the study institution or the Ethics Research Committee.

All patient information and identifiers were delinked from the collected data before sending to the data analyst. The study findings were presented to the University of Nairobi, Department of Obstetrics and Gynecology as part of the requirement of the MMed course.

## CHAPTER 3 RESULTS

### 3.1 socio-demographic characteristics

**Table 3.1: Socio-demographic characteristics of women presenting at KNH with second trimester abortion (2013-2018)**

Characteristic		N=150	Percentage (%)
Age in years	$\bar{x}=28$ (SD 5.7)		
Marital status	Married	105	76.4
	Single	34	24.6
Education Status	Primary	42	30.2
	Secondary	70	50.6
	Tertiary	27	19.2
Occupation	Business	5	4.0
	Employed	45	32.0
	Unemployed	89	64.0
Parity	Primiparous	54	38.8
	Multiparous	85	61.2
Gestational age	$\bar{x}=17$ weeks SD (2.7)		
	13-15 weeks	39	28.1
	16 weeks and above	100	71.9

The sociodemographic characteristics of patients who presented with second trimester abortion are as shown in table 3.1. The mean age was 28 years (SD 5.74).

Majority of the patients had secondary school education (50.6%), unemployed (64%), multiparous (61.2%) and presented at a gestational age of 16 weeks and above (71.9%).

### **3.2: Prevalence of methods (medical versus surgical) used in management of second trimester abortion**

#### **3.4 Prevalence of methods used in the management of second trimester abortion at KNH**

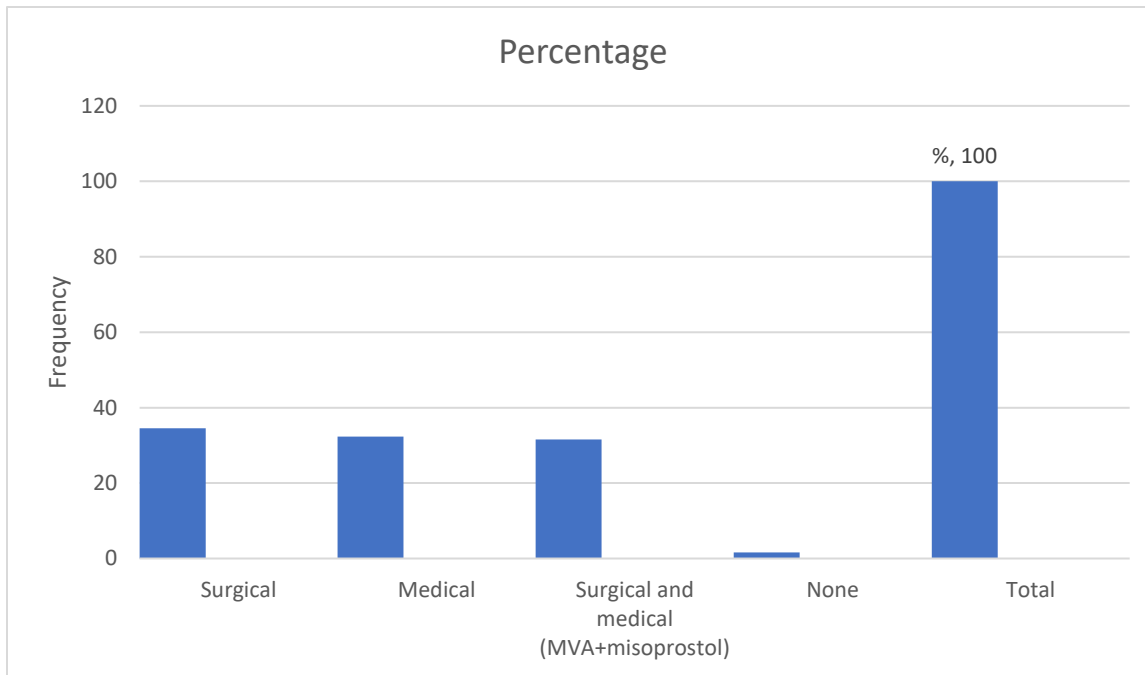


Figure 3.1: Bar graph illustrating proportion of methods used in management of second trimester abortion at Kenyatta National Hospital.

As shown in figure 4.1, the prevalence of methods of management of second trimester abortion were similar among the 3 main categories at 34.5%, 32.3% and 31.6% for surgical, medical, surgical and medical management (MVA+Misoprostol) respectively.

1.4% of patients spontaneously expelled their pregnancy and have been categorized as none (no intervention) in the chart above.

**Table 3.2: Prevalence of specific management methods used in second trimester abortion at Kenyatta National Hospital**

Method of Management		Number	Percentage
Medical (N=45)	Oxytocin	5	28.1
	Misoprostol	28	59.6
	Misoprostol and oxytocin	12	12.3
Surgical (N=48)	MVA	45	93.7
	D&C	1	2.1
	Suction curettage	1	2.1
	Foley catheter	1	2.1
Surgical+Medical (N=46)	MVA+Misoprostol	46	100

As depicted in table 3.2, misoprostol was the main medical method for managing second trimester abortion (59.6%) and MVA was the main surgical technique (93.7%).



### **3.3 The prevalence of complications of second trimester abortion**

86% of the study population were successfully treated without complications

Table 3.3 below shows the various complications, the number and percentage of women who suffered that particular complication

**Table 3.3: Prevalence of complications following management of second trimester abortion at KNH**

<b>Complication</b>	<b>Number N=139</b>	<b>Percentage</b>
Retained POCs	8	5.8
Haemorrhage	6	4.3
Failed initial method	3	2.1
Infection	1	0.7
Organ damage	1	0.7

Retained products of conception was the most commonly encountered complication as depicted above.

### **3.4 Association between the method of management (medical versus surgical) and the outcomes and complications of second trimester abortion**

**Table 3.4: Comparison of prevalence of complications: surgical management vs medical management following treatment of second trimester abortions at KNH**

Complication	Surgical	Medical
Failed initial method	0	3
Hemorrhage with transfusion	4	2
Infection	1	0
retained POCs	0	8
organ damage	0	1

As shown in the table above the patients who underwent medical abortion experienced more complications other than hemorrhage and infection as compared to those who underwent a surgical procedure.

**Table 3.5 and 3.6 Association between the method of management (medical versus surgical) and outcomes and complications of second trimester abortion**

Fisher's exact test was used to check for association between the method of management and the outcomes.

COMPLICATION	Surgical n=91	Medical n=48	P value
Haemorrhage	4	2	0.267
Retained POCs	0	8	0.062
Infection	1	0	0.324

Table 3.6

Complication	Surgical management N=91	Medical Management N=48	P value
No	86	38	0.33
Yes	5	10	0.53

A p value of 0.05 was considered as significant.

There was no statistically significant association between the method of management and outcomes.

## CHAPTER 4 DISCUSSION

In this descriptive cross-sectional study conducted at the Kenyatta National Hospital it was found that a third of patients with second trimester abortion underwent medical management, another third underwent surgical management and the remaining third underwent both medical and surgical management. The main medical method involved use of misoprostol and the main surgical technique was MVA as shown in table 3.2. This is in contrast to prevalence of methods elsewhere notably in the western world where D&E is the commonest method. For example, in the USA and England, the procedure accounts for 96% and 75% of cases of second trimester abortions respectively. However, in China, medical methods are preferred with virtually all cases managed by a combination of mifepristone-misoprostol.(39)

No patient in this study underwent D&E, this in spite of several studies demonstrating the procedure as being superior to medical methods. A systematic review by Gemzel Daniels et al (40) that compared efficacy, side effects, adverse events and acceptability of surgical versus medical methods of abortion methods in the second trimester found that the incidence of complications were much lower with D&E as compared to medical methods. The complications found to be lower included hemorrhage, febrile morbidity, cervicovaginal trauma and prostaglandin reaction.

There was also no patient who underwent medical induction with mifepristone. This in spite of the drug being locally available and studies having shown it to be a suitable adjunct when administered in combination with a prostaglandin. Bygdemann et al (41) demonstrated a shortened induction to abortion interval (from 15 hours to 6 hours) when mifepristone is administered 36-48 hours prior to giving a prostaglandin.

86% of patients were treated successfully without complications. For those who experienced complications, retained POCs was the commonest complication (5.8%) with haemorrhage following at 4.3% and failed initial method at 2.1%. No case of cervical/uterine perforation was noted. Other than haemorrhage and infection, these complications were seen in patients managed medically.

This compares to a study done by Ashok et al(42) which demonstrated an incidence of retained POCs of 8% and haemorrhage at 2% with medically managed second trimester abortions. Complications following surgical management of second trimester were also fewer in the above study when compared to medical methods (Retained POCs incidence at 0.02% and haemorrhage at 0.09%). The incidence of complications in these studies are lower and this may be attributable to the surgical technique used in the study(D&E).

Fischer's exact test was used to determine any association between the method of management (surgical versus medical) and outcome. There was no statistically significant association between the method of management and outcome. This was in contrast to the study by Autry AM(27) which showed a statistically significant difference, the odds ratio of experiencing an adverse event being significantly lower for a surgically managed second trimester abortion as compared to medical methods (OR 0.1 95% C.I. 0.0-0.3, p value of 0.02 )/The difference may be attributed to the study power with this study having more subjects that experienced complications. However, the results were similar to the study by Grimes et al 2004(26) that did not show any statistically significant difference in outcome between surgical and medical methods. Larger randomized controlled studies may be required to assess the association between method of management of second trimester abortion and outcome.

## **CONCLUSION**

The prevalence of methods of management of second trimester abortion were similar among the 3 main categories at 34.5%, 32.3% and 31.6% for surgical, medical, surgical and medical management (MVA+Misoprostol) respectively.

The complication rate was 14% and did not vary by method of management.

## **RECOMMENDATIONS**

- Development and standardization of protocols of management of second trimester abortion.
- The introduction of Dilatation and evacuation and mifepristone as appropriate management methods of second trimester abortion due to their proven efficacy and safety advantage.

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## ANNEX 1

### **5.1 Supportive management of second trimester abortion at KNH**

#### **5.1.0 Use of analgesics in the management of second trimester abortion**

It was found that 66% of patients seen received analgesics while approximately 34% did not. The drug of choice was paracetamol as shown in the table below.

Pain killer	No. (%)
Paracetamol	31 (33.7)
Diclofenac	29 (31.5)
Tramadol	8 (8.7)
Morphine	1 (1.0)
Paracetamol & Diclofenac	12 (13.0)
Paracetamol & Tramadol	8 (8.7)
Paracetamol & Morphine	1 (1.0)
Diclofenac & Tramadol	1 (1.0)
Tramadol & Morphine	1 (1.0)

Table 5.1: Analgesic use in the management of second trimester abortion at KNH

#### **5.1.2 Use of antibiotics in the management of second trimester abortion**

Out of 139 clients, 107 (76.9%) were given at least one antibiotic, while 32(23.1%) did not.

In the group managed surgically, 75% (36 patients) received antibiotics while 25% (12) did not.

For those who underwent both surgical and medical procedures 11% did not receive antibiotics

For medically managed abortion, 67% received antibiotics while 33% did not.

The preferred regimen was a combination of Amoxicillin-clavulanic acid and metronidazole at 42% followed by Amoxicillin monotherapy at 15%. Only 2% of patients received doxycycline or a combination of doxycycline and metronidazole.

### **5.1.3 Post abortal care and family planning**

Only 11% of patients seen received family planning counselling and support.

## **5.2 Discussion of supportive management of second trimester abortion at KNH**

It was found in this study that 71% of patients did not receive the correct dosage of misoprostol. This may partly account for the higher rates of failed initial method or retained POCs seen with medical induction seen in this study.

For supportive management 66% of patients received analgesics, 34% did not. The preferred drug was paracetamol (33%). The WHO recommends that all women should be offered appropriate pain management before and or during medical/surgical abortion with the recommendation to individualize each woman's pain management needs and a utilization of both pharmacological and non-pharmacological means. (9)

Notably, WHO does not recommend utilization of paracetamol, for pain control during abortion(9). Recommended medication include use of NSAIDs for example ibuprofen 400-800 mgs, anxiolytics like diazepam 5-10 mgs and paracervical blocks with lidocaine for surgical management. For second trimester abortions, it is also recommended that one of oral or parenteral opioids or epidural anaesthesia is administered. Conscious sedation or general anaesthesia may also be used for surgical cases though this is not recommended as a routine.(9)

Only 12.1% of patients in the study received an opioid either in combination or as monotherapy for pain control. No patient received sedatives/anxiolytics/paracervical blocks further outlining a significant deficiency in pain management.

As regards use of antibiotics, 67% of patients who were managed medically for second trimester abortions received antibiotics. This is in contrast to the WHO recommendations which do not recommend antibiotic prophylaxis for medical abortion(9). Conversely not all patients managed

surgically received antibiotics though this is the current WHO recommendation (25% did not receive for those managed surgically and 11% did not receive for those managed both surgically and medically)(9)

Further studies are required to determine whether the preferred regimen in this study (amoxicillin-clavulanic acid with metronidazole) provides adequate cover for prophylaxis as a Cochrane review recommends that antibiotic choice should take into account the local epidemiology of genital tract infections including sexually transmitted infections.(44)

It was found that only 11% of patients in this study were offered post abortion care services with family planning counselling and support. The WHO recommends that this service should be offered universally across all patients.(9)

**ANNEX 2**

**Annex 2: Letter to IRB**

DR ERIC SIMIYU

(MBChB)

H58/74505/2014

MMed Obstetrics and Gynecology

The Chairperson,  
Ethics, Research and Standards Committee,  
Kenyatta National Hospital and University of Nairobi,  
P.O. Box 20723,  
Nairobi

Thro'  
The Dean,  
School of Medicine,  
Thro'  
The Chairperson,  
Department of Obstetrics and Gynecology

Dear Sir/Madam,

RE: SUBMISSION OF MASTERS DEGREE RESEARCH PROPOSAL FOR APPROVAL

I wish to submit my research proposal for approval by your esteemed committee. I am currently a second-year student pursuing a Master's Degree in Obstetrics and Gynecology at the University of Nairobi, College of Health Sciences.

Yours Sincerely,

Dr. Eric Simiyu,

Department of Obstetrics and Gynecology,

School of Medicine,

University of Nairobi



**ANNEX 3: QUESTIONNAIRE**

**Management, practice and outcomes of second trimester pregnancy losses in Kenyatta National Hospital**

1. Serial number .....

2. Date when admitted to hospital

\_\_\_\_/\_\_\_\_/\_\_\_\_

3. Time when admitted to hospital

\_\_\_\_\_

4. Time when definitive management was started

\_\_\_\_\_

5. Year of Birth (*dd/mm/year*)

\_\_\_\_/\_\_\_\_/\_\_\_\_

6. Parity:

Number of live births (*more than 28 weeks*) \_\_\_\_\_

Number of miscarriages (*less than 28 weeks*) \_\_\_\_\_

7. Date of the last menstrual period (*1<sup>st</sup> day of when the bleeding started*)

\_\_\_\_/\_\_\_\_/\_\_\_\_

8. Date when first ultrasound was done, if any

\_\_\_\_/\_\_\_\_/\_\_\_\_

9. Clinical presentation and period in days (*mark as appropriate*)

i. Per Vaginal Bleeding for \_\_\_\_\_ days

- ii. Lower abdominal pain for \_\_\_\_\_ days
- iii. Draining of liquor for \_\_\_\_\_ days
- iv. Any other symptom (*kindly specify*) \_\_\_\_\_ for \_\_\_\_\_ days

10. Clinical examination (*at admission*)

a. Vital signs

- i. Temperature (*in degrees Celsius*) \_\_\_\_\_
- ii. Respiratory rate (*breaths per minute*) \_\_\_\_\_
- iii. Pulse rate (*beats per minute*) \_\_\_\_\_
- iv. Blood pressure (*systolic/diastolic*) \_\_\_\_/\_\_\_\_

b. Abdominal examination

- i. Fundal height (*in weeks*) \_\_\_\_\_ weeks

- ii. Tenderness (*mark as appropriate*)  Mild  
 Moderate  
 Severe

- iii. Any other system findings (*kindly specify*)  


---



---



---

c. Pelvic Examination (*mark as appropriate*)

i. Per vaginal bleeding

ii. Draining of liquor

Kindly describe the color and smell of the liquor \_\_\_\_\_

---

iii. Any other discharge

Kindly describe the color and smell of the discharge \_\_\_\_\_

---

## 11. Investigations

### a. Laboratory

	<b>Parameter</b>	<b>Results</b>	<b>Normal Range</b>	<b>Date when done</b>
1	WBC Count (total)			
2	Haemoglobin level			
3	Platelet count			
4	Blood Grouping			
5	Creatine			
6	Urea			
7	Total bilirubin			
8	Other, indicate			

### b. Radiological

i. Pelvic ultrasound (*briefly indicate findings*)

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- ii. Any other radiological examination (*kindly specify and indicate the findings*)

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12. Management

a. Supportive (*tick as appropriate*)

- i. Intravenous fluids (*kindly specify type and amount per day*)

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- ii. Blood transfusion (*kindly indicate product and amount transfused*)

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- iii. Pain killers (*kindly indicate dosage and amount per day*)

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- iv. Antibiotics (*kindly indicate dosage and amount per day*)

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- v. Any other supportive management (*kindly specify*)

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b. Definitive management

i. Medical (*indicate the drug used, and the dosage*)

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ii. Surgical (*indicate method*)

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13. Treatment outcomes

a. Complete resolution of the symptoms

b. Failed initial induction

c. Infection

d. Cervical laceration and repair

e. Retained products of conception

f. Hemorrhage

g. Organ damage

h. Hospital readmission

14. Date when patient was discharged from the hospital (*dd/mm/year*)

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**ANNEX 4: BUDGET**

ITEM DESCRIPTION	COST KSH
1. Transport	10000
2. Research assistant at KSH 8000 each per month for 3 months	24000
3. Printing of data collection forms	10000
4. Printing and binding of manuscripts and proposal	5000
5. Statistician	50000
6. Printing of posters	2000
7. Miscellaneous	5000
<b>Total</b>	<b>100000</b>

**ANNEX 5: STUDY TIMELINES**

Timeframe/ Activity	July 17	Aug 17	Sept 7	Oct 17	Nov 17	Dec 17	Dec 17	Jan 18	Feb 18	Mar 18	Apr18	May 18	Jun 18	Jul 18	Aug 18	Aug - Dec 18	
<b>Proposal Development and defense</b>																	
<b>Ethical clearance</b>																	
<b>Clinical evaluation</b>																	
<b>Data collection</b>																	
<b>Data Analysis, thesis writing and defense</b>																	
<b>Dissemination of results to key stakeholders</b>																	