PREVALENCE AND FACTORS ASSOCIATED WITH MATERNAL NEAR-MISSES AT KENYATTA NATIONAL HOSPITAL; A 3 YEAR RETROSPECTIVE ANALYSIS

PRINCIPAL INVESTIGATOTR:

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DECLARATION

I declare that this research is my original work and it has not been presented by another party elsewhere for purposes of being awarded a university degree. I further declare that any data or statements obtained from other research papers have been referenced here – in.

Signature:  **Date:** 31st September, 2023

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CERTIFICATE OF AUTHENTICATION

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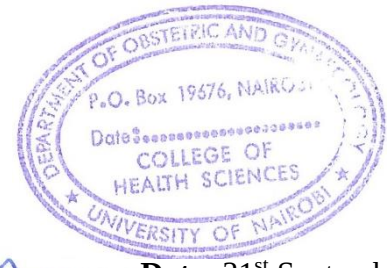

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Thank you.

DEDICATION

DEDICATION

I dedicate this work to my dear children Yohan, Amarisse and Becky for keeping me going when the going got tough with your kind and innocent words of encouragement. I give thanks to my parents and siblings for the spiritual support throughout this journey. Indeed, your encouragement was a shot in my arm. To my colleagues Cedric, Sheila and Sarah, thank you for setting and maintaining the much needed tempo and momentum. I further dedicate this work to all the mothers who gave their life bringing forth another. I thank the almighty God for bestowing upon me His mercies, good health and strength.

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LIST OF ABBREVIATIONS

MNM – Maternal Near Miss

NMCR – Near Miss Case Review

KNH – Kenyatta National Hospital

MI – Mortality Index

MNMMR - Maternal Near Miss to Mortality Ratio

MMR - Maternal Mortality ratio

WHO – World Health Organisation

KMTC – Kenya Medical Training College

KDHS – Kenya Demographic Health Survey

ARF – Acute Renal Failure

CPR – Cardiopulmonary resuscitation

BTU – Blood Transfusion Unit

ICU – Intensive Care Unit

Definitions

Maternal near miss – refers to a woman who nearly died but survived a complication that occurred during pregnancy, delivery or within 42 days after termination of a pregnancy as a result of an obstetric complication

Maternal Near miss ratio – refers to the number of maternal near miss cases per 1000 live births.

Maternal near miss mortality ratio – refers to the ratio between maternal near miss cases and maternal mortality, with higher ratios indicating better care.

Maternal mortality – death of a woman while still expectant or within 42 days of termination of pregnancy irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.

Severe Maternal outcome – refers to a life threatening condition, including maternal deaths and near miss cases.

Mortality index – number of maternal deaths divided by the number of women with severe life threatening conditions, expressed as a percentage. Higher mortality indices denote poor quality of care

Potentially Life Threatening Condition – a category of clinical conditions and diseases that threaten the life of a woman during pregnancy, labour and after termination of pregnancy.

ABSTRACT

Background: The third sustainable development goal aims to reduce the global maternal mortality ratio to less than 70 per 100,000 live births by 2030. Traditionally, maternal mortality audits have been the usual channel employed to mitigate the ever high mortality rates. Kenya's maternal mortality ratio has reduced from 488 to 362, but a lot is still desired in terms of achieving significant reduction of the rates. In-depth reviews of maternal near misses, defined as women who nearly died but survived life threatening conditions in pregnancy, childbirth or puerperium, may be the silver lining to this dark cloud. Near misses occur frequently, and maternal mortalities almost invariably arise from them. Many high income countries are turning to the use of NMCR as a strategy for bettering patient care and hence significantly reduce maternal mortality. In Kenya, prevalence of near miss events and factors associated with them is not routinely reported or published. MNM risk factor identification will lead to heightened vigilance hence better preparedness and management practices and overall improvement in quality of care in maternal and new-born services.

Objective: To determine the prevalence and factors associated with maternal near misses at Kenyatta National Hospital between 1st January 2017 and 31st December 2019.

Methodology: A cross sectional study with a case control component undertaken retrospectively over a period of 3 years. Study population shall be women admitted into KNH for delivery or pregnancy related care during the 3 year interval. Maternal near misses shall be determined by subjecting records of women who experienced SMO to WHO NM criteria. The case control study will be used to evaluate factors associated with development of MNM. Cases will be women admitted at KNH with confirmed pregnancy for delivery or with pregnancy related conditions or in puerperium, with complications that are commensurate with the WHO NM criteria. Controls will be patients having the same admission date as the cases, with normal deliveries. Data will be collected by 6 research assistants through the use of a questionnaire. Collected data will be analysed using SPSS version21. Descriptive analysis of cases and controls' socio-demographics will be done, with categorical variables being summarized as proportions and frequencies with continuous variables being summarized as means, medians and interquartile ranges. Inferential analysis will be done, with univariate and multivariate logistic regression performed to obtain odds ratios of risk factors associated with MNM, with statistical significance at $p < 0.05$.

Key Words: Maternal Near Miss, KNH, Mortality Index,

CHAPTER I: INTRODUCTION

Background

In 2009, WHO defined a near miss as being a woman who nearly died but survived a complication that occurred during pregnancy, delivery or within 42 days after termination of a pregnancy. Subsequently, criteria encompassing laboratory, clinical, and management-based parameters for the diagnosis of a near miss were developed. Traditionally, auditing of incidences of maternal mortality has been the norm in assessing quality of maternal care within reproductive health units. However, evaluating the similarities, differences and relationships between women who died and those who survived life threatening conditions provides a more comprehensive audit of maternal health systems. As such, WHO advocates for the use of near miss case reviews (NMCR) as an adjunct to maternal mortality audits, with the aim of achieving further reduction in maternal mortalities and in a bid to achieve the target of the third sustainable development goal. This is further supported by the fact that more information can be gotten first hand from the near miss case, as opposed to mortality audits where analysis is done retrospectively. Furthermore, the process of NMCR is likely to be more acceptable by health workers because it negates the blame and feeling of guilt that is usually associated with auditing maternal mortalities. Given that near misses occur more frequently than maternal deaths, most developed nations have turned to near miss case reviewing as a strategy to further improve management practices for expectant women within their maternity units with life threatening conditions that would have otherwise resulted in mortalities , using the information generated from the reviews to improve their systems. Studies have been conducted to analyse the effectiveness of NMCR with results indicating its usefulness and benefits albeit the different tools used. Results of a systematic review on use of near miss case reviews in low-income and middle-income countries showed a significant reduction in maternal mortality figures measured prior to and after implementation of the review cycle (OR 0.77, 95% CI 0.61 – 0.98) (1). Furthermore, a significant reduction in uterine rupture, maternal sepsis and post-partum haemorrhage was observed in three out of six studies in this review, while all the 17 studies showed that NMCR cycle resulted in some alteration of facility physical structure, staffing needs, training, equipment and organisation of care. WHO's near miss approach in high mortality settings was further validated through a prospective cohort study conducted in Zanzibar, whose findings showed that of the 26, 842

women studied, 335 had severe maternal outcomes, with 256 near misses and 79 maternal deaths and concluded that the number of organ dysfunction markers was highly correlated to the risk of mortality (2).

A systematic review analysing qualitative studies on barriers and facilitators to effective implementation of individual NMCR in LMIC established that the most frequent barriers included lack of guidelines and local protocols, poor training on conducting NMCR, fear of blame, hierarchical differences amongst staff members, poor understanding of benefits on NMCR among others. On the other hand, major facilitators of NMCR included good stewardship, training of all key staff, clarity in staff's perception of the benefits of NMCR among others (3).

WHO developed a manual on performance of a near miss case review cycle, which outlines that cases be identified by care providers in a facility every month, the aim being to use the cases to evaluate service provision against evidence-based guidelines, local protocols and standards of care. Both quality and substandard practices are identified (4). Action points on improving quality of care are generated and their implementation monitored. The process is then done cyclically so as to sustain the improved quality of care provided. Certain indices specific to near misses have also derived, for comparative purposes and for inferences to be made regarding their trends, notably near miss prevalence, near miss to mortality rate as well as mortality index.

Kenyatta National Hospital is a level 6 facility and the country's main referral hospital. Consequently, it is prone to receiving clients with conditions that are likely to result in development of near miss morbidities or mortalities. Unpublished data from a prior study describing the causes of MNM morbidity and mortality at KNH in 2009 suggested that the prevalence of near misses at KNH was 4.7% with a mortality index of 0.176. Hypertension and HIV/AIDS were the leading causes of death and haemorrhage was the leading cause of near miss morbidity (5). Identification of factors associated with MNM events would be of great importance in identifying mothers who are at risk of developing such adverse outcomes upon admission, thereby instituting timely and targeted interventions upon admission into its reproductive health units. The overall outcome of this will be a significant improvement in quality of care of maternal and new-born services within the facility.

WHO Maternal Near Miss Criteria

BOX 40-e1 The WHO Maternal Near-Miss Criteria

Clinical Criteria

- Acute cyanosis
- Gasping[a]
- Respiratory rate > 40 or < 6/min
- Shock[b]
- Oliguria nonresponsive to fluids or diuretics[c]
- Clotting failure[d]
- Loss of consciousness lasting ≥ 12 hours[e]
- Loss of consciousness *and* absence of pulse/heart beat
- Stroke[f]
- Uncontrollable fit/total paralysis[g]
- Jaundice in the presence of preeclampsia[h]

Laboratory-Based Criteria

- Oxygen saturation < 90% for ≥ 60 minutes
- Pao_2/Fio_2 < 200 mm Hg
- Creatinine ≥ 300 µmol/L or ≥ 3.5 mg/dL
- Bilirubin > 100 µmol/L or > 6.0 mg/dL
- pH < 7.1
- Lactate > 5
- Acute thrombocytopenia (< 50,000 platelets)
- Loss of consciousness *and* the presence of glucose and ketoacids in urine

Management-Based Criteria

- Hysterectomy after infection or hemorrhage
- Use of continuous vasoactive drugs[i]
- Transfusion of ≥ 5 units of red blood cells
- Intubation and ventilation for ≥ 60 minutes not related to anesthesia
- Dialysis for acute renal failure
- Cardiopulmonary resuscitation

CHAPTER II: LITERATURE REVIEW

Overview of Chapter

This chapter evaluates data from available research on maternal near miss, on prevalence and factors associated with MNM development, which include select socio-demographic, medical and obstetric parameters as well as three delays.

Prevalence of Near misses

Due to variations in identification of MNN cases, estimation of near miss prevalence globally is difficult. WHO conducted a systematic review in 2004 on severe acute maternal morbidity world-wide. Prevalence varied between 0.80% and 8.23% for studies that used disease specific criteria, between 0.38% - 1.09% for studies that used organ system criteria and between 0.01% and 2.99% for studies that used management based criteria (6). A similar trend was found in a systematic review that analysed 82 studies, which gave estimates of near misses based on the criteria used. Findings showed that prevalence ranged between 0.6% to 14.98%, 0.04% to 4.54% and 0.14 and 0.92% for disease specific criteria, management based criteria organ based dysfunction (Mantel) criteria respectively. The values were higher in LMIC of Asia and Africa (7). A recent systematic review however found that the global pooled prevalence for MNM was 18.67 per 1000 live births (95% CI 16.28 – 21.06) (8).

WHO postulates that the severe maternal outcome prevalence in a population is generally 7.5 per 1000 live births. Studies conducted in Africa have shown varied prevalence for MNM. A descriptive study on MNM incidence in the public health sector of Harare showed a near miss ratio of 9.3 per 1000 live births (9). A rate similar to this was found in a prospective cohort study conducted in two referral hospitals in Uganda, where the near miss rate was 8.3 per 1000 live births (10). A slightly lower rate was found in a study conducted in South Africa in 2017 where the near miss rate was 5.83 per 1000 live births (11). Near misses have been extensively studies in Ethiopia, with the prevalence ranging between 4.97% and 8.0% (12) (13).

Local unpublished data from two previous studies conducted at KNH in 2001 and 2009 show that the prevalence of near miss events are 5.8% and 4.7% respectively (5). Owiti et al enrolled 142 women into the cross sectional study, that showed hypertensive disorders and HIV being the commonest causes of near miss morbidity. Mwebia et al 2018 conducted a quasi-experimental study in a county referral hospital in Embu to establish the effects of free maternity policy on near misses, and found that post-partum haemorrhage and severe pre-eclampsia were the commonest causes of MNM. She also found that there was an increase in cases of post-partum haemorrhage with a reduction of cases of severe pre-eclampsia(14). Among regional studies, Ethiopian studies have reported some of the highest near miss rates, with one recent study giving a MNM ratio of 20.8% (9.1% – 38.8%)(15).

Socio-demographic characteristics as risk factors for MNM development

Socio-demographic characteristics would include but not limited to parameters like marital status, age, residence, education level, occupation.

Age

Research has shown an association between extreme age and severe maternal outcomes. Oliveira et al 2004 assessed MNM and mortality among adolescents and older women in Ethiopia, and established that the risk for MNM or mortality was higher among older women by 25%. Even though MNMR and MR were high among the adolescents too, further analysis showed that younger age wasn't an independent risk factor but old age (>35 years) was an independent risk factor for severe maternal outcomes. They further established an increase in near miss and mortality ratios with increasing age. A similar trend was found in a study conducted on predictors of maternal death and near miss morbidity, which established a twofold risk of developing a near miss event amongst women aged between 35 – 39 years (OR 2.3, 95% CI 1.2 – 4.4) and a fivefold risk of near miss development amongst women who were 40 years and above (OR 5.0, 95% CI 1.8 – 14.4)(16). An unmatched case control study in Ethiopia found higher odds of developing MNM events for women younger than 16 years in their first pregnancy (AOR = 2.5; 95% CI:1.12 - 5.63) (17). A Brazilian demographic health survey established a 9 fold risk of developing severe maternal morbidity in women aged 40 years and above (aOR 9.6, 95% CI 1.26 – 72.82) (18).

Level of education

Level of education is another risk factor for experiencing a near miss event, given that it influences decision making as well as ability to recognize signs of complications when they occur, in pregnancy. A study in Ethiopia did establish that women with no formal education were 3 times more likely to experience a MNM event (AOR = 3.2; 95%CI 1.24 - 8.12) (17). In another study conducted in rural Ethiopia, illiterate parturients were significantly more likely to experience MNM (p <0.001), as compared to those who were exposed to formal education (13). A multi - country cross sectional study conducted in 2014, assessing education and severe maternal outcomes found that low education was significantly associated with severe maternal outcomes (aOR 2.07, 95% CI 1.46 – 2.95). Parturients with low education were two times more likely to develop maternal near miss (aOR1.80, 95% CI1.25 – 2.57) and approximately five times more likely to develop maternal morality than well-educated ones (aOR5.62, 95% CI3.45 – 9.16) (19). A similar study in Brazil found that women with no education were twice as likely to develop severe maternal outcomes compared to educated ones (aOR 2.18, 95% CI 1.15 – 4.10)(18). A study on determinants of maternal near miss conducted in Morocco in 2015 established that illiteracy was associated with a two-fold risk of developing a maternal near miss (OR 2.35, 95%CI 1.07 – 5.15) (20).

Obstetric characteristics as risk factors for MNM development

Mode of delivery

Studies have demonstrated that the mode of delivery has the potential to predispose a woman to development of severe maternal outcome. A study on predictors of MNM conducted in South Ethiopia established that women with a history of prior caesarean section had a 7 fold risk of developing MNM compared to controls (aOR 7.68, 95% CI 3.11 – 18.96) (21). 229 women were included in this hospital based study (77 cases and 152 controls). A study conducted in Brazil established that women who had a caesarean section and those with higher caesarean delivery rates were approximately three times more likely to develop severe maternal outcome respectively (OR 1.9, 95% CI 1.0 – 3.6 & OR 2.4 95% CI = 1.1-4.9) (22). Similar findings were found in a review of survey data in Brazil in 2016 which found a 2 fold risk of development of a near miss event amongst women who underwent an elective caesarean section (aOR 2.54, 95% CI 1.67-3.88)(23). This study found an estimated near

miss incidence of approximately 10.2 per 1000 live births. Assisted vaginal deliveries too have been shown to increase the likelihood of developing a maternal near miss, as evidenced by a study in Nigeria in 2013 which established that the risk of developing a near miss among women who had undergone assisted delivery was two times higher compared to controls (OR 2.55, 95% CI 1.34 – 4.83) (24). In the same study, emergency caesarean sections were associated with a three-fold risk of developing a MNM event (OR 3.72, 95% CI 0.93 – 14.9).

Antenatal clinic attendance

Antenatal clinic attendance does play a major role in early detection and management of pregnancy related complications, thereby averting adverse outcomes. A study in Brazil in 2016 found that mothers who failed to attend any antenatal clinics had a 4 fold risk of developing a near miss compared to women who had gone for at least one antenatal clinic visit (aOR 4.65, 95% CI 1.51 – 14.31) (23). Similar findings were found in a study in Ethiopia, in which a five-fold risk of developing a maternal near miss was found among women who failed to attend antenatal clinics as compared to controls (aOR 5.58, 95% CI 1.94 – 16.07) (25). Another Ethiopian study on maternal near miss determinants in western Ethiopia found that women who lacked antenatal care had a six-fold risk of developing maternal near miss compared to the controls (OR 6.02, 95% CI 1.55 – 23.28) (12). A retrospective study in Kowloon Hospital of China established that women with less than 6 prenatal attendances had a six-fold risk of developing a near miss event (aOR 6.76; 95% CI, 0.76–45.8) (26). Admission into ICU and receiving blood transfusion within half an hour of requisition were found to be protective factors (aOR, 6.75; 95% CI, 0.89–34.6 and aOR, 3.79; 95% CI, 0.65–8.67 respectively). Similar trends were found in the study conducted in Morocco, which established a four-fold risk of near miss development amongst women who had not attended any antenatal clinic (OR 3.97, 95% CI 1.42 – 11.09) (20).

Pre-existing medical condition

Presence of a pre-existing medical condition has been shown to increase the risk of development of near miss events amongst expectant women. An Ethiopian study established that a history of a medical condition was reported in 55.3% of their cases compared to 33.2% of the controls. Women with chronic medical disorders, notably diabetes mellitus, hypertensive disorders and cardiovascular diseases, had four-fold risk of developing a near

miss event (aOR 3.5, 95% CI 1.78 – 6.93) (17). Another Ethiopian study established that women who had a prior history of anaemia had odds five times higher than controls, of developing a near miss event (aOR 5.26, 95 CI 2.89 – 9.57) (13). This was consistent with results from a study conducted in 2007 in USA, with similar results, establishing that with expectant women having a chronic medical condition had a two-fold risk of developing a near miss event (OR2.7, 95% CI 1.5 – 4.8) (16).

Induction of Labour

Induction of labour is another obstetric factor that has been demonstrated to raise the risk of developing near miss events. Two Ethiopian studies demonstrated that labour induction has potential to trigger sever maternal outcomes. An unmatched case control study found that labour induction was associated with a nine–fold risk of developing near miss events (aOR 9.4, 95% CI 2.97 – 29.7) (12). The second study had similar findings, establishing that women who had undergone induction of labour were three times more likely to develop near miss events than controls (aOR 3.0, 95% CI 1.44 – 6.17) (17). A Brazilian study on near misses established that there were higher proportions of near misses amongst women admitted for induction of labour (RR 1.7, 95% CI 1.0 – 2.7) (27).

Delays and maternal near miss development

Delays in seeking as well as in receiving quality and appropriate health services have been shown to significantly influence the development of near miss events. These delays include delay in deciding to seek health care (first delay), delay in reaching a health facility (second delay) and delay in provision of appropriate and adequate care within a health facility (third delay). In A retrospective study conducted in Brazil on near misses and severe maternal morbidity established that expectant women who experienced a third delay had a 13 fold risk of developing a near miss event (OR: 13.3; 95% CI: 6.7 – 26.4) (28). A study conducted in China in 2012 established that women who delayed in seeking services had a four-fold risk of developing a near miss event (aOR, 4.76; 95% CI, 0.89 –13.6) (26). These findings were consistent with those found by a study in Ethiopia in 2017, which demonstrated that women who experienced a phase one delay had a two-fold risk of developing a near miss event (aOR2.79, 95CI 1.42 – 5.50) (21). Similarly, a Nigerian study conducted prospectively in 2013 established that women who had experienced a phase one delay were two times more

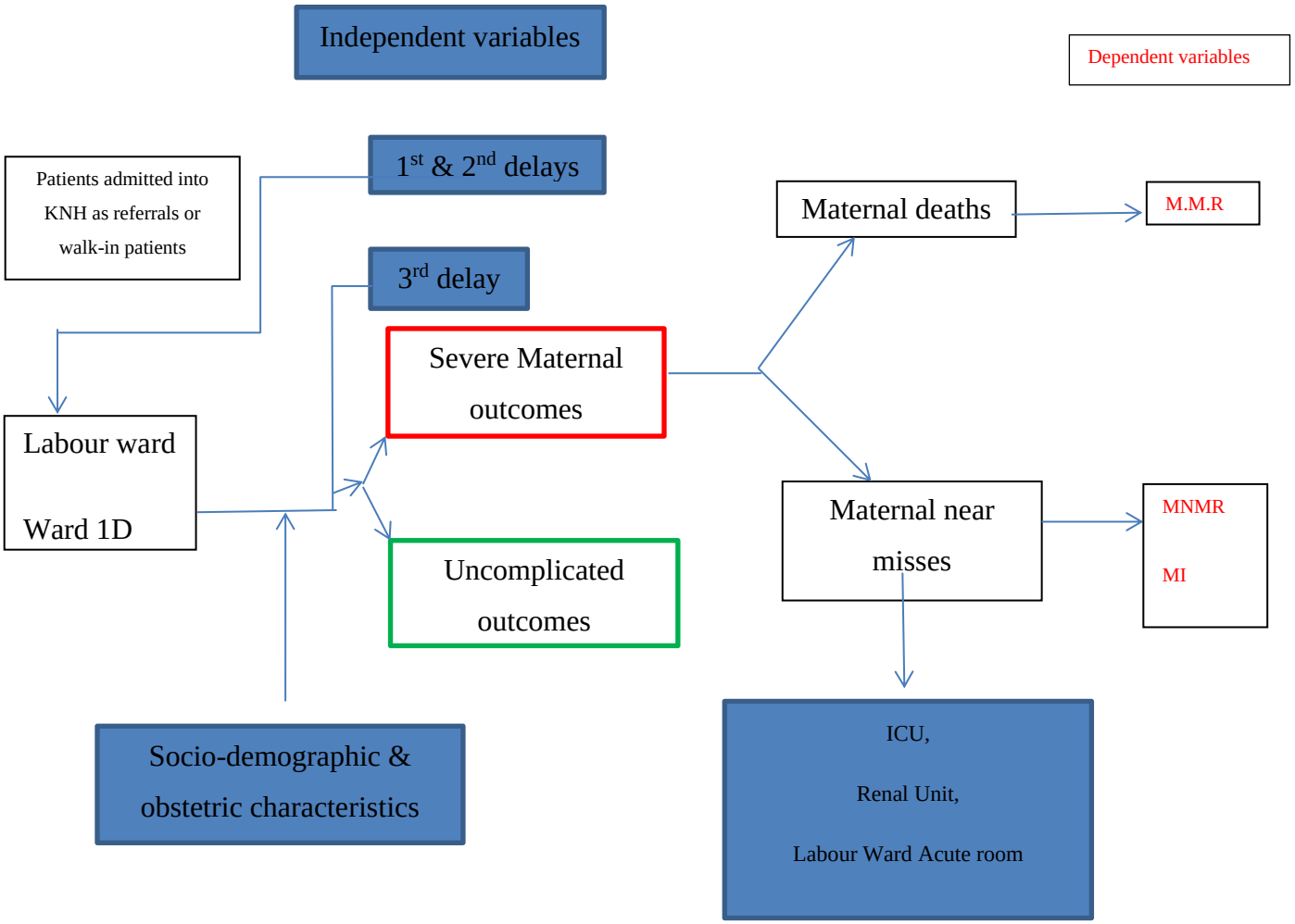
likely to develop a near miss event compared to controls (OR 2.07; 95% CI 1.03-4.17) (24). A study in Morocco established that women who had experienced a first delay had an 8 fold risk of developing near miss events than the control group (OR 8.7, 95CI 3.97- 19.12) as well as a four-fold risk of developing a near miss upon experiencing a 3rd delay (OR 4.03, 95% CI 1.75 -9.25) (20).

Statement of the Problem

In 2017, World Health Organization estimated that approximately 295,000 women passed on as a result of obstetric complications and even though the period between the year 2000 and 2017 experienced a 38% reduction in maternal mortality ratio, Africa (Sub Saharan) and Asia (Southern) contributed the most(86%) of global maternal deaths in 2017, with 254,000 maternal deaths per 100,000 live births (29).

Locally, the Kenya Demographic and Health Survey of 2014 showed that maternal mortality trends in Kenya have steadily declined, from 488 in 2008 to 362 per 100,000 live births in 2014 (30). Given that mortalities almost invariably arise from near miss morbidities, an evaluation of near misses is of utmost importance as it would provide an opportunity to analyse the unique characteristics that these cases have, thereby allowing for the profiling of expectant women seeking services in health facilities with the aim of identifying their risk factors. This would serve as an indirect way of preventing maternal morbidity and mortality, as it would allow for heightened surveillance of potential complications and subsequent institution of preventive measures. It is therefore imperative that efforts be channelled towards strengthening health systems with the aim of achieving a significant reduction in maternal morbidities and mortalities. One way would be to undertake systematic and standardised reviews of maternal near-miss cases. This is what this study seeks to achieve.

Conceptual Framework



Women getting admitted into the reproductive units within KNH will have either a complicated or a non-complicated pregnancy experience, depending on the interaction of a number of factors. Prior to admission, they may have experienced a first delay, a second delay or both, putting them at risk of developing near miss morbidities. Post admission, various factors may affect their outcomes, including socio-demographic factors, third delays, obstetric factors as well as past medical history. A majority will end up having desirable outcomes, but some develop severe maternal outcomes, which include maternal mortalities or near miss morbidities. This latter group constitutes the population of interest in this study.

Study Justification

Data on near misses is not routinely recorded or published at KNH and nationally. There is limited local published data on the prevalence, hence burden of maternal near and more importantly factors associated with their development. Previous studies conducted at KNH on near misses focused mainly on prevalence through the use of cross sectional study designs. Besides determining current prevalence, my study seeks to evaluate factors associated with their development, by using a nested case control approach. The study findings have the potential to influence the introduction of near miss case reviewing (NMCR) as an adjunct to maternal mortality reviews, which would in turn translate into better preparedness, surveillance and management of such conditions within the reproductive health unit at KNH. Furthermore, the study would provide the baseline information that would allow for possible future studies evaluating effects of implementation of NMCRs on quality of care of mothers with near miss events.

Research Question

What is the prevalence and factors associated with maternal near misses at Kenyatta National Hospital?

Research Objectives

Broad Objective

To determine the incidence and identify factors associated with maternal near misses at Kenyatta National Hospital over the period between 1st January 2017 and 31st December 2019.

Specific Objectives

Among women admitted at KNH for delivery or pregnancy related care between 1st Jan 2017 to 31st Dec 2019,

1. To determine the prevalence of maternal near misses over the 3 year period.

2. To describe the various near miss morbidities at Kenyatta National Hospital over the 3 year period.
3. To determine the mortality index for the 3 year study period.
4. To evaluate factors associated with development of near miss morbidities amongst expectant women at KNH over the 3 year period.

CHAPTER III: METHODOLOGY

Study design

A cross sectional study with a case-control component. The study was conducted retrospectively over the period between 1st January 2017 and 31st December 2019.

Study site

The study was undertaken at KNH, one of the two level 6 facilities in Kenya. It has a bed capacity of 1,800 with all major specialties, offering specialised treatment as its core mandate. It has a reproductive health unit comprises 3 antenatal/postnatal wards, maternity wing with two functional theatres, 1 gynaecological ward and 1 oncology ward, fistula and family planning unit. These units are manned by consultants, registrars, nurses and midwives and receive support from other key departments, namely blood transfusion unit, renal unit, radio-oncology unit, intensive care unit, and various specialised laboratories. Upon receiving or diagnosing a case of maternal near miss, the patient is managed and monitored within the appropriate ward in the reproductive health unit, or admitted into the other supporting departments such as ICU or renal unit for further management and monitoring, depending on the kind of complication affecting them. Upon successful management, the client is discharged home and booked for follow up in the appropriate clinic, until such a time when they are deemed fit to discontinue follow up. Subsequently, cases and controls shall be drawn from labour ward, ward 1D, ICU, renal unit as well as the antenatal/postnatal wards.

Study population

This comprised of women admitted at KNH for delivery or pregnancy related care.

Inclusion criteria

The inclusion criteria for the cross sectional study as well as cases for the case control study were women with a pregnancy related complications commensurate with the WHO Near Miss criteria, with evidence of admission into KNH, confirmed pregnancy or puerperium, date of admission and discharge, presence of working diagnoses within the 3 year study period.

Inclusion criteria for controls were women admitted on the same day as cases but without any complications of pregnancy, delivery or puerperium within the 3 year study period.

Exclusion criteria

- Women admitted with complications after 42 days postpartum or post pregnancy termination.
- Women admitted with pseudocyesis.
- Women with unconfirmed pregnancy status.
- Women whose records lacked key study variables such as age, parity, level of education

Sample size Calculation

Given the study design, two sample sizes were calculated, one to establish the minimum required sample size for prevalence determination and the second to determine the required number of cases and controls needed for the evaluation of factors associated with near miss development.

The study relied on the maternal data at KNH's reproductive unit for a period of 3 years, starting from 1st January 2017 through 31st December 2019. Data obtained by the researcher from Health Information System registry at KNH indicated that during the study period, the total admissions in labour ward and ward 1D were 48,342, which formed the sampling frame. The sample size was calculated using the formula developed by Yamane Taro in 1967, $n = \frac{N}{1+N*e2}$ (Akech, 2016; p33). Where,

n = sample size

N = population from which cases and controls shall be derived, which is 10,923

e = significance error, which is **0.05**

Substituting the values in the formula:

$$n = \frac{48{,}342}{1+\{48{,}342\ x\ (0.05x\ 0.05)\}} = \frac{48{,}342}{1+120.855}$$

n = 48,342/121.855

n = 393.91, rounded off to 394.

Adjusting for non-response, a further 10% shall be added, thus the final sample size shall be 394 + 39.4 = 433.4 this will be rounded off to 433 records.

Sample Size for (unmatched) case-control study

Sample size for the case control study was calculated using StatCalc in Epi info version 7 software for matched case control study, based on the following assumptions, derived from a similar study conducted in Ethiopia (13): power of 80%, 95% confidence interval, controls to cases ratio of 2:1, proportion of exposed controls 4.11%, proportion of exposed cases 10.78%, giving an odds ratio of 2.82. This gave 157 cases and 314 controls, giving a total sample size of 471 required to evaluate factors associated with near misses.

Sampling procedure

Consecutive sampling was employed for both the cross sectional and case control studies in recruitment of study participants. 2 controls were selected consecutively for each case until the required sample size was achieved.

Data variables

objective	**Data variables**	
	independent	**Dependent (outcome)**
1	• Total live births, • total Mortalities, • Total ectopic pregnancies, • Total miscarriages • Total maternal near misses	Prevalence of near misses Maternal near miss ratio (MNMR)
2	• Total near misses based on clinical criteria • Total near misses based on intervention • Total near misses based on organ dysfunction	
3	MMR	Mortality index
4	• Age, parity • education level • delivery mode	

	• prior near miss • pre-existing comorbidity	

Data collection, security and management

Six Research assistants underwent 3 days of training on the use of the data collection tool, a modification of the WHO Near Miss criteria, after which a dry – run on their use of the same conducted to assess whether the tool required any adjustments or structural changes. Data was then recorded on the modified WHO data collection tool. The principle investigator randomly picked filled forms to check on correctness as a quality control measure. These were then captured into an electronic excel database that was password protected and finally submitted for statistical analysis. The data and results were stored electronically in a password protected disc drive, only accessible to the statistician and principle investigator.

Data analysis

Data was analysed using SPSS version21. Descriptive analysis of cases and controls' socio-demographics was done and summarized as proportions and frequencies (categorical) or as means, medians and interquartile ranges (continuous).

Chi-square test was done to compare categorical variables

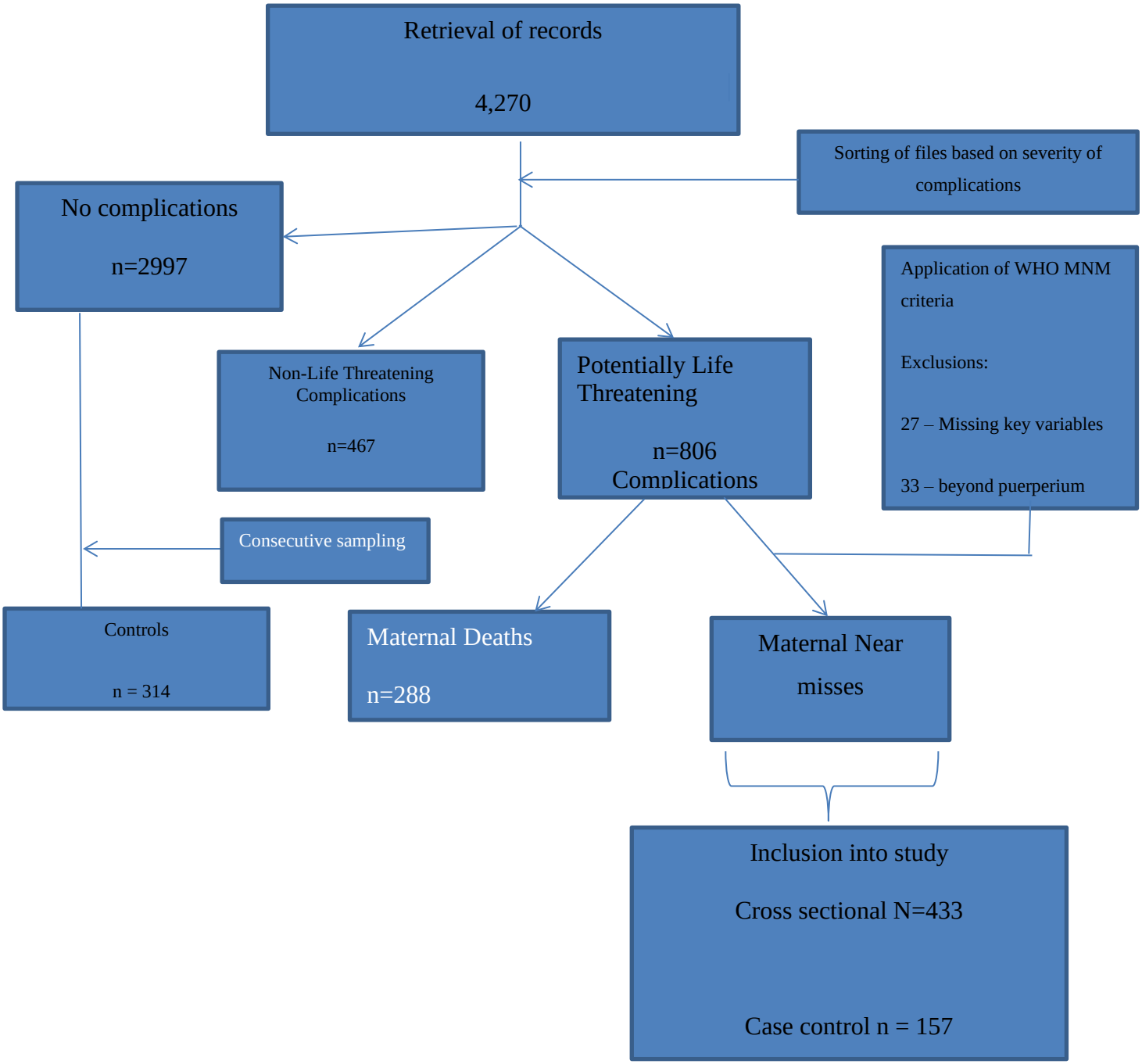
Inferential analysis was done, with univariate and multivariate logistic regression performed to obtain odds ratios, crude and adjusted respectively, of factors associated with MNM, with statistical significance at $\boldsymbol{p < 0.05}$.

Ethical considerations

Ethical approval was sought from Kenyatta National Hospital/University of Nairobi Ethics & Research Review Committee for approval, upon which the letter of approval was submitted to the officers in charge of Labour ward, ward 1D, renal unit, ICU, and record department prior to commencement of data collection.

Patient identities were not included in the data retrieval process and details extracted from the files remained confidential, and only used for purposes of this study. Backed up data was stored in a password protected drive under the custody of the principle investigator

Study Flow Diagram



CHAPTER FOUR: RESULTS

4.0: Overview

A total of 4270 maternal patient files were assessed with 433 were selected as the study data sources for the cross-sectional study. As summarised in ***Table 1*** below, the mean age for the near miss cases was 28.53 (SD= 5.857), mean parity was 2 (SD = 1.277) and gravida was 2 (SD = 1.399). The mothers who experience near miss population were admitted for an average 7.64 days (SD = 12.504). Even though majority, N = 338 (78.1%), of the mothers who experienced near miss events had no history of abortions, 15.7% (N = 68) had at least one miscarriage/abortion while 6% (N = 26) had more than two abortions. Majority of the near miss mothers were married (81.1%), with at least secondary education (64.7%), unemployed (53.6%), and delivered through spontaneous vaginal delivery (69.7%).

Table 1: Descriptive Analysis Output for Baseline Socio-Demographic Characteristics

Variable	Category	Sample	Frequency	Mean	SD
Age	< 20 yrs.	24	5.5	28.53	5.857
	20 – 29 yrs.	225	52.0		
	30 – 39 yrs.	168	38.8		
	≥40 yrs.	16	3.7		
Level of education	None	23	5.3		
	Primary	130	30		
	Secondary	174	40.2		
	Tertiary	106	24.5		
Marital Status	Single	82	18.9		
	Married	351	81.1		
Occupation	Unemployed	232	53.6		
	Informal employment	165	38.1		
	Formal employment	36	8.3		

Table 2: Descriptive Analysis Output for Baseline Obstetric Characteristics

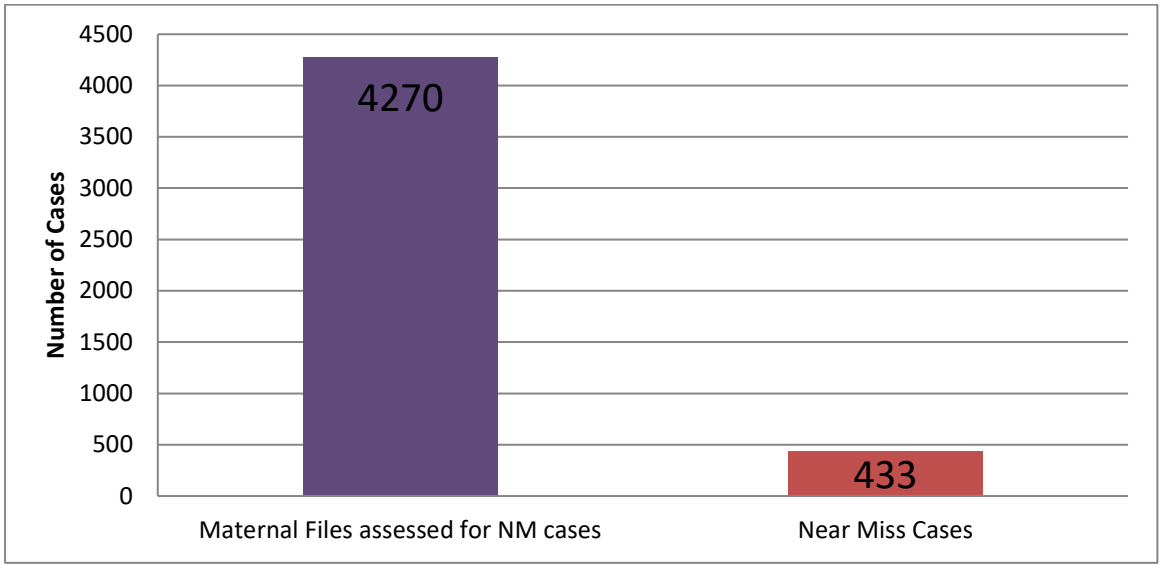
Variable	Category	Sample	Frequency	Mean	SD
Parity	Nulliparous	23	5.3	1.99	1.277
	Para 1-2	291	67.2		
	≥Para 3	119	27.5		
Gravidity	Primigravida	4	0.9	2.29	1.399
	Gravida 1 - 2	271	63.1		
	≥Gravida 3	156	36.0		
History of miscarriage	0	338	78.1		
	1	68	15.7		
	≥2	26	6.0		
Delivery mode	SVD	302	69.7		
	CS	111	25.6		
	Complete abortion	14	3.2		
	Others	6	1.4		
Hospital stay	1 day	49	11.3	7.64	12.504
	2 – 7 days	280	64.6		
	Over 1 week	104	24.1		

4.1: The Prevalence of Maternal Near Misses

Out of the 4270 maternal files assessed for the period 1st January 2017 through 31st December 2019, 433 qualified as near miss cases as shown in ***Figure I*** below. This translates to a prevalence of 10.14% for the near miss occurrences.

Amongst them, 155 (36%) were clinic attendees at Kenyatta National Hospital while 117(27%) of them were referrals from other facilities. The remaining proportion of them were walk-in patients.

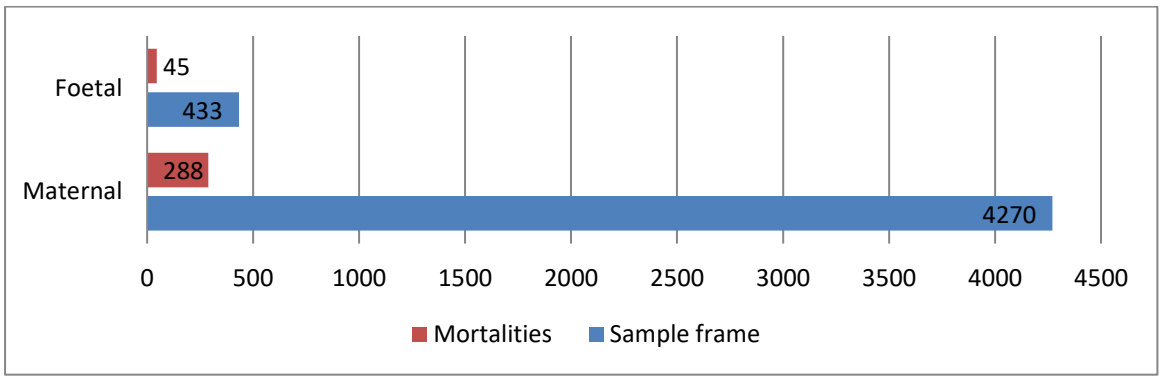
Figure I: Total samples and Maternal Near Miss Data



4.2: Maternal Mortalities and Still Births

In assessing the maternal mortality index, out of the 4270 files, there were 288 cases of maternal deaths. This represents a prevalence of 6.74% mortality cases for the study period in question. From the near miss cases, there was stillbirth prevalence of 10.39%. These findings are illustrated in the ***Figure II*** below.

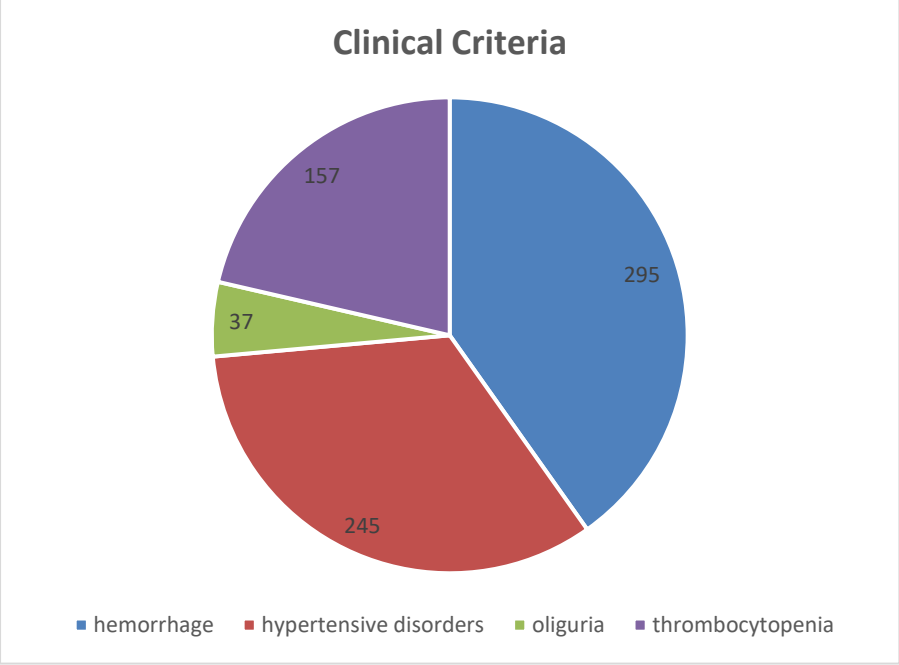
Figure II: Mortality Indices for both maternal and foetus.



4.3: Near Miss Morbidities at Kenyatta National Hospital

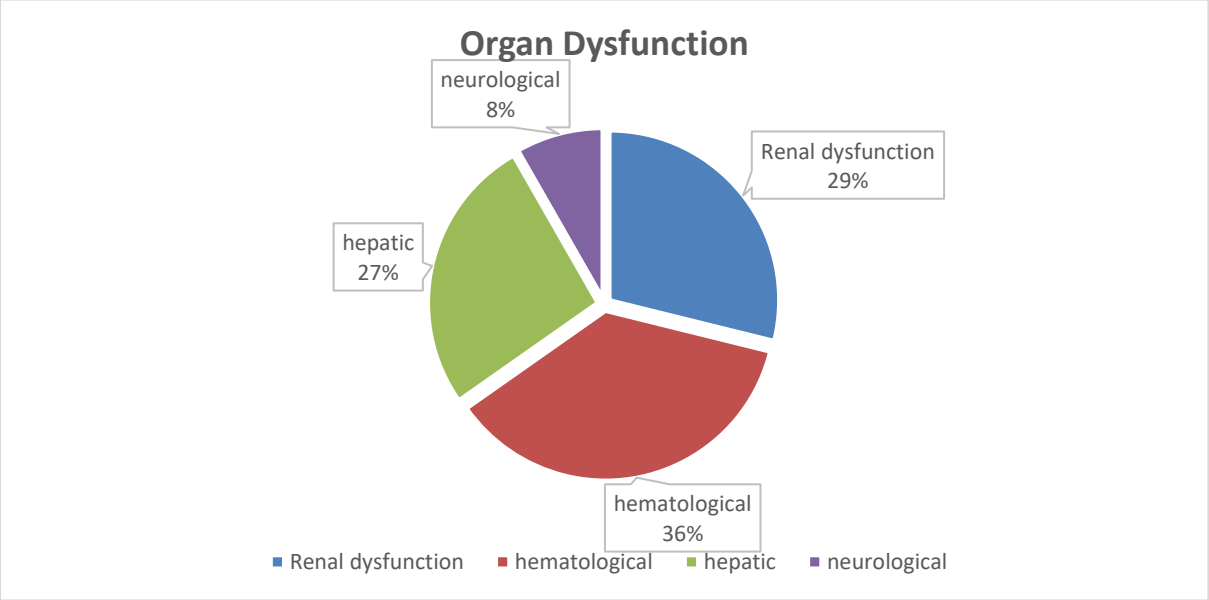
We analysed the distribution of near misses at KNH based on their criteria within the WHO near miss classification. Obstetric haemorrhage with a frequency of 68% (N = 295) was the commonest morbidity in the clinical criteria, followed by hypertensive disorders at 56.6% (eclampsia 10.4%%, n = 45), severe pre-eclampsia 47%, n = 204), thrombocytopenia 36.2% (N = 157), oliguria 8.5% (N = 37). These findings are as shown in ***Figure III*** below.

Figure III: Distribution of Severe Complications Associated with Near Miss Cases by Clinical Criteria



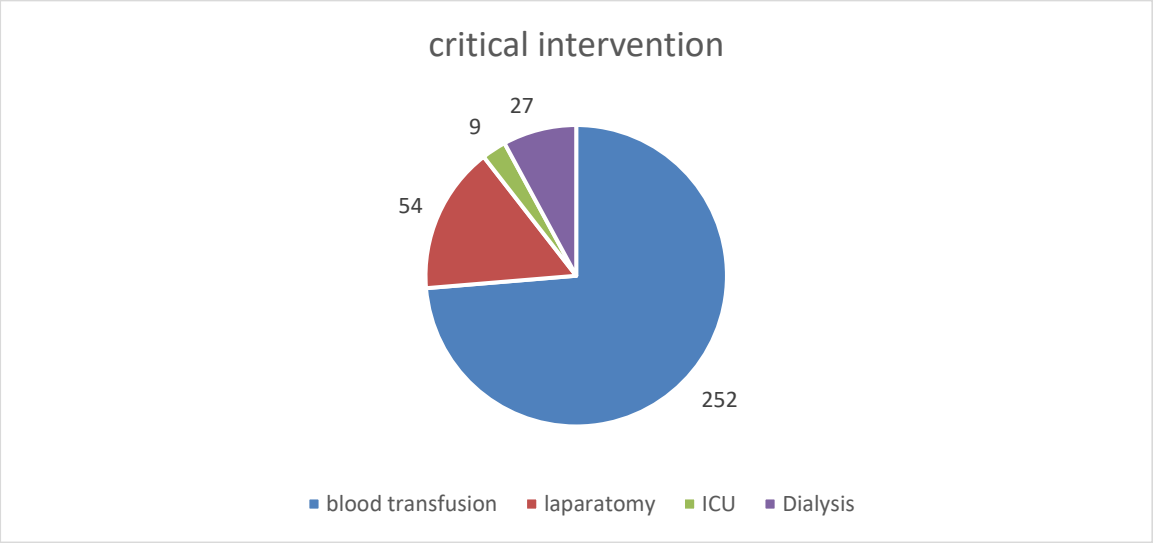
The second category of morbidities associated with near miss cases as identified in the WHO tool is organ dysfunctions. As illustrated in ***Figure IV*** below, haematological dysfunction was found to be the most frequent with 198 cases(36%), followed by renal dysfunction that was prevalent at 29% (n = 157) then by hepatic dysfunction at 27% (N=144) and finally neurologic dysfunction 8% (n = 45)

Figure IV: Distribution of Near Miss Morbidities by Organ dysfunction Criteria



The most common critical intervention for the mothers with near miss morbidities was use of blood products (transfusion) 58.19% (n= 252) with 12.5% (n=54) undergoing laparotomy and 2.1% (N = 9) being admitted to ICU (See ***Figure V*** below). For those transfused, the mean number of units of blood transfused was 1.30 (SD 1.212) with the highest number of units transfused to a single patient being five. Figure V: Critical Interventions to Near Miss Morbidities

Figure V: Distribution of Near Misses by critical intervention



4.4: Factors Associated with Development of Near Miss Morbidities

4.4a: Sociodemographic and Obstetric Factors

Part of the study arm was a matched case control study involving 157 near miss cases comparatively assessed with 314 controls characterised by mothers who had uncomplicated deliveries. The objective was to assess for sociodemographic, obstetrical, and maternal underlying factors associated with maternal near miss occurrence. Using Chi-square and risk ratio analysis, the findings indicated presence of variables that increased the odds of having a near miss event at KNH as summarized in ***Table II*** below. Not having a formal employment increased risks of near miss events by 4 times (OR = 4.0 95% CI: 2.10 – 7.59, $p < 0.001$). Illiteracy was a factor considering 27% of cases compared to 6.7% of the controls had primary education as the highest education level, which raised the likelihood of near miss occurrence by 5 times (OR = 5.3, 95% CI: 2.99 – 9.26, $p < 0.001$).

Obstetric factors such as parity, gravidity and gestation were also found to have statistically significant risk ratios. With 79.0% of the cases having parity of not more than two compared to 65.0% of the controls, the likelihood of near miss was two times higher is cases that controls (OR = 2.0, 95% CI: 1.29 – 3.17, $p = 0.002$). Similarly, gravidity of utmost two, observed in 70.5% of cases compared to 46.8% of controls, increased the odds of near miss occurrence by 2.7 times (OR = 2.7, 95% CI: 1.80 – 4.09, $p < 0.001$).Gestation in weeks was categorised into those below or above 37 weeks. The chances of near miss occurrences were 6 times greater (OR = 6.2, 95% CI: 3.37 – 11. 31, $p < 0.001$) among the 26.1% of cases compared to 5.4% of the controls whose gestation was below 37 weeks. Notably, 26.1% cases versus 5.4% controls had a history of miscarriage. Having a history of abortions seems to improve as opposed to worsen the probability of having near miss events (OR = 0.4, 95% CI: 3.37 – 11.31, $p < 0.001$).

Table 3: Sociodemographic and Obstetric Variables as Risk Factors for Near Miss Occurrence

Variable	Case *[N = 157]* n (%)	Controls *[N = 314]* n (%)	Odds Ratio (CI 95%)	P-value
Age				
≤ Below 25Yrs	53 (33.8)	104 (33.1)	1.0(0.69 – 1.54)	P = 0.890
> 25 Years	104(66.2)	210(66.9)		
Marital Status				
Single	23(14.6)	81(25.8)	0.5(0.29 – 0.82)	P = 0.067
Married	134(85.4)	233(74.2)		
Occupation				
No Formal Employment	145(92.4)	236(75.2)	4.0(2.10 – 7.59)	P < 0.001
Formally Employed	12(7.6)	78(24.8)		
Level of Education				
Highest Primary Level	43(27.4)	21(6.7)	5.3(2.99 – 9.26)	P < 0.001
Secondary and beyond	114(72.6)	293(93.3)		
Parity				
≤2	124(79.0)	204(65.0)	2.0(1.29 – 3.17)	P = 0.002
≥3	33(21.0)	110(35.0)		
Gravidity				
≤2	110(70.5)	147(46.8)	2.7(1.80 – 4.09)	P < 0.001
≥3	46(29.5)	167(53.2)		
History of Abortions				
Yes	28(17.8)	148(38.2)	0.4(0.22 – 0.57)	P < 0.001
No	129 (82.2)	194(61.8)		
Gestation in Weeks				
Below 37 Weeks	41(26.1)	17(5.4)	6.2(3.37 – 11.31)	P < 0.001
Over 37 Weeks	116(73.9)	297(94.6)		
Previous C/S				
Yes	29(18.5)	10(3.2)	6.9(3.26 – 14.55)	P < 0.001
No	128(81.5)	304(96.7)		

4.4b: Maternal Underlying Conditions

Some of the mothers with uncomplicated deliveries still had underlying conditions. Therefore, the association between the underlying maternal conditions (anaemia and HIV) and near miss events was analysed by running a bivariate analysis. Mothers with anaemia had 5.2 times greater odds of developing near miss morbidities compared to those without anaemia (OR = 5.2, 95% CI: 2.25 – 12.32, p < 0.001). However, HIV infections with a frequency of 7.0% among the cases and 8.6% among the controls did not have any statistically significant effects on near miss risks (See ***Table III*** below).

Table 4: Association between Underlying Maternal Conditions and Near Miss Occurrence

Variable	**Case** ***[N = 157]*** **n (%)**	**Controls** ***[N = 314]*** **n (%)**	**Odds Ratio (CI 95%)**	**P-value**
Anaemia Present				
Yes	19 (12.1)	8(2.5)	5.2(2.25 – 12.32)	P < 0.001
No	138(87.9)	306(97.5)		
HIV Infections				
Yes	11(7.0)	27(8.6)	0.8(0.39 – 1.66)	P = 0.550
No	146(93.0)	287(91.4)		

Having established the factors with statistical significance, the next step involved running a hierarchical multivariate logistical analysis to arrive at the actual variables associated with near miss after accounting for the impact of the other variables. The findings are as presented in Table IV below with adjusted Odds Ratio and P-value. The multivariate analysis ruled out the effects of parity, gravidity, and anaemia on near miss cases. Among the social demographics characteristics, not having formal employment (aOR = 4.9, 95% CI: 2.28 – 10.57, p < 0.001) and not having gone past primary level of education (aOR = 5.8, 95% CI: 2.99 – 11.37, p <0.001) increased the odds of near miss occurrence by 4.9 times and 5.8 times respectively. Under obstetric parameters, gestation below 37 weeks increased the odds of near miss by roughly seven times (aOR = 6.9, 95% CI: 3.46 – 14.00, p < 0.001). The history of abortions had a statistically significant modulating effect on near miss cases (aOR = 0.4

95% CI: 0.20 – 0.843, p = 0.009). Lastly, having a previous caesarean section raised the odds of developing near miss morbidity by eight (aOR = 8.1 95% CI: 2.33 – 28.41, p = 0.001)

Table 5: Multivariate Logistical Analysis for Factors Associated with Near Miss

Variables	**Coefficient (B)**	**Adjusted Odds Ratio (aOR) [95% CI]**	**P – value**
Occupation No Formal Employment Formally Employed	1.51	4.9(2.28 – 10.57)	P < 0.001
Level of Education Highest Primary Level Secondary and beyond	1.76	5.8(2.99 – 11.37)	P < 0.001
Parity ≤2 ≥3	0.66	1.9(0.76 – 4.86)	P = 0.166
Gravidity ≤2 ≥3	0.33	1.5(0.577 – 3.74)	P = 0.490
History of Abortions Yes No	-0.95	0.4(0.20 – 0.843)	P = 0.009
Gestation in Weeks Below 37 Weeks Over 37 Weeks	1.91	6.9(3.46 – 14.00)	P < 0.001
Anaemia Present Yes No	-.0.17	1.6(0.35 – 7.41)	P = 0.848
Previous CS Yes No	2.09	8.1(2.33 – 28.41)	P = 0.001

CHAPTER FIVE: DISCUSSION

Maternal near misses continue to provide invaluable information geared towards improving quality of care for expectant and postpartum mothers. In our study, a total of 4270 patient files were screened, with 433 meeting the inclusion criteria for maternal near misses, giving a prevalence of 10.14%. In this study, the mean age of the women was 28.53 years, with a majority of them having a parity of two (67.2%). Most of the women had attained secondary education (40%). 69.7% of them delivered vaginally, with the average length of stay being7.64 days.

Our prevalence of 10.14% was higher than that observed by Owiti et al (2007), who established a prevalence of 4.7%, through a cross sectional study conducted prospectively at the same facility. This might be attributed to an increase in workload or referrals to KNH. This prevalence is consistent with that of a study conducted in Zimbabwe that established a rate of 9.3%. Similar studies conducted in the region however, had higher prevalences in comparison to our study. Tolesa D et al in Ethiopia (2020) found a prevalence of 16.1%, while Yemane et al (2020) found a prevalence of 24.85%.

In the clinical criteria for diagnosis of MNM, our study established that severe postpartum haemorrhage and hypertensive disorders were the leading causes of near misses, at 667.7% and 17.5% respectively. This was consistent with similar local studies conducted by Mweiba et al (2018) as well as Owiti et al, with Owiti et al (2007). This finding is consistent with other regional studies such as that conducted by Mekango et al (2017), where haemorrhage then hypertensive disorders in pregnancy were the leading causes of near miss morbidity. This trend was observed in Brasil by a study conducted by Galvao et al (2015), the only difference being hypertensive disorders were the leading cause of near miss morbidity (67.5%) followed by obstetric haemorrhage (15%). Renal and hepatic dysfunctions were the leading causes of morbidity in the organ dysfunction /laboratory criteria, comprising 57%and 14%. In the last criteria of critical intervention use of blood products (58.95%), laparotomy (12.5%) and ICU admission (2.1%) constituted the most cases of near misses

In our study, the mortality index was calculated to be 39.9%. This figure is way beyond the recommended level by WHO of <5%, as it represents an estimate of how a health facility is performing in dealing with complex and severe cases. A study by Singh V et al (2021) in

India on maternal near miss as a surrogate indicator of quality of care had a mortality index of 19.9%, which was higher than WHO's recommendation but lower than our study findings. Similarly, Mansuri et al (India, 2019) found a high mortality index of 24.23% with a near missto mortality ratio of 3.13:1. Manyahi et al (Tanzania, 2020) found a mortality index of 11%. This was lower than our study finding, even though this study focused on near misses attributable to hypertensive disorders, over a 1 year period.

A case control study was conducted to establish factors associated with MNM morbidity. Lack of formal employment (aOR4.9, CI 2.28 – 10.57) was found to be significantly associated with MNM morbidities. This may be explained by the fact that formal employment ensures a steady income, thereby rendering the woman economically empowered to access better medical care.

Low level of education (aOR5.8, CI 2.99 – 11.37) were found to be associated with near miss morbidity. Similar findings were found by Firdawek et al (Ethiopia, 2018), who established that low education was associated with severe maternal outcomes (OR2.07, CI 1.46 – 2.95) and 5 times greater odds of experiencing mortality than educated ones (OR5.6, CI 3.45 – 9.16). similarly, Assarag et al (2015, Morocco) established that illiteracy was associated with a 2 times greater odds of developing maternal near miss (OR 2.35, CI 1.07 – 5.15). This association may be explained by the fact that education influences ability to identify danger signs as well as decision to seek timely medical attention

Previous history of miscarriages (aOR0.4, CI0.20 – 0.843) has been associated with development of near miss morbidities. Galvao et al (Brasil, 2014) established that previous history of miscarriages was associated with 3 times greater odds of developing NM. Little is known is known of the association, but those with the association tend to develop near misses related to hemorrhage and infection/sepsis

Previous history of caesarean sections (aOR8.1, CI 2.33 – 28.41) was found to be associated with near miss morbidity. Galvao et al (Brasil, 2014) established that previous c/sections and high c/s rates had 2 times greater odds of developing MNM (OR1.9, CI 1.0 – 3.6). Similarly, Kasahun et al (Ethiopia, 2018) established that previous cesarean section posed 8 times greater odds of developing MNM

Our study found that a gestation less than 37 weeks (aOR6.9, CI 3.46 – 14.00) was associated with near miss morbidity. Galvao et al established that conditions diagnosing MNM were associated with earlier gestation at admission (p=0.016)

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1: Conclusion

Our study established that the prevalence of MNM at KNH has increased from a previous finding of 4.7% in 2007 to 10.14%, with the leading near miss morbidities being severe postpartum haemorrhage followed by hypertensive disorders of pregnancy. Furthermore, the commonest organ dysfunction amongst near miss cases was found to be haematological dysfunction, followed closely by renal dysfunction, with use of blood and blood products being the leading critical intervention amongst near miss cases. The mortality index however, was higher than the WHO recommended level and points at gaps in management of complex and severe cases. This thus, gives us an opportunity to audit near miss cases by way of near miss case reviews in a bid to improve quality of care and subsequently improve on our near miss indices**.**

6.2: Recommendations

1. Given the prevalence, there is need to consider undertaking near miss case reviews as a way of continuously gathering information with the aim of improving quality of care, at KNH
2. Patients with known risk factors for near miss morbidities, such as patients with previous caesarean section scars and anaemia should be managed, with a lot of vigilance due to their propensity to develop near miss morbidities
3. Departments that offer supportive services such as renal unit and blood transfusion unit need to be enabled to offer timely and quality services so as to ensure better outcomes for near miss cases

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Appendixes

Appendix 1: Budget

Item	Unit cost (Kshs)	quantity	Total
Research assistants	15,000	6	90,000
Stationery & printing	25,000		25,000
Back up device	6500	1	6500
Miscellaneous	10,000		10,000
Statistician	50,000	**1**	50,000
Grand total			**240,500**

Appendix 2: Timeline

	January – April 2020	May 2020	June – July 2020	August 2020	September 2020	June 2022
Proposal development						
Proposal presentation						
Ethical Approval						
Data collection & analysis						
Presentation of results						
Submission of thesis						

Appendix 3: WHO Near Miss Criteria

Criteria	Description
Clinical criteria	- Severe pre eclampsia - Severe postpartum haemorrhage - Severe sepsis - Uterine rupture - Severe complication of abortion
Critical interventions/intensive care use	- Admission to ICU - Laparotomy (includes hysterectomy, excluding caesarean section) - Use of blood products - Interventional radiology
Organ dysfunction	• Cardiovascular dysfunction Shock, cardiac arrest, CPR, hypo perfusion (lactate >5mmol/l), severe acidosis(pH<7.1) • Respiratory dysfunction Acute cyanosis, gasping, tachypnoea (RR>40), bradypnoea (RR<6), intubation & ventilation unrelated to anaesthesia, severe hypoxemia (Oxygen saturations <90%) for > 60 minutes • Renal dysfunction Oliguria unresponsive to fluids and diuretics, dialysis for ARF, acute azotaemia (Cr ≥300micromol/ml) • Haematological dysfunction Failure to form clot, massive RBC transfusion (≥5 units), severe acute thrombocytopenia(<50,000/ml) • Hepatic dysfunction Jaundice in pre-eclampsia, severe acute hyperbilirubinemia (>100micromol/l or >6mg/dl) • Neurological dysfunction Prolonged unconsciousness(>12hours)/coma, stroke, uncontrollable fits, status epilepticus, total paralysis

Appendix 4: WHO Near Miss Tool

Maternal Near- Miss Tool

Individual data collection form

WHO MNMA 1.1

IDENTIFICATION

File No:

SCREENING QUESTIONS

In the questions 1 to 4, please specify:
0= The condition was not present during the hospital stay
1= The condition was present at arrival or within 12 hours of hospital arrival
2= The condition developed after 12 hours of hospital arrival
3= Information not available / unknown or not applicable

1. Severe complications / potentially life-threatening conditions
- A0 Severe postpartum haemorrhage
- A1 Severe preeclampsia
- A2 Eclampsia
- A3 Sepsis or severe systemic infection
- A4 Ruptured uterus
- A5 Other (specify)

2. Critical interventions or intensive care unit admission
- B0 Use of blood products (includes any blood transfusion)
- B1 Interventional radiology (uterine artery embolization)
- B2 Laparotomy
- B3 Admission to Intensive Care Unit

3. Organ dysfunction / life-threatening conditions
- C0 **Cardiovascular dysfunction**
  [shock, use of continuous vasoactive drugs, cardiac arrest, cardio-pulmonary resuscitation, severe hypoperfusion (lactate >5 mmol/L or >45mg/dL) or severe acidosis (pH<7.1)]
- C1 **Respiratory dysfunction**
  [acute cyanosis, gasping, severe tachypnea (respiratory rate>40 bpm), severe bradypnea (respiratory rate<6 bpm), severe hypoxemia (PAO2/FiO2<200 O2 saturation <90% for ≥60min) or intubation and ventilation not related to anaesthesia]
- C2 **Renal dysfunction**
  [oliguria non responsive to fluids or diuretics, dialysis for acute renal failure or severe acute azotemia (creatinine ≥300umol/ml or ≥3.5mg/dL)]
- C3 **Coagulation/hematologic dysfunction**
  [failure to form clots, massive transfusion of blood or red cells (≥ 5 units) or severe acute thrombocytopenia (<50,000 platelets/ml)]
- C4 **Hepatic dysfunction**
  [jaundice in the presence of pre-eclampsia, severe acute hyperbilirubinemia (bilirubin>100umol/L or >6.0mg/dL)]
- C5 **Neurologic dysfunction**
- C6 **Uterine dysfunction / Hysterectomy**
  [haemorrhage or infection leading to hysterectomy]

4. Maternal deaths (if applicable)
- D0 Death during pregnancy or within 42 days of termination of pregnancy

Please note:
i. If you answered "1" or "2" to any of the questions 1 to 4, go to question 5
ii. If you answered "0" to all of the questions 1 to 4, the woman is not eligible for this assessment. Do not answer the questions 5 to 14
iii. In case of doubt on questions 1 to 4, consult the attending physician
iv. In the questions 5 to 14, if information is not available, unknown or not applicable, fill with "9"(s)

MATERNAL INFORMATION

5. Date of hospital admission d d m m y y y y E0

8. Final mode of delivery / end of pregnancy. Please specify: E3

2= Caesarean section
3= Complete abortion
4= Curettage / vacuum aspiration
6= Laparotomy for ectopic pregnancy
7= Laparotomy for ruptured uterus
8= Women discharged or died still pregnant
9= Unknown / other

9. Best estimate of gestational age in completed weeks (obstetric/neonatal) at:

Delivery or abortion (not applicable if Q8="8") E4

Maternal death or hospital discharge (applicable if Q8="8") E5

10. Regarding the vital status of the infant, please specify: 0=Alive 1=Dead

At birth E6

At hospital discharge or on the 7th day of life if still in the hospital E7

PROCESS INDICATORS

11. About conditions at arrival in the facility and the referral process, specify: (0=No 1=Yes)
- F0 Delivery or abortion occurred before arrival at any health facility
- F1 Delivery within 3 hours of arrival in the health facility
- F2 Laparotomy within 3 hours of hospital arrival or in other hospital
- F3 Woman referred from other health facility
- F4 Woman referred to any higher complexity hospital

12. About the use of interventions, please specify whether the woman received any of the following : (0=No 1=Yes)

Prevention of postpartum haemorrhage
- G0 Oxytocin
- G1 Other uterotonics

Treatment of postpartum haemorrhage
- H0 Oxytocin
- H1 Ergometrine
- H2 Misoprostol
- H3 Other uterotonics
- H4 Tranexamic acid
- H5 Removal of retained products
- H6 Balloon or condom tamponade
- H7 Artery ligation (uterine/hypogastric)
- H8 Hysterectomy
- H9 Abdominal packing

Anticonvulsant
- I0 Magnesium sulfate
- I1 Other anticonvulsant

Antibiotics
- J0 Prophylactic antibiotic during caesarean section
- J1 Parenteral, therapeutic antibiotics

UNDERLYING CAUSES OF DEATH / NEAR MISS

13. Please specify: (0=No 1=Yes)
- L0 Pregnancy with abortive outcome (abortion/ectopic pregnancy)
- L2 Hypertensive disorders
- L3 Pregnancy-related infection
- L4 Other obstetric disease or complication
- L5 Medical/surgical/mental disease or complication
- L6 Unanticipated complications of management
- L7 Coincidental conditions
- L8 Unknown

CONTRIBUTORY / ASSOCIATED CONDITIONS

14. Please specify: (0=No 1=Yes)
- M0 Anaemia
- M1 HIV infection

6.	Date of delivery or uterine evacuation	d d m m y y y y E1	M2 Previous caesarean section M3 Prolonged/obstructed labour M4 Other conditions (specify) M5
7.	Date of hospital discharge or death	d d m m y y y y	M6

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12th November 2020

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Dear Dr. Khalumi

RESEARCH PROPOSAL – PREVALENCE AND FACTORS ASSOCIATED WITH MATERNAL NEAR-MISSES AT KENYATTA NATIONAL HOSPITAL; A 3 YEAR RETROSPECTIVE ANALYSIS (P318/06/2020)

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 used.
b. 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. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. 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*).
g. 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.

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

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