



A Research Project

In partial fulfilment of the requirements for the degree M Med (Obstetrics and Gynaecology) at the Nelson R Mandela School of Medicine, Faculty of Health Sciences at the University of Kwa-Zulu Natal

A retrospective study to identify the prevalence of severe maternal morbidity or “near misses” in obstetric patients who are admitted to maternity high care and the Intensive Care Unit at King Edward VIII Hospital

Dr Mzuvele Archwell Hlabisa

Department of Obstetrics and Gynaecology

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SUPERVISORS APPROVAL

As the candidates supervisor I have approved this thesis for submission

Signed: 

Dr Wendy Dhlomo-Mphatswe

Date: 29/04/2019

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DEDICATION

I dedicate this work to God, family, my wife, Lungile, my two daughters, Uminathi and Enzokuhle Hlabisa; my parents Sibongile and Phila Hlabisa.

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ABBREVIATIONS

SMOR	Severe maternal outcome ratio
MI	Mortality index
SD	Standard deviation
WHO	World Health Organization
MNM	Maternal Near Miss
NMR	Near miss ratio
BLACD	Bleeding associated with caesarean delivery
OH	Obstetric Haemorrhage
ICU	Intensive Care Unit
MHCU	Maternity High Care Unit
MM	Maternal Mortality
LMICs	Low-Middle Income Countries
HMICs	High-Middle income countries
iMMR	Institutional Maternal Mortality rate

SUMMARY

INTRODUCTION

Maternal mortality (MM) is still high in low- and middle-income countries; severe life-threatening maternal morbidity, that also called maternal near miss (MNM) leads to MM and is a maker for quality of obstetric care. MNM occurs where a life-threatening condition has occurred in a woman who is currently pregnant or within 42 days since the end of it. The purpose of our study was to establish the prevalence of maternal near misses (MNM), near-miss ratio (NMR) and to determine underlying causes of MNMs.

AIMS AND OBJECTIVES

The overall aim of the study was to describe the near misses in obstetric patients and study the associated factors associated with near misses

METHODS

A retrospective observational study conducted between 01 April 2015 and 31 March 2016 at King Edward VIII regional hospital in Durban, South Africa. Clinical records of 142 obstetric patients admitted to the intensive care unit (ICU) and maternity high care (MHC) wards were reviewed using the WHO organ dysfunction criteria to identify the maternal near-miss (MNM) cases and underlying causes.

RESULTS

A total of 54 maternal near miss (MNM) were identified; 6253 live births and 16 maternal deaths occurred. The MNM:MM ratio was 3.4:1, MMR 256/100 000 live births, and the NMR 8.6 per 1 000 live births. Obstetric haemorrhage was the prime cause of MNM; there were 29 (53.7%) cases of obstetric haemorrhage either as a sole complication or in association with hypertension; followed by hypertensive disorders, pregnancy related infection, medical disorders and other obstetric causes in 16.7%, 13.0%, 13.0% and 1.9% patients respectively. Post-partum haemorrhage (PPH) was the leading cause of obstetric haemorrhage in 20 women (69.0%) accompanied by a caesarean section rate of 86.2% among those with severe obstetric haemorrhage.

CONCLUSION

Avoidable morbidity from obstetric haemorrhage remains high and poses a great threat to maternal survival; reduction of unnecessary caesarean section delivery and intensified efforts to improve the standard of management during delivery, are required to remedy this. Regular facility audits and continuous surveillance of near misses is feasible and is able to identify key causes of morbidity. Reducing MNM is critical to the reduction of maternal mortality.

CHAPTER ONE

INTRODUCTION AND LITERATURE REVIEW

INTRODUCTION AND LITERATURE REVIEW

BACKGROUND

Approximately 15% of all expectant mothers will experience a pregnancy associated complication, some of which will result in severe maternal morbidity or death(1). Severe maternal morbidity or maternal near miss (MNM) refers to an event where a life-threatening event has occurred where a woman would have died in the absence of an intervention. Approximately 830 expectant mothers die daily as a consequence of a pregnancy related condition or childbirth(2). Most of these deaths occur in low- and middle- income countries. Sub-Saharan Africa has a maternal mortality ratio of 500 per 100 000 live births(3). While maternal mortality rate has been considered the single most reliable yardsticks to measure the quality of obstetric care and is reliably reported and tracked, there has been very little focus on maternal near misses.

The prevalence of MNM in Sub-Saharan Africa ranges from 1.1% to 10.1% of all deliveries (4). The MNM Rate in South Africa is unknown, reasons for this are unclear but are likely to be as a result of the unilateral focus on maternal mortality. The reasons for this include the fact that maternal near miss audits are laborious and are not as easy to classify as maternal death owing to the many criteria for near miss(5).

There are continuous efforts to improve maternal death especially in low and middle-income countries, these efforts culminated in the adoption of the Millennium Development Goals (MDG) previously and the Sustainable Development Goals (SGA) recently. Maternal deaths declined by 45% globally as a result of MDGs efforts to enhance the health ,prevent death and maternal complications associated with childbirth (6). Sub-Saharan Africa reduced maternal deaths where the “iMMR for potentially preventable deaths decreased from 100 per 100 000 live births in 2008-2010 to 92.6 and then to 83.3 in 2011-2013 and 2014-2016 respectively”(7)

Although there are many prevalence studies on maternal mortality there is a growing consensus globally, that more information can be obtained from studies that address maternal near misses. There is no maternal death in the absence of preceding morbidity whether acute or chronic; identifying near misses and improving on these will improve maternal mortality. As such it is critical for healthcare workers to identify

those conditions that are avoidable and treatable in order to preserve the lives of the women with complicated pregnancies(1) (8). Furthermore, maternal near-misses occur more frequently compared to maternal deaths, approximately five to seven times more than maternal mortality(2)(9).

South Africa has a well-established Confidential Enquiries program into Maternal Deaths and the introduction of research into maternal near-miss morbidities, using standardized tools to identify near misses and improve quality of care could reduce the maternal mortality rate. The WHO has developed resource dependent guidelines for assessing and identifying maternal near misses; lessons learnt from these cases can improve the quality of care allow for more rapid responses.

Although much has been gained in our understanding of the causes of maternal death a challenge still exists. Further reductions can be achieved through identification of risk factors associated maternal near misses.

Literature Review

Severe maternal morbidity or maternal near miss is defined as pregnant woman with severe life-threatening conditions who nearly die but, with good luck or good care, survive (9). WHO defines maternal near-miss morbidity as, “a woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy (5). Maternal near miss ratio (MNMR) refers to the number of maternal near-miss cases per 1000 live births and determining this ratio allows health policy makers to determine how much resources and care they need to allocate to a certain facility.

When a woman experiences a near miss or severe maternal morbidity, her survival will depend on the disease, her pre-morbid function, the health facility level of care and the healthcare personnel skills level (10) ,(11). Studying the number of near miss is key to the diagnoses of health system failures and may lead to early

interventions or remedial actions. Therefore, SMM audits at an institutional, regional or national level are a valuable measure of the quality of maternity care. Their utilization can guide healthcare workers on areas that need to be improved.

Correlation between causes of maternal deaths and SMM has not consistently been demonstrated, in a study in Johannesburg primary obstetric causes of SMM and maternal deaths did not correlate but the types of avoidable factors were similar (12). This suggests that SMM cannot be used as a proxy for maternal mortality, because it may, be behind most if not every maternal death. There are inherent system failures within the process of care of women during pregnancy or childbirth. The same is true for severe maternal morbidity; even though women would have survived; there are often long-term repercussions for the patient and her family, which may negatively affect the future health of the patient. These could include adverse reproductive health outcomes, poor quality of life, posttraumatic stress syndrome, poor sexual function, postpartum depression and even impaired daily functioning of the patient (13).

Another undesired outcome of SMM is that of litigation of healthcare professionals for events that are perceived or found to have been preventable or due to negligence. Lawsuits in obstetrics generally centre on errors of omission or commission generally in relation to diagnosis, counselling and treatment, this invariably leads to increasing global trend in litigation with high indemnity cost (14).

Malpractice lawsuits can be mitigated against and reduced through the reduction of SMMs and making labour and childbirth much safer.

Review process is recommended but there are challenges especially with regard to national review processes. These relate to cost, time and access to full notes.

Despite these, some developed countries have undertaken these audits albeit still in

the research domain. In developed countries where maternal mortality is rare, these audits would be manageable and valuable, New Zealand and some European countries have embarked on setting up national review processes and tools (15), (16). However, in developing countries, which still contend with poor, reporting of maternal deaths, institutional reviews as part of a data driven quality improvement would be necessary. It is widely established that frequent review of performance data leads to improvements in clinical behaviour(15).

Although improvements have been made towards finding consistent definition of severe maternal morbidity, there are still inconsistencies in the definition and criteria used to identify SMMs of maternal near misses. Three approaches are often used; namely disease-specific criteria (e.g., severe pre-eclampsia and severe post-partum haemorrhage), management-based criteria (i.e., admission to ICU and need for a blood transfusion) or organ system dysfunction-based criteria a diagnosis-based approach depending on the context where the review is undertaken(5). None of these approaches are perfect; as such they can lead to different estimates of MNM rate.

The definition of maternal morbidity has evolved from the initial premise that all maternal morbidity was preventable or was as a result of interventions, omissions, incorrect treatment or from such chains of events. Indeed, not all MNM are because of a fault, however many of these events or cases are avoidable. Therefore, the issue at hand is not the severe maternal mortality as such but rather the preventability thereof. In a New Zealand study, 36% of all SMM were preventable, even where these cases were not preventable improvement in clinical care would have mitigated against the complications. In a South African nearly 60% of all maternal deaths are as a result of avoidable factors(17). Avoidable factors have been shown to be similar to those of maternal mortality such as haemorrhage and hypertension (18),(12),(17).

Among the different strategies aimed at improving quality of care at maternity services, the facility-based maternal near-miss case review cycle was proposed by WHO in 2004 as a type of clinical audit (17),(20),(21). The WHO recommends that maternal morbidity be audited as means of assessing preventable cases to inform policy, and developing interventions such as training to improve healthcare. Audits coupled with feedback and targeted quality improvement initiatives through a clinician champion were, shown to result in improved clinical behaviour according to a Cochrane review (22),(23), (5).

The WHO proposed three methods of identifying maternal near miss, namely:

1. Clinical related to a specific disease entity, starting with the specific disease then for each disease defining morbidity. For example; Pre-eclampsia is the disease, and if complicated by renal failure, eclampsia or pulmonary oedema it is used to defined a near miss or severe morbidity(24). This method is believed to be straightforward to interpret, allows calculation of complication rates and allows assessment of the quality of care for a certain disease(5).

2. Management or Intervention based criteria uses a certain intervention such as Intensive care unit admission or hysterectomy. This method is biased by the resources available in a particular establishment (5).

3. Organ dysfunction-based criteria, is similar to the confidential enquires into maternal death systems. It relies on the availability of basic critical care monitoring and functioning laboratory. However, it is the most time consuming as cases cannot simply be extracted from registers. Critically ill women can be identified and allows the monitoring of diseases that should not cause death with appropriate care such as postpartum haemorrhage (5).

CHAPTER TWO
METHODOLOGY

THE CURRENT STUDY

Research question

A retrospective study to identify the prevalence of severe maternal morbidity or “near misses” in obstetric patients who are admitted to maternity high care and the Intensive Care Unit at King Edward VIII Hospital

Aims and objectives

The overall aim of the study was to determine the near misses in obstetric patients and study the associated factors associated with near misses

Methods

An audit of maternal “near miss” cases from of 01 April 2015 to 31 March 2016 was undertaken at a tertiary research facility in Kwa Zulu Natal. Ours is a tertiary care institution with primary health centres attached to it. It is a referral hospital for both public and private hospitals in Durban and other surrounding districts in Durban. There are approximately 600 deliveries per month in this facility with an additional number of high-risk patients who access the hospital for intensive care unit services after delivery in other facilities.

In addition to providing twenty-four-hour emergency obstetric services, the hospital also provided antenatal care and delivery services for both low and high-risk pregnant women. Hospital had 24-hour facility for blood component therapy. High care unit (HCU) in labour room complex and intensive care ICU with 24-hour facility for multidisciplinary specialty also function well.

For the purpose of this study the WHO Organ dysfunction-based criteria to define near mis/ life-threatening conditions was used. Cardiovascular dysfunction evidenced by either shock, cardiac arrest, lactate >5mmol/l or >45mg/dl, severe acidosis (pH <7) or use of continuous vasoactive drugs. Respiratory dysfunction evidence by acute cyanosis, gasping, respiratory rate >40 or < 6 breaths per minute, severe hypoxaemia (oxygen saturation <90% for 1 hour or PaO₂/FiO₂ <200) or intubation and ventilation not related to anaesthesia; Uterine dysfunction evidenced by either haemorrhage or infection leading to hysterectomy; Renal dysfunction evidenced by oliguria not

responsive to fluids /diuretics, severe acute renal failure(creatinine >300umol/ml) or dialysis for acute renal failure; Coagulation dysfunction evidenced by failure to form clots, platelet count <50,000 or massive transfusion of blood/red cells(=5 units); Hepatic dysfunction manifested by jaundice in presence of pre-eclampsia or severe hyperbilirubinemia and finally neurological dysfunction due coma lasting >12 hrs, stroke, status epilepticus/uncontrollable seizures or total paralysis. Those patients any morbid condition like Severe postpartum haemorrhage, Severe pre-eclampsia, Eclampsia,

Sepsis or severe systemic infection without organ dysfunction were classified as potentially life-threatening conditions. Table 1 was adopted from the WHO Maternal near miss tool.

Study design and study setting

This is a retrospective observational descriptive study, conducted at King Edward VIII hospital, in Durban. This hospital provides regional and tertiary high-risk obstetrics and gynaecology services in Durban and beyond.

Sampling

All clinical records of patients that were admitted, in the ICU and maternity high care for the period of 01 April 2015 to 31 March 2016 will be reviewed to answer the objectives of the study. This facility has an average of 1000 deliveries per month with a four bed maternal high care next to the labour ward and a 12 ICU bed occupancy whose availability depends on staffing issues and therefore vary over time. All patients delivering during the study period were eligible for inclusion in the study. The primary objective is the identification of near miss in patients who were either in the puerperium or pregnant at the time of admission to high care or ICU facility. Therefore, the sample was drawn from the maternity high care and intensive care unit of King Edward VII Hospital.

Target study population

The study population consisted of women who nearly died but survived a complication in pregnancy, childbirth or the puerperium. This included patients who were admitted in the ICU or maternal high care unit.

Inclusion criteria

1. Pregnant women at any gestation who were admitted to the intensive care unit or maternity high care.
2. Women within 42 days of delivery who were admitted to the intensive care unit or maternity high care.

Exclusion criteria

1. Women presenting after 42 days of termination of pregnancy/ delivery
2. Admissions to maternity high care or ICU which resulted in a maternal death
3. Abortions and ectopic pregnancies
4. Poorly documented maternity files

Sampling method and Sample size

The sample comprised of all pregnant women and those in the puerperium who met the criteria of a maternal “near miss” according to the WHO tool and are admitted to the maternity high care and ICU for the entire study period. This was expected to be approximately 300 to 500 patient files.

Data Collection and Source of data

Data was collected from patient charts and entered into a study data extraction sheet which will include demographic; relevant clinical information and the results of investigations. The data extraction tool was adapted from the validated WHO near miss tool for the identification of maternal near miss and quality of care. The Femhealth questionnaire was adopted in certain part and used together with the WHO near miss tool questionnaire in appendices to extract information from patient charts. The Femhealth questionnaire had the WHO organ dysfunction criteria for near misses and the second questionnaire included other variables, as listed below. Neonatal outcome variables from the Femhealth questionnaire, were not used as they were not part of

the study objectives. Variables that were studied included in the data collection sheet as well as but not limited to the following:

1. Age
2. Parity
3. HIV status
4. Mode of delivery
5. Obstetric complications
6. Length of hospital stay
7. Pregnancy outcome

Formulae to determine “near miss” and maternal deaths rates and ratios

“near miss” ratio = $\text{NM} / \text{Live births} \times 1000$

Maternal Mortality ratio = $\text{MD} / \text{live births} \times 100000$ live births

Severe Mortality Outcome ratio or Near Miss Ratio = $\text{MDs} + \text{NMSs} / \text{live births} \times 1000$

Mortality index = $\text{MDs} / \text{MNSs} + \text{MDs} \times 100\%$

Statistical Processing of Data

Descriptive Statistics

SPSS (version 25) software for windows was used for quantitative data analysis. Descriptive statistics such as frequency, percentage, mean, median and standard deviation was used.

Ethical consideration

Ethical approval to conduct the study was obtained from the Biomedical Research Ethics Committee (BREC) of University of KwaZulu Natal (UKZN). Further approval was sought with the hospital management of King Edward hospital prior to conducting the study.

Regulatory Approval

Ethical clearance was obtained from BREC (Biomedical Research Ethics and Committees) (BE:008/17) University of Kwa Zulu Natal, Postgraduate Education and Research Office, Nelson R Mandela, School of Medicine, University of Kwa Zulu Natal, The Hospital Management: King Edward Hospital and KZN, Department of Health.

Table 1. Criteria for Potentially life-threatening conditions and Life-threatening conditions (Near Miss)(25)

WHO Maternal Near Miss identification criteria

Box: Maternal life-threatening conditions			
Dysfunctional system	Clinical criteria	Laboratory markers	Management based proxies
Cardiovascular	() Shock () Cardiac arrest	() Severe hypoperfusion (lactate>5 mmol/L or >45mg/dL) () Severe Acidosis (pH<7.1)	() Use of continuous vasoactive drugs () Cardio-pulmonary resuscitation
Respiratory	() Acute cyanosis () Gasping () Severe tachypnea (Respiratory rate >40 bpm) () Severe bradypnea (Respiratory rate <6 bpm)	() Severe hypoxemia (Oxygen saturation < 90% for ≥ 60 minutes or PaO ₂ /FiO ₂ <200)	() Intubation and ventilation not related to anaesthesia
Renal	() Oliguria non responsive to fluids or diuretics	() Severe acute azotemia (Creatinine ≥300µmol/l or ≥3.5 mg/dL)	() Dialysis for acute renal failure
Haematologic/Coagulation	() Failure to form clots	() Severe acute thrombocytopenia (<50,000 platelets/ml)	() Massive transfusion of blood / red cells (≥ 5 units)
Hepatic	() Jaundice in the presence of preeclampsia	() Severe acute hyperbilirubinemia (Bilirubin>100 µmol/l or >6.0 mg/dL)	
Neurologic	() Prolonged unconsciousness (lasting >12h) () Stroke () Uncontrollable fit / status epilepticus () Global paralysis		
Alternative severity proxy			() Hysterectomy following infection or haemorrhage

❖ A set of organ dysfunction markers including Basic laboratory tests & Management-related markers

❖Clinical criteria based on the clinical assessment where laboratory and other techniques are not available

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WHO Potentially life-threatening conditions(PTLC)

Severe postpartum haemorrhage

Severe pre-eclampsia

Eclampsia

Sepsis or severe systemic infection.

Ruptured uterus

CHAPTER THREE

RESULTS

RESULTS

A total of 173 patients were admitted to the patients were admitted to the maternity high care (MHC) and intensive care unit (ICU) of which 54 were identified as maternal near misses (figure 1). The 63 cases that were excluded had missing antenatal records and some were found in the high care admission book despite being admitted in the isolation room adjacent to labour ward high care and not high care requiring. There were 473 ICU admissions over the 1-year period 445 were excluded because some died, some were male and some had missing records of the pregnancy and related information. During the study period there were 6253 live births from 6525 deliveries and 16 maternal deaths giving rise to a near miss ratio (NMR) was 8.6 per 1000 live births and a maternal mortality ratio (MMR) of 255,9 per 100 000 deliveries. The mortality index was 22.8. The MNM:MD ratio was 3.4. There were 88 participants who did not meet the criteria for a near miss but had morbidity that was sufficient to be potentially life threatening if unattended to; these patients were grouped to have potentially life -threatening conditions (PLTC). The remaining 31 admitted patients to high care did not have morbidity that warranted classification as either a near-miss or a PLTC; figure 1 illustrates the exclusions that were made during the chart review.

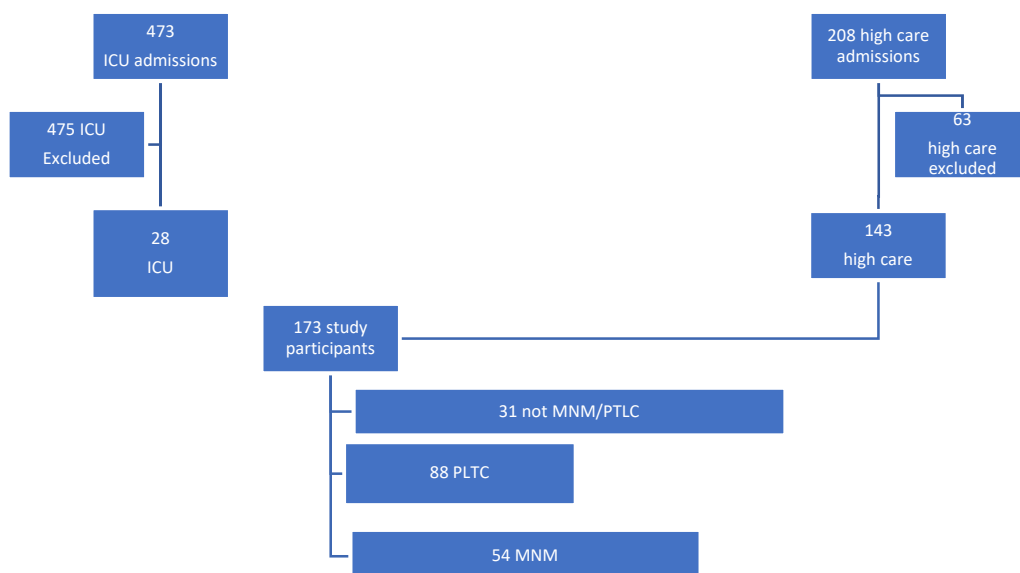


Figure 1: Study sample Flow chart

Socio-demographic characteristics of the study participants.

Characteristics of study participants we stratified into two categories of NM and PLTC as shown in **Table 1**. Overall, the majority of study participants were of the African race 140 (98.6%), unmarried 137 (96.5%) and had basic educational achievement. More than half of the study participants were HIV negative; 76 (53.5%) and 48 (33.8%) tested HIV positive. The mean CD4 count for all HIV positive women was 421, this was not significantly different from the NM and PTLC group; 439 and 406 respectively. All but four of the HIV positive participants were on antiretroviral therapy, the treatment status of the other two HIV positive participants was not documented. The majority of patients had a viral load less than 40 as shown in **table 2**.

Table 2: Socio-Demographic Characteristics of participants

	Near miss (n = 54) Mean [range] or n (%)	Potentially Life threatening (n = 88) Mean [range] or n (%)
Age (years)		
18 – 24	23 (42.6)	39 (44.3)
25 – 30	15 (27.8)	27 (30.7)
31 - 36	16 (29.6)	22 (25.0)
Race		
African	54 (100.0)	86 (97.7)
Indian	0 (0.0)	1 (1.1)
White	0 (0.0)	1 (1.1)
Marital Status (Single)	52 (96.3)	85 (96.6)
HIV status		
Negative	22 (40.7)	54 (61.4)
Positive	21 (38.9)	27 (30.7)
Unknown	11 (20.4)	7 (7.9)
CD4 count	439 [35; 775]	406 [62; 773]
Antiretroviral therapy		
Yes	18 (85.7)	24 (88.9)
No	2 (9.5)	2 (7.4)
Unknown	1 (4.8)	1 (3.7)

Viral Load		
<50 copies/ml	7 (38.9)	5(20.8)
>50 copies/ml	3 (16.7)	5(20.8)
Unknown	8 (44.4)	14(58.3)
Gestation (weeks)		
<28	2 (3.7)	7 (7.9)
28+1 - 37+0	25 (46.0)	44 (50.0)
37+1- 42	15 (27.0)	34 (38.6)
Not documented	12(22.2)	3(3.4)
Mode of Delivery		
Vaginal Delivery	6 (11.1)	12 (13.6)
Caesarian Section	45 (83.3)	72 (81.8)
Not documented	3 (5.6)	4 (4.5)
ICU Admission	28 (51.9)	0 (0.0)
No. days in ICU	4.8 [1; 30]	0
Critical interventions		
Use of blood products	24 (51.0)	13 (14.8)
No. of blood units	3 [1; 11]	1 [1; 4]
5 or more blood units	8 (33.3)	1 (7.7)
Hysterectomy	11 (20.4)	0 (0.0)

Near misses

Maternal near-misses were identified using the WHO criteria which identifies patients with one or more organ dysfunction as shown in figure 2. Of the 54 NMs; 33 (61.1%) had single organ dysfunction, 15 had two affected organs and the remaining six had multiple affected organs (**figure 2**). The underlying contributors to NMs were obstetric haemorrhage 15 (27.8%), haemorrhage and hypertension 14 (25.9%), hypertensive disorders 9 (16.7%), pregnancy related infection 7 (13.0%), medical disorders 7 (13.0%) and one (1.9%) had other obstetric causes (**figure 3**).

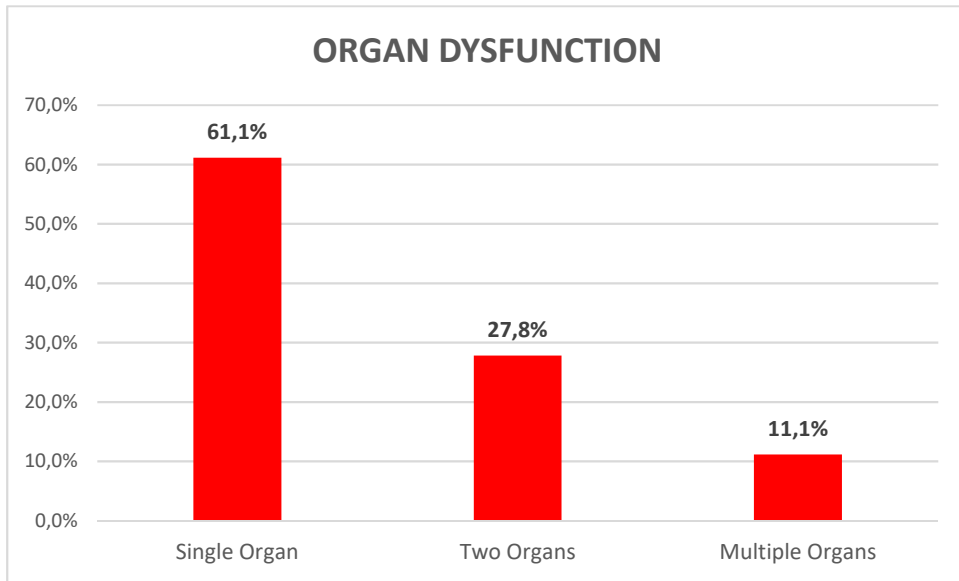


Figure 2: Organ dysfunction in near miss cases

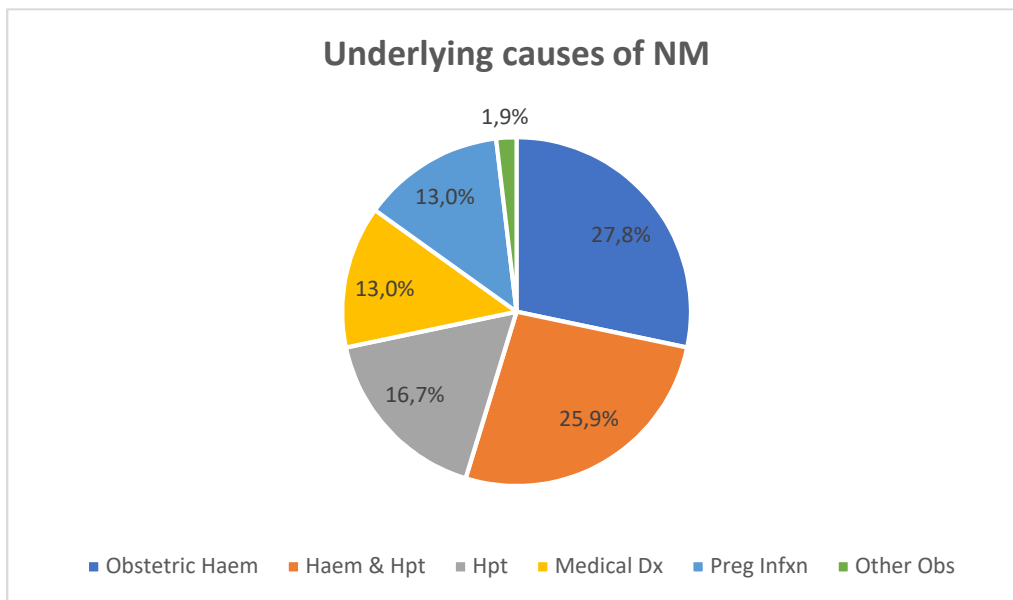


Figure 3.

Underlying causes on Near miss

Obstetric haemorrhage

Obstetric haemorrhage was the leading cause of NM; in total there were 29 (53.7%) cases of obstetric haemorrhage either as a sole complication or in association with hypertension (figure 3). In the NM participants; 14 of these cases were associated with hypertension and the remaining 15 were sole complications. Post-partum haemorrhage (PPH) was the leading cause of obstetric haemorrhage in 20 women (69.0%), while 9 (31.0%) had antepartum haemorrhage. Underlying causes of the PPH are shown in **table 3**; APH was as a result of abruptio placentae in 8 women

and one patient had uterine rupture. Of all of the 29 patients with massive obstetric haemorrhage, twenty-five were delivered via caesarean section (86,2%) vs four had normal vaginal delivery (13,8%); of the 25 caesarean section deliveries, 11 (44,0%) ended up with a hysterectomy. Almost all women who had severe obstetric haemorrhage received blood products 24 (82,7%), with a total of 83 units of blood products being transfused among the 24 patients (range 1-11units). On average, each patient received three units of blood, with 8 (33.3%) receiving massive blood transfusion (5 or more units).

Table 3: Underlying causes of post-partum haemorrhage

Causes of PPH	N=20 n (%)
Atonic uterus	6 (30.0)
Placenta previa	4 (20.0)
Vaginal/cervical tears	3 (15.0)
Retained placenta	1 (5.0)
Broad ligament haematoma	1 (5.0)
Multifibroid uterus	1 (5.0)
Not specified	4 (20.0)

Hypertensive disorder and other disorders

There were 27 participants who had pregnancies complicated by hypertensive disorders among NMs, these were largely due to severe pre-eclampsia 11(40,7%) and Eclampsia 11(40,7%); gestational hypertension 3 (11,1%) and chronic hypertension 2 (7,4%) accounted for the rest.

Only 1(1.8%) of 54 near miss cases had renal dysfunction requiring dialysis and 13(24%) had haematological dysfunction mainly identified by massive blood transfusion 8 (61.5%).

Critical interventions for maternal near miss

There were 28 admissions to the intensive care unit with an average stay of 4.8 days, admission to ICU accounted for 51.9% of all near misses. Other critical interventions included laparotomy in 8 participants and blood transfusion 28; there were no interventional radiology interventions

Potentially life-threatening conditions:

Forty patients (45%) had Severe pre-eclampsia, 29 (33%) had severe post-partum haemorrhage, 14 (16%) had Eclampsia and 3 (3%) had ruptured uteri than did not result in a hysterectomy or organ dysfunction.

Critical interventions for PTLC

Two main interventions utilized in the in the 88 patients with PTLCs were blood transfusion and laparotomy 31 (35,2%) and 2 (2,3%) respectively; 33 PTLC participants received no critical interventions. None of the patients in this group had interventional radiology procedures or ICU admission

Referral patterns and mode of transport

Most of the patients were patients that presented to hospital by themselves or were resident admissions at KEH who were being treated for high risk pregnancies. The rest were referrals from district hospital and primary health facilities as shown in table 4.

Table 4 : Referral patterns and mode of transport

	Near misses n (%)	PLTC n (%)
Referral		
Self	34 (62.9)	47 (53.4)
PHC	4 (7.4)	27 (30.7)
District Hospital	8 (14.8)	14 (15.9)
Not documented	8 (14.8)	
Mode of transport		
Ambulance	20 (37.0)	17 (19.3)
Other	20 (37.0)	12 (13.6)
Not documented	14 (25.9)	59 (67.0)

CHAPTER FOUR
DISCUSSION AND CONCLUSION

DISCUSSION

We found a high near miss incidence ratio (NMR) of 8.6 per 1000 live births using the strict WHO organ dysfunction criteria. An India study using the same criteria reported a higher NMR of 11.2 per 1000 and MNM:MD ratio of 2.05:1 (26). Other studies in South Africa found an NMR of 5.83 and 5.1 per 1000 live births in Cape Town and Pretoria respectively (27),(28). This is lower than the what we reported owing to the difference in population demographics, available resources and inherent disparities in South Africa. Since the NMR indicates the level of health care resources that will be required in an area a lower ratio is preferable, albeit there is no ideal target that has been set.

The MNM:MD of 3.4:1 in our study was worse than what has been reported by in a study by Iwuh et al which reported an MNM:MD ratio of 8:1(29) and 8.6:1 reported from a study done in the Pretoria Academic Complex, South Africa (28). This may be due to the particularly high maternal deaths that occurred during this period and the stringent WHO organ dysfunction criteria that only identifies fewer severe cases of near misses thus making the MNM:MD ratio narrow. Iwuh et al used clinical, laboratory and management criteria; while other studies also had a larger sample size and identified more near misses comparatively, while experiencing fewer maternal deaths (27).

The high maternal mortality rate in our study was consistent with what is often seen in tertiary hospitals; the institutional mortality rate has been reported to be 160 percent higher in tertiary hospitals compared to regional and central hospitals (7).

The saving mothers report also indicates that a large proportion of these deaths had initially presented at community healthcare centres (43%) , district hospitals (50%) and in regional hospitals before dying in provincial tertiary hospitals (7).

It is undeniable that a higher MNM:MD ratio indicates better quality of care as it is derived from the number of cases of near misses compared to number of maternal deaths (30) (31), however where different criteria are used to identify near misses, the ratio may vary greatly thus affecting its utility as a proxy for quality of care. A recent systematic review by the world health organization showed that “using disease-specific, management-specific, or organ dysfunction-based criteria, the percentages of near-miss cases were 0.6% to 14.98%, 0.04% to 4.54%, and 0.14% to 2.3%, respectively” (23).The same reviewers also state that the organ dysfunction

criteria are the most reproducible across similar settings however can be labour intensive if inclusion criteria used are not strict. Despite the high NM, it is encouraging that most of the deliveries ended with a live birth 32 (59.2%), however further research is required to evaluate the impact of near misses on fetal outcomes and long term effects.

Obstetric haemorrhage (OH) is a leading cause of MNM as it remains so for maternal deaths (26)(4)(32). In a WHO systematic review of maternal deaths, obstetric haemorrhage was found to be the leading cause, in our setting it is the third leading cause with non-pregnancy related infections as a leading cause followed by hypertensive disorders of pregnancy (23),(7). Women with OH survived because of the availability of blood products, skills to control bleeding and timeous intervention such as a hysterectomy which was performed in 44% of all patients who had OH in our study. Despite the success in controlling what could have been a disastrous end it is important to note that 86.2% of these cases of massive obstetric haemorrhage were delivered via caesarean section. While caesarean section delivery cannot always be avoided in the context of managing high risk patients but every effort and attempt still need to be made to reduce caesarean delivery rate. Caesarean section delivery has been strongly associated with maternal deaths resulting in 33% avoidable deaths due to bleeding before and after caesarean section delivery. In a systematic review that reviewed outcomes of near misses and maternal mortality from PPH, the likely-hood of death was fivefold higher in LMICs compared to HMICs (33). This underpins how high the risk of death is owing to OH.

A large audit of bleeding during and after caesarean delivery in Gauteng reported that the main health system issues associated with near misses due to bleeding during and after caesarean delivery is delays in ambulance transfer from lower levels of care to tertiary hospitals and delays from decision to incision time which was an average of 4 hours especially in overloaded tertiary hospitals. Despite these, maternal deaths were rare which means that the health system is largely intact in recognizing and responding to such complications (33).

The second most frequent cause of MNM were hypertensive disorders, a population based incidence of 12% for hypertension was found in south Africa in 2004 (34).

Hypertension is often first detected in pregnancy with a study conducted in sub-Saharan women demonstrating that only 50% women with hypertension are aware of it (35). Every effort has to be made to detect it throughout pregnancy if we are to reduce its effect on near miss and mortality. A study in the same facility conducted in 1993 showed that 18% of admissions to KEH Viii obstetric care unit have an elevated blood pressure (36). The pattern of primary causes of near miss in this study mirrors observations of several studies with hypertensive disorders and haemorrhage being the leading causes in low- and middle- income countries (37),(38) ,(39) ,(40).

The leading causes of maternal near misses and potentially life-threatening conditions were the same, we are of the view that if different criteria were used to identify near misses either than the organ dysfunction criteria, many of the case of PTLC would have been classified as near misses. None the less, considering the risk and consequences PTLC or near misses, attention has to be given to these patients if maternal deaths are to be avoided.

Strengths of this study is that it used the WHO organ dysfunction criteria includes the ability to focus both on the critically ill patient and the associated severe disease spectrum. This study provides information about near misses in a community where they have not been studied and highlights the leading causes of near-miss. It demonstrates that the rate is higher than in other parts of South Africa, albeit the classification systems used may have not been consistent with other studies. It further demonstrates a survival pattern in women with no prior morbidity to potentially life threatening complications and near misses. The drawback is that this only possible where a minimum level of care is present such as ICU, institutions without these facilities may be better served by other criteria to identify near misses.

Limitations

The follow-up time used by the WHO to define maternal near-miss has a duration of 42 days postpartum. However, our follow-up time was limited to only the length of the hospital stay, despite this it is unlikely that many near misses would have been missed as most severe morbidity occurs at the time of delivery or immediately after. The other limitation of the study was that our study was carried out only in one facility due to resource constraints, as such the results may not be entirely generalizable to

other facilities. The exclusion of morbidity associated with ectopic pregnancies and miscarriages was one other limitation due to logistics.

CONCLUSION

Avoidable morbidity from obstetric haemorrhage remains high and poses a great threat to maternal survival; reduction of caesarean section delivery and intensified efforts to improve the quality of care during delivery are required to remedy this. Regular facility audits and continuous surveillance of near misses is feasible and is able to identify key causes of morbidity. This study highlights that the key conditions that lead to maternal morbidity are obstetric haemorrhage, hypertensive disorders and pregnancy related infection. Particularly obstetric haemorrhage related to caesarean section seems to be the most significant contributor to maternal morbidity. Improved care of these conditions is critical to the reduction of maternal morbidity. The stringent WHO criteria is more reproducible and identifies severe morbidity, however may under-estimate the number of near misses thus affecting the MNM:MD ratio.

RECOMMENDATIONS

Frequent audits into maternal near misses needs to be conducted as means of reducing maternal maternity. The criteria for identification of near misses needs to be standardized and targets that translate to the basic minimum standard of quality of obstetric care need to be set.

Given the fact that obstetric haemorrhage related to caesarean section is the leading cause of near misses; concerted efforts to reduce the number of unnecessary caesarean section are critical to reduce morbidity. Implementation of the recommendations of the saving mothers report to reduce both morbidity and mortality.

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APPENDICES

Annexure 1: King Edward Hospital approval.



health

Department:
Health
PROVINCE OF KWAZULU-NATAL

OFFICE OF THE HOSPITAL CEO
KING EDWARD VIII HOSPITAL

Private Bag X02, CONGELLA, 4013
Corner of Rick Turner (Francois Road) & Sydney Road
Tel: 031-3603853, Fax: 031-2061457, Email: re:oice.khuzwayo@kznhealth.gov.za
www.kznhealth.gov.za

Ref.: KE 2/7/11(18/2017)
Enq.: Mrs. R. Sibiya
Research Programming

3 April 2017

Dr. MA Hlabisa
Discipline of Obstetrics & Gynaecology
Nelson R. Mandela School of Medicine
UNIVERSITY OF KWAZULU-NATAL

Dear Dr. Hlabisa

Protocol: "A respective study to identify the prevalence of severe maternal morbidity or "near misses" in obstetric patients who are admitted to Maternity High Care and the Intensive Care Unit at King Edward VIII Hospital. Degree-MMed; BREC Ref. No. BE008/17

Permission to conduct research at King Edward VIII Hospital is provisionally granted, pending approval by the Provincial Health Research Committee, KZN Department of Health.

Kindly note the following:-

- The research will only commence once confirmation from the Provincial Health Research Committee in the KZN Department of Health has been received.
- Signing of an indemnity form at Room 8, CEO Complex before commencement with your study.
- King Edward VIII Hospital received full acknowledgment in the study on all Publications and reports and also kindly present a copy of the publication or report on completion.

The Management of King Edward VIII Hospital reserves the right to terminate the permission for the study should circumstances so dictate.

Yours faithfully

DR. SA MOODLEY
ACTING SENIOR MEDICAL MANAGER

Fighting Disease, Fighting Poverty, Giving Hope

SUPPORTED/NOT-SUPPORTED

06/04/2017

DATE

Annexure 2: Ethical clearance from BREC (Bio-Medical Research and Ethics Committee) University of Kwa Zulu-Natal



17 July 2017

Dr MA Hlabisa (205501627)
Discipline of Obstetrics and Gynaecology
School of Clinical Medicine
Mzuvelehiabisa@yahoo.com

Dear Dr Hlabisa

Protocol: A retrospective study to identify the prevalence of severe maternal morbidity or 'near misses' in obstetric patients who are admitted to maternity high care and the Intensive Care Unit at King Edward VIII Hospital. Degree: MMed
BREC reference number: BE006/17

EXPEDITED APPROVAL

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application received on 12 December 2016.

The study was provisionally approved pending appropriate responses to queries raised. Your response received on 04 July 2017 to BREC letter dated 30 June 2017 have been noted by a sub-committee of the Biomedical Research Ethics Committee. The conditions have now been met and the study is given full ethics approval and may begin as from 17 July 2017.

This approval is valid for one year from 17 July 2017. To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2015), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-ethics.aspx>.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be RATIFIED by a full Committee at its next meeting taking place on 08 August 2017.

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely,

Professor V Rambiritch
Deputy Chair: Biomedical Research Ethics Committee

cc supervisor: vp@ukzn.ac.za
cc postgraduate administrator: ms@ukzn.ac.za

Biomedical Research Ethics Committee
Professor J Tsoka-Gwegweni (Chair)
Westville Campus, Govan Mbeki Building
Postal Address: Private Bag 354001, Durban 4000

Telephone: +27 (0) 31 200 2480 Facsimile: +27 (0) 31 282 4626 Email: brec@ukzn.ac.za

Annexure 3 : Kwa Zulu-Natal Department of Health District Office Approval



health

Department:
Health
PROVINCE OF KWAZULU-NATAL

Physical Address: 330 Langalibalele Street, Pietermaritzburg
Postal Address: Private Bag X9051
Tel: 033 395 2805/ 3189/ 3123 Fax: 033 394 3782
Email: hrkm@kznhealth.gov.za
www.kznhealth.gov.za

DIRECTORATE:

Health Research & Knowledge
Management

HRKM Ref: 221/17
NHRD Ref: KZ_2017RP44_988

Date: 15 June 2017
Dear Dr MA Hlabisa
UKZN

Approval of research

1. The research proposal titled '**A retrospective study to identify the prevalence of severe maternal morbidity or "near misses" in obstetric patients who are admitted to maternity high care and the Intensive Care Unit at King Edward VIII Hospital**' was reviewed by the KwaZulu-Natal Department of Health.

The proposal is hereby **approved** for research to be undertaken at King Edward VIII Hospital.

2. You are requested to take note of the following:
 - a. Make the necessary arrangement with the identified facility before commencing with your research project.
 - b. Provide an interim progress report and final report (electronic and hard copies) when your research is complete.
3. Your final report must be posted to **HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200** and e-mail an electronic copy to hrkm@kznhealth.gov.za

For any additional information please contact Mr X. Xaba on 033-395 2805.

Yours Sincerely

Dr E Lutge

Chairperson, Health Research Committee

Date: 21/06/17.

Annexure 4: Study Questionnaire

King Edward VII Hospital Maternal Near Miss Audit



Data collection form

Participant number: _____

Hospital number: _____

Data extraction date: _____

Ward: ICU

LW HIGH CARE

Date of admission: _____

Date of discharge: _____

Number of days in ICU: _____

Number of days in LW HIGH CARE: _____

Demographic Information

1.1 Date of birth: / / / /

1.2 Age at last birthday:

1.3 Race:

1. African
2. White
3. Indian
4. Coloured

1.4 Marital Status:

5. Married
6. Divorced
7. Single
8. Widowed
9. Not recorded

1.5 Educational Status

10. Illiterate
 11. Read and write
 12. Primary School
 13. Secondary School
 14. College/ University)
-

King Edward VII Hospital Maternal Near Miss Audit



2.0 Past Obstetric History

Year	Mode of delivery	Birth Weight	Gender	Outcome (Alive or Demised)

3.0 Medical History

3.1 HIV status

HIV Positive HIV Negative HIV status unknown
 CD4 count: _____ Viral Load: _____
 On ART Not on ART Not documented

3.2 Booking bloods: RH Positive Negative

RPR: Positive Negative

HB: g/dl

Drug history:

Recreational Drugs:

Traditional medication:

Questionnaire FEMHealth

STUDY ON NEAR-MISSES AND MATERNAL AND PERINATAL DEATHS

CERRHUD, Benin - AFRIC Santé, Burkina Faso - CAREF, Mali - INAS, Maroc - LSHTM, UK

**INDIVIDUAL
FORM**

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Instructions

The target population is specified in the title of each section. Certain sections can be skipped according to the patient. If the information is not known, record a "9" in the field.

Echantillon(s) au(x)quel(s) appartient ce dossier

- | | | | |
|---|---|--|---|
| <input type="checkbox"/> Caesarean | <input type="checkbox"/> Neonatal near-miss | <input type="checkbox"/> Twins | <input type="checkbox"/> Other admissions |
| <input type="checkbox"/> Maternal near-miss | <input type="checkbox"/> Neonatal death | <input type="checkbox"/> Breech presentation | |
| <input type="checkbox"/> Maternal death | <input type="checkbox"/> Stillbirth | <input type="checkbox"/> Vacuum/forceps | |

IDENTIFICATION

A1 All women included in the study sample

1. Health facility name
2. Health facility code
3. Woman's ID number
4. Date form filled
 / /
5. Researcher name
6. Researcher code
7. Woman's name
8. Town
9. Village/neighbourhood
10. Administrative area of origin
11. District of origin
12. Admission date
 / /
13. Admission time
 :
14. Maternity record number

15. Admission mode
 Self-referred
 Referred from another facility
- If referred
16. Name of referring facility
 17. Date of arrival at referring facility
 / /
 18. Time of arrival at referring facility
 :
 19. Date of decision to refer
 / /
 20. Time of decision to refer
 :
 21. Date of departure from facility
 / /
 22. Time of departure from facility
 :
 23. Means of transport used
 Ambulance
 Personal vehicle
 Other
- If referred from a study facility
24. Code of referring facility
- If readmitted
25. Date of readmission
 / /
 26. Time of readmission
 :
 27. Preceding record number

A2 All women included in the study sample

28. Age (years)
29. Status
 Married
 Single
 Widowed
 Other

30. Type of insurance
31. Woman's occupation
32. Partner's occupation

A3 All women included in the study sample

33. Number of pregnancies
34. Number of live births
35. Number of stillbirths
36. Number of children alive (today)

37. Number of children died (born alive)
38. Does the women have a history of caesarean or abdominal scar?
 Oui Non NSP
39. Does the woman have a history of abortion?
 Oui Non NSP
40. Does the woman have FGM?
 Oui Non NSP
41. Did the woman receive antenatal care?
 Oui Non NSP

Questionnaire FEMHealth

STUDY OF NEAR-MISSES AND MATERNAL AND PERINATAL DEATHS

CERRHUD, Benin - AFRIC Santé, Burkina Faso - CAREF, Mali - INAS, Maroc - LSHTM, UK

**INDIVIDUAL
FORM**

Page 2/6

A3 REPRODUCTIVE HISTORY (CONT)
All women included in the study sample

42. Reason for admission

- Normal delivery
- Complicated delivery
- Extra-uterine pregnancy
- Other complication during delivery
- Prophylactic caesarean
- Abortion, miscarriage, or post-abortion complication
- Postpartum complication

If readmitted

43. Reason for readmission

- Normal delivery
- Complicated delivery
- Other complication during delivery
- Prophylactic caesarean
- Abortion, miscarriage, or post-abortion complication
- Postpartum complication

44. Was the foetal heart beat audible upon admission?

- Yes
- No
- Not perceived
- Not measured

45. Date of delivery or end of pregnancy

/ 5
 j j m m a a

46. Time of delivery or end of pregnancy

H
 h h m m

47. Gestational age

- Estimated at term
- Estimated pre-term
- Estimated post-term
- Unknown

If known 48. Weeks of amenorrhea

49. Month of pregnancy

Were the following interventions done?

51. External version Oui Non NSP

52. Hysterectomy Oui Non NSP

57. Time of laboratory request

:
 j j m m a a
 h h m m

If abortion, miscarriage or extra-uterine pregnancy: go to question

50. Mode of delivery

- Vaginal - perineum intact
- Vaginal - episiotomy
- Vaginal - with tears
- Vaginal - not specified
- Instrumental - vacuum/forceps
- Planned caesarean
- Emergency intrapartum caesarean
- Emergency antepartum caesarean
- Laparotomy for uterine rupture
- Destructive - symphysiotomy
- Destructive - craniotomy/embryotom
- Unknown

6

S

61. Vital status of woman at discharge Alive

62. Date of discharge or death of woman

/ /
 j j m m a a

63. Time of discharge or death of woman

:
 h h m m

65. Time of second discharge or death

:
 h h m m

If alive 66. Mode of exit

- Normal discharge
- Left against medical advice
- Referred to other hospital
- Escaped

If dead 67. Time of death

- Dead on arrival
- Dead between arrival and admission
- Dead in the first 24hrs
- Dead after 24hrs

If referred 68. Referral facility name

69. Reason for referral

70. Date of decision to refer

/ /
 j j m m a a

71. Time of decision to refer

:
 h h m m

If referred to a study facility 72. Referral facility code

Questionnaire FEMHealth

STUDY OF NEAR-MISSES AND MATERNAL AND PERINATAL DEATHS

CERRHUD, Benin - AFRICSanté, Burkina Faso - CAREF, Mali - INAS, Maroc - LSHTM, UK

**INDIVIDUAL
FORM**
Page 3/6

B SERIOUS COMPLICATIONS All women with complications or dead

73. **Haemorrhage** Oui Non
- Placenta praevia
 - Placenta accreta/increta/percreta
 - Retro-placental haematoma
 - Other first trimester haemorrhage
 - Haemorrhage during delivery (no other specification)
 - Uterine rupture
 - Postpartum haemorrhage (no other specification)
 - Other obstetric haemorrhage

74. **Hypertension** Oui Non
- Pre-eclampsia
 - Eclampsia
 - HELLP
 - Chronic hypertension

75. **Anaemia (Hb < 11g/dl)** Oui Non
- a) Haemoglobin level (g/dl)
- Unknown

76. **Infection** Oui Non
- Unspecified infection
 - Puerperal endometritis
 - Pyelonephritis
 - Septicaemia
 - Peritonitis
 - Parietal suppuration
 - Malaria
 - Other systemic infection

77. **Dystocia** Oui Non
- Non Uterine pre-rupture
 - Prolonged labour
 - Foeto-pelvic disproportion

78. **Other pathologies** Oui Non
- HIV/AIDS
 - Embolic diseases (thrombosis/amniotic fluid or gaseous embolism)
 - Heart disease
 - Sickle-cell disease
 - Other (specify: _____)

C NEWBORN All newborns (included stillborn foetuses)

79. Total number of newborns

Newborn 1

- 80a. **Presentation**
- Cephalic
 - Breech
 - Transverse/face/brow
 - Other (specify _____)

- 81a. **Sex** Female Male Unknown

82a. **Birthweight (g)**

- 83a. **Alive or stillborn?**
- Alive
 - Fresh stillbirth
 - Macerated stillbirth
 - Stillbirth (not specified)
 - Unknown

84a. **If stillborn, cause of stillbirth**

85a. **Apgar at 5min** Unknown

86a. **Neonatal complications?** Oui Non

Newborn 2

- 80b. **Presentation**
- Cephalic
 - Breech
 - Transverse/face/brow
 - Other (specify _____)

- 81b. **Sexe** Female Male Unknown

82b. **Birthweight (g)**

- 83b. **Alive or stillborn?**
- Alive
 - Fresh stillbirth
 - Macerated stillbirth
 - Stillbirth (not specified)
 - Unknown

84b. **If stillborn, cause of stillbirth**

85b. **Apgar at 5min** Unknown

86b. **Neonatal complications?** Oui Non

87a. **Neonatal complications** Specify

87b. **Neonatal complications** Specify

88a. **Birth trauma** Oui Non

If yes, specify:

89a. **Baby referred to another facility?** Oui Non

90a. **Admitted to special care or intensive care unit?** Oui Non

91a. **If yes, number of days**

92a. **Vital status at discharge**

- Alive
- Dead in the first 24hrs
- Dead after 24hrs
- Dead (timing not specified)
- Unknown

93a. **If dead, cause of death**

94a. **Date of discharge, referral or death of baby** / /

j j m m a a

88b. Oui Non

89b. Oui Non

90b. Oui Non

91b. **If yes, number of days**

92b. **Vital status at discharge**

- Alive
- Dead in the first 24hrs
- Dead after 24hrs
- Dead (timing not specified)
- Unknown

93b. **If dead, cause of death**

94b. **Date of discharge, referral or death of baby** / /

j j m m a a

Questionnaire FEMHealth

STUDY OF NEAR-MISSES AND MATERNAL AND PERINATAL DEATHS

CERRHUD, Benin - AFRIC Santé, Burkina Faso - CAREF, Mali - INAS, Maroc - LSHTM, UK

INDIVIDUAL
FORM

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D CAESAREANS AND LAPAROTOMIES All caesareans and laparotomies for uterine rupture

95. Date of decision of intervention / /
j j m m a a
96. Time of decision of intervention :
h h m m
97. Date of intervention / /
j j m m a a
98. Time of beginning of intervention :
h h m m
99. Time of end of intervention :
h h m m
- 100. Indication for caesarean or laparotomy**
- a) Foeto-pelvic disproportion Oui Non
If yes: Small or deformed pelvis
 Foetal macrosomia
 Unspecified disproportion
- b) Severe antepartum haemorrhage Oui Non
If yes: Placenta praevia
 Retro-placental haematoma
 Yes (no specification)
- c) Uterine rupture or pre-rupture Oui Non
If yes: Uterine rupture
 Uterine pre-rupture
- g) (Pre-)eclampsia Oui Non
If yes: Eclampsia
 Pre-eclampsia

- d) Malpresentation Oui Non
If yes: Transverse
 Oblique
 Brow
 Face with posterior chin/"enclaved" face
 Arm or shoulder
- e) Poor progression of labour Oui Non
If yes: Prolonged labour
 Failed induction
 Other
 Yes (no specification)
- f) Previous caesarean Oui Non
- h) Foetal indication Oui Non
If yes: Foetal distress
 Cord prolapse
 Cord around neck
 Intra-uterine growth retardation
- i) Breech presentation Oui Non
- j) Psychosocial indications Oui Non
 Yes, maternal request
 Yes, "precious" pregnancy
- k) Other Oui Non
Specify: _____
- Indication not specified

Quality of care indicators for caesareans and laparotomies of uterine rupture

101. Before the surgery,
- a) Was the haemoglobin level checked? Oui Non NSP
- b) Was the foetal heart beat checked just before the anaesthesia? N/A (stillborn) Oui Non NSP
- c) Were prophylactic antibiotics prescribed? Oui Non NSP
If yes: **102.** When were they administered?
 Before the surgery
 During the surgery
 After the surgery
103. During the surgery, was prophylactic oxytocin administered? Oui Non NSP
104. During the first 2hrs post-surgery, did someone monitor every 30 minutes:
- a) Arterial blood pressure
 Yes Done less frequently No NSP
- b) Respiratory rate?
 Yes Done less frequently No NSP
- c) Pulse?
 Yes Done less frequently No NSP

105. Morbidity during or after caesarean
- Blood transfusion
 Wound infection
 Puerperal fever
 Evacuation of a haematoma
 Secondary postpartum haemorrhage
 Severe postpartum anaemia
 Septicaemia
 Hysterectomy
106. Severe incidents linked to caesareans
- Admission for over 1 week due to post-surgical infection
 Anaesthetic accident
 Accident of blood transfusion
 Uterine artery pierced
 Accident of other organs
 Return to operating room
 Other specify _____
107. Caesarean after failed instrumental delivery Oui Non NSP

Questionnaire FEMHealth

STUDY OF NEAR-MISS AND MATERNAL AND PERINATAL DEATHS

INDIVIDUAL
FORM

CERRHUD, Benin - AFRICSanté, Burkina Faso - CAREF, Mali - INAS, Maroc - LSHTM, UK

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<p>E</p> <p>MATERNAL NEAR-MISS All women in state of near-miss</p>	<p>109. When did the state of near-miss occur?</p> <p><input type="checkbox"/> Before arrival at the facility <input type="checkbox"/> During hospitalisation</p> <p>110. Did the woman require intensive care?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> No</p>
<p>108. Is the woman considered to be in a state of near-miss?</p> <p><input type="checkbox"/> Yes - according to clinical criteria (AUDOBEM) <input type="checkbox"/> Yes - according to organ dysfunction criteria (WHO) <input type="checkbox"/> Yes - anaemia <input type="checkbox"/> No</p>	<p>Clinical criteria</p> <p>111. Uterine rupture and pre-rupture</p> <p><input type="checkbox"/> Dystocia with rapid maternal pulse or fetal distress AND sub-pubic tenderness or bandl ring</p> <p><input type="checkbox"/> Diagnosis of rupture/pre-rupture in medical record</p> <p><input type="checkbox"/> Dystocia with shock or cardiac arrest <input type="checkbox"/> Dystocia requiring laparotomy</p> <p>112. Haemorrhage</p> <p><input type="checkbox"/> Haemorrhage with state of shock <input type="checkbox"/> Haemorrhage with cardiac arrest <input type="checkbox"/> Haemorrhage with laparotomy <input type="checkbox"/> Haemorrhage with blood transfusion</p>
<p>Organ dysfunction criteria</p> <p>116. Cardiovascular dysfunction</p> <p><input type="checkbox"/> Shock <input type="checkbox"/> Cardiac arrest <input type="checkbox"/> Severe hypoperfusion (lactate >5mmol/l or >45mg/dl) <input type="checkbox"/> Severe acidosis (pH<7.1) <input type="checkbox"/> Use of continuous vasoactive drugs <input type="checkbox"/> Cardio-pulmonary resuscitation</p> <p>117. Respiratory dysfunction</p> <p><input type="checkbox"/> Acute cyanosis <input type="checkbox"/> Gasping <input type="checkbox"/> Severe tachypnea (respiratory rate/min>40) <input type="checkbox"/> Severe bradypnea (respiratory rate/min<6) <input type="checkbox"/> Severe hypoxaemia (O2 saturation <90% for =60min or PaO2/FiO2<200) <input type="checkbox"/> Intubation and ventilation not related to anaesthesia</p> <p>118. Uterine dysfunction</p> <p><input type="checkbox"/> Haemorrhage or infection leading to hysterectomy</p>	<p>113. Infections</p> <p><input type="checkbox"/> Temp >38,0° or <36,5 or obstetric infectious seat AND jaundice or state of shock or cardiac arrest</p> <p><input type="checkbox"/> Diagnosis of septicaemia in medical record</p> <p>114. Severe pre-eclampsia</p> <p><input type="checkbox"/> Dyastolic BP >=110 mmHg or Proteinuria/albuminuria +++ AND hyper reflectivity or headache or blurred vision or oliguria or high abdominal pain or pulmonary oedema or jaundice</p> <p>115. Eclampsia</p> <p><input type="checkbox"/> Dyastolic BP>=90 mm Hg or proteinuria/albuminuria ++ AND convulsions or coma</p>
<p>Anaemia criteria</p> <p>123. Severe anaemia</p> <div style="border: 1px solid black; padding: 5px; display: inline-block;"> <input type="checkbox"/> Haemoglobin level <4g/dl OR haematocrit level <12% </div> <p style="text-align: center; margin: 0;">OR</p> <div style="border: 1px solid black; padding: 5px; display: inline-block;"> <input type="checkbox"/> Haemoglobin level 4-7g/dl; OR <input type="checkbox"/> Cutaneo-mucosal pallor or haematocrit level <20% AND <input type="checkbox"/> State of shock (cold sweat + thready pulse + cold extremities + tachycardia) <input type="checkbox"/> Difficulty breathing <input type="checkbox"/> Blood transfusion performed <input type="checkbox"/> Blood transfusion requested </div>	<p>119. Renal dysfunction</p> <p><input type="checkbox"/> Oliguria non responsive to fluids or diuretics <input type="checkbox"/> Severe acute azotemia (creatinine >300umol/ml <input type="checkbox"/> Dialysis for acute renal failure or >3.5mg/dL)</p> <p>120. Coagulation dysfunction</p> <p><input type="checkbox"/> Failure to form clots <input type="checkbox"/> Severe acute thrombocytopenia (<50,000 platelets/ml) <input type="checkbox"/> Massive transfusion of blood or red cells (=5 units)</p> <p>121. Hepatic dysfunction</p> <p><input type="checkbox"/> Jaundice in the presence of pre-eclampsia <input type="checkbox"/> Severe hyperbilirubinemia</p> <p>122. Neurological dysfunction</p> <p><input type="checkbox"/> Prolonged unconsciousness or coma lasting >12hrs <input type="checkbox"/> Stroke <input type="checkbox"/> Status epilepticus / uncontrollable fits <input type="checkbox"/> Total paralysis</p>

G OTHER QUALITY OF CARE INDICATORS
All women included in study sample

At admission
 126. Was arterial pressure measured? Oui Non NSP

All women with twins
 127. When was the diagnosis made?
 Before admission
 Upon admission
 During delivery

All women with breech presentation:
 128. When was the diagnosis made?
 Before admission
 Upon admission
 During delivery

Treatment and monitoring of parturient during delivery
 129. All women:
 Was the foetal heart rate measured at least once during the active (second) phase of labour?
 N/A (stillbirth diagnosed before delivery) Oui Non NSP

All women admitted during latent or active phase:
 130. Was a partogramme used?
 N/A (ex: expulsive phase) Oui Non NSP

All women with instrumental delivery
 131. Was the position of the occiput determined? Oui Non NSP
 132. Was the presentation engaged?
 Pelvic floor
 Mid-cavity
 Higher
 No
 Unknown
 133. How long did the active phase of labour last? (min)
 Unknown

After delivery and before discharge
 134. For the woman: in the 6 hours following delivery, were the following signs measured at least once?
 a) Pulse Oui Non
 b) Arterial pressure Oui Non
 c) Uterine bleeding Oui Non
 d) Temperature Oui Non
 135. For the baby: in the 6 hours following delivery, were the following signs measured at least once?
 a) Colour Oui Non
 b) Breathing Oui Non
 c) Feeding Oui Non
 d) Temperature Oui Non
 136. Return to labour room for revision of placental retention
 Oui Non
 137. Is the final diagnosis the same as the one given at admission?
 Oui Non NSP
 If yes, specify: _____

IDENTIFICATION

 Facility code (1-20): Individual identification code:
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

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**
[prolonged unconsciousness / coma (lasting >12 hours), stroke, status epilepticus / uncontrollable fits, total paralysis]
- C6 **Uterine dysfunction / Hysterectomy**
[haemorrhage or infection leading to hysterectomy]

4. Maternal deaths

- D0 Death during pregnancy or within 42 days of termination of pregnancy
- D1 Death after 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 AND PERINATAL INFORMATION

- 5. Date of hospital admission

d	d	m	m	y	y	y	y

 E0
- 6. Date of delivery or uterine evacuation

d	d	m	m	y	y	y	y

 E1
- 7. Date of hospital discharge or death

d	d	m	m	y	y	y	y

 Date

--	--	--	--	--	--	--	--

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

- 1= Vaginal Delivery
- 2= Caesarean section
- 3= Complete abortion
- 4= Curettage / vacuum aspiration
- 5= Medical methods for uterine evacuation
- 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 uterotonic

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

Fetal lung maturation

- K0 Corticosteroids (betamethasone or dexamethasone)

UNDERLYING CAUSES OF DEATH / NEAR MISS
13. Please specify: (0=No 1=Yes)

- L0 Pregnancy with abortive outcome (abortion/ectopic pregnancy)
- L1 Obstetric haemorrhage
- 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
- M2 Previous caesarean section
- M3 Prolonged/obstructed labour
- M4 Other condition specified in the local manual of operations
- M5 Other condition specified in the local manual of operations
- M6 Other condition specified in the local manual of operations