# INCIDENCE OF EMERGENCY PERIPARTUM

# HYSTERECTOMY IN KENYATTA NATIONAL HOSPITAL

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# DECLARATION

I declare that this is my original work and has not been presented for a degree in any other university.

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#### DEDICATION

I dedicate this project to the Almighty God, my creator, my strong pillar, my source of inspiration, wisdom, knowledge and understanding. He has been the source of my strength throughout this program and on his wings only have I soared. I also dedicate this work to my beloved wife,**Marthe Nzeba Mashala**, whose supportive prayers and encouragement have made sure that I give it all it takes to finish that which I have started. To my beloved children,**Obed Mashala**, **Jemimah Mashala** and **Keziah Mashala**, who have been affected in every way possible by this quest, thank you and God bless you.

### LIST OF ABREVIATIONS

AMTSL:	Active Management Third Stage of Labor
AOR:	Adjusted Odds Ratio
AKI:	Acute Kidney Injury
CI:	Confidence interval
CS:	Cesarean Section
DIC:	Disseminated Intravascular Coagulopathy
EOH:	Emergency Obstetric Hysterectomy
EPH:	Emergency Peripartum Hysterectomy
HMC:	Hachioji Medical center
HIC:	High-Income Country
LMIC:	Low and Middle Income Country
KNH:	Kenyatta National Hospital
MDG5:	Fifth Millennium Development Goals
MMR:	Maternal Mortality Rate
PP-AKI:	Postpartum Acute Kidney Injury
PPH:	Postpartum Hemorrhage
PAH:	Partial Abdominal Hysterectomy
PAS:	Placenta accreta syndrome
PATH:	Program for Appropriate Technology in Health
TAH:	Total Abdominal Hysterectomy
TTI:	Temperature Time Indication
TI:	Temperature Indication
SHO:	Senior House Office
PAH:	Partial Abdominal Hysterectomy

- UAE: United Arab Emirates
- USA: United State of America
- UNFPA: United Nations Population Agency
- UNICEF: United Nations Emergency Children's Fund
- WHO: World Health Organization

#### **OPERATIONAL DEFINITION**

**Emergency peripartum hysterectomy**: This is a life-saving procedure carried out when conservative measures fail to control obstetric hemorrhage.

Postpartum hemorrhage (PPH): this is a heavy per vaginal bleeding after birth.

It can be:

- Primary PPH: This is the loss of 500ml or more of blood within the first 24 hours after delivery. Primary PPH can be minor, where you lose 500-1000ml and major when you lose > 1000mls of Blood.
- Secondary PPH: This occurs when you have abnormal or heavy vaginal bleeding more than 24hours and up to 12 weeks after delivery,

### LIST OF TABLES

### LIST OF FIGURES

Figure 1:	Conceptual	Framework7	1
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## TABLE OF CONTENTS

#### Contents

DECLARATION	Error! Bookmark not defined.
CERTIFICATE OF SUPERVISORS	iii
CERTIFICATE OF AUTHENTICITY:	iii
ACKNOWLEDGEMENT	V
DEDICATION	vi
LIST OF ABREVIATIONS	vii
OPERATIONAL DEFINITION	ix
LIST OF TABLES	Х
LIST OF FIGURES	xi
TABLE OF CONTENTS	xii
ABSTRACT	xiv
CHAPTER ONE	1
I.0 INTRODUCTION	1
I.1 Background of the study	1
CHAPTER TWO	3
2.0 LITTERATURE REVIEW	3
2.1 Introduction	3
2.2 Previous studies	
2.3 Problem statement and Study justification	7
2.4 Conceptual Framework	7
2.5 Research Question	8
2.6 Research Objectives	8
2.6.1 Broad objective	8
2.6.2 Specific objectives	8
CHAPTER THREE	9
3.0 RESEARCH METHODOLOGY	9
3.1 Study design	9
3.2 Study site and setting	9
3.3 Target population	10
3.4 Inclusion criteria	
3.5 Exclusion criteria	
3.6 SAMPLE SIZE DETERMINATION AND F	ORMULA10
3.7 Sampling procedure	
3.8 Data collection	
3.9 Study materials and training procedures	

3.10 Data management and analysis
3.11 Ethical considerations
3.12 Study limitation and how to minimize them12
CHAPTER FOUR
4.0 RESULTS
4.1 Introduction
4.2 Baseline Socio-demographic characteristics of patients with postpartum hemorrhage who underwent emergency peripartum hysterectomy 2013-202813
4.3 Baseline Obstetric and Surgical characteristics of patients with postpartum hysterectomy who underwent emergency peripartum hysterectomy 2013-201814
4.4 Incidence of Emergency Peripartum Hysterectomies at the Kenyatta National Hospital
4.5 Indications and type of Hysterectomy of patients with Postpartum hemorrhage who underwent Emergency Peripartum Hysterectomy in KNH 2013-201816
4.6 Poor outcomes of mother and the fetus17
4.7 Complications of the patient with postpartum hemorrhage who underwent emergency peripartum hysterectomy in KNH 2013-2018
CHAPTER FIVE
5.0 DISCUSION
CHAPTER SIX
6.0 CONCLUSION AND RECOMMENDATIONS
6.1 Conclusion
6.2 Recommendations
REFERENCES
ANNEX
Annex 1 Timelines

#### ABSTRACT

**Introduction:** Emergency Peripartum Hysterectomy (EPH) is a lifesaving obstetric procedure reserved for conditions where the conservative management of postpartum hemorrhage (PPH) has completely failed and there is presence of life threatening hemorrhage during or immediately after abdominal or vaginal deliveries. The incidences of EPH vary from 0.24 to 8.7 for every1000 deliveries Globally. EPH is more frequent after cesarean section (c/s) compared to vaginal births. The incidence of EPH at Kenyatta National Hospital (KNH) is unknown/ undocumented. The hospital has 11000 deliveries and 4500 cesarean section giving a c/s rate of 40.9%. Since placenta Accreta syndrome (PAS), which is one of the risk factors for EPH, occurs more commonly in repeat C/S, understanding the management of the patients with EPH is important.

**Objectives:** To determine the incidence, indications and pregnancy outcomes post emergency peripartum hysterectomy amongst patients in KNH 2013-2018.

**Methodology:** This was a descriptive retrospective cohort study conducted at the Kenyatta National Hospital maternity unit,

**Results:** The incidence of EPH was found to be 1.19 per 1000 deliveries. The common indications for EPH were uterine atony (57%), followed by uterine rapture (19.0%), and abnormal placentation (18.0%). The most frequent complications post EPH were Partial abdominal hysterectomy (91.0%), maternal mortality (2.0%), and perinatal mortality (9.0%), and DIC (18.0%). In terms of blood transfusions, 69.0% of the participants had 1- 3 units, while 74.0% of the women had 1- 3 units of Fresh Frozen Plasma (FFP).

**Conclusion:** The incidence of EPH was 1.19 per 1000 deliveries, and the primary indication of EPH was uterine atony. Post EPH complications included maternal mortality (2.0%), perinatal mortality (9.0%), and DIC (18.0%).

**Recommendation**: To sensitize women and health care workers on the importance of ANC and vaginal delivery, and to avoid unnecessary induction of labour and cesarean section for good outcomes.

#### **CHAPTER ONE**

#### **I.0 INTRODUCTION**

#### I.1 Background of the study

Emergency peripartum hysterectomy (EPH) is the surgical removal of uterus either at the time or within 24 hours of delivery. It is a lifesaving procedure reserved for conditions where obstetric hemorrhages persist despite conservative management procedures instituted. Post-Partum Hemorrhage (PPH), if not managed, is associated with high maternal morbidity and mortality. One of management of PPH is EPH. The incidence of EPH is reported to range globally from 0.24 to 8.7 per 1000 deliveries (1). The incidence is higher in low and middle-income countries due to poor uptake of antenatal care (ANC) and lack of skilled birth attendance. In high-income countries, such as USA and Canada, The incidence of EPH is on the rise due to increase in cesarean section (C/S)(2). The rise in C/S rates appears to have resulted in the increase in Placenta Accreta Spectrum (PAS). Likewise, the increase in PAS has led to an increase in PPH and EPH. PAS is an abnormal trophoblast invasion of part or all of the myometrium. There are 3 grades of PAS: placenta accreta is an abnormal trophoblast invasion of part or all of the placenta into the myometrium of the uterine wall, placenta percreta occurs when chorionic villi invade the full thickness of uterine wall, placenta increta occurs when chorionic villi invade into the myometrium. Maternal morbidity and mortality occur due to excessive life threatening hemorrhage, which often requires blood transfusion (3). Rate of maternal mortality have due to PPH are on the increase and this can be attributed to PAS because of severe and sometimes life threatening hemorrhage, which often require blood transfusion. Accounting for up to 35% maternal mortality globally. Patients having placenta accreta spectrum also have higher chances of Hysterectomy (4).

The WHO health targets for Sustainable Development Goal (SDG) 3 by 2030, include reducing the global maternal mortality ratio to less than 70 per 100 000 live births. The targets also aim a traducing neonatal mortality to at least as low as 12 per 1000 live births (5).

Each year about 14 million of women worldwide suffer from PPH and there is an increase in the trend. In addition, maternal mortality recorded due to hemorrhage is 1 per 1000 deliveries in low and middle-income countries (LMIC). Approximately, 99% of the mortality recorded from PPH arises from the LMIC, compared with simply 1% from the high incoming countries (HIC)(5,6).

World Health Organization (WHO) recommended active management of the third stage of labor in vaginal delivery as a good way to prevent PPH. It includes prophylactic use of uterotonic drugs; Oxytocin injection is the preferred first line uterotonic medication in PPH management, since it has greater efficiency compared to ergometrine plus other uterotonics. In addition, It has few adverse effects. However, the oxytocin requires the cold chain storage to maintain its efficiency (7). Even though Active Management of the Third Stage of Labor (AMTSL) minimizes postpartum hemorrhage,3%-16.5% of women will still experience PPH (8).With the increasing trends of C/S, there will be increased incidence of PAS, which will be a big contributor to PPH, leading to EPH. This study, therefore, intended to determine the incidence, indication, type of EPH and feto-maternal outcomes in KNH.

#### **CHAPTER TWO**

#### 2.0 LITTERATURE REVIEW

#### **2.1Introduction**

The incidence, indication, type and outcomes of EPH differ from region to region. There has been an increasing trend in C/S rates worldwide, and this has resulted in an increasing incidence of EPH.

#### **2.2Previous studies**

Joana et al defined EPH as uncommon obstetric procedure, usually performed as a life saving measure in case of intractable obstetric hemorrhage after delivery (9). The study which was done by Koh et al 2009 found that there are several possible reasons for excessive bleeding during and after the third stage of labor: uterine atony (failure of the uterus to contract properly after delivery), trauma (cervical, vaginal, or perineal lacerations), retained or adherent placental tissue, clotting disorders, and inverted or ruptured uterus. Uterine atony is the leading cause of immediate PPH, accounting for75-90% (10,11).

A retrospective case-notice evaluation study carried out by kaushalya et al., from 2006 to 2016, in a western Australian population on EPH, reported EPH incidence of 1.1 per 1000 deliveries. Abnormal placentation (placenta Previa) was the most common cause of EPH, representing 66.7%. Among women undergoing an EPH, 22.2% had a history of one previous cesarean delivery and 33.0% had two or more of cesarean section, respectively. Moreover, there was one case of maternal mortality due to hypovolemic shock; 84.0% of blood transfusions was recorded, with more than half of these women meeting the criteria for massive transfusion protocol of more than 4 units of packed red cells (12).

Another retrospective study was performed in 38 hospitals in China by Qiang et al from January to December 2011.That study reported forty-three peripartum hysterectomy cases out of 114420 deliveries, with an EPH incidence of 0.38%. Abnormal placentation was the most common indication for EPH: Placenta/accrete accounted for 95% (13).

A descriptive retrospective study done by Yulong et al, from 2004 to 2018 in China, on Emergency obstetric hysterectomy (EOH), reported an EPH incidence of 0.63 per 1000 deliveries. In that study, the common indications for EPH were postpartum prothrombin activity (61.5%), placenta accrete (43.76%), uterine atony (37.5%), uterine rupture (17.5%) and grand multiparty (32.5%). A total of 41 patients had subtotal abdominal hysterectomy (STAH) and 55 patients had Total abdominal hysterectomy (TAH). There was no difference in the maternal complication following TAH or PTAH (14).

In a retrospective research performed in Turkey by Demirci et al from January 2000 to January 2008, the incidence of EPH was 0.37 per1000 deliveries. The common indications for EPH were placenta accrete (53.8%) and uterine atony (25.6%). Maternal deaths accounted for 15.4%, bladder injury15.4%, and laparotomy 35.4% of the EPH outcome complications. Transfusion of more than 10 units of blood cells accounted for 15.6% of the EPH outcome complications. The number of previous C/S was associated with increased risk of placenta accrete (15).

Stella et al., in a retrospective study from 2000 January to 2013 January, hadan EPH incidence of 2.2 per 1000deliveries. A total of 49 EPH cases were carried out after cesarean section and 2 after vaginal birth. Abnormal placentation (49.0%) was the most common indication, uterine atony (41.2%), and uterine rupture (98%). A total of 80% of patients who underwent EPH with abnormal placentation had at least 1

previous C/S. a total of45.1% of patients underwent total hysterectomy, and 28 patients underwent subtotal hysterectomy (16).

Tomoyoshi et al carried out a retrospective study from 1998 to 2012 in Tokyo. That study had13cases of EPH among 42,119 deliveries: the EPH incidence of 0.31 per1000 deliveries was reported. They found that the uterine rupture was the most common indication at 38.5%. However, disseminate intravascular coagulopathy (DIC) was the most frequent pre and postoperative complication (17).

In Quetta Pakistan, Mahrukh et al conducted a comparative prospective study on EPH. They had 12.642 deliveries, and an EPH incidence of ~ 4 per 1000 deliveries. Almost 82.6% of their patients did not have antenatal care prior to their presentation to the hospital for delivery. They recorded 8.7% of maternal mortality. The commonest indication for EPH was uterine rupture at 45.7%. An Australia study had an incidence of 0.85 per 1000 deliveries and A USA study had an incidence of 1.4 per 1000 deliveries (18).

A descriptive study done by Anshuja et al in New Delhi, from2006 to 2014 had an EPH incidence of 1.19per 1000 deliveries. The common indications for EPH were uterine atony (45.87%)and rupture uterus (18.56%). A total of 9.79% of women had disseminated intravascular coagulation (DIC). The case maternal fatality was 7.2% and perinatal mortality was 30% (19).

A study by Jaya et al., carried out from 2006 to July 2014 in Kasturba Hospital, New Delhi, reported an EPH incidence of 0.030% per 100,000 deliveries. The most common indications for EPH were uterine atony (25%), placenta accrete (21%), and uterine rupture (17.5%). The most frequent sequelae were feverish illness (19.2%) and DIC (13.5%). The maternal mortality was 17.7% while perinatal mortality was 37.5%(20).

Muna et al dida descriptive study from2000 to 2015in Dubai. They hadan EPH incidence of 0.47 per 1000 deliveries. The common indications for EPH were abnormal placentation (previa and /or accreta) was the most common indication for EPH, and uterine atony. The most common post EPH complications were massive transfusion and urinary tract injuries. One case of maternal death occurred (21).

A retrospective study done in Egypt, by Allian et al. from 2003 to 2008, reported an EPH incidence of 2.24 per 1000 deliveries. The primary indications for hysterectomies were uterine rupture (77%), abnormal placentation (placenta previa/accreta/ increta) at 39.6%, and uterine atony at 24.8% (22).

A retrospective cohort study on EPH, carried out by Ahmed et al from 2009 to December 2014, had an EPH incidence of 1.30 per 1000 deliveries. The common indications of EPH were uterine atony (48.78%), abnormal placentation (21.95%) and rupture uterus (20.32%). The 39.02% maternal mortality was 39.0%, while the perinatal mortality was 20.32%(23).

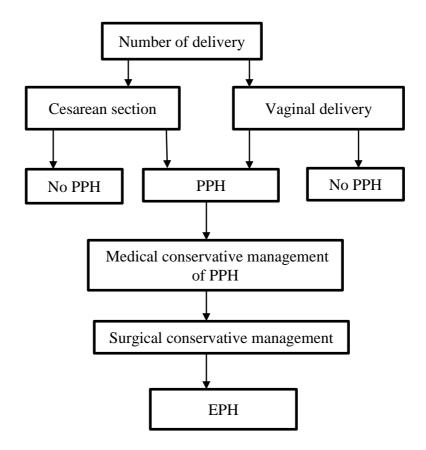
A Nigeria study Akenitayo et al., carried out from 2010 to 2013, reported an EPH incidence of 2.6 per 1000 deliveries. The common indications for EPH were uterine rupture(44.1%), uterine atony (37.3%) and morbidly adherent placenta(17.6%). Subtotal hysterectomy was performed in 67.6 % of the cases. Maternal mortality rate was 11.8% and perinatal mortality was 55.9%(24).

There is no study that has been done on incidence, indication, type of hysterectomy and feto-maternal outcome at KNH.

#### 2.3Problem statement and Study justification

PPH contributes to 75-90% of all maternal deaths. The highest numbers are observed in the LMIC. When PPH occurs, efforts are made to manage it immediately and this involves set protocols. The KNH labor ward has its own protocol. In situations where medical and surgical conservative management fail, Emergency postpartum Hysterectomy is carried out. This can either be partial or total abdominal hysterectomy. The incidence of PPH in KNH was 9.2% and maternal mortality was 1.9% as at 2018. Some patients with PPH had EPH whose incidence in KNH is unknown.

This study, therefore, will help to change the policy in management of PPH in KNH.



#### 2.4 Conceptual Framework

Figure 1: Conceptual Framework

#### **Elaborate conceptual framework**

There are two modes of deliveries: Cesarean section and vaginal delivery. Postpartum haemorrhage (PPH) with minimal bleeding is well controlled by uterotonics. When there is excessive bleeding secondary to PPH and medical conservative management fails, surgical conservative management can help to control the bleeding. In case the bleeding is not controlled and is becoming life threatening, Emergency Peripartum Hysterectomy (EPH) is performed.

#### **2.5Research Question**

What is the incidence, indication and pregnancy outcome post peripartum hysterectomy, amongst patients who had PPH in KNH, 2013 - 2018?

#### 2.6Research Objectives

#### **2.6.1Broad objective**

To determine the incidence, indication, and pregnancy outcomes post-peripartum hysterectomy amongst patients had PPH in KNH, 2013- 2018.

#### 2.6.2 Specific objectives

Among patients with PPH in KNH 2013-2018, determine:

- 1. The incidence of Peripartum hysterectomy
- 2. The indications and type of emergency peripartum hysterectomy (total or partial abdominal Hysterectomy)
- 3. Poor maternal outcomes
- 4. Poor neonatal outcomes

#### **CHAPTER THREE**

#### **3.0 RESEARCH METHODOLOGY**

#### 3.1Study design

This was a descriptive retrospective cohort study.

#### **3.2Study site and setting**

The research was carried out at KNH Obstetrics ward unit.

KNH is the largest teaching and referral hospital in Kenya a bed capacity of 1800. It is located in Nairobi about4km to west of the city center. The hospital records more than 10000 deliveries per years.

The maternity unit of the hospital comprises of a labor ward, and two operating theatres. The unit is covered by midwives, medical registrars, and consultant obstetricians who work in shifts (25).

Postpartum Hemorrhage is managed following 4Ts (Tone, Trauma, Tissue, and Thrombin). The medical conservative management is mainly done by the use of uterotonics; the most commonly used is oxytocin, followed by misoprostol, egormetrine, and cabetocin. Moreover, in cases of uterine atony, maneuvers such as uterine massage, bimanual compression of uterus, and tamponade balloon are used. When medical management fails the surgical conservative management is used, including, suturing cervix, vaginal wall or vulvar in case of trauma. When this fails, laparotomy may be employed, and B lynch, bilateral ligature of uterine arteries are done. When this also fails EPH is performed to save life of the women (26,27,28,29).

#### **3.3Target population**

This comprised all pregnant women who were delivered in the KNH Obstetric unit and had PPH.

#### **3.4Inclusion criteria**

Women who delivered in KNH and who had had EPH, within the period of 2013 - 2018 of study.

#### **3.5Exclusion criteria**

Women who were admitted in KNH as referral and who had had EPH performed outside KNH.

#### **3.6 SAMPLE SIZE DETERMINATION AND FORMULA**

#### A formula for calculating Sample size for descriptive Cohort study was used

Sample size for population given:  $x = Z^2 \times \frac{P(1-P)}{M^2}$ 

Where:

S= sample size for population given Z= Z -score for 95% Confidence Interval = 1.96 P= Population proportion (assumed to be 50% = 0.5) M= Margin of Error = 5% = 0.05 S =  $(1.96)^2 \times 0.5 (1-0.5)/(0.05)^2$ S = 384.16

Sample size for the adjusted population (based on the Dubai study by Tahlak, M.A, et

al (2018), had 79 EPH cases = approximated population of 100

Adjusted S = (S)/1+ [(S-1)/population] Adjusted S = 384.16/1+ [(384.16-1)/100] Adjusted S = 384.16/(1+3.8316) Adjusted S = 384.16/4.8316 Adjusted S = 79.5 = 80 (Thus, the minimum required sample size = 80)

#### **3.7Sampling procedure**

All the mothers who had EPH from  $1^{st}$  of January 2013 to December 2018 were included in this study period.

#### 3.8 Data collection

All the records of the patients who had PPH during the study period were retrieved.

For this study the major source of the data was done in KNH central registry and health records and information unit in the maternity department. The files and registers of patients that met our inclusion criteria for the study were reviewed and relevant information was extracted. The data was collected by research assistant or by the principal investigator. The password protected computer was used as data store, iCloud. A structured data collection tool was used to help for collection of data and it is in annex 1.

#### 3.9 Study materials and training procedures

Material used for this included stationery, questionnaire, registries, hard drives, password protected computers and iCloud.

One-research assistant, with experience in data collection, received appropriate training.

#### 3.10 Data management and analysis

Data was collected following all peripartum hysterectomies performed in the period of study and analyzed by SPSS version 21. Descriptive statistics was presented in the tables and charts. The incidence, indications and pregnancy outcomes post EPH was done by continuous variables (mean with standard deviation. Data on categorical variables, such as participant's age, marital status, residence, level of education, Antenatal care, hemoglobin level and gestation at the time of EPH were presented in the tables as percentages. Data on the type of EPH performed was presented in the table as percentages.

#### **3.11Ethical considerations**

The study was submitted and approved by the research committee of the Kenyatta National Hospital, University of Nairobi. In this study we used a weaver because we didn't need to be in contact with the patient. The mass storage devices such as USB and external hard driver was used to ensure the confidentiality and security of data and the physical security of the hard copy documents. Information collected remained confidential and they was not used for any other purposes a part from the study.

#### 3.12Study limitation and how to minimize them

We had issue of missing or incomplete data. But we did our best to have more documents from different level of our maternity where the information of patient was captured, like file of patient and registries (labor ward, theatre).

#### **CHAPTER FOUR**

#### **4.0 RESULTS**

#### **4.1 Introduction**

A total of 83839 deliveries were conducted between 2013 and 2018. Out of these, a total of 100 cases of patients who underwent EPH were found. The number of patients whose records were eligible for inclusion in the study was 85 (9 files could not be traced while 6 files had incomplete information).

# 4.2Baseline Socio-demographic characteristics of patients with postpartum hemorrhage who underwent emergency peripartum hysterectomy 2013-2028

As shown in table1, a majority of the participants, 42 (50%) were aged between 30 to 39 years, while only one participant (1%) was less than 20 years. Thirty- five (41%) were aged between 21 to 29 years while 7 (8%) were more than 40 years of age. The mean age for the study participants was 21 years (SD:2.5).

A majority of the women who underwent EPH were married, 64 (75%), the rest, 21 (25%) being single. Most of them resided in the city, 47 (55%), with a majority having attained Secondary school level of education, 32 (37.5%). Table 2 shows the distribution of the socio demographic characteristics among the women who had EPH.

VARIABLE	N= 85	PERCENTAGE (%)
1. Age (years)		
Less than 20	1	1
21 to 29	35	41
30 to 39	42	50
40 and above	7	8
Marital Status		
Married	64	75
Single	21	25
Residence		
City	47	55
Rural Area	38	45
Level of Education		
University	03	03.5
Collage	22	26
Secondary	32	37.5
Primary	28	33

 Table 1: Baseline socio-demographic characteristics of patients with postpartum hemorrhage who underwent emergency peripartum from 2013 to 2018.

# 4.3 Baseline Obstetric and Surgical characteristics of patients with postpartum

#### hysterectomy who underwent emergency peripartum hysterectomy 2013-2018

The obstetric characteristics of the study participants were described as shown in table 2.Most of the women were multiparous, 72 (85%). Of the 85 participants, 55 (65%) had attended between 2 to 4 antenatal clinics; with only 1 (1%) having attended the WHO recommended 8 ANC visits. The level of hemoglobin during the ANC visit was assessed, where a majority, 54 (75%), of the participants had levels of between 9 to 12mg/dl. Most of the women, 53 (62%), had 'term' pregnancies (defined as pregnancy of at least 37 weeks plus 6 days).

As shown in table 2 that describes the patients who had a history of prior surgical intervention performed on the uterus, 52 of the study participants (61%) had undergone at least one Cesarean delivery. Six of the participants (7%) had undergone

myomectomy, with an equal number (3, 50%) due to mucosal or intramural fibroids.

Out of the 15 (18%) participants who had undergone MVA procedure, 14 (93%) had

the MVA procedure done in less than 3 months period before the index pregnancy.

Table2:Baseline	obstetrics	and	surgical	cha	racteristics	of	patients	with
postpartum hemori	rhage unde	erwent	t emerge	ncy	peripartum	hy	sterector	ıy in
KNH, 2013-2018								

VARIABLE	N = 85	PERCENTAGE (%)
Parity		
Primigravida	13	15
Multigravida	72	85
Antenatal care		
1	16	19
2 to 4	55	65
5 to 7	13	15
More than 8	01	01
Hemoglobin level		
5 to 8	13	18
9 to 12	54	75
13 to 15	05	07
Previous Cesarean section		
Yes	52	61
No	33	39
Myomectomy		
Mucosal Fibroid	3	50
Intramural Fibroid	3	50
History of MVA		
Within 1 to 3 months	14	93
Between 4 to 8 months	01	07

# 4.4 Incidence of Emergency Peripartum Hysterectomies at the Kenyatta National Hospital

This was calculated as the total number of EPH performed between the 2013 and 2018 (100) divided by the total number of deliveries conducted over the same period (83,839). This gave an incidence of 1.19 EPH per 1000 deliveries.

# 4.5Indications and type of Hysterectomy of patients with postpartum hemorrhage who underwent Emergency Peripartum Hysterectomy in KNH 2013-2018

Figure 3 shows the indications for performing emergency peripartum hysterectomy at the Kenyatta National Hospital. A majority of the EPH, 57 (79%) were performed for patients with a diagnosis of uterine atony, followed by uterine rapture, 26 (19%), abnormal placentation 25 (18%), and lastly due to abruption placenta, 8 (6%). Of the 26 patients with uterine rapture, 16 (62%) had partial rapture while 10 (38%) had complete rapture. Out of the 85 EPH assessed during the study, 77 (91%) were partial abdominal hysterectomies while 8 (9%) were total abdominal hysterectomies.

VARIABLE	N = 85	PERCENTAGE (%)
IN	DICATION	
Uterine Atony	79	57
Uterine Rupture	26	19
Abnormal Placentation	25	18
Abruption Placenta	8	6
	ТҮРЕ	
Partial Abdominal Hysterectomy	77	91
Total Abdominal Hysterectomy	08	09

Table 3. Indication and type of hysterectomy of patients with postpartum hemorrhage who underwent emergency peripartum hysterectomy in KNH 2013-2018

#### 4.6 Poor outcomes of mother and the fetus

The maternal and neonatal outcomes following EPH were described as shown in table 7. A majority of the mothers, 69 (80%) were stable and discharged for follow up in the clinic, 13 (15%) were admitted to the ICU, 3 (3%) had poor reversal following general anesthesia while 2 (2%) died. Out of the 111 recorded neonatal events, 65 (59%) were admitted in the new born unit, 19 (17%) were stillbirths, 17 (15%) were stable and discharged for follow up in the clinic while 10 (9%) died.

 Table 4:Poor outcomes of the mother and the neonatal

VARIABLE	N= 87 EVENTS	PERCENTAGE (%)		
Maternal				
Death	02	2		
Poor Reversal During Anesthesia	03	3		
Admission to the Intensive Care	13	15		
Unit	69	80		
Neonatal				
Stillbirth	19	17		
Deaths	10	09		
Admission to the New-born Unit	65	59		
Stable	17	15		

# 4.7 Complications of the patient with postpartum hemorrhage who underwent emergency peripartum hysterectomy in KNH 2013-2018.

As part of the study outcomes, complications emanating from the management of the patients who underwent EPH were noted. Fifteen participants (18%) were diagnosed with disseminated intra vascular coagulopathy, followed by 12 (14%) who had prolonged intubation and post-operative wound infection respectively. Ten participants (12%) had documented history of fever and sepsis each, 9 (11%) had history of ureteral/bladder injury, while 7 (8%) participants had a history of urinary tract infection. Six patients (7%) developed acute kidney injury following the operation while 2 (2%) develop vesico-vaginal fistula. As part of supportive therapy, whole blood and blood products are usually used during EPH. In this study, 55 (69%) of the patients received 1 to 3 units of whole blood while 25 (31%) received 4 to 6 units. Twenty-five (74%) of the patients received 1-2 units of FFPs while 09 (26%) received 3 to 4 units of FFPs.

VARIABLE	N= 85	PERCENTAGE (%)
Fever	10	12
Acute Kidney injury	6	8
Wound infection	12	14
Urinary Tract Infection	7	8
Vesico-Vaginal Fistula	2	2
Sepsis	10	12
Prolonged intubation	12	14
Pneumonia	2	2
Ureteral/Bladder injury	9	10
Deep Venous Thrombosis	1	1
Disseminated Intravascular Coagulopathy	15	18
Blood Transfusion		
1- 3 units	55	69
4 – 6 units	25	31
Fresh Frozen Plasma		
1-2 units	25	74
3 – 4 units	09	26

Table 5: Complications and supportive management of patients with postpartumhemorrhage who underwent emergency peripartum hysterectomy 2013- 2018.

#### **CHAPTER FIVE**

#### **5.0 DISCUSION**

In this study, incidence of EPH is 1.19 per 1000 deliveries. The uterine atony was the commonest indication of EPH. The type of EPH that was most practiced was Partial Abdominal Hysterectomy, and there were maternal and perinatal mortalities, with other complications.

These findings are comparable to previous studies done in India and Nigeria.

Anshuja et al. (2014), in an India study reported an EPH incidence of 1.92% per 1000 deliveries. They also had uterine atony (46.0%) as the commonest indication of EPH. They had 7.2% of maternal mortality and 11.8% of perinatal mortality. Both of the present study and the Indian study used similar methodology. However, the differences could be attributed to the fact that in this present study, the patients were of the black race unlike the Indian race in the previous study (19).

The findings in this study are also comparable to a previous Nigeria study by Akenitayo et al (2016), which reported an EPH incidence of 2.6 % per 1000 deliveries. However, the commonest indication for EPH was uterine rupture (44.1%), followed by uterine atony (37.3%). Similar to the present study, the most commonly practiced type of EPH was Partial Abdominal Hysterectomy (67.0%). However, unlike in this present study, they reported very high maternal (11.0%) and perinatal mortalities (55.9%). This could be attributed, perhaps to the high prevalence of uterine rupture as the main indication of EPH in the Nigerian study (24).

Demirci et al conducted a study; the patients were transfused more than 10 units of red blood cell (15). Compare to our study where we did not reach even 10 units, 55 (69%) patients received 1 to 2 units of whole blood cells while 25 patients

31% received 4 et 6 units, we had noted 25 (74%) patients received 1 to 2 FFPs while 9(26%) patients received 3 to 4 units of FFPs.

Admission in the Intensive Care Unit we had 15% of patients that was quite low than 39% that was found in the study conducted by Anshuja et al (19).

This present study reported 18% of DIC, which was very high compared to the study done by Tomoyoshi et al that found that DIC had 9.79 %, in a Japanese study (17). This could probably be because of protracted delays in managing PPH.

The incidence of EPH is higher in low and middle-income countries due to poor uptake of antenatal care (ANC) and lack of skilled birth attendance. In this present study, out of the 85 participants, 55 (65%) had attended between 2 to 4 antenatal clinics; with only 1 (1%) having attended the WHO recommended 8 ANC visits. However, this ANC uptake is better compared to a Pakistan study, which had higher EPH incidence due to poor ANC uptake: in the Quetta Pakistan, Mahrukh et al conducted a comparative prospective study on EPH. They had 12.642 deliveries, and an EPH incidence of ~ 4 per 1000 deliveries. Almost 82.6% of their patients did not have antenatal care prior to their presentation to the hospital for delivery. They recorded 8.7% of maternal mortality (18).

#### **CHAPTER SIX**

#### 6.0 CONCLUSION AND RECOMMENDATIONS

#### **6.1** Conclusion

The incidence of emergency peripartum hysterectomy was 1.19 per 1000 deliveries.

The commonest indication for hysterectomy was uterine atony at 57.0%, while the commonest type of hysterectomy was partial abdominal hysterectomy at 91.0%.

The maternal mortality was at 2.0%, while the perinatal mortality was at 9.0%.

It was noted that majority of our patients were not attending Antenatal clinic according to WHO recommendation (8 visits per pregnancy).

Cesarean section remains main factor for EPH in our settings. Assessment of women's risks and reduction of number of cesarean section deliveries, by limiting the rate of the primary cesarean section contribute to prevention of EPH.

#### **6.2. Recommendations**

To sensitize women on importance of antenatal clinic in pregnancy for good outcome, good preparation of delivery.

To sensitize the healthcare workers on importance of vaginal delivery in possibility of avoiding cesarean section and unnecessary induction of labor once fails; lead to cesarean section, and on importance of documentation on the file of the patient.

22

#### REFERENCES

- Lovina S.M. Machado Emergency peripartum Hysterectomy: incidence, indications, risk factors and outcome. North American Journal of Medical Sciences 2011 Aug; v. 3(8): 358-361 available on PMC.
- Abiodun O. O, Hassan T. O. Emergency Peripartum Hysterectomy in a Developing Country, Bayero University/Aminu Kano Teaching Hospital, Kano, Nigeria, J. ObstetGynynaecol can October2012; 34(10): 954-960.
- 3. Alison G., Cahill, MD, MSCI; Richard Beige, MD, MSc; R. Phillips Heine, MD; Robert M. Silver, MD; and Joseph R. Wax, MD. And American collage of obstetricians and gynecology and society for maternal fetal Medicine Placenta accrete spectrum No 529, July 2012 document available on www.acog.org.
- Countdown to 2015; Maternal, Newborn and child survival (internet). WHO and UNICEF, Millennium Development Goal 5. 2018. Available at <u>http://www.countdown2015mnch.org/documents/2012report/2012-</u> <u>complete.pdf.</u>
- 5. Envision2030; Maternal, Newborn and child survival (internet). WHO and UNICEF, good health and well-being, Department of economic and social Affaire, Sustainable Development Goal 3. 2030. Available at <u>http://www.un.org.development/desa/disabilities/envision2030</u>
- POPPHI. Pilot use of oxytocin in a Uniject device for AMTSL in Mali. Evaluation of safety and feasibility of a new delivery technology. PATH, 2008. Available at: <u>http://www.pphprevention.org/files/unijectReportMali</u> FINAL, pdf. October 2012.

- 7. Stanton CK et al. Impact on postpartum hemorrhage of prophylactic administration of oxytocin 10 IU via Uniject by peripheral health care provider at home births design of community-based cluster-randomized trial. BMC pregnancy childbirth, 2012,12:42
- De Groot AN, Vree TB, Walker GJA. Stability of oral oxytocin in tropical climates: Results of simulation studies on oral ergometrine, oral methylergometrine, buccal oxytocin and buccaldesamino-oxytocin. Geneva,WHO1994: <u>http://apps.who.int/medecinedocs/pdf/s223e/s223.pdf</u>.
- Updated WHO recommendation on Tranexamic Acid for the Treatment of Postpartum Hemorrhage 2017. Available on<u>www.mcsprogrm.org</u>
- Joana Ferreira carvalho, AdeleideCubal, Silvia Torres, Fernada Costa, and Olimpia do Carmo, emergency perpartum Hysterectomy, volume 2012, article ID721918, htt://dx.doi.org/10.5402/2012/721918, Sept. 11.2012. Available on Google Scholar.
- PATH. Postpartum hemorrhage. 2011 [cited 2012 Sep 18];<u>http://www.pphprevention.org/pph.php.</u>
- Haeri S, Dildy III GA. Maternal Mortality From Hemorrhage. Seminars in Perinatology. 2012 Feb; 36(1): 48–55.
- Arulpragasam K. Hyanes G. Epee- Bekima M. Emergency paripartum hysterectomy in a western Australian population 10 years retrospective case note analysis. Aust. N2j obstet. Gynaecol.2018 November 8. ANZJOG (Australia new Zealand Journal obstetric and Gynecology). PubMed.
- 14. Qiangwei, weiyuan Zhang, Men chen, Li Zhang, Guolin He, Xinghui Liu,Peripartum hysterectomy in 38 hospitals in china; a population based

study March 2014, Volume 289(3): 549-53, doi: 10.1007/s 00404-013-3— 2-x. Epub 2013 Aug29 Archives of gynecology and obstetrics, PubMed.

- Yulong Zhang; Jianying Yan; Qing Han; Tingting Yang; LihongCai; MeimeiGuo; emergency obstetric hysterectomy for life threatening postpartum hemorrhage: A 12 year review china, 2017nov; 96(45); e8443.
   Doi: 10.1097/MD.00000000008443. Available on PubMed.gov
- 16. OyaDernirci, Ahmet S., Tugrul, EntuquilYilmaz, Yadigar S., Eren emergency peripartum hysterectomy in a tertiary obstetric center: 9 years evaluation journal of obstetric/ gynecology research 2011Aug; 37(8): 1054-60.doi: 10.1111/j.1447-0756.2010.01484.x.Epub 2011 Apr 12. Available on PubMed.gov
- 17. Stella D'arpe, et Al,emergencyperipartum hysterectomy in a tertiary teaching hospital: a 14-year review, Archives of Gynecology and Obstetrics April 2015, volume291, Issue 4. Pp841- 847 (2015) Available on GoogleScholar.
- 18. Tomoyoshi Nohira, Takamoto Onodera, Keiichi Isaka emergency postpartum hysterectomy: incidence, trends, indications, and complications. January 2014, doi: 10.14390/jsshp.2.88 Tokyo medical University, Hypertension Research in pregnancy@2014Japan society for the study of hypertension in pregnancy.
- 19. Mahrukh Fatima, PashtoonMurtazakasi, ShahnazNaseen, Baloch and Abaseen Khan afghan, experience of emergency peripartum at a tertiary care hospital in Quetta, Pakistan, ISRN Obstetric and gynecology volume 2011, Article ID 854202, 4 pages htt://dx.doi.org/10.5402/2011/854202 Available on International Scholarly Research Notices (ISRN) cross ref.

- AnshujaSingla, RajlaxmiMundhaa, LatikaPhogat, Sumita Mehta, and ShaliniRajaram, Emergency peripartum hysterectomy; indication and outcome in a tertiary care setting. 1 march 2017; 11(3): QC01-QC03. Doi: 10.7860/JCDR/2017/19665.9347. Guru TegRahadur Hospital Delhi, in India Available on PMC. Journal of Clinical & Diagnostic Research.
- Jaya Chawla, Col D. Arora, Mohini Paul, and Sangita N. Ajmani Emergency Obstetric Hysterectomy: A retrospective Study from a Teaching Hospital in North India over Eight Years. Oman Med J. 2015 May; 30(3): 181-186. Doi: 19.5001/omj. 2015.39 available Oman medical journal, PMC4459165.
- 22. MunaAbdulrazzaqTahlak, MaheraAbdulrahman, NawalMahmoodHubaishi, Muchtaq Omar, Fatima Cherifi, ShaziaMagray et al. Emergency peripartum hysterectomy in the Dubai health system: Afifteen year experience. Article December 2017, doi: 104274/tjod. 55492. Available on PubMed.
- 23. Allian IS, Gomaa IA, Fathi HM, Sukkar GF, Incidence of emergency peripartum Hysterectomy in Ain-shams University Maternity Hospital, Egypt: a retrospective study. GynecolObstet 2014 Nov; 290(5): 891-6. Doi: 10.1007/s00404-014-3306-5. Epub 2014 Jun 15. Available on PubMed.gv
- 24. Ahmed M. Abbas, Ahmed Y. Abdelbadee, Mariam T. Amin, Reham M. Abdelrahman, Sara M. Tolba, Ahmed R. Abdelkarim et al Emergency peripartum Hysterectomy in a tertiary hospital in Upper Egypt: six years analysis. Volume 5, No 4 April 2016, doihtt//dx.doi.org/10.18203/2320-1770.ijrcog20160848. Available on www.ijrcog.org

- 25. A. Akenitayo, N. Olagbuji, K. Aberoba, Akadiri, A. Olofinbiyi, Bakare. Emergency peripartum hysterectomy: A multicenter study of incidence, indications and outcomes in southwestern Nigeria June 201, Volume 20, Issue 6, pp. 1230-1236, maternal and child health journal, 2016, PubMed, Google scholar.
- 26. Google (23october 2016" location of Kenyatta national hospital (map)Google maps. Google Retrieved 23.october 2016.
- 27. Sarah Sanders, MD the 4 T's of Postpartum Hemorrhage, in critic care/ Resus, Ob/Gyn Feb 6,2019 AliEM (Academic Life in Emergency Medicine, Department of Emergency Medicine North western University.
- Anderson J, Etches D. Prevention and management of postpartum hemorrhage. AmFam Physician. 2007; 75(6): 875-882. https: www.ncbinlm.nih.gov/pubmed/17390600.
- 29. Management of postpartum hemorrhage in the emergency department First 10E, First10EM, <u>https://first10em.com/2015/06/22/management-of-</u> <u>postpartum-hemorrhage-in-the-emergency-department</u>. Published 22,2015. Accessed February 1,2019.
- 30. American. C. ACOG Practice Bulletin; Clinical Management Guideline for Obstetrician- gynecologsist Number 76,October 2006; postpartum hemorrhage. Obstet and gynecol. 2006; 108(4); 1039-1047. https://www.ncbi.nlm,nih.gov/pubmed/17012482.
- 31. Tahlak, M. A., Abdulrahman, M., Hubaishi, N. M., Omar, M., Cherifi, F., Magray, S., & Carrick, F. R. (2018). Emergency peripartum hysterectomy in the Dubai health system: A fifteen-year experience. *Turkish journal of obstetrics and gynecology*, 15(1), 1–7. <u>https://doi.org/10.4274/tjod.55492</u>

### ANNEX

# ANNEX 1: TIMELINES

ACTIVITY	PROJECT MONTHS 2019 TO 2020															
	1	2	3	4	5	6	7	8	9	10	12	1	2	3	4	5
1.Proposal	4															
development																
2. Proposal																
Presentation																
3.Ethical										$\rightarrow$						
clearance																
4.Pretesting																
5. Data												~				
collection																
6. Data																
analysis																
7. Report														4	$\rightarrow$	
writing																
8.																
Presentation															1	$\leftrightarrow$
and																
dissemination																

# ANNEX 2: BUDGET AND BUDGET JUSTIFICATION

Item	Unit cost (ksh)	Unit	Total cost	
			(ksh)	
Research Assistant	25000	1	25000	
Printing	12000	1	12000	
Flash Drives and	4500	2	9000	
stationery				
Communication/airtime	2000	2	4000	
Statistician/ Data	30000	1	30000	
analysis				
Photocopy and Bonding	10000	6	10000	
Total cost			80000	

# Annex 3: Study Instruments

#### **COLLACTION DATA TOOL**

SECTION A
Age
<20
20-29
30-39
>40
Maternal status:
- Married
- Single
- Divorcee
Level of Education:
- University
- Collage
- Primary
- Never been to school
Residence:
- City
- Rural area
History of Previous Cesarean section
SECTION B
Parity:

- Primigravida
- Multigravida

Normal delivery

Cesarean section

Myomectomy:

- Mucosal Fibroid
- Intramural fibroid
- Serosal fibroid

#### MVA

Rupture uterus

- Partial rupture uterus
- Total rupture uterus

Type:

- Partial abdominal hysterectomy
- Total abdominal hysterectomy

Coagulation disease

Hemoglobin level

**SECTION C** 

Fetal outcome

- Still birth
- Live Birth

Neonatal outcome:

- Neonatal death
- Alive

**SECTION D** 

a)	Maternal outcome:
1.	Maternal mortality
2.	Mean hospital stay
3.	Mean duration of hospital
4.	Prolonged hospital stay
5.	Mean unit of blood transfused
6.	Total number of blood transfused (during entail
	hospital stay):
	1-3 units
	4-6 units
	7units
7.	Complications:
-	Fever
-	AKI
-	Wound infection
-	UTI
-	Ileus
-	Vesicovaginal
-	Transfusion reaction
-	Sepsis
-	Duration intubation
-	Ureteral/ bladder injury
-	Pneumonia
-	DVT
-	Disseminated intravascular coagulation
-	Pelvic hematoma



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30<sup>th</sup> January

Dear Dr. Nyime

RESEARCH PROPOSAL: INCIDENCE OF EMERGENCY PERIPARTUM HYSTERECTOMY IN KENYATTA NATIONAL HOSPITAL (Descriptive cohort study 2013 – 2018) (P799/09/2019)

KNH-UON ERC

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This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and <u>approved</u> your above research proposal. The approval period is 30<sup>th</sup> January 2020 – 29<sup>th</sup> January 2021.

This approval is subject to compliance with the following requirements:

- a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
- c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
- d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
- e. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (Attach a comprehensive progress report to support the renewal).
- f. Submission of an <u>executive summary</u> report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

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For more details consult the KNH- UoN ERC websitehttp://www.erc.wonbil.ac.ke

Yours sincerely,

THERE PROF. M. L. CHINDIA

SECRETARY, KNH-UON ERC

c.c. The Principal, College of Health Sciences, UoN The Director, CS, KNH The Chairperson, KNH- UoN ERC The Assistant Director, Health Information, KNH The Dean, School of Medicine, UoN The Chair, Dept. of Obstetrics and Gynecology, UoN Supervisors: Prof. Omondi Ogutu, Dept. of Obs/Gynae, UoN Dr. Rose Kosgei, Dept. of Obs/Gynae, UoN

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