THE PREVALENCE, ASSOCIATED FACTORS, MANAGEMENT AND OUTCOMES OF POSTPARTUM HEMORRHAGE AMONG WOMEN ADMITTED TO PRINCESS CHRISTIAN MATERNITY HOSPITAL IN FREETOWN, SIERRA LEONE: A RETROSPECTIVE STUDY.

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A dissertation Submitted to the Department of Obstetrics and Gynecology, Faculty of Health Sciences in Partial Fulfillment for the Award of Masters of Medicine, University of Nairobi.

DECLARATION

This research is my original work and has not been submitted for any academic award or published in any other university or any other institution of higher learning for the award of a degree.

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LIST OF ABBREVAIATIONS

ERC Ethics Review Committee

MMR Maternal mortality ratio

PCMH Princess Christian Maternity Hospital

PPH Postpartum Hemorrhage

TBA Traditional Birth Attendants

UN United Nations

WHO World Health Organization

OPERATIONAL DEFINITIONS

PPH - Blood loss that is greater or equal to 1000ml within the first 24 hours after cesarean delivery and 500 or more after vaginal delivery.

Severe PPH – It is blood loss \geq 1500 mL or the need for blood transfusion for excessive bleeding at the time of delivery.

Eclampsia - It is an obstetrics condition wherein there are seizures during pregnancy occurring due to abnormality in the placentation and usually associated with raised blood pressure and proteinuria

Severe Sepsis – It is systemic infection with associated systolic blood pressure < 90 mm Hg, mean arterial pressure (MAP) < 65 mm Hg, or decrease of 40 mm Hg in systolic pressure compared with baseline; unresponsive to crystalloid fluid challenge of 20 to 40 mL/kg.

Severe complications of abortion and shock – These are complications that are associated with either spontaneous abortion or uterine evacuation process (either as a therapeutic or iatrogenic measure). Infection and blood loss can occasionally occur after the evacuation process.

ABSTRACT

Background: Postpartum Hemorrhage (PPH) is a leading cause of maternal deaths globally and is associated with 73% of all maternal deaths in low-income setting. The number of women who suffer from PPH globally is estimated at 14 million annually, with approximately 99% of the PPH related deaths occurring in low and middle-income countries. In Sierra Leone, PPH is estimated to be associated with 46% maternal deaths annually. In spite of this, the prevalence, management, and burden of PPH in Sierra Leone has not been documented, hence forming the basis of this research.

Objective: To determine the prevalence, associated factors, management and outcomes of mothers admitted with postpartum hemorrhage (PPH) in Princess Christian Maternity Hospital between 2014 and 2018.

Methodology: The study utilized a cross sectional descriptive study research design. Records of 1,225 patients' files for patients who were treated at the Princess Christian Maternity Hospital between 2014 and 2018 were retrieved. The collected data was cleaned and analyzed using Statistical Package for Social Sciences (SPSS) version 25. Chi-square analysis and logistic regression tests were used to determine the association of the sociodemographic and clinical factors and PPH.

Results: The average age was 25 ± 6 years, 935 (77%) were married. The prevalence of PPH was 18%. Bivariate analysis found that, referral case, p <0.0001 (OR =0.2, 95%CI,0.1 – 0.3), previous mode of delivery, p = 0.007, (OR = 0.5, 95% CI,0.3 – 0.6). Mode of current delivery, p <0.0001 (OR = 0.4, 95%CI,0.3 – 0.6), parity, p =0.01, (OR = 1.2, 95%CI,1.1 – 1.6) and presence of obstetric complications, p <0.0001, (OR = 1.3, 95% CI,0.8 – 1.8) were independent factors associated with postpartum hemorrhage. In multivariate analysis, referral cases, p = 0.00, (AOR = 0.2, 95% CI, 0.1 – 0.3), parity p = 0.004, (AOR = 1.3, 95%CI, 1.1 – 1.6), presence of eclampsia, p = 0.019, (OR = 2.3, 95%CI, 1.5, 3.2) and previous PPH, p = 0.014, (OR = 2.0, 95%CI, 1.1, 3.0) were associated with development of PPH. Uterotonic was the first line intervention used in management of PPH among all PPH cases. There was 31% maternal mortality associated with PPH.

Conclusion: The prevalence of PPH was 18% is still high with associated 31% mortality rate. It is essential to maintain closer surveillance and monitoring of mothers in the hours immediately following birth to detect and manage excessive blood loss and reduce severe PPH and associated morbidity. Diversification of resources is essential to controlling the high cases of referrals.

Key Words: Post-partum hemorrhage, Management, Outcomes

CHAPTER ONE: INTRODUCTION

1.1.Background

Pregnancy is associated with vulnerability to infections and other comorbidities. Pregnant women therefore require keener and more improved care to minimize deaths related to poor management. Globally, approximately more than 50% of maternal deaths occur in weak humanitarian settings. The maternal mortality rate in developing countries in 2015 was approximately 239 per 100,000; this was very high compared to the maternal mortality rate in developed countries with 12 per 100,000 live births (1).

The global maternal mortality has been significantly high, with approximately 830 women dying due to birth-related complications daily (2). In 2015, it was estimated that around 303,000 women died because of pregnancy-related complications and childbirth. Approximately 99% of all maternal deaths occur in developing countries with an increased risk among young adolescents and youths (3)(4). Post-Partum Hemorrhage (PPH), defined by the World Health Organization (WHO) as blood loss that is greater or equal to 1000ml within the first 24 hours after cesarean delivery and 500 or more after vaginal delivery, is a leading cause of maternal mortality (5). According to CHAMPION Study, 73% of pregnant women die as a result of PPH in low resource settings (6).

Sierra Leone has been experiencing healthcare challenges, especially reproductive health. The maternal mortality ratio (MMR) in Sierra Leone is approximately 1360 deaths per 100,000 live births (7). These statistics are high compared to the Millennium Development Goals (MDG), which highlighted that Sierra Leone was set to achieve 450 maternal deaths per 100,000 live births by 2015(8). Information from the Ministry of Health in Sierra Leone identifies that ante and post-partum hemorrhage accounts for 46% of maternal deaths in the country annually(8). Thus, there was need to understand the burden, management, and outcomes of PPH.

1.2.Problem Statement

Post-Partum Hemorrhage has been a major maternal health problem over the years. It is a leading cause of maternal morbidity and mortality in developing countries. An estimated 30% of all maternal deaths are attributed to PPH annually (10). Sierra Leone has 46% of maternal deaths associated with PPH complications. Management of PPH requires improved technology and increased level of expertise. The common PPH management methods include uterine massage, manual uterine evacuation and uterotonics (8).

The Sierra Leone health system is developing and thus there are risks involved in managing PPH as well as other maternal conditions. The State of Sierra Leone healthcare was made worse during the civil from 1991 to 2002(11). The healthcare infrastructure was extensively destroyed. The rate of maternal mortality in the country has been very high with approximately 1360 deaths per 100,000 live births (12).

Obstetric hemorrhage in Sierra Leone has been associated with 46% of the total maternal deaths. This study therefore aims at understanding the burden, management and outcomes of PPH in Sierra Leone. The study was conducted at the Princess Christian Maternity Hospital (PCMH) hospital which is the leading Obstetrics and Gynecology hospital in the country.

CHAPTER TWO: LITERATURE REVIEW

2.1. Etiology of Post-Partum Hemorrhage

Post-Partum Hemorrhage is caused by different factors although the existing primary causes include uterine atony, genital tract lacerations, retained placenta, uterine inversion and abnormal placentation (13). Controlling these factors provides a well-defined environment where it is easy to help develop better processes that define an improved focus on maternal care. Management of these conditions has been a major challenge in low income and developing countries contributing to an increasing PPH related mortality.

2.2. Epidemiology of Post-Partum Hemorrhage

Globally, approximately 14 million women suffer from PPH annually. The CHAMPION study identified that 73% of all maternal deaths are associated with PPH in low income settings (6). However, according to Akhter et al. (2003), the incidence of PPH in developed countries average between 0.8% to 7.9%. The reduced rate of PPH in developed countries is mainly attributed to increased quality of maternal care. The study further highlights that a higher percentage approximately two-thirds of PPH occurs in patients with vaginal deliveries (15). The American College of Obstetricians and Gynecologists in 2014 highlighted the need to re-assess the underlying risk factors for PPH to develop better management practices in an obstetric cohort that is exposed to the current intrapartum care and practices (16).

Determinants of PPH have been studied widely with a key emphasis on the need to manage this condition and improve health outcomes (10). According to Ongeri et al. (2016) in a study conducted in Kenya involving women living in Nairobi, PPH is common in vaginal deliveries and highly prevalent in women with multiparas, prolonged augmented labor, episiotomy, preeclampsia, multiple pregnancies, vacuum delivery and retained placenta (11).

During normal delivery, women lose approximately 500ml of blood, although the amount of blood loss can increase significantly based on other available risk factors. According to

Magann et al. (2005), approximately 51.5% of women who undergo vaginal delivery without complications lose more than 1000ml of blood. Research however shows that the amount of blood lost during labor is mainly inaccurately assessed and underestimated (12).

Driessen et al. (2011) determined that the rate of PPH in vaginal births was approximately 3.9%. The study further highlighted that there are two forms of PPH which include early PPH and late PPH. Early PPH occur within the 24 hours after delivery while late PPH occurs between 24 hours and six weeks after delivery (19).

Sierra Leone has been experiencing healthcare challenges, especially reproductive health. The maternal mortality ratio (MMR) in Sierra Leone is approximately 1360 deaths per 100,000 live births (7). These statistics are high compared to the Millennium Development Goals (MDG), which highlighted that Sierra Leone was set to achieve 450 maternal deaths per 100,000 live births by 2015(8). Information from the Ministry of Health in Sierra Leone identifies that ante and post-partum hemorrhage accounts for 46% of maternal deaths in the country annually(8). Thus, there is a need to understand the burden, management, and outcomes of PPH.

2.3. Maternal characteristics

The development of PPH has been associated with different maternal characteristics. In a study conducted by Ononge et al., the risk factors for PPH among all deliveries included caesarian section delivery, multiple pregnancy, HIV status and foetal macrosomia. Women who give birth to large babies (≥4000g) tend to over-distend the uterus which is linked to uterine atony (15).

The highest burden of PPH is in sub-Saharan Africa which accounts for 10.5% of all maternal deaths in the region. Oyelese and Ananth identified that risk factors for PPH include uterine atony, genital tract injuries, trauma and failure of the blood coagulation. Uterine atony attributes to approximately 75% of PPH (20). In addition, McCormick et al., also found that

past PPH history of the mother, older age, preterm birth, labour induction, CS and non-use of oxytocic (21).

According to WHO CHAMPION Study conducted in 10 countries, women with induced labor with uterotonics, with episiotomy and babies with weight of greater than 3500 g has a higher chance of refractory PPH. The study further revealed that uterine atony was the sole cause of PPH in 53% of the respondents. Tears that required suturing were responsible for 12% of PPH cases identified. Placental challenges were also associated with 11% of PPH in the responsive groups and 5.6% in the refractory PPH group.

A prospective study was performed to determine risk factors associated with immediate Post-partum hemorrhage after vaginal deliveries in the South American population. All the vaginal births that were included in the study between October 2003 and October 2005 from 24 maternity units in Argentina and Uruguay. The findings showed that the prevalence of PPH was moderate at 10.8% while severe PPH prevalence was 1.9% (22).

In a study conducted by Liu et al (2015) retained placenta, episiotomy, perineal suture, macrosomia and multi-pregnancy were at an increased risk of developing PPH. Thus the management of PPH should focus on controlling the risk factor in ensuring that there is efficient delivery without development of major complications. The study identified that effective management of third stage labor, low birth weight and multiparity were crucial in controlling PPH (23).

In another retrospective study performed by Buzaglo et al. (2015) between 1988 and 2012 with the aim of determining the risk factors for early PPH, there was a strong emphasis that the presence of PPH in patient history was associated with increased risk of the condition developing again. The results from the study showed that the prevalence of PPH in the first vaginal deliveries was 0.8% (40).

The ability to predict risk factors associated with PPH has been difficult especially considering that around 75% of women with PPH do not always have manifestation of any risk factors. However, Caughey et al (2016) determined that over-distended uterus and uterine muscle exhaustion were identified as risk factors associated with increased PPH (25). Independent risk factors of PPH included extended treatment with Oxytocin and induction of labor. Teal (2014) conducted a study in New Mexico that sought to determine factors associated with major obstetric hemorrhage in 37,497 women. The findings from the study revealed that factors associated with significant risk for PPH were placental abruption, placenta previa, multiple pregnancy, and obesity. The study further revealed that multiparity was also a factor in predicting increased risk of PPH (26).

2.4. Management of Post-Partum Hemorrhage

Medical and surgical approaches in the management of PPH have changed significantly in recent years. The first line management entails supportive management with fluids and blood products, while managing the primary cause. The common interventions include Oxytocin and Carbetocin. The second line of treatment of severe PPH has included Intrauterine balloon tamponade and interventional radiology techniques (27). However, there is limited data on the application of these treatment mechanisms after vaginal delivery. There is a greater emphasis on different approaches that help define an improved level of emphasis on quality of clinical practice (28).

2.4.1. First line management of PPH

According to CHAMPION study which was conducted in 12 countries identified that Oxytocin and HS Carbetocin were identified as essential first line management of PPH. Oxytocin is recommended in first line management of PPH because it is more efficient that ergometrine and other uterotonics and is associated with few side effects. Although, oxytocin is usually unstable at room temperature and require special storage temperatures to remain effective. HS carbotocin was also found to be non-inferior for prevention of blood loss greater than 500 ml while its inferiority for blood loss greater than 1000 ml was not demonstrated (6). Thus the use of oxytocin is unreliable in resource limited countries due to the needed skill among healthcare professionals.

The treatment and management of PPH focuses on resuscitation of the patient while identifying and treating the specific cause. However, in many cases, the management may involve surgical interventions. Ample intravenous (IV) access should be obtained. Cumulative blood loss evaluation is important, and a focus should be on early initiation of protocols for the release of blood products and massive transfusion protocols (29). Rapid identification of the cause of PPH and initiating treatment should be made simultaneously. To

improve outcomes, the resuscitation should be done in an OR setting as anesthesia may be indicated in the management of difficult lacerations, correct uterine inversion, removal of retained products, or if surgical exploration is indicated (30).

The treatment and management of postpartum hemorrhage are focused on resuscitation of the patient while identifying and treating the specific cause. Maintaining hemodynamic stability of the patient is important to ensure continued perfusion to vital organs. Ample intravenous (IV) access should be obtained. Careful direct assessment of cumulative blood loss is important, and a focus should be on early initiation of protocols for the release of blood products and massive transfusion protocols (31).

Rapid identification of the cause of postpartum hemorrhage and initiating treatment should be made simultaneously. Transfer to an operating suite with anesthesia assistance may be indicated for help with a difficult laceration repair, to correct uterine inversion, to help provide analgesia if needed for removal of retained products, or if surgical exploration is indicated. If the PPH is due to uterine atony, treatment modalities include medical management with uterotonic agents, uterine tamponade, pelvic artery embolization, and surgical management (32).

2.4.2. Second line management of PPH

Medical management with uterotonic and pharmacologic agents is typically the first step if uterine atony is identified. While oxytocin is given routinely by most institutions at the time of delivery, additional uterotonic medications may be given with bimanual massage in an initial response to hemorrhage. Other uterotonic agents include ergot alkaloids, and prostaglandins (33).

Treatment of PPH involves different stages based on the severity of the condition. A common treatment method is the first line treatment for PPH which includes uterotonic agents.

However, there are situation where the PPH persists where it is impossible to manage using first line of treatment. In such situations, alternative methods are used which include uterine balloon tamponade (UBT), B-Lynch, surgical interventions, uterine artery embolization as well as non-pneumatic anti-shock trousers. Women with uncontrolled hemorrhage often die. Until recently, UBT devices were unavailable in these regions (34). Uterine artery embolization is not done in Sierra Leone.

2.4.3. Use of Intra Uterine Devices

In a multi country study conducted in Sierra Leone, Ghana, and Kenya, ESM -UBT devices were employed with a key focus on controlling PPH. A total of 92 facilities were selected including 201 women who were treated using an ESM-UBT device for uncontrolled PPH. Based on the assessment conducted, approximately 94% of women recovered fully. The average age of the women with PPH in Kenya was 27.1 years and 25.8 years in Sierra Leone. The average prior pregnancy in both Kenya and Sierra Leone was 2 pregnancies (28).

In another study conducted in Sierra Leone focusing on the use of intravenous oxytocin and misoprostol, it was demonstrated that the two are equally effective in managing uterine atony induced PPH. The results from the study indicated that majority of women with PPH had an average age of 25.4 years. Management of PPH was done using oxytocin and misoprostol which were administered intravenously for PPH (35). The research further revealed that loss of blood could easily lead to hypotension and hypovolemic shock.

2.5.Outcomes of Postpartum Hemorrhage

Post-Partum Hemorrhage remains a major factor in maternal morbidity especially in developing countries due to limited resources and level of expertise needed to manage the condition (36). One of the major outcomes of PPH is mortality (37). According to the World

Health Organization, PPH accounts for approximately 35% of maternal pregnancy-related deaths (38).

The common outcomes of extended PPH include recurrent PPH in subsequent pregnancies and infertility based on the techniques used in management of the condition. Occurrence of PPH in previous pregnancy was associated with a high risk of occurrence in subsequent pregnancies. Bharati et al. (2013) found that there was less percentage of women who conceive again after first pregnancy with PPH complications. However, despite these factors, there has been a significant improvement in prevention as well as management of PPH especially in cases where the condition is detected and managed early.

2.6. Conceptual framework

The conceptual framework provides the research approach with a key understanding of the research objectives. The key elements that were evaluated in the research include patient socio-demographics, risk factors, PPH management, and outcomes. The independent variables included in the study are Patient characteristics, attendance of antenatal clinic, and risk factors. The intermediating variable is PPH management. The dependent variable is PPH outcomes.

Independent variables Patient Characteristics Outcome variables • Age Occupation Dependent variables Marital status Outcomes PPH Recovered Yes Death No Risk factors • Retained placenta • Multiple pregnancy Intervening variables • Hypertension • Post term pregnancy PPH Management • Mode of delivery • Uterotonics • Manual removal of placenta

• Repair of laceration

Source (Author, 2020).

Figure 1: Conceptual Framework

2.7. Justification of the study

Sierra Leone has a weak healthcare system which is unable to handle most of the preventable medical conditions. Infant and maternal mortality remain high due to inadequate resources as well as lack of knowledge on common conditions such as PPH which will provide the basis of evidence based healthcare practices. Therefore the study provide a key area in maternal health where the findings will help in improving maternal health as well as policy development in healthcare (39). The findings from the study will help identify the burden, common interventions and outcomes of PPH in Sierra Leone. The study will also provide a different perspective on the underlying challenges among expectant mothers especially considering that there is less information regarding the underlying risks during and after labor and the development of PPH. Understanding risk factors associated with PPH will be crucial in development of an evidence-based practice in controlling its occurrence.

2.8. Research question

What is the prevalence, associated factors, management and outcomes of mothers admitted with postpartum hemorrhage (PPH) in Princess Christian Maternity Hospital in Sierra Leone?

2.9. Research Objectives

2.9.1. Main objective

To determine the prevalence, associated factors, management and outcome of mothers admitted with postpartum hemorrhage (PPH) in Princess Christian Maternity Hospital in Sierra Leone between 2014 -2018.

2.9.2. Specific objectives

- To determine the prevalence of postpartum hemorrhage in Princes Christian Maternity Hospital.
- ii. To examine factors (socio-demographic, obstetrics and Medical) associated with PPH and those without PPH in Princes Christian Maternity Hospital.

- To determine the proportion of women with PPH treated with Uterotonic,UBT, Repair of laceration, B-Lynch suture and hysterectomy in PrincesChristian Maternity Hospital.
- iv. To determine the proportion of women with PPH who recovered, recovered with sequalae and those who died Princes Christian Maternity Hospital.

CHAPTER THREE: METHODOLOGY

3.1.Study Design

This was a comparative cross-sectional study. The study focused on determining the

prevalence and outcome of PPH within a five-year period between 2014 and 2018.

Retrospective study design is essential in determining the trend of PPH in Sierra Leone based

on data from 2014 - 2018. This design is the most suited for this study because it allowed the

researcher to investigate specific aspects relating to PPH.

3.2.Study Site/Location

The study was conducted at the Princess Christian Maternity Hospital which is located at

Fourah Bay Road in the Eastern part of Freetown, the Capital City of Sierra Leone. It is

housed in the same compound as the Ola During Children Hospital, the main referral and

teaching hospital for pediatrics in the country. It is the main referral and teaching hospital for

obstetrics and gynaecology in Sierra Leone making it convenience for such study. In

addition, the hospital has robust record keeping system hence making it suitable for data

retrospective data collection. The PCMH is a 144 bed capacity tertiary institution for

Obstetrics and Gynecological services in Western area. It has two major and one minor

theatres. The Hospital has 378 employees with 305 being healthcare professional while 73 are

support staff.

3.3.Study population

The study population included mothers who delivered between 2014 and 2018 and referrals

at the PCMH.

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3.4.Inclusion/exclusion criteria

3.4.1. Inclusion criteria

- 1. Patients who delivered in the hospital from 2014 to 2018
- 2. Patients who delivered elsewhere and were referred to PCMH for management

3.4.2. Exclusion criteria

1. Patients with files that are not completely documented with information pertaining PPH, management and outcome.

3.5. Sample size determination

According to Carolli et al. (2008), the prevalence of PPH across all modes of deliveries in Sub-Saharan Africa was 10.5% (48). The sample size was calculated using Fischer's formula.

$$no = z^2 pq/e2$$

Where No is the sample population

Z2 is the abscissa of the normal curve (1.96)

P is the estimated prevalence in the population (0.15)

q is (1-p) the proportion of an attribute that is absent in the population (0.85)

e is the margin of error included in the study (2%)

Therefore the sample size was

$$n = Z2Pq/e2$$

$$n = (1.96^2) (0.15*0.85)/0.0004$$

= 0.4898/.0004

= 1225

The sample size included 1,225 patient files for a 5-year period

Thus, the sample for each year was approximately 1225/5

= 245

The sample for each year from 2014 to 2018 was 245.

3.6. Sampling technique

The study adopted a systematic sampling technique beginning in 2014. Systematic random sampling presented an equal chance to the patient file selection from the sampling frame. A serialized list of women who delivered in the hospital and met the inclusion criteria was drawn to ensure a better representation of data. The systematic sampling technique control bias through ensuring that every individual within the sampling frame has an equal chance of being selected.

3.7. Study variables

Variable	Definition			
Independent	Socio demographic characteristics, Parity, gravida, risk			
	factors			
Intermediate	Management: Uterotonics, UBT, B-lynch, Hysterectomy			
Dependent	Outcomes: Recovered fully, Died			

3.8. Research Tool

A data abstraction tool was used to retrieve information from patient files. The data abstraction tool captured information relating to the study research problem. Using data abstraction tool to extract information made the whole process easy and accurate especially considering the five-year period that was investigated.

3.9. Pretest, Reliability and Validity of the Tool

A pre-test was conducted at the Princess Christian Maternity Hospital to assess the ease in data retrieval as well as investigate whether information sought was available in-patient files. The pretest helped in identifying that there were only two outcomes hat would be easily retrieved from the files which were alive and died.

3.10. Data Collection procedure

The data collection was done through retrieval of patient files based on inclusion criteria. The sample size of 245 per year was distributed equally across a 12-month period in each year. In each month, a sample of 20 patient files was retrieved. All patients' files that meet the inclusion criteria in each month were retrieved and divided by 20 which are the targeted files to ensure that every patient has a chance of being recruited in an orderly manner. On average, there were 625 deliveries at PCMH monthly hence in getting the targeted 20 files we divided 625/20 = 30. The starting point was selected as the first file of the month and every subsequent 30^{th} file was selected.

3.11. Study Flowchart

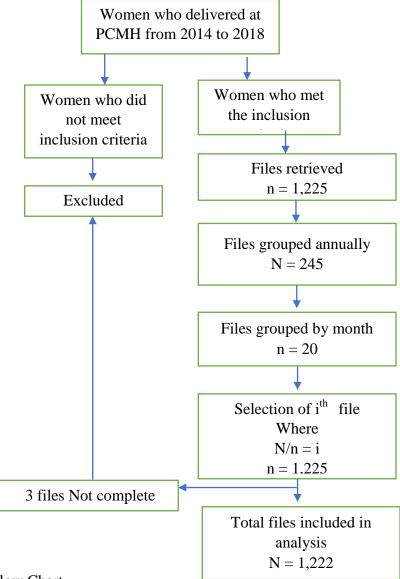


Figure 2: Study Flow Chart

3.12. Data Cleaning and Entry

The data was collected using a data abstraction tool, entered in Epidata version 3.1, exported into SPSS version 25 software for cleaning and analysis.

3.13. Data Analysis and Presentation

Maternal factors (socio-demographic, obstetrics and Medical)

Descriptive statistics was used to describe the socio-demographic characteristics, medical and Obstetric complications in both women with PPH and those without PPH.

To determine the prevalence of postpartum hemorrhage in Princes Christian Maternity Hospital

The prevalence was calculated based on the formulae as shown

Prevalence =
$$\frac{Number\ of\ patients\ with\ PPH}{Number\ of\ patients\ included\ in\ the\ study\ (n)}*100$$

To compare factors (socio-demographic, obstetrics and Medical) associated with PPH and those without PPH in Princess Christian Maternity Hospital.

The factors associated with were described based on descriptive and inferential statistics. The Descriptive analysis was done to help understand the distribution of socio-demographic, obstetrics and medical factors for both women with PPH and women without PPH based on the identified sample population.

A chi- square test for association was conducted to determine factors (socio-demographic, obstetrics and Medical) associated with PPH.

To determine the proportion of women with PPH treated with Uterotonic, UBT, Repair of laceration, B-Lynch suture and hysterectomy in Princes Christian Maternity Hospital

The proportion of women with PPH treated with Uterotonic, UBT, repair of laceration, B-Lynch suture and hysterectomy was analyzed using descriptive statistics which helped compare the use of different PPH management interventions. The data was presented using frequencies and percentages.

To determine the proportion of women with PPH who recovered, recovered with sequalae and those who died Princes Christian Maternity Hospital

The Outcome of women with PPH was based on descriptive statistics highlighting the frequencies and percentages of women who Recovered, Recovered with Sequalae and those who died.

3.14. Data Storage

The retrieved patient data was stored in a locked cabinet and will be kept for a period of three years. The laptop that was used in the analysis of the data will have a password to limit access by authorized personnel only. The data stored in softcopy form was stored by the researcher in the university repository for future access and reference.

3.15. Ethical Consideration

The nature of the study limits the underlying ethical issues which need to be exhaustively developed. Approval to carry out the study was sought from KNH-UoN ERC and Sierra Leone Ethics Committee. Permission was sought from the PCMH hospital management to allow access of the patient files. Confidentiality, anonymity and privacy was fully guaranteed throughout the study considering that no personal identifiers on patient files were retrieved.

CHAPTER FOUR: RESULTS

4.1.Introduction

The study sought to investigate the prevalence, associated factors, management, and outcomes of mothers admitted with postpartum hemorrhage in Princess Christian Maternity Hospital in Free Town Sierra Leone between 2014 and 2018. The study population was 1225 patients, where 1222 were successfully included in data analysis. The 3 excluded from the analysis did not have a patient outcome. The data was analyzed using both descriptive and inferential methods. The results are presented in Tables and charts.

4.2.Demographic and clinical characteristics of women who delivered at PCMH

Patient characteristics, both demographics, and clinical factors were assessed. In assessing demographic factors among respondents, as illustrated in Table 1. Results showed that 935(76.5%) of women were married with an average age of 25 years and a standard deviation of 6 years. The findings further revealed that 693(56.4%) women were unemployed. Less than half of cases, 514 (42.1%), were referrals. In clinical characteristics assessed among the respondents, 737(60.3%) had a prior pregnancy, where 574(47%) of them delivered via spontaneous vaginal delivery. The average gravidity and parity were 2 with a standard deviation of 1 for both. Majority of women in the current pregnancy, 1006(82.3%) delivered via Spontaneous vaginal Delivery. Assessment of obstetric complications present revealed that, 560(45.8%) had obstetric complications.

Table 1:Patient demographic and clinical characteristics

	Patient demographic chara	cteristics	
		Frequency (n =1,222)	Percent
Marital status	Single	287	23.5
	Married	935	76.5
	Mean ±SD	25.2±6.1	
A	Median (IQR)	25(20-30)	
Age	<30 Years	916	75.0
	>30 Years	306	25.0
Employment status	Salaried	87	7.1
• •	Self-employed	442	36.2
	Unemployed	693	56.4
Referral	Yes	514	42.1
	No	708	57.9
	Clinical characteristi	ics	
Delivery prior to this	Yes	737	60.3
pregnancy	No	485	39.7
Method of delivery in	Vaginal Delivery (SVD + breech)	574	47.0
the prior pregnancy	Caesarian section	134	11.0
	Vaginal birth after c-section	28	2.3
	Mean ±SD	2±1	
C	Median (IQR)	2(1-3)	
Gravidity	≤2	859	70.3
	>2	363	29.7
	Mean ±SD	2±1	
Donitor	Median (IQR)	2(1 -3)	
Parity	≤2	972	79.6
	>2	250	20.4
Mode of delivery in	Spontaneous vaginal Delivery	1006	82.3
this pregnancy	Caesarian section	156	12.8
	Vaginal birth after c-section	49	4.0
History of DDH	Yes	198	16
History of PPH	No	1024	84
Tryin Dagon are are	Yes	93	8
Twin Pregnancy	No	1,129	92
Obstetric complication	Yes	560	45.8
present	No	662	54.2

4.3. The prevalence of postpartum hemorrhage in Princes Christian Maternity Hospital

The researcher also sought to determine the prevalence of postpartum hemorrhage in Princes Christian Maternity Hospital for over five year-period. The findings showed the combined prevalence of postpartum hemorrhage was 217(18%), 95%CI, [15, 20] % as shown in Figure 3.

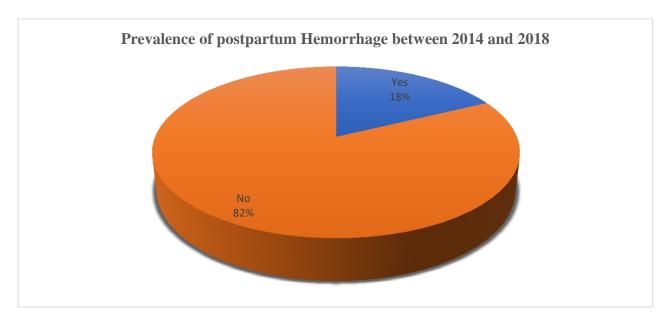


Figure 3: Prevalence of postpartum hemorrhage between 2014 and 2018

4.3.1. The prevalence of PPH annually at PCMH

The study's findings showed that the prevalence of PPH in 2014, 2015, 2016, 2017, and 2018 was 19.9%, 15.5%, 22.2%, 16.5%, and 16.3%, respectively, as shown in Figure 4.

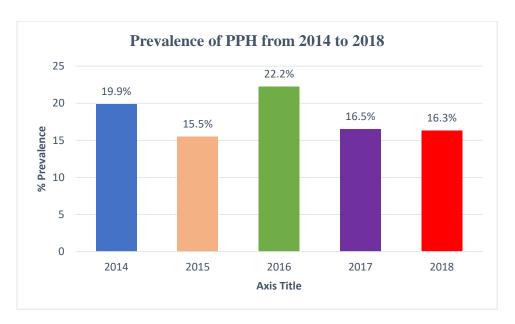


Figure 4: Prevalence of Postpartum hemorrhage between 2014 and 2018

4.3.2. Causes of postpartum hemorrhage among women who delivered at PCMH

The causes of postpartum hemorrhage and obstetric complications were also assessed as shown in Table 2, uterine atony, 88(40%) was the most common cause of postpartum hemorrhage among women who delivered and PCMH.

Table 2: Causes of PPH and Obstetric complications present

		Frequency	Percent
Causes of PPH (n = 217)	Uterine atony	88	40
	Retained placenta	65	30
	Perineal injury	41	18
	Cervical injury	21	11
	Coagulopathy	2	1

4.4.Factors (socio-demographic, obstetrics, and Medical) associated with PPH and those without PPH in Princess Christian Maternity Hospital

Bivariate analysis

The study also examined factors associated with PPH in women delivered in PCMH from 2014 to 2018, as shown in Table 3. The analysis included both bivariate and multivariate analyses. In bivariate analysis, referral, mode of delivery in a previous pregnancy, mode of

delivery in the current pregnancy, parity, and obstetric complications were independent factors associated with PPH among women at PCMH. The findings revealed that women who were not referred to PCMH from other hospitals were 0.2 times less likely to develop PPH, p<0.0001, (OR =0.2, 95%CI, 0.1-0.3). The findings showed that women who delivered previously via spontaneous vaginal delivery were 0.5 times less likely to develop PPH, p =0.007, (OR = 0.5, 95%CI, 0.3-0.6). The women who delivered in their current pregnancy through spontaneous vaginal delivery were 0.4 times less likely to develop PPH, p<0.0001, (OR = 0.4, 95%CI, 0.3-0.6). in assessing parity, the results showed that women who had parity of more than 2 were 1.2 times more likely to develop PPH, p =0.01, (OR = 1.2, 95%CI, 0.1-0.6). Women with obstetric complications were 1.3 times more likely to develop PPH, p<0.0001, (OR = 1.3, 95%CI, 0.8-1.8).

Table 3: Bivariate analysis

				Bivariate analy	Bivariate analysis		
		PPH	No PPH	P-value	OR (95%CI)		
		n (%)	n (%)	1 -value	OR (75 /0C1)		
Age	≥30 Years	166(76.5)	750(74.6)				
Age	>30 Years	51(23.5)	255(25.4)	0.667	0.9(0.6, 1.3)		
Marital status	Single	45(20.7)	242(24)				
Walitai status	Married	172(79.3)	763(76)	0.064	1.2(0.8,1.7)		
	Salaried	20(9.2)	67(6.7)				
Occupation	Self employed	84(38.7)	358(35.6)	0.258	0.8(0.7,1.03)		
	Unemployed	113(52.1)	570(56.7)				
Referral	Yes	164(75.6)	352(35)				
Referrat	No	53(24.4)	653(65)	P<0.0001	0.2(0.1,0.23)		
Mode of delivery in prior	Spontaneous vaginal Delivery	122(85.9)	461(76.2)				
Mode of delivery in prior delivery	Caesarian section	16(11.3)	118(19.5)	0.007	0.5(0.3,0.6)		
	Vaginal birth after c-section	4(2.8)	26(4.3)				
	Spontaneous vaginal Delivery	198(91.2)	817(81.3)	P<0.0001	0.4(0.3,0.6)		
Mode of delivery in this pregnancy	Caesarian section	16(7.3)	140(13.9)				
	Vaginal birth after c-section	4(1.5)	48(4.8)				
D:'	≤2	155(71.4)	817(81.3)				
Parity	> 2	62(28.5)	188(18.7)	0.01	1.2(1.1, 2.2)		
C	≤ 2	142(65.4)	623(62)				
Gravidity	> 2	75(34.6)	292(38)	0.203	1.1(0.1,1.5)		
Deat III at a see of DDII	Yes	145(67)	53(5)				
Past History of PPH	No	72(33)	952(95)	P<0.0001	2.3(1.5,3.2)		
Tarin masananan	Yes	59(27)	34(34)				
Twin pregnancy	No	158(73)	971(96)	P<0.0001	0.1(0.05,0.5)		
Obstetric complications	Yes	131(60.4)	429(42.7)				
	No	86(39.6)	576(57.3)	P<0.0001	1.3(0.8,1.8)		
Types of obstetric complications present	Preeclampsia	150(47.6)	78(60)	0.019	2.3(1.5, 3.2)		
	Macrosomia	15(4.8)	10(3.2)				
	1110103011110	15(1.0)	10(3.2)				

Multivariate analysis

In multivariate analysis, after adjusting for maternal characteristics, referral, parity, and presence of obstetric complications were associated with PPH development. Patients who were referred to PCMH hospital were 0.2 times likely to develop PPH, p <0.0001, (AOR = 0.2, 95%CI, 0.1 - 0.3). Women with parity greater than 2 were 1.3 times more likely to develop PPH, p = 0.004, (AOR = 1.3, 95%CI, 1.1 - 1.6). Women with previous PPH were 2 times more likely to develop PPH, p = 0.014, (OR = 2.0, 95%CI, 1.1, 3.0). Women with obstetric complications were 1.4 times more likely to develop PPH, p<0.0001, (AOR = 1.4, 95%CI, 1.2 - 1.7). In assessing specific obstetric complications present, the results also revealed that women with pre-eclampsia were 2.3 times more likely to develop PPH, p = 0.019, (OR = 2.3, 95%CI, 1.5, 3.2).

Table 4: Multivariate analysis

		Multivariate analysis		
		P-value	AOR (95%CI)	
Referral	Yes No	P<0.0001	0.2(0.1,0.3)	
Mode of delivery in prior delivery	Spontaneous vaginal Delivery Caesarian section Vaginal birth after c-section	0.555	0.8(0.4,1.5)	
Mode of delivery in this pregnancy	Spontaneous vaginal Delivery Caesarian section Vaginal birth after c-section	0.554	0.8(0.4,1.6)	
Parity	≤2 > 2	0.004	1.3(1.1,1.6)	
Past History of PPH	Yes No	2	2.0(1.6,3,6)	
Twin pregnancy	Yes No	0.735	1.2(0.3, 4.6)	
Obstetric complications	Yes No	0.001	1.4(1.2,1.7)	
Types of obstetric complications present	Preeclampsia Macrosomia	0.01	1.5(1.1, 2.0)	

4.5. The proportion of women with PPH treated with Uterotonic, UBT, Repair of laceration, B-Lynch suture, and hysterectomy in Princess Christian Maternity Hospital.

In assessing the management of postpartum hemorrhage in PCMH, the results found that all of the patients were initially managed with uterotonics. In addition to uterotonics, repair of laceration, 85(40%), manual removal of placenta, 65(30%) and evacuation of retained products, 25(12%). The majority of the women who had PPH, 200(92%), had a blood transfusion, as shown in Table 4.

Table 5: Management methods of postpartum hemorrhage among women in PCMH

Method used to manage the condition						
		Frequency (n)	Percentage (%)			
Management method	Uterotonics	217	100			
	Manual removal of placenta/ Evacuation of the uterus	65	30			
	Repair of laceration	62	40			
	B-Lynch suture	49	23			
	Hysterectomy	20	9			
Blood transfusion	Yes	200	92			
	No	17	8			

4.6. The proportion of women with PPH who recovered and maternal mortality rate at the Princess Christian Maternity Hospital.

Women with PPH who recovered and those who died, are shown in Figure 3. The results showed that 67 (31%) of women who had PPH died.

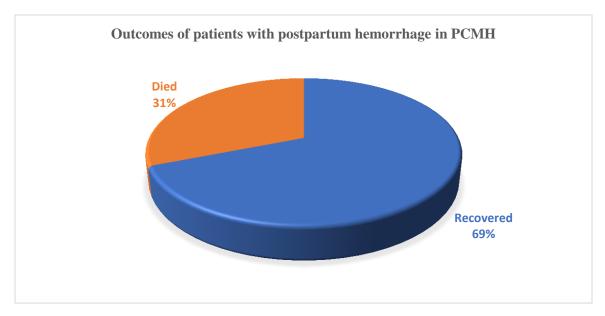


Figure 5: Outcomes of patients with postpartum hemorrhage in PCMH

CHAPTER FIVE: DISCUSSION

The study sought to investigate, the prevalence, associated factors, management and outcomes of post-partum hemorrhage among women who delivered at PCMH between 2014 and 2018. The findings from this study revealed that the average age of the women was 25 years. The findings also revealed that majority of the respondents were married. In Sierra Leone, most of women are married at very young ages which explain the average age of 25 years among the study respondents. The findings from this study also revealed that almost half of the respondents were referral cases. PCMH is the largest referral hospital for obstetrics and gynecology services hence offers a point of referral to many smaller hospitals in Sierra Leone which explains higher number of referral cases.

The evaluation of the prevalence of PPH in PCMH between 2014 and 2018 found that the prevalence was eighteen percent. The yearly prevalence across the five-year period as identified in this study from 2014 to 2018 was 19.9%, 15.5%, 22.2%, 16.5%, and 16.3%, respectively. These findings are within the range of a systematic review study that was conducted in Africa revealing that the prevalence of PPH varies significantly in Africa with 3% in Nigeria and 23% in Cameroon (40). The findings from this study are also agreeable to a cross sectional study conducted in Ethiopia which revealed that the prevalence of PPH was 17% (40).

PPH has become a major issue especially in developing countries such as Sierra Leone which do not have high quality of care resources to effectively control such cases. Uterine atony occurred in almost half of women with PPH. These results are comparable to the WHO CHAMPION study which found that uterine atony was the main cause of PPH among 53% of the respondents across 12 countries. In addition, majority of women who had PPH across 28 countries was caused by uterine atony. Other causes of PPH that were identified in this study were, retained placenta and perineal injury. In a cross sectional study conducted in India

among women with PPH, it was found that the leading causes were uterine atony, retained placenta and perineal injury (41).

Referral cases, mode of delivery in prior pregnancy, parity, mode of delivery in this pregnancy, presence of obstetric complications were independent factors associated with the development of PPH among women who delivered at PCMH over the five-year period. The findings revealed that cases that referral cases to PCMH were more likely to develop PPH. This can be attributed to the fact that PPH is one of the complications leading to referral to PCMH for management. These findings are comparable to a cross sectional descriptive study that was conducted in Mali and Senegal which revealed that transfer to another facility was associated with increased risk of PPH(42). Similarly, Mpemba et al. (43) revealed that increased number of referrals especially among women who are already experience labor was associated with increased risk of PPH and adverse outcomes.

Modes of delivery in both present and past deliveries were associated factor to development of PPH. Women who gave birth in prior pregnancy through caesarian section as well the current mode of delivery. Women who delivered through caesarian in previous delivery were more likely to develop PPH. These findings are comparable to a Danish retrospective study which revealed that prior caesarian delivery was associated with increased risk of PPH in subsequent deliveries (44). The study also identified that women who gave birth via caesarian section in the current pregnancy were highly associated with development of PPH. These findings are similar to those from Ononge et al.(15) in a study conducted in Uganda which revealed that delivery through caesarian section was associated with a two times risk of developing PPH. Further, McCormick et al. (21) also revealed that caesarian section was associated with increased risk of PPH. However in a study conducted in Kenya, found that PPH was more common in women who delivered through SVD (17). The difference might be as a result of more women deliver through SVD than CS.

The results have also showed that parity was a significant independent factor associated with PPH. A higher parity was associated with a 1.3 times increased chance of PPH among women at PCMH. These findings are analogous to most of the studies investigating risk factors of PPH (21)(15)(42).

The results from this study also found that presence of obstetric complication was associated with an increased risk of PPH. Women who presented with any obstetric complication were 1.3 times more likely to develop PPH compared to those without obstetric complications. These findings reflect those from a study conducted in United States which revealed obstetric and labor complications among young women aged between 11 and 19 years were more likely to lead to PPH (45). Thus, in assessing the specific obstetric complications identified in this study, women with preeclampsia were 2.3 times more likely to develop PPH. These findings are analogous to Cavazos-rehg et al. (45) who found that young women below 25 years who developed preeclampsia had increased odds of developing PPH. Similarly in a study conducted in Mali and Senegal, preeclampsia and eclampsia were associated with increased occurrence of PPH among young women (42). Women with previous history of PPH were 2 times more likely to develop PPH in the current pregnancy. These results are echoed by a study conducted in Uganda which revealed that women with previous history of PPH has a double odds of PPH in subsequent deliveries (15). In addition McCormick et al. (21) also stressed that women having history of PPH were more likely to have a reoccurrence in current pregnancy.

The study also assessed the different interventions that are being utilized at PCMH in management of PPH. The results found that the primary intervention for all women who had PPH was uterotonics. The focus on Uterotonics has been an approved mode of PPH management by World Health Organization. According to WHO CHAMPION study conducted in 12 countries, it was acknowledged that Oxytocin and HS Carbetocin were

identified as essential first line management of PPH (6). The utilization of uterotonics has been majorly because it is more efficient and effective with few side effects. Similarly in a study conducted in 28 countries in the world, it was revealed that 93% of the women who had PPH received uterotonics as a first line of management (46).

Other methods of management of PPH as identified in this study included manual removal of placenta, evacuation of retained products, repair of lacerations, B-Lynch suture and hysterectomy. Different studies have presented focus on different methods of PPH management. Kominiarek and Kilpatrick identified that (34), balloon tamponade (UBT), B-Lynch, surgical interventions, uterine artery embolization are common PPH interventions. Urner et al. (47)identified manual removal of retained placenta as a major intervention in management of PPH. In case report published regarding management of PPH, it was identified that B-Lynch suture was essential surgical intervention in controlling PPH (48).

The findings from this study also revealed that there were thirty-one percent of deaths associated with PPH at PCMH over the five-year period. In Sierra Leone, PPH is a leading cause of maternal deaths with more than 30% deaths associated to PPH nationally. The findings from our study show that PCMH which is a leading referral hospital has comparable maternal deaths to the national statistics. According to report published by the Sierra Leone ministry of health and sanitation, approximately 32% of maternal deaths were associated with PPH (49). According to Lancaster et al, PPH is associated with 30 to 50% of all pregnancy related deaths in sub-Saharan Africa (50). In a study conducted in Madagascar, approximately 25% of maternal deaths were associated with PPH (51).

CHAPTER SIX: CONCLUSION AND RECCOMMENDATION

Conclusion

Postpartum hemorrhage remains a challenge in maternal reproductive health with a 18% prevalence at PCMH. The study also revealed that the commonly identified causes of uterine atony, retained placenta and perineal injury. Associated risk factors that were identified in the study include referral case, prior caesarian section delivery, parity, current mode of delivery and presence of obstetric complications. The significant obstetric complications that were identified in the study included preeclampsia, past history of PPH. Multivariate analysis found referral cases, high parity and presence of obstetric complications as factors associated with PPH in PCMH. First line of management of PPH identified was Uterotonics which has been widely adopted in healthcare settings as recommended by World Health Organization as first line treatment of PPH. Other interventions identified in the study were manual removal of placenta, evacuation of retained products, B-Lynch suture and repair of laceration. Maternal mortality associated with PPH is still high with the study revealing that there were 31% maternal deaths associated with PPH in PCMH.

Recommendation

Improving maternal health to control occurrence of PPH has been a major reproductive health aim across different countries. Thus, it is crucial to ensure integration of specific elements that promote change in low resource settings.

- ❖ To ensure close surveillance of all women in the hours immediately following birth to detect and manage excessive blood loss and reduce severe PPH and associated morbidity.
- ❖ To encourage frequent health checkups among expectant mothers to control adverse effects of underlying risk factors such as past history of PPH, Obstetric complications and parity.

- ❖ To strengthen the referral system to ensure seamless patient movement.
- ❖ Future Research should seek to assess the effectiveness of using uterotonics as first line management intervention in managing PPH.

Strengths of the study

- The study explored prevalence, associated factors, management and outcomes of PPH.
- The study assessed PPH and associated factors over a five-year period.
- The study was done in the biggest referral and teaching maternity hospital in Sierra Leone

Limitations of the study

- Diagnosis of PPH was already documented in the files hence the researcher could not verify its accuracy.
- The study initially sought to assess the sequelae but it was not documented in patient files.
- The information on whether the patient attended ANC was not documented in patient files.

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APPENDICES

Appendix I: Data Abstraction Tool

Section A: Socio-Demographic factors

1.	What was the patient's age at admission?					
2	What was her marital status?					
۷.	Single []					
	Single []					
	Married []					
	Widowed/Separated []					
3.	What was her occupation?					
	Salaried []					
	Self-employed []					
	Unemployed []					
4.	Was she referred to Princes Christian Maternity Hospital?					
	Yes [] No []					
Section	n B: Burden of Post-Partum Hemorrhage					
5.	Had she delivered prior to this pregnancy?					
	Yes [] No []					
6.	If yes what was the mode of delivery					
	Spontaneous Vaginal Delivery (SVD) []					
	Caesarian Section CS []					
	Vaginal Birth after C-Section (VBAC) []					
7.	What was the mode of delivery in this pregnancy?					
	Spontaneous Vaginal Delivery (SVD) []					
	Caesarian Section CS []					

	Vaginal Birth after C-Section (VBAC) []
8.	Was there PPH?
	Yes [] No []
9.	What were the causes of PPH?
	Uterine atony []
	Retained placenta []
	Perineal injury []
	Cervical injury []
	Coagulopathy []
10.	Parity
11.	Gravidity
12.	What were the Obstetric complications present?
	Preeclampsia []
	Previous history of PPH
	Twin pregnancy []
	Polyhydramnios
	Macrosomia
	Others (specify)
	None []
Section	n C: Management and Outcomes
13.	Did the patient undergo blood transfusion?
	Yes [] No []
14.	What was the method used to manage the condition?
	Manual removal of placenta []
	Evacuation of retained products in theatre ()
	Repair of laceration []
	Uterotonic []
	B-Lynch suture []
	Hysterectomy []
	Balloon tamponade []
	Others [specify]

15.	What were the outcomes of the intervention used?
	Full recovery []
	Death []

Appendix II: Letter to Ethics

Dr. Osman Kakay Resident Obs/Gynae University of Nairobi NAIROBI. 25/05/2020

THE RESEARCH AND ETHICS REVIEW COMMITTEE, KNH/UON PO BOX 20723- 00202 NAIROBI,

Dear sir/ madam,

RE: REQUEST FOR AUTHORITY TO CONDUCT RESEARCH IN KNH.

I am a student at University of Nairobi Undertaking a Master of Medicine (M.Med) in the department of Obstetrics and Gynecology.

I am requesting for your authorization to carry out research on the **Associated** factors, Management and Outcomes of Post-Partum hemorrhage among Women Admitted at Princess Maternity Hospital in Freetown, Sierra Leone as part of my academic requirements.

Attached is a copy of my research proposal for your perusal.

Thank you in advance

Yours faithfully;

Dr. Osman Kakay

REG NO. H58/10675/2018

Appendix III: Workplan

Activity/Year	Nov 2019	May 2020	Jun 2020	Jul 2020	Aug 2020	Sep 2020	Oct 2002	Nov 200	Dec 2020
Proposal Development									
Approval									
Data collection									
Analysis and Presentation									

Appendix V: KNH-UoN ERC Approval



UNIVERSITY OF NAIROBI COLLEGE OF HEALTH SCIENCES P O BOX 19676 Code 00202 Telegrams: varsity Tel:(254-020) 2726300 Ext 44355

Ref: KNH-ERC/A/394

KNH-UON FRC

Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
ebook: https://www.facebook.com/uor
ter: @UONKNH ERC https://witter.com/UO

KENYATTA NATIONAL HOSPITAL P O BOX 20723 Code 00202 Fax: 725272 Telegrams: MEDSUP, Nairobi

12th November 2020

Dr. Osman Kakay Reg. No.H58/10675/2018 Dept. of Obstetrics and Gynaecology School of Medicine College of Health Sciences University of Nairobi

RESEARCH PROPOSAL - THE PREVALENCE, ASSOCIATED FACTORS, MANAGEMENT AND OUTCOMES OF POSTPARTUM HEMORRHAGE AMONG WOMEN ADMITTED TO PRINCESS CHRISTIAN MATERNITY HOSPITAL; A RETROSPECTIVE STUDY (P316/06/2020)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and approved your above research proposal. The approval period is 12th November 2020 – 11th November 2021.

This approval is subject to compliance with the following requirements:

- a. Only approved documents (informed consents, study instruments, advertising materials etc) will be
- All changes (amendments, deviations, violations etc.) are submitted for review and approval by
- All changes (differentials, seviations, violations (SAEs) as a substitution of the KNH-UoN ERC before implementation.

 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.

 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.

 Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each
- batch of shipment.
 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).

 Submission of an executive summary 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.

Protect to discover

For more details consult the KNH- UoN ERC website http://www.erc.uonbi.ac.ke

Yours sincerely,

PROF. M. L. CHINDIA

SECRETARY, KNH-UoN ERC

The Principal, College of Health Sciences, UoN The Senior Director, CS, KNH

The Chairperson, KNH- UoN ERC

The Assistant Director, Health Information Dept, KNH

The Dean, School of Medicine, UoN

The Chair, Dept.of Obstetrics and Gynaecology, UoN
Supervisors: Prof. Omondi Ogutu, Dept.of Obstetrics and Gynaecology, UoN
Dr. George Gwako, Dept.of Obstetrics and Gynaecology, UoN

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Appendix VI: Letter from Sierra Leone Ethics



GOVERNMENT OF SIERRA LEONE Office of the Sierra Leone Ethics and Scientific Review Committee Directorate of Training and Research 5th Floor, Youyi Building Brookfields, Freetown Ministry of Health and Sanitation

3rd April, 2020

Principal Investigator

To: Dr Osman Kakay (M. Med Candidate)

Obstetrics and Gynaecology Department

University of Nairobi

Kenya

kalkulux@gmail.com

Study Title: Prevalence, Management, and Outcome of Postpartum Haemorrhage

among Women Admitted to Princess Christian Maternity Hospital. A

Retrospective Study

Version: March, 2020

Study Site: Princess Christian maternity Hospital, Freetown

Supervisor: Professor Omondi Ogutu

Chair, Department of Obstetrics and Gynaecology

University of Nairobi omogutu@gmail.com

Submission Type: First protocol version submitted for review

Committee Action: Expedited Review

Approval Date: 03 April, 2020

The Sierra Leone Ethics and Scientific Review Committee (SLESRC) having conducted an expedited review of the above study protocol and determined that it presents minimal risk to subjects, hereby grants ethical and scientific approval for it to be conducted in Sierra Leone. The approval is valid for the period, 03 April, 2020 – 02 April, 2021. It is your responsibility to obtain re-approval/extension for any on-going research prior to its expiration date. The request for re-approval/extension must be supported by a progress report.

For further enquiries please contact: efoday@health.gov.sl



GOVERNMENT OF SIERRA LEONE Office of the Sierra Leone Ethics and Scientific Review Committee Directorate of Training and Research 5th Floor, Youyi Building Brookfields, Freetown <u>Ministry of Health and Sanitation</u>

3rd April, 2020

Principal Investigator

To: Dr Osman Kakay (M. Med Candidate)

Obstetrics and Gynaecology Department

University of Nairobi

Kenya

kalkulux@gmail.com

Study Title: Prevalence, Management, and Outcome of Postpartum Haemorrhage

among Women Admitted to Princess Christian Maternity Hospital. A

Retrospective Study

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Chair, Department of Obstetrics and Gynaecology

University of Nairobi omogutu@gmail.com

Submission Type: First protocol version submitted for review

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For further enquiries please contact: efoday@health.gov.sl