

**VALIDATION OF A MODIFIED OBSTETRIC EARLY WARNING SYSTEM  
FOR PREDICTING SEVERE MATERNAL OUTCOME AT MOI TEACHING  
AND REFERRAL HOSPITAL, ELDORET**

**BY**

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## DECLARATION

### Student Declaration

I declare that this research thesis is my original work and has not been presented in any other university or institution for the award of any degree or academic credit.

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## **DEDICATION**

This work is dedicated to all our patients and all those who support and care for them in their unique individual journeys throughout motherhood.

## ABSTRACT

**Background:** Maternal death remains high in developing countries. Mothers who survive complications suffer severe morbidity. These mothers, termed, 'near-miss' are defined by World Health Organization(WHO) as women who nearly died from a complication that occurred during pregnancy, childbirth or within 42 days of delivery. Near-miss cases and maternal deaths constitute severe maternal outcome (SMO). To prevent SMO, a system known as Modified Early Obstetric Warning System (MOEWS) for tracking significant changes ('triggers') in vital signs among obstetric patients and initiating corrective measures is suggested. The use of the MOEWS in Moi Teaching and Referral Hospital (MTRH) and Kenya remains limited, and its ability to predicting SMO remains unexplored.

**Objective:** To determine the validity of the MEOVS for predicting SMO, the vital sign triggers that are associated with SMO and perinatal outcomes of mothers with SMO at MTRH, Eldoret

**Methods:** A retrospective cohort study was conducted at Riley Mother and Baby Hospital, MTRH, among mothers admitted consecutively and discharged or died from 1<sup>st</sup> January 2019 up to when the desired sample size of 3200 patients was achieved. Maternal mortality was established as defined by WHO. Maternal near-miss was defined by WHO clinical, Intervention-based and Disease-based criteria Mothers were grouped into two outcome groups; either experiencing or not experiencing SMO. Their vital signs 24 hours prior to either outcome were then tabulated on a MOEWS chart and determined whether they met a vital sign trigger threshold. The sensitivity, specificity, positive predictive value(PPV) and negative predictive value(NPV) were determined. Associations were determined between the various vital signs and occurrence of SMO. Perinatal outcomes were also determined.

**Results:** Majority of patients were aged 20 to 34 years, were married and attained secondary level education. The sociodemographic and obstetric factors associated with occurrence of SMO were age over 35 years(aOR=1.56), having a previous caesarean delivery(aOR=2.19), caesarean delivery in the index pregnancy(aOR=2.09), being a referral(aOR=3.43), not attending antenatal care (aOR=2.53) and admission in the period between 28 to 37 weeks(aOR=2.81) and in the postpartum period(aOR 51.3). The sensitivity of MOEWS was 77%, specificity 98%, PPV 61% and NPV 98%. Vital signs independently associated with occurrence of SMO were heart rate(aOR 30.61), respiratory rate(aOR 3.36), systolic blood pressure(aOR 12.8) and diastolic blood pressure(aOR 45.8). Neonates born to mothers with SMO had higher rates of still birth, low birth weight and admission to newborn unit.

**Conclusion:** The MOEWS chart has a high specificity and NPV but low sensitivity and PPV. Triggers for respiratory rate, heart rate, diastolic and systolic blood pressure are likely to be associated with SMO. Mothers with SMO are most likely to have adverse fetal outcomes.

**Recommendation:** The MOEWS chart is an important tool for screening high risk patients for SMO such as mothers with severe preeclampsia, referrals, mothers admitted at less than 37 weeks and postnatal mothers. Provision of specialized neonatal care for babies born to mothers with SMO should be anticipated.

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## ABBREVIATIONS

<b>CEMACH</b>	Confidential Enquiry into Maternal and Child Health
<b>EWS</b>	Early Warning System
<b>MOEWS</b>	Modified Obstetric Early Warning System
<b>MTRH</b>	Moi Teaching and Referral Hospital
<b>NHS</b>	National Health Service
<b>NPV</b>	Negative predictive value
<b>PPV</b>	Positive predictive value
<b>SAMM</b>	Severe acute maternal morbidity
<b>SMO</b>	Severe Maternal Outcome
<b>WHO</b>	World Health Organisation

**OPERATIONAL DEFINITIONS**

<b>Acute severe azotemia</b>	Creatinine equal to or over 300 µmol/l or 3.5 mg/dl.
<b>Cardiac arrest</b>	Sudden absence of pulse and loss of consciousness.
<b>Cardiopulmonary resuscitation</b>	A set of emergency procedures including chest compressions and lung ventilation applied in cardiac arrest victims.
<b>Eclampsia</b>	Generalized fits in a patient without previous history of epilepsy. Includes coma in pre-eclampsia.
<b>Failure to form clots</b>	The clinical inability to form clots or a patient with disseminated intravascular coagulation. Clinically, absence of clotting from the IV site or suture after 7–10 minutes.
<b>Gasp ing</b>	A terminal respiratory pattern. The breath is convulsively and audibly caught.
<b>Hysterectomy</b>	In the maternal near-miss context, surgical removal of the uterus following infection or haemorrhage.
<b>Life-threatening condition</b>	Any of these five conditions: severe postpartum haemorrhage, severe preeclampsia, eclampsia, sepsis or systemic infection or uterine rupture
<b>Live birth (LB)</b>	refers to the birth of an offspring which breathes or shows evidence of life.

<b>Macerated still birth</b>	A still birth with skin and organ changes associated with death
<b>Massive transfusion</b>	Transfusion of considerable amount of blood or red cells, that is, transfusion of more than 5 units of blood or red blood cells.
<b>Maternal death (MD)</b>	is the death of a woman at 28 weeks of pregnancy or more or within 42 days of termination of pregnancy or its management, but not from accidental or incidental causes.
<b>Maternal Near Miss ratio (MNMR)</b>	refers to the number of maternal near-miss cases per 1000 live births (MNMR = MNM/LB).
<b>Maternal near-miss (MNM)</b>	refers to any woman who fits either the WHO clinical or management-based criteria for near miss (as outlined in Table 1) and/or had one of the five life threatening conditions of severe postpartum haemorrhage, severe preeclampsia, eclampsia, sepsis or systemic infection and uterine rupture
<b>Maternal near-miss mortality ratio (MNM : 1 MD)</b>	refers to the ratio between maternal near miss cases and maternal deaths. Higher ratios indicate better care.
<b>Metabolic coma</b>	loss of consciousness and the presence of glucose plus ketoacids in urine.

<b>Mortality index</b>	refers to the number of maternal deaths divided by the number of women with SMO expressed as a percentage [ $MI = MD/(MNM + MD)$ ].
<b>Negative Predictive Value</b>	Refers to the ability of a test to predict that the proportion of cases with a negative test actually do not have the condition; In this case, those without a trigger on the MOEWS do not have SMO.
<b>Oliguria non-responsive to fluids or diuretics</b>	A urinary output of less than 30 ml per hour for 4 hours or less than 400 ml per 24 h non-responsive to fluids or diuretics.
<b>Positive Predictive Value</b>	Refers to ability of a test to predict that the proportion of cases with positive test results actually have a condition. In this case, the proportion of patients who have a trigger and actually have SMO
<b>Prolonged unconsciousness</b>	Any loss of consciousness lasting more than 12 hours, involving complete or almost complete lack of responsiveness to external stimuli. A state compatible with Coma Glasgow Scale (GCS) less than 10.
<b>Sensitivity</b>	Refers to the ability of a test to correctly identify all people who have a condition; in this case, that all those who had SMO would have vital sign triggers on the MOEWS chart

<b>Severe acidosis</b>	a blood pH less than 7.1.
<b>Severe acute hyperbilirubinemia</b>	Bilirubin greater than 100 $\mu\text{mol/l}$ or greater than 6.0 mg/dl.
<b>Severe acute thrombocytopenia</b>	An acute reduction in the number of platelets in the blood to less than 50 000 platelets/ml.
<b>Severe bradypnea</b>	Respiratory rate less than six breaths per minute.
<b>Severe hypoperfusion</b>	Lactate more than 5 mmol/l or 45 mg/dl.
<b>Severe maternal outcome (SMO)</b>	refers to maternal deaths and maternal near-miss cases.
<b>Severe maternal outcome ratio (SMOR)</b>	refers to the total number of women who had near miss and maternal death (MNM + MD) per 1000 live births (LB). The formula for its derivation is: $[\text{SMOR} = (\text{MNM} + \text{MD})/\text{LB}]$ .
<b>Severe postpartum haemorrhage</b>	Genital bleeding after delivery as defined by blood loss of 1000 ml or more or any bleeding with hypotension or requiring blood transfusion.
<b>Severe pre-eclampsia</b>	Persistent systolic blood pressure of 160 mmHg or more or a diastolic blood pressure of 110 mmHg; proteinuria of 3 grams or more in 24 hours; oliguria of less than 400ml in 24 hours; and HELLP syndrome or pulmonary oedema.  Excludes eclampsia
<b>Severe systemic infection or sepsis</b>	Presence of fever (body temperature more than 38°C), a confirmed or suspected infection (e.g. chorioamnionitis, endometritis, pneumonia), and

at least one of the following: heart rate greater than 90, respiratory rate more than 20, leukopenia (white blood cells less than 4000), leukocytosis (white blood cells above 12,000).

**Specificity**

Refers to the ability of a test to correctly identify all people who do not have the condition. That is, all those without SMO will not have vital sign triggers on the MOEWS chart

**Still birth**

A baby born with no signs of life after 28 weeks gestation

**Uterine rupture**

Rupture of uterine wall during labour confirmed by laparotomy.

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## CHAPTER ONE

### 1.1 Background

Globally, measures aimed at reducing maternal deaths and morbidity have been taken over time, with some resultant gains noted which have led to improved maternal outcomes. While maternal mortality continues to be a great indicator of national and global health, the morbidity associated with complications of pregnancy and delivery continue to be an important area of concern in reproductive health. Focus is therefore placed on both the women that die in pregnancy and delivery as well as those that suffer near-fatal complications, referred to as 'near-miss' or severe acute maternal morbidity morbidity.(SAMM) (Say, Souza, & Pattinson, 2009)

Maternal mortality is defined as “the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes”. Conversely, a maternal near miss is defined as a woman who nearly died but survived a complication that occurred during pregnancy, child birth or within 42 days of termination of pregnancy’. The combination of both maternal deaths and near miss constitutes severe maternal outcome. (SMO) (WHO, 2011)

Maternal mortality declined by 44% between 1990 and 2015, from 385 to 216 per 100,000 live births. In addition, the lifetime risk of a mother dying from pregnancy and childbirth fell from 1 in 73 to 1 in 180. Despite these notable improvements, developing countries still contribute to 99% of all maternal mortalities worldwide. Sub-Saharan Africa (SSA) continues to bear the highest brunt of maternal mortality, with 66% of all deaths occurring here. The lifetime risk of a woman dying from pregnancy related causes in SSA is 1 in 36 as compared to 1 in 4900 in the developed world. (World Bank

Group, 2015) While the global median maternal mortality rate (MMR) was 54 deaths per 100,000 live births in 2015, it exceeded 500 in 20 SSA countries, including Kenya. This is despite the SSA region having the highest reduction in the absolute lifetime risk of maternal death from 1990 to 2015.(Alkema et al., 2016) Moreover, it is estimated that between 2003 and 2009, nearly 73% of all maternal deaths were due to direct causes. 83.8% of these deaths occurred in SSA and Southern Asia. Of the direct causes, it was concluded that obstetric haemorrhage, sepsis and hypertensive disease alone were responsible for over half of all the maternal deaths. (Say et al., 2014)

The leading causes of death have been shown to vary by region. Direct causes are still responsible for the highest number of maternal deaths in low and middle income countries. In Africa and Asia, obstetric hemorrhage was shown to be the leading cause of maternal deaths at 34% and 31% respectively. Conversely, in Latin America, hypertensive disorders were the leading cause of death at around 26%. In addition, deaths due to sepsis were highest in Africa with mothers having a two-fold risk of death compared to high income countries. (Khan et al., 2006)

In Kenya the maternal mortality rate (MMR) followed a similar pattern of decline as the international rates, from 687 deaths per 100,000 live births in 1990 to 342 deaths per 100,000 in 2017. (World Bank Group, 2017). According to the Kenya Demographic and Health Survey(KDHS) of 2014, MMR was 362 per 100,000 live births (KDHS, 2014). This was a decline from the 488 per 100,000 recorded in the 2009 KDHS. (KDHS, 2009).

With regards to maternal morbidity, different definitions for SAMM were initially used by different medical practitioners due to lack of a standardized criteria. A large systematic review carried out showed the prevalence of SAMM to vary from 0.8 to 8%

in those that used disease specific criteria (A mother was described as having SAMM if she had one of severe hemorrhage, sepsis, preeclampsia or eclampsia), 0.38 to 1.1% to those that used organ damage-based criteria (based on a defined set of laboratory criteria) and 0.01 to 3% in those using management-based criteria. It was however not possible to confidently conclude these statistics due to different definition criteria for maternal near miss.(Say, Pattinson, & Gülmezoglu, 2004).

Subsequently, a WHO working group which sought to harmonize the working definition of SAMM or 'near miss' was formed. In its conclusion, three interrelated criteria were arrived at and defined as useful, either independently or in unison in identifying maternal near miss. The three were the clinical criteria related to the disease entity, the specific medical intervention related to that disease and the organ system dysfunction related to the disease. (Say et al., 2009) These three criteria are summarized in Table 1. The WHO criteria will be used to define maternal near miss in this study.

Following the definition of the criteria for near-miss, in twenty health facilities in Kenya included in a WHO multi country survey of 29 countries in 2014, the near miss rate among 20,354 women was 0.38% and mortality at 0.27%, hence a total SMO of 0.65% or 65 per 10,000. Hypertensive disease in pregnancy was the largest contributor to mortality at 35% while obstetric haemorrhage was the largest cause of near misses at 52.5%.(Souza, 2014)

Notable though, is that on review, majority of these deaths and complications after review are preventable. Previously, it has been noted that delays in the provision of adequate obstetric care, otherwise known as 'the third delay' has been identified as one of the factors that affects the onset of an obstetric complication and its outcome.

Administrative issues and clinical lack of awareness have been noted as some of the causes of delay in instituting management in obstetric patients. (Chhabra, 2014)

The seventh United Kingdom Confidential Enquiry into Maternal Deaths and Child Health report (CEMACH) of 2003-2005 noted that most of these deaths resulted from signs of maternal deterioration and eventual collapse that went unnoticed. This was probably masked by the rarity of such events and by the physiological changes in pregnancy which made such deterioration difficult to predict. Following the enquiry, it was agreed that an early maternal Warning system be developed for use in all National Health Service (NHS) facilities. (Lewis et al., 2007)

Subsequently a Modified Obstetric Early Warning System (MOEWS), a 'track' and 'trigger' system for patient vital sign monitoring was adopted. The 'track' component of the EWS follows the progress and changes of the patient's vital signs over time, while the 'trigger' component is based on a score system that would alert the care-giving team to changes in the patient's physiological status, and may also on appropriate action should such a change occur, such as the attending nurse informing a doctor. The score system is based on a colour-coded system, with a total red score on one parameter or at least two yellow scores on two parameters constituting a trigger. One yellow score for one parameter or a white score means no trigger. (Breslin et al., 2012)

A large systematic review of literature showed a generalized trend towards improved patient outcome with implementation of obstetric early warning systems, although that improvement highly depended on the responsiveness of the management team. It was also shown that most MOEWS models had high sensitivity (72 to 97%) and specificity

(67 to 98%) for predicting severe maternal outcome, but very low positive predictive values, with a median 41%. (Umar et al, 2019)

The modified MOEWS put forward by the CEMACH group in 2007 was found to have favourable ability to predict adverse maternal outcome. (Carle, Alexander, Columb, & Johal, 2013)

The objective of this study is to externally validate the modified obstetric warning system suggested by the CEMACH team for predicting severe maternal outcome at Moi Teaching and Referral Hospital and Kenya in general.

## **1.2 Statement of the Problem**

Maternal mortality continues to be unacceptably high in low-income countries and it's evident that most of these deaths are preventable. For example, in a nationwide survey of 54 large facilities in the country, none of the patients who suffered mortality or near-miss received a timely and complete package of care recommended for their diagnosis and about 36% of them got near miss within the hospital premises. (Owolabi et al., 2018) The use of MOEWS has been shown to be of potential great value in predicting and improving maternal outcomes in most settings. However, the use of such a system in MTRH and largely Kenya has not been extensively implemented. This study aimed to evaluate its value in predicting maternal outcomes, and providing the basis for its use in the facility and the country.

## **1.3 Justification of the Study**

The use of MOEWS charts has been previously shown to significantly improve maternal outcomes. There is paucity of data in the use of MOEWS charts in Kenya and particularly in MTRH, and a protocol for its use in monitoring maternal vital signs does not exist. As such, the researchers purposed to find out the value of the MOEWS tool

in predicting adverse maternal outcomes in MTRH and its probable application within the facility and other facilities within Kenya and the East African region.

#### **1.4 Significance of the Study**

The study aimed to act as a pioneer towards the initiation and implementation of the use of obstetric early warning sign systems in Moi Teaching and Referral Hospital and Kenya as a whole. The findings would be of great value in informing protocol development in management of obstetric patients. The findings would also guide policy makers at institutional and at all levels of government in policy formulation in strategies aimed at improving maternal outcomes. It would offer new knowledge in development and use of MOEWS in low resource settings and act as a base for further research in the area.

#### **1.5 Research Questions**

1. What is the predictive validity of the Modified Obstetric Early Warning System for severe maternal outcome at MTRH?
2. Which individual vital signs, when they trigger the MOEWS, are more likely to be associated with a severe maternal outcome at MTRH?
3. What are the fetal outcomes among mothers that suffer severe maternal outcomes at MTRH ?

## **1.6 Broad Objective**

1. To determine the ability of the MOEWS model to predict Severe Maternal Outcome and to describe the associated fetal outcomes in obstetric patients admitted at MTRH, Eldoret

## **1.7 Specific Objectives**

1. To determine the predictive ability of MOEWS for near miss and maternal mortality at MTRH, Eldoret in terms of sensitivity, specificity, negative predictive value and positive predictive value.
2. To investigate the association between the individual vital signs that trigger on the MOEWS chart and the occurrence of severe maternal outcomes among obstetric patients at MTRH, Eldoret
3. To describe the fetal outcomes among mothers that suffer severe maternal outcomes at MTRH, Eldoret

## CHAPTER TWO

### 2.0 LITERATURE REVIEW

#### 2.1 The concept of Early Obstetric Warning Systems

In the audit of maternal deaths, it has been found that the deaths followed a pattern of maternal deterioration that, had it been detected, some of the deaths would have been prevented. (USA MMRCs., 2018) The United Kingdom Confidential Enquiry into Maternal and Child Health (CEMACH) report of 2003-2005 had previously noted this and made a proposition to come up with a system for early detection and possible correction of the maternal deterioration. It was noted that alterations of the maternal physiology due to changes in pregnancy make it difficult to pick these subtle changes in maternal vital signs. Thus, a Modified Obstetric Early Warning System (MOEWS) model based on a multiple variable vital sign scoring system was adopted and suggested for use in the United Kingdom National Health Service facilities. (Lewis et al., 2007) Consequently, several Early Warning System (EWS) models have been developed for use in the obstetric population, all having varied sensitivities, specificities and predictive values. For example, in response to the CEMACH 2003-2005 recommendation for the development of more obstetrics-oriented early warning system models, Carle and colleagues developed and validated a MOEWS tool from 4440 obstetric patients admitted to intensive care and was found to predict maternal adverse outcomes with area under the curve for receiver operating curve of 0.937. This compared well to the MOEWS model put forward by the CEMACH group (Carle et al., 2013) Contrary to the EWS tool developed by Carle and colleagues that was based on patients in critical care settings, a different EWS tool developed specifically for use in resource-limited settings has recently been developed and validated. The tool used a combination of statistical clinical predictors for SMO. The final model consisted of



abnormal systolic blood pressure, high diastolic blood pressure, temperature above 38 degrees, high pulse, previous caesarean delivery and current caesarean delivery. This chart was found to have sensitivity of 86% and specificity of 92%. (Umar et al., 2020) It was further noted earlier that subtle changes in vital signs in the period of eight to twenty four hours prior to cardiopulmonary arrest in critically ill patients was predictive for a catastrophic outcome. (Mathukia, Fan, Vadyak, Biege, & Krishnamurthy, 2015)

In the same regard, the use of a MOEWS has been shown in many studies between the years 1997 to 2018 as providing better maternal outcomes. They had a high specificity and sensitivity for predicting adverse maternal outcomes, but very low positive predictive values. This means that most MOEWS were prone to a high false-positive rate and led to user apathy or fatigue. However, many of the studies analysed were done in high resource settings. (Umar et al., 2019)

## **2.2 The WHO ‘near miss’ concept**

Usually in many maternal death audits, it was noted that mothers who do not die due to complications of pregnancy may be more prevalent than mothers who actually die. These mothers however may survive, sometimes with life-long complications of pregnancy or pregnancy-related conditions. Compared to women without maternal near miss, mothers who suffered maternal near-miss had comparatively lower quality of life by standard scores, were worse in social interactions and suffered catastrophic economic losses. They also had significant sexual dysfunction. (von Rosen et al., 2021) It was previously noted that no standard single definition of these patients existed, making it difficult to analyze the individual cases. This group of mothers, termed ‘near miss’ are those that would have died had prompt medical attention not been sought or those that suffered severe morbidity despite not dying. (Pattinson & Hall, 2003) The

WHO sought to standardize the criteria of identifying these mothers by coming up with criteria that clearly defined 'near miss'. A WHO working group formed came up with standard definition criteria that identified this special group of obstetric patients. This is a criteria based on clinical findings of the patient, medical intervention that the patient underwent and end-organ function based criteria using specialized laboratory tests. (Say et al., 2009)

**Table 1 WHO near miss definition criteria**

Clinical criteria	Intervention based criteria	Organ system dysfunction criteria
<ul style="list-style-type: none"> <li>• Acute cyanosis</li> <li>• Gaspings</li> <li>• Respiratory rate of more than 40 or less than 6 breaths per minute</li> <li>• Shock</li> <li>• Oliguria</li> <li>• Clotting failure</li> <li>• Unconscious for more than 12hours</li> <li>• Cardiac arrest</li> <li>• Stroke</li> <li>• Uncontrollable fits or total paralysis</li> <li>• Jaundice in preeclampsia</li> </ul>	<ul style="list-style-type: none"> <li>• Use of continuous vasoactive drugs</li> <li>• Cardiopulmonary resuscitation</li> <li>• Intubation and ventilation not related to anaesthesia</li> <li>• Dialysis for acute renal failure</li> <li>• Massive transfusion of blood/red cells of more than 5 units</li> <li>• Hysterectomy following infection or haemorrhage</li> </ul>	<ul style="list-style-type: none"> <li>• Oxygen saturation of less than 90% for more than 60 minutes</li> <li>• PaO<sub>2</sub> /FiO<sub>2</sub> of less than 200mmHg</li> <li>• Creatinine of more than 3.5mg/dl or 300 µmol/l</li> <li>• pH less than 7.1</li> <li>• lactate greater than 5mEq/ml</li> <li>• Acute thrombocytopenia of less than 50,000/ml</li> <li>• Bilirubin of more than 100µmol/l or 6mg/dl</li> <li>• Loss of consciousness and ketoacids in urine</li> </ul>

Five major conditions are associated with most adverse maternal outcomes and are commonly termed as potentially life-threatening conditions. These are severe postpartum haemorrhage, severe pre-eclampsia, eclampsia, sepsis/severe systemic infection, and ruptured uterus. These conditions are found in almost all mothers who suffer severe outcomes. Independently, these conditions are also used as criteria for

defining near miss, and constitute the **Disease-based criteria**. (WHO, 2011) The Disease-based criteria will also be used to define near-miss in this study. The presence of any of the parameters under the criteria defined constitutes a near-miss.

Several evaluations of the performance of the WHO near miss criteria in different settings have been carried out. A systematic review of literature on the use of the WHO criteria for assessing maternal near miss (MNM) in the low-resource setting of Sub-Saharan Africa between the years 2009 and 2017 showed that as a whole, the criteria was difficult to use as a standard of measurement. This was because of lack of uniform availability of facilities and resources especially for the intervention and laboratory-based criteria. In some instances, locally adopted criteria were used, hampering uniformity and probably leading to underestimation of the MNM rate. Only few studies used the WHO near miss criteria unaltered, and there was need to adapt a locally feasible version to evaluate maternal near miss in resource limited settings. (Tura et al., 2019)

In another study that sought to validate the WHO criteria, it was found that the laboratory-based criteria alone identified 83% of deaths while management based criteria identified 94% of the patients who died. Combined, these methods identified all the near-misses and deaths. The use of vasoactive drugs and mechanical ventilation was the most common predictor of maternal deaths. The WHO scoring system using the intervention and laboratory criteria compared favourably with the Sequential organ Failure Score (SOFA) of organ dysfunction used as the gold standard of assessing organ dysfunction. The WHO criteria were 99% sensitive and 61% specific in identifying the near miss cases as identified by the SOFA score. The criteria were found to be a good predictor for planning early referral and specialized care. (Cecatti et al., 2011)

Subsequently, in a study done to evaluate the use of only the clinical criteria to predict SMO, which could be useful in settings with limitations of intervention and laboratory services, it was shown that the clinical criteria alone was just as sensitive as all three criteria combined. The sensitivity and specificity of the clinical criteria both approached 100%. The use of disease based criteria (based on the five WHO defined life-threatening conditions) and clinical criteria would be useful in low resource settings and would avoid underreporting occasioned by the absence of sophisticated interventions and laboratory tests. (Nelissen et al., 2013)

Additionally, a study carried out to compare the ability of the WHO MNM criteria to determine SMO in high and low resource settings, it was shown that disease-based criteria based on the five life-threatening disease entities, had the highest prediction rate for SMO at 87%, followed by intervention based criteria at 79% while laboratory based criteria had the lowest rate at 38%, largely due to unavailability of records and unavailability of laboratory tests in low resource settings. Reducing the threshold for the number of blood transfusions in the intervention criteria from 5 to 1 unit significantly increased the rate of SMO detection. Again the WHO criteria did not provide a standard measure of SMO that could be comparable in both high and low resource settings. (Witteveen et al., 2017)

In a study done in Zanzibar, there was found to be a high correlation between the number of patients diagnosed with SMO via the organ dysfunction criteria (laboratory criteria) and mortality, with the likelihood of death increasing by 89% with every additional marker. The WHO organ-based criteria were shown to have strong prediction ability for maternal death. (Id et al., 2019)

In this study, as has been shown in the studies above, lack of resources may hamper use of the laboratory-based criteria, usually considered the gold standard for assessing end

organ damage. A combination of the other criteria, that is, disease-based criteria, clinical criteria and intervention-based criteria are comparable to the gold standard. Therefore, these three criteria will be used to as gold standard to define near-miss.

### **2.3 Effectiveness of MOEWS in improving vital sign recording**

The effectiveness of MOEWS is highly dependent on correct and consistent documentation of patient vitals. This way any alterations in the vital signs could be noted, a likely cause for the change sought and probable corrective measures put in place.

A large review of a database of patients admitted to a large district hospital in the United Kingdom over a period of two years showed lack of uniformity of recording patient's vital signs. The frequency of recording of observations was highest in the mornings and evenings and reduced overnight. This pattern was consistent throughout all the days of the week. The patients who were deemed sicker had more observations done regularly, although the follow up observations were less adhered to. Concerns for this were likely attributed to staffing shortages and the likelihood of staff to stick to specific observation times despite set guidelines, say before ward rounds or after ward round decisions. (Hands et al., 2013)

In a randomized trial on the use of early warning charts in a South African Hospital, EWS scoring charts were used to record vitals in the intervention wards while standard charts were used in the non-intervention wards. It was noted that there was a significant twenty-four fold increase in the measurement of respiratory rate in the intervention wards, as well as doubling of patients that had all their vital signs fully charted. (Kyriacos, Jelsma, James, & Jordan, 2015)

A retrospective study done in New Zealand looking at the value of EWS in detecting severe maternal morbidity (admission to the ICU, cardiothoracic or vascular intensive

care unit or the obstetric HDU) as an endpoint employed the use of patient vitals scores on a EWS chart. BY consensus, it was shown that around 8% of the identified cases could probably have had better outcomes with the use of EWS. It was noted that none of the patients had a complete set of recordings for respiratory rate, heart rate, blood pressure or temperature taken every time. Respiratory rate was the most ignored parameter, missing in 60% of ICU and in 91% of HDU vital sign recordings.(Austin et al., 2014)

In another study it was noted that, barriers that interfere with work flow and prevent prompt surveillance or interventions on patients affect the quality of MOES use. Human factors and ethnographic factors are some of the areas that need further evaluation to assess their impact on the utilization of MOEWS. (Mhyre et al., 2014)

A criteria-based audit done in Uganda to assess the impact of six interventions in reducing fetal and maternal deaths due to obstructed labour in a national referral hospital was carried out. The six interventions were intravenous fluids, intravenous antibiotics, monitoring of maternal vital signs, bladder catheterization, delivery within two hours, and blood grouping and cross matching. Initially, only 15% of patients had their blood pressure taken and only 17% a pulse rate record. No temperature had been recorded. A MOEWS chart system was introduced to evaluate the recording of maternal vital signs A re-audit after four months showed no improvement in the recording of vital these signs. Lack of essential tools for taking measurements, health-worker apathy and a large number of patients were fronted as possible reasons for these observations. (Kayiga, Ajeani, Kiondo, & Kaye, 2016)

In a large evaluation of the MOEWS systems in use, it was seen that majority of providers did not record vital signs frequently, with respiratory rate being the most ignored, despite showing great value in predicting outcomes. A high workload, health

workers ignoring the perceptibly well-looking patients and a view of probable over-intervention were some of the barriers that prevented vital sign measurement. (Smith et al., 2017)

In addition, in comparing the use of single-parameter score warning charts and multiple-parameter, it was found that charts that relied on multiple scoring parameters were more likely to have all parameters recorded in order to calculate the aggregate score. Respiratory rate was the most ignored vital sign in single-parameter charts. (Mhyre et al., 2014)

#### **2.4 The predictive ability of MOEWS for near miss or maternal mortality**

The MOEWS chart suggested for use by the CEMACH team has been used as a predictor of maternal outcomes in various settings.

The diagnosis of SMO, that is, maternal mortality and near-miss as defined by WHO near-miss criteria, is the gold standard for defining the end-point of interest against which the ability of the MOEWS to predict the same is measured.

A prospective study in the United Kingdom involving 676 women after delivery, aimed to evaluate the value of MOEWS as a predictor of obstetric morbidity. The MOEWS chart suggested by the CEMACH group was used in this study. Approximately one-third of patients triggered the MOEWS chart, with about 13% fitting the criteria for morbidity. The criteria of defining near miss or morbidity was however not pointed out clearly in this study. The MOEWS was found to be 89% sensitive, 79% specific, had a positive predictive value of 39% and negative predictive value of 98%. There was no mortality or ICU admission noted. The MOEWS was shown to be a valuable tool for predicting maternal morbidity. (Singh, Mcglennan, England, & Simons, 2012)

In another prospective study in India using the same MOEWS chart, among 1065 obstetric patients, 16% developed morbidity almost comparable to the study by Singh

and colleagues above. Hypertensive disease, anaemia, haemorrhage and sepsis were noted to be major contributors to obstetric morbidity. The MOEWS chart for the defined morbidity as per the study was found to be 86% sensitive, 85% specific, with PPV and NPV of 53% and 96% respectively. Again, a specific criteria of assigning morbidity was lacking in the study. (Guleria, Singh, & Jain, 2017)

In Uganda, a prospective cohort study to validate the CEMACH MOEWS as being able to correctly identify women at risk of developing obstetric morbidity in 2016 followed 502 mothers. This was one of the few studies on MOEWS use in low resource settings in East Africa. 32% of them triggered and 11% of them had the predefined obstetric morbidity, which was dependent on the clinician's diagnosis. MOEWS was 81% sensitive, 76% specific with PPV 36% and NPV of 96%. Of the mothers who triggered the MOEWS, just over one-third was due to postpartum haemorrhage while just over one-quarter was due to preeclampsia. However, in this study the definition of maternal morbidity as an end point was not explicitly stated and seemed to vary depending on the attending physician's judgment. (Otuu, Kizito, Daniel, & Peter, 2018)



In another retrospective cohort study in Colombia, which looked at the ability of the MOEWS chart developed by the NHS to predict mortality in critically ill patients, 702 patients admitted for critical care were evaluated. 4.1% of these mothers died. The mortality rate was found to be higher in patients who had higher MEWS scores. No women with MEWS score of 0 died, while mortality rate was 6.3% for women with scores above 6. The AUC value for discriminating maternal death was found to be 0.84. MOEWS was found to probably have value in predicting mortality in pregnancy and postpartum. (Paternina-caicedo et al., 2016)

In a retrospective cohort study among 364 to determine the ability of MEWS to determine maternal morbidity and mortality caused by obstetric sepsis (chorioamnionitis or endometritis), it was shown that six different MOEWS had low sensitivity of around 40%. This could however probably be attributed to statistical physiological range differences created during model development to accommodate all parameters owing to physiological changes in pregnancy. (Edward et al., 2015) A review of this study found this low sensitivity to be probably due to early intervention for chorioamnionitis using antibiotics empirically. (Page, 2015)

## **2.5 The association of individual vital signs that triggered the MOEWS charts and the occurrence of severe maternal outcomes**

In the auditing of maternal deaths, single parameter and multiple-parameter, also called aggregate scoring systems have been used. In single parameter models, a single vital sign, say heart rate is used to predict clinical deterioration in a patient. In a multiple parameter model, multiple vital signs are used to make up an aggregate score. The multiple parameter scores may be more sensitive in the overall prediction of a deteriorating patient since aggregate scores may trigger a response even though

individually they may not have been high enough to warrant an action. (Mcneill & Bryden, 2013)

In a prospective study that evaluated the ability of the NHS MOEWS chart to predict severe maternal outcome, the vital signs that triggered the chart most often were also assessed. The most frequent trigger was high blood pressure in 42% of the cases, followed by tachycardia at 28% and low blood pressure 18%. Temperature, respiratory rate and oxygen saturation (SPO2) were the least frequent triggers (6%, 4% and 2%, respectively). There was no correlation analysed between the individual vital signs and the occurrence of severe maternal morbidity. (Singh et al., 2012)

In addition, in a large prospective cohort study conducted in a tertiary hospital in Finland, the significance of the various vital signs in predicting adverse maternal outcomes for preeclampsia, PPH and puerperal sepsis was assessed in high risk, postnatal women. The three conditions were selected due to their large contribution to maternal morbidity and mortality. It was found out that red triggers independently were associated with near miss for all three conditions. Moreover, red triggers for systolic blood pressure and diastolic blood pressure were associated with preeclampsia, while a red trigger for heart rate was independently associated with PPH and puerperal sepsis. (Hannola et al., 2021)

In another review of literature, respiratory rate was found to be the best predictor of patient deterioration. In this case however the patient end point outcomes were not clearly defined as whether mortality or severe morbidity. An increased respiratory rate from baseline was the greatest predictor of non-survival, while those that had initial high respiratory rates that reduced were more likely to survive. This study however was done among general medical and surgical patients without particular analysis of obstetric patients. (Brekke et al., 2019)

Elsewhere, in a study to develop a model assessing the ability of the saturation of oxygen to predict adverse outcomes in women with preeclampsia, it was shown that women with SPO<sub>2</sub> of between 90% and 93% were 18 times more likely to suffer severe morbidity and mortality compared to women with saturations above 98%. In this group of women, SPO<sub>2</sub> was able to predict adverse outcomes with AUROC of 0.71. (Millman et al., 2010)

To the best of the author's knowledge, studies that assess the correlation between the individual vital signs in a multiple parameter scoring system as predictors of adverse maternal outcomes are limited.

## **2.6 Fetal Outcomes among Mothers who suffered Severe Maternal Outcomes**

In a bid to find out what the fetal outcomes of mothers who suffer severe morbidity or even die from obstetric complications, several studies have been carried out.

To begin with, in a prospective cohort study conducted in five public hospitals in Addis Ababa, Ethiopia aimed to assess the risk of adverse perinatal outcomes among mothers who had maternal near miss as per the WHO criteria. Among the 828 women followed up, 207 of them suffered maternal near-miss. When adjustment for confounders was done, it was found out that there was a five times risk of adverse perinatal outcome for mothers who suffered a near miss event. Such mothers had significantly increased risk for still birth, preterm birth, having low birth weight babies and risk of neonatal admission to neonatal intensive care. Mothers having a previous history of stillbirth and primary education or less also had higher risk of having an adverse perinatal outcome. (Liyew, Yalew, Afework, & Essén, 2018)

In a large, multicenter study done in Gambia, particular interest was given to infants born to mothers who had severe acute maternal morbidity (SAMM). The study looked

at data obtained retrospectively from hospitals attending to over half of all hospital births in the country. SAMM was defined using disease entity and management criteria. It was found out that the rate of still birth was 6 times higher in women who had SAMM compared to those who did not meet the criteria for SAMM. It was also noted that mothers with severe obstetric haemorrhage, sepsis and hypertensive disease had a higher incidence of still birth. Women with SAMM who had vaginal deliveries had a 4 times higher incidence of stillbirth compared to those with cesarean delivery. Among all still births, over two-thirds were among women with SAMM. Three quarters of macerated still births occurred in women who also had SAMM. (Cham, Sundby, & Vangen, 2009)

In addition, another study done to evaluate the association between quality of care in different districts in Rwanda and its association with SMO, with particular focus on characteristics of the patients and clinical outcomes was carried out. This was a prospective case control study carried out among centres providing care to around 10% obstetric patients nationally. Cases of SMO were defined by WHO criteria. Controls of similar demographic characteristics were used. It was found that for every maternal death, there were 16 patients with near miss. Moreover, after analysis, close to 90% of patients with SMO had the 5 life threatening conditions. Mothers who had stillbirths also had 181 times higher chance of having a SMO. (Sayinzoga et al., 2017)

Elsewhere, in a large countrywide study in the United Kingdom done among all hospitals caring for pregnant women, a large audit of all SMO cases was done. The study was aimed at assessing the risk factors and adverse neonatal outcomes associated with maternal deaths between 2009 and 2013. The cases were 383 mothers who died and controls were 1516 mothers. It was found out that mothers who died were 4 times more likely to have a stillbirth. Mothers who suffered mortality also had seven times

higher risk of admission to neonatal ICU. Maternal mortality was also associated with more babies dying in infancy. (Nair, Knight, & Kurinczuk, 2016)

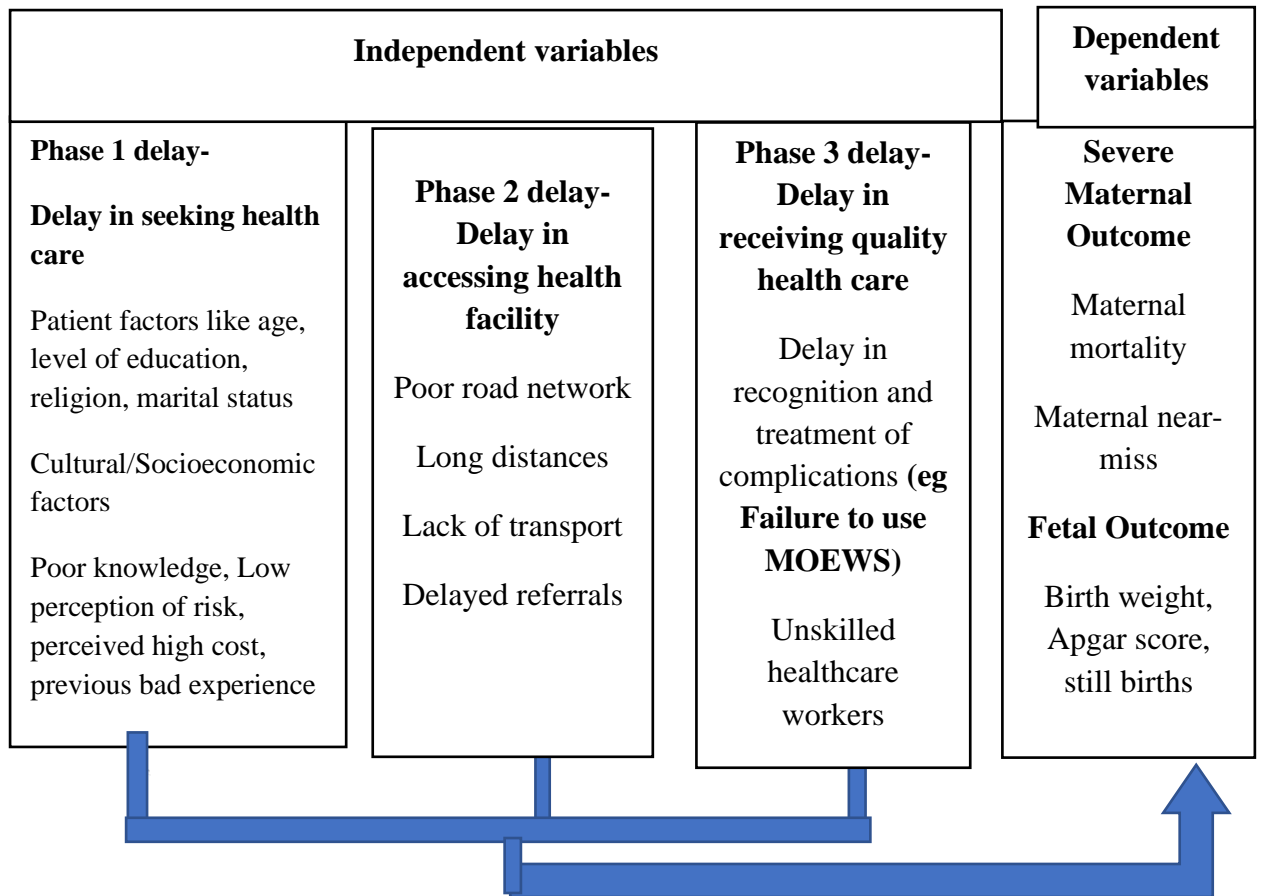
Additionally, the rate of still birth has been shown to increase with increasing maternal mortality. In a large review of literature looking maternal mortality and still births among 188 countries in terms of quality of care, there was seen to be an increase of 4 still births for every maternal death. There were noted disparities between low and middle income countries of 16 times and 5 times increases of stillbirths for every maternal death respectively. (Mcclure & Goldenberg, 2014)

Hypertensive disorders, specifically severe preeclampsia and eclampsia are among disease entities of disease which constitute life-threatening conditions according to WHO. The risk of stillbirth has been shown to increase up to seven-fold in patients with severe pre-eclampsia after 36 weeks. The rate of stillbirth is also double in patients with severe preeclampsia compared to patients with preeclampsia without severe features. Severe preeclampsia is also associated with a higher incidence of late preterm birth (babies born between 34-37 weeks gestation). These infants are at higher risk of respiratory complications. They are nine times more likely to have respiratory distress syndrome and eighteen times more likely to require neonatal ICU care compared to term newborns. (Backes et al., 2011)

Overall, it has been acknowledged that conditions that are related to poor maternal outcomes are inextricably linked to adverse fetal outcomes. (Mengistu et al., 2020)

## **2.7 Theoretical Framework**

Severe maternal outcome and by extension, neonatal outcome is the culmination of an interplay of many factors. The Three-Delay Model postulated by Thaddeus and Maine (1991) suggests that delays in seeking health care (first delay), delay in accessing a health facility (second delay) and delay of receiving quality care (third delay) interact and eventually cause severe fetal-maternal outcomes. The delays are caused by several factors. Patient factors such as age, level of education, marital status or socio-cultural background may impact on their decision to seek care. Infrastructural factors and delays in the referral process may affect the ability of the patient to access the healthcare facilities. The failure to detect patient deterioration and take corrective measures, as may be achieved using MOEWS charts constitutes a third delay, as may lack of equipment and skills among health care workers at the health facility. The interrelationship between the factors that determine fetal and maternal outcomes are depicted below. However, not all these factors could be tested due to methodological and temporal factors



## 2.7 Summary of Literature Review

From evidence, it has been shown that maternal deterioration is a predictable cascade that can be prevented. The development of a MOEWS system, taking into account the physiological changes in pregnancy, may be useful in this regard. The MOEWS systems have been largely developed and validated in high resource settings, and the development of MOEWS suited for low resource settings still remains underdeveloped.

Criteria for determining near-miss have been developed but their use is not uniform due to low resources, especially for laboratory-based criteria which is considered gold-standard. Therefore, the use of a combination of more accessible criteria such as clinical criteria, intervention-based criteria and disease-based criteria may be equally as effective for determining maternal near-miss or mortality.

Limited studies have explored the association between the various vital sign triggers on the MOEWS chart and this needs further evaluation. In addition, SMO has been associated with severe fetal outcomes, and this study will also assess what the association is in our setting.



## **CHAPTER THREE**

### **3.0 METHODOLOGY**

#### **3.1 Research Design**

The study was a retrospective cohort using prospectively collected data. The study was conducted using secondary data to externally validate a pre-developed MOEWS tool for predicting severe maternal outcome. Initially, before data collection, the maternal outcomes of having or not having SMO were determined to guide the period data needed to be collected, that is 24 hours before either outcome. Thereafter, all vital signs 24 hours were prospectively collected and plotted on the MOEWS chart.

#### **3.2 Study area**

The study was conducted at the Riley Mother and Child Hospital, Moi Teaching and Referral Hospital (MTRH), Eldoret. MTRH is currently the second largest National Teaching and Referral Hospital (level 6 Public Hospital) in the country with a bed capacity of 991 patients, an average number of 1200 patients at any time and about 1500 out patients per day. Moi Teaching and Referral Hospital is located along Nandi Road in Eldoret Town, Uasin Gishu County. The Hospital serves residents of Western Kenya Region, parts of Eastern Uganda and Southern Sudan with a population of approximately 24 million.

The Riley Mother and Baby Hospital is a 75,000 square feet division of MTRH dedicated exclusively to offering all-day-round specialised maternity and newborn care, including a neonatal ICU and two dedicated fulltime theatres. Over 12,000 deliveries are conducted at MTRH annually. Care at the hospital is offered by a large team of consultants, doctors on specialized training (fellows and residents), medical officers, medical officer interns, nurses and clinical officer interns. The hospital also has access

to other non-obstetric specialties, with an ICU and cardiac care unit. There is also an attached laboratory and blood transfusion service unit offering round the clock services.

### 3.3 Sample size estimation

The sample size was estimated using Buderer's formula (Buderer, 1996); where  
 $n(\text{sample size}) \text{ based on sensitivity} = [Z^2_{1-\alpha/2}(S_N)(1-S_N)] \div [L^2 \times (\text{Prevalence})]$  and  $n$  based  
 on specificity  $= [Z^2_{1-\alpha/2}(S_P)(1-S_P)] \div [L^2 \times (1-\text{prevalence})]$

where;

$S_N$  was the anticipated sensitivity of the chart

$S_P$  was the anticipated specificity of the chart

$1-\alpha$  was the size of the critical region (confidence level)

$Z_{1-\alpha/2}$  was the standard normal deviation corresponding to the critical region  $\alpha$

$L^2$  was the absolute precision desired on either side (5%)

According to the MOEWS chart, the expected sensitivity and specificity was 89% and 79% respectively according to a validation study by Singh and colleagues. (Singh et al., 2012). The rate of severe maternal outcome in a study by Watau and colleagues at Kenyatta National Hospital, a large referral hospital in Kenya was found to be approximately 4.7%. (Watau, Odawa, & Ong'ech, 2013)

Therefore, using sensitivity  $n = [1.96^2 \times 0.89 \times (1-0.89)] \div [0.05^2 \times 0.047] = 3200$

Using specificity  $n = [1.96^2 \times 0.79 \times (1-0.79)] \div [0.05^2 \times (1-0.047)] = 267$

Therefore the sample size required was 3200 patients.

### **3.4 Sampling technique**

A census of all consecutive admissions that occur at RMBH or the Intensive Care Unit (ICU) or Cardiac Care Unit during the duration of the study was done until the required sample size was achieved. The study encompassed all patients admitted consecutively from 1<sup>st</sup> January 2019 until the sample size was achieved.

The inpatient (IP.) numbers for all patients admitted and discharged or died during the duration of the study were obtained in order of date of admission. The files were then obtained from the records department and assessed for completeness before inclusion into the study.

### **3.5 Target population**

The study included mothers who were admitted to the hospital either to the labour ward, antenatal wards, postnatal wards or the critical care unit, from 28 weeks gestation to 6 weeks after delivery. This included walk-in patients from home and referrals.

### **3.6 Study population**

This was made up of all mothers who were consecutively admitted to the hospital during the study period with a gestation of 28 weeks to 42 days postpartum.

### **3.7 Eligibility criteria**

#### **3.7.1 Inclusion criteria**

1. All women who were at 28 weeks of gestation diagnosed by either the last menstrual period or obstetric ultrasound scan and those up to 42 days postpartum admitted to the RMBH labour ward, antenatal, postpartum ward, the high dependency unit (HDU) or intensive care unit (ICU) were included.

2. These patients must also have had their vital signs routinely recorded prior to discharge or death.

### **3.7.2 Exclusion criteria**

1. Women without recorded estimated gestation by date either by dates or any trimester ultrasound were excluded from the study.
2. Women with incomplete vital signs for systolic blood pressure, diastolic blood pressure, pulse rate, respiratory rate, temperature or oxygen saturation at admission and 24 hours before occurrence of SMO or discharge were be excluded from the study.
3. Women whose outcomes at discharge (alive or dead) were not clearly stated were also excluded.

### **3.8 Data sources**

Patient admission files served as the primary source of all the data. The patient vital signs were collected from the MTRH admission booklets, daily vital signs observation charts, dated and signed daily or major ward round notes, nurse's daily cadex, intra-operative observations in theatre and post-anaesthesia care unit (PACU) observation charts. After determining the date and time of occurrence of SMO or discharge for patients without SMO, the vital signs recorded for the duration of 24 hours prior to either event were recorded on a MOEWS chart labeled with the patient's initials, parity and inpatient (IP) number. The time and date that the vitals were taken and the absolute values of vitals were filled from the earliest to the latest for the period of 24 hours up to when the patient suffered SMO or was discharged. All vital signs taken in that 24-hour period were filled in regardless of the interval they were taken. They were then assessed if they counted as triggers or not depending on the colour-coded area of the chart they fall on.

### **3.9 Data Collection Tools**

The colour-coded MOEWS chart recommended by the CEMACH group (Chart 1) was used for assessing for triggers by the vital signs recorded in the data sources for patient vital signs.

A data abstraction tool was used to collect data on the patient's demographic characteristics, obstetric history, the length of hospital stay, maternal and neonatal outcomes. It was used to record whether SMO occurred or did not occur, and the type of SMO, either mortality or near miss. The clinical and intervention-based and disease-based criteria was used to determine maternal near miss for all cases. For the disease-based criteria, patients who suffered any of the 5 life threatening conditions, that is, severe preeclampsia, eclampsia, severe postpartum hemorrhage, severe sepsis and ruptured uterus were recorded as maternal near miss. The actual value of measured parameters or type of intervention was also recorded. Patients who on review are recommended for admission to the intensive care unit (ICU) were recorded as having SMO, whether they got an admission space in the facility or not. Neonatal outcomes were recorded from the delivery notes or from clinician notes. Any patient readmitted was started on a new MOEWS chart for that admission.



### **3.11 Data collection procedure**

Consecutive patients admitted to the labour ward, antenatal ward, postnatal wards, intensive cardiac unit (ICU), High Dependency Unit (HDU) and cardiac care unit (CCU) during the duration of the study were included in the study. All complete files including laboratory results and treatment sheets were obtained from the records department and analysed. Files that had missing vital sign records or maternal outcomes at discharge were excluded. The maternal outcomes were recorded as SMO/ no SMO and the type of SMO specified. The MOEWS chart recommended by the CEMACH 2007 group was used to record all vital signs taken for patients for the period of 24 hours before and up to when SMO occurred. For patients without SMO, the vital signs recorded were for the period of 24 hours prior to discharge. A password protected Microsoft Access database was constructed, accessible only to the PI, the statistician and the data entry clerks. The principal investigator (PI), and the research assistants would routinely cross-check the data for completeness.

#### **3.9.1 Filling in the MOEWS chart**

The chart used had the patients Inpatient (IP) number, initials of their name, ward first admitted to; (antenatal, postnatal, labour ward, ICU, HDU or CCU) and date of birth. The date and time the vital signs were taken were also recorded. The vital signs recorded were systolic blood pressure, diastolic blood pressure, heart rate, respiratory rate, temperature and oxygen saturation (SPO<sub>2</sub>). Vital signs included were for the 24-hour period prior to occurrence of SMO for patients with morbidity or mortality. For patients with no SMO at discharge, vital signs were recorded for 24 hours or less before discharge. A different chart was used for any readmissions of the same patient and filled appropriately.

### 3.9.2 Determining Triggers

A trigger is a vital sign that warns a healthcare worker either to increase monitoring of a patient or take further escalation action towards the care of that patient. (Shields et al., 2016) The CEMACH MOEWS tool uses a range of vital sign ranges. The ranges are colour coded, with white being deemed normal ranges, yellow denoting mildly elevated values and red denoting severely elevated values. A trigger in this chart was denoted as either a combination of at least two mildly elevated (yellow) vital sign measurements of two different vital sign parameters taken at the same time (for example, a yellow vital sign measurement on heart rate and a yellow one of respiratory rate constitute a trigger) or one severely elevated (red) vital sign measurement. The value of the vital sign was marked with an x on the column of the date and time the vital sign was taken. The value of the individual vital sign was taken as a trigger or not depending on the colour code it fell on. The value of each vital sign was recorded on the data abstraction sheet, stating whether it fell on the white, yellow or red zones. Aggregation of all the vital signs were to determine a trigger as stated above.

**Table 2: Vital sign ranges used to define MOEWS chart triggers**

<b>VITAL SIGN (UNITS IN BRACKETS)</b>	<b>NORMAL VALUE</b>	<b>YELLOW TRIGGER</b>	<b>RED TRIGGER</b>
<b>Systolic blood pressure (mmHg)</b>	100 to 150	>90 to <100 and >150 to 160	<90 and >160
<b>Diastolic blood pressure (mmHg)</b>	<90	>90 to 100	>100
<b>Temperature (degrees Celsius)</b>	36 to 38	35 to <36	<35 and >38
<b>Heart rate (beats per minutes)</b>	50 to 100	>40 to <50 and >100 120	<40 and >120
<b>Respiratory rate (breaths per minute)</b>	11 to 20	21 to 30	0 to 10 and >30
<b>SPO2 (%)</b>	95 to 100		<95

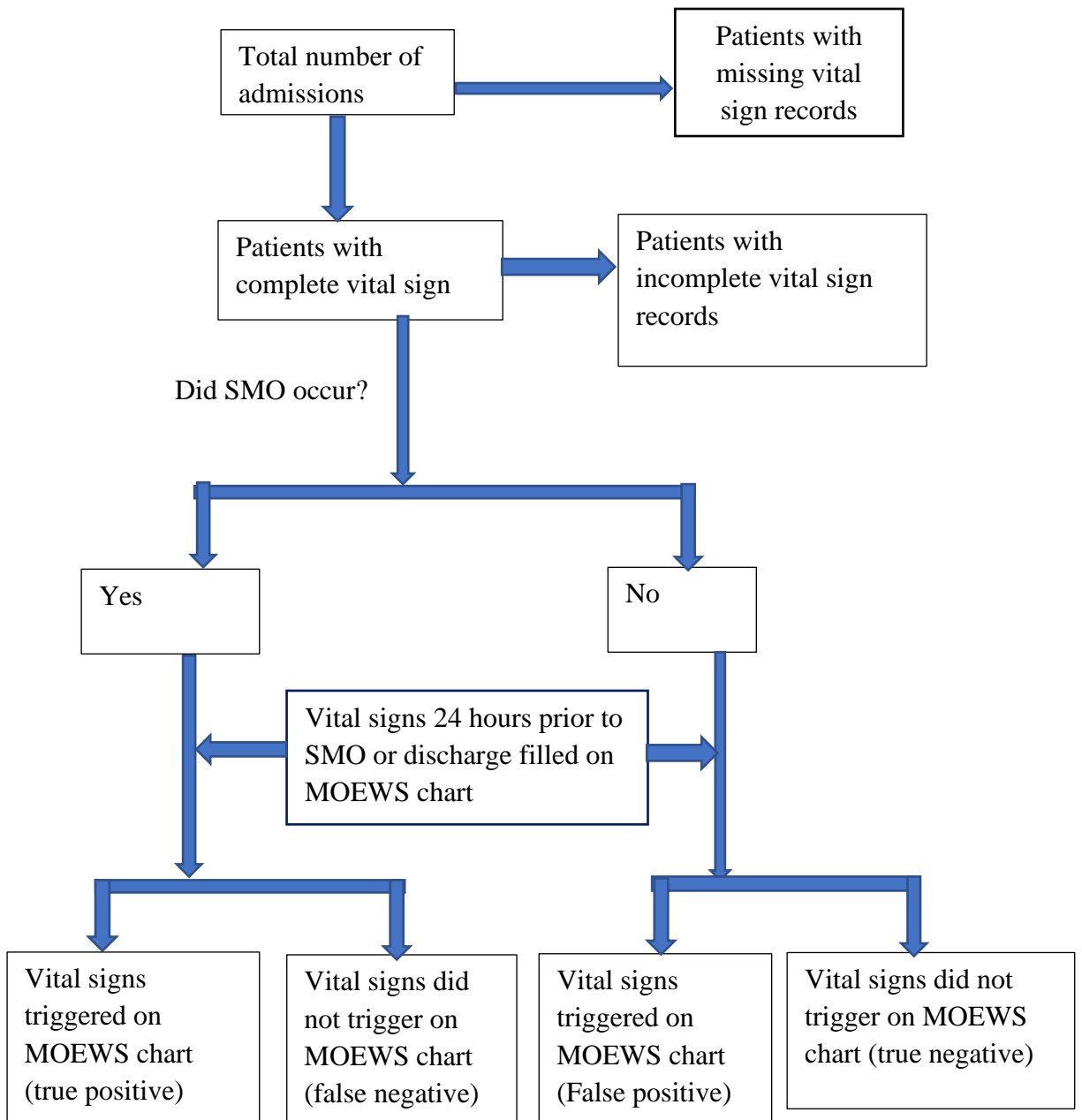


### **3.9.3 Determination of True Positive (TP), False Positive (FP), True Negative (TN) and False Negative (FN)**

For any patient who had SMO and any of their vital signs for the last 24 hours prior to occurrence of SMO constituted a trigger on the MOEWS chart, that is, one red level vital sign measurement or two yellow level measurements of two different vital sign parameters, then that measurement was taken as a true positive. On the contrary, any patient who had SMO and whose vital signs over the last 24 hours prior to its occurrence did not constitute a trigger on the MOEWS chart was considered a false negative.

Additionally, if any patient did not suffer SMO, and their vital signs over the last 24 hours prior to discharge did not constitute any trigger on the MOEWS chart, they were considered as true negative. Lastly, if a patient did not suffer SMO and their vital signs over the last 24 hours prior to discharge had any trigger, they were determined to be false positive.

The method of this determination of these values is summarized in the flow diagram below



**Figure 1: Flow of data collection procedure**

### **3.10 Outcomes**

#### **3.10.1 Primary Outcome**

The primary outcome was determined as the occurrence of SMO, that is, mortality or near miss as defined by the WHO clinical and intervention-based criteria. Near misses were not recorded using laboratory based criteria alone in absence of either clinical or intervention-based criteria. (Refer to Table 1)

#### **3.10.2 Secondary outcomes**

Secondary outcomes were;

1. Fetal outcomes for patients with SMO

Fetal outcomes for these patients including birth weight, gender, mode of delivery, whether live birth, fresh still birth or macerated still birth, five (5) and ten (10) minute APGAR (Appearance, Pulse, Grimace, Activity, respiration) scores and admission to a new born unit were all recorded.

### **3.12 Data Analysis and reporting**

The characteristics of the study population were summarized by measures of dispersion (means and standard deviations or medians and interquartile range) for continuous data and percentages for categorical data. Fishers exact test and chi-square test were used to test associations between variables.

The primary outcome (maternal near-miss by WHO criteria or mortality) was classified as a binary variable (occurred/did not occur) as derived from the patient's records. The sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were calculated as follows;

Sensitivity= [true positive/ (true positive + false negative)] ×100%

Specificity= [true negative/ (true negative+ false positive)] ×100%

PPV= [true positive/ (true positive + false positive)] × 100%

NPV= [true negative/ (true negative + false negative)] × 100%

The secondary outcome was summarized as continuous variables and analyzed by measures of dispersion and central tendency. Frequency tables were used to describe categorical outcomes. Chi square test was used to calculate the significance of the association between the vital signs and the occurrence of severe maternal outcomes. The association between the individual vital signs and the occurrence of near miss, mortality or both was determined using logistic regression. In addition, classification and regression trees were used to assess the vital signs based on MOEWS that best predict SMO.

All analyses were performed at 95% level of confidence.

### **3.13 Publication and dissemination**

The knowledge obtained through this study will be shared with health service providers as evidence for best practice and disseminated through publication and conferences. Confidential information will not be shared.

Authorship on publications, conference presentations, abstracts and other materials generated from this study will reflect contribution to design, execution, ethical considerations and analysis of the study.

### **3.14 Ethical considerations**

Written permission was obtained from the MTRH management to conduct the study in the institution. A study protocol was submitted for approval by the Institutional Research and Ethics Committee (IREC). Any alterations in the study protocol were reported to IREC.

All patient data was collected in confidence and stored in locked cabinets. Any information in soft copy was password protected and kept offline as much as possible, and was not shared or used elsewhere without IREC or MTRH management approval.

## CHAPTER FOUR

### 4.0 FINDINGS

#### 4.1 RESULTS

**Table 3: Patient demographic characteristics**

Variable	Category	Frequency	Percentage
Age at admission	Mean (SD)	26.1 (5.6)	
Age group	≤19	250	7.8
	20 -34	2686	83.6
	≥ 35	277	8.6
Marital status	Married	2506	78.0
	Never married	668	20.8
	Divorced	31	1.0
	Widowed	8	0.2
Highest Level of education reached	None	97	3.0
	Pre-primary	38	1.2
	Primary	672	20.9
	Secondary	1413	44.0
	Tertiary	993	30.9

According to Table 3, the average age of patients was 26.1 (SD 5.6) and this ranged from 13 to 46 years. Majority of mothers (83.6%) were aged 20-34 years, with those below 19 years being 7.8%. It was also found that 8.6% of mothers were above 35 years. Majority of patients (78%) were married followed by those who were single (20.8%). Very few (4.2%) had not attained primary education level, while 30.9% had attained tertiary level of education.

**Table 4: Maternal Obstetric characteristics among the admitted patients**

Variable	Category	Frequency	Percentage
Parity	0	1446	45.0
	1	830	25.8
	2 – 4	857	26.7
	≥5	80	2.5
Previous pregnancy outcome	Term live birth	1622	86.3
	Abortion	188	10.0
	Still birth	33	1.8
	Preterm live birth	37	1.9
Delivery mode in previous pregnancy	SVD	1443	85.2
	C/S	250	14.8
Period of current Admission	28 – 36 wks	467	14.5
	≥37 wks	2717	84.6
	Postpartum	29	0.1

As per the table 4, most of the patients screened (45%) were nulliparous while 2.5% of patients had at least 5 or more deliveries. In the previous pregnancy, 86.3% delivered term live births, 10% had abortions and 1.9% had preterm live births. For those that had delivered in the previous pregnancy, majority (85.2%) of the patients delivered vaginally. Over four-fifths (84.6%) were admitted in the most recent pregnancy at or beyond 37 weeks gestation.

**Table 5: Maternal mode of admission and antenatal care attendance among admitted patients**

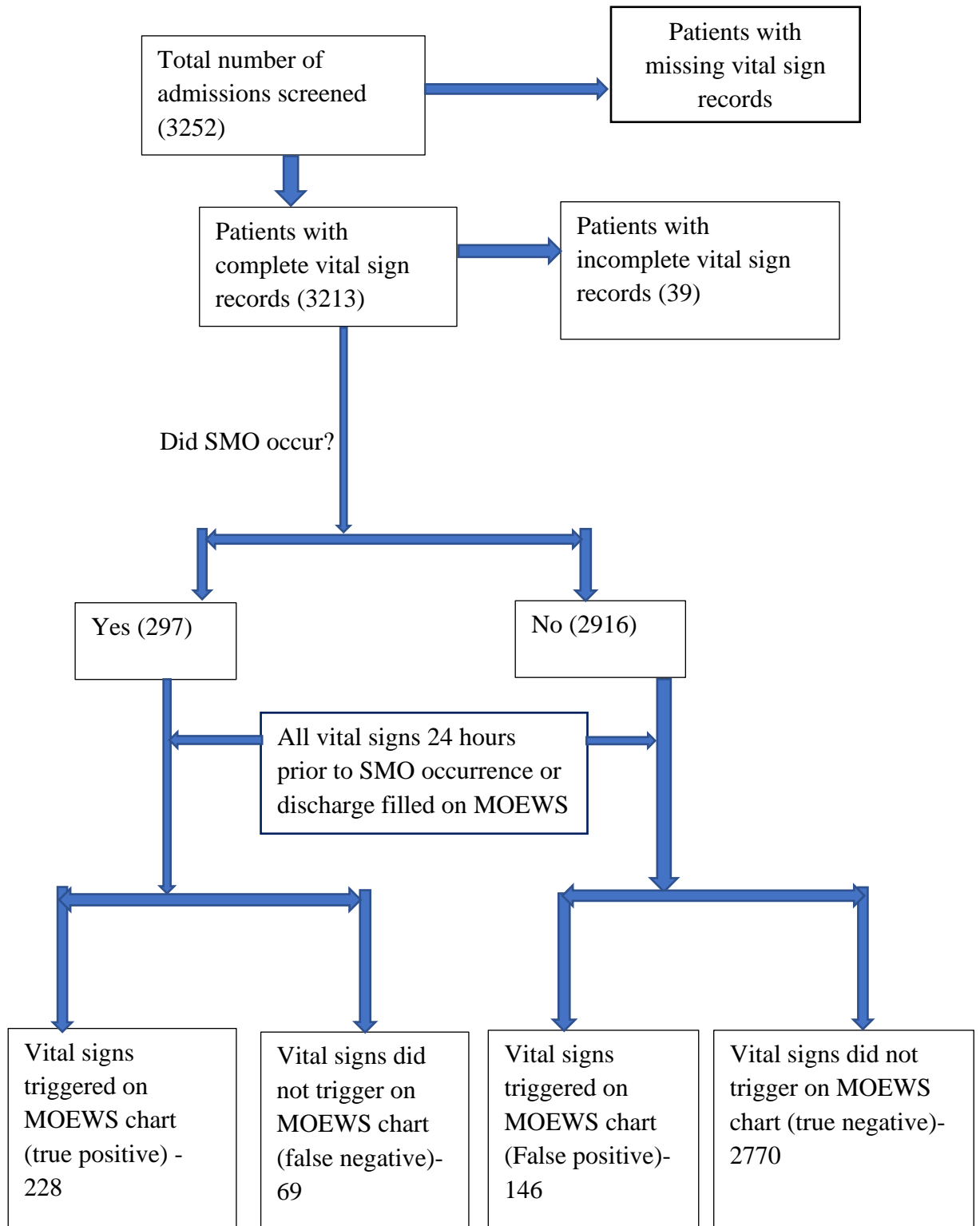
Variable	Category	Frequency	Percentage
Admission mode	From home	3125	97.3
	Referral	88	2.7
Time from decision to refer to admission at MTRH(Hrs)	Median	140 (75, 210)	
ANC attendance	No	44	1.4
	Yes	3164	98.6
ANC Hemoglobin	≥11	2526	79.5
	<11	651	20.5
VDRL	Negative	3172	99.8
	Positive	7	0.2
HIV status	Negative	3106	97.7
	Positive	73	2.3
Place admitted	Antenatal ward	1599	49.8
	Labour ward	1579	49.1
	Postnatal ward	27	0.8
	Cardiac unit	6	0.2
	ICU / HDU	2	0.1
Rhesus factor	Negative	58	1.8
	Positive	3119	98.2

Only 2.7% of the patients came to the hospital as referrals and the average decision-to-arrival time was 140 minutes (CI 75 to 210). Almost all patients (98.6%) had attended ANC at least once. At antenatal care, hemoglobin was at least 11gm/dL for 79.5% of the patients, VDRL and HIV tests were positive for 0.2% and 2.3% respectively. Of the total patients, 49.8% were admitted in antenatal ward while 49.1% were admitted in labour ward. Majority (98.2%) of the patients screened were rhesus positive. This information is summarized in the Table 5.



#### **4.1.1 Distribution of patients into True Positive, False positive, True Negative and True Positive**

In order to be able to expose the requisite sample size of patients to the MOEWS chart, 3252 patient records were screened. Of these, 3213 patients met the inclusion criteria and 39 records were found to be incomplete with missing vital signs for the duration of 24 hours prior to discharge or occurrence of severe maternal outcome. Of the 3213 patients reviewed, 297 patients had SMO while 2916 did not. The distribution of the test parameters (true positive, false positive, true negative and false negative is summarized in the Figure 2 below.



**Figure 2: Flow chart of summary of results**

**Table 6: Maternal outcomes**

Variable	Category	Frequency	Percentage
SMO occurrence	No	2,916	90.8
	Yes	297	9.2
SMO type	Near miss	291	98.0
	Mortality	6	2
If patient suffered from a potentially life threatening condition	No	2,977	92.6
	Yes	236	7.4
Life-threatening conditions among all SMO cases	Severe PET	164	55.2
	Severe PPH	39	13.1
	Sepsis	18	6.0
	Eclampsia	5	1.7
	Ruptured uterus	5	1.7
Where SMO occurred	At MTRH	267	90.5
	At referring facility	30	9.5

According to the Table 6, there were 297(9.2%) patients who suffered SMO, majority of whom (98%) were cases of near miss. Of all the patients with SMO, 6 (2%) died. There were 291 patients out of the 3213 patients screened who had near miss, giving an overall near miss rate of 9%. A greater proportion (90.5%) of the SMO occurred at MTRH, while only 9.5% of the SMO occurred at the referring facility prior to referral. Among all patients with near-miss, the 5 major life-threatening conditions were the attributable cause in 236 (81%) of them. Overall, severe PET was the most common cause of SMO at 55%. This was followed by severe PPH at 13.3%.

### Calculation of Maternal near-miss indicators

The intra-hospital maternal mortality ratio, that is the approximate number of maternal deaths per 100,000 live births was calculated as follows:

$\frac{\text{number of maternal deaths}}{\text{total number of live births}} \times 100,000$ ; therefore  $\frac{6}{3033} \times 100,000$ . This was found to be 197 per 100,000 live births.

The severe maternal outcome ratio (SMOR) refers to the total number of patients with SMO (maternal deaths and near miss) per 1000 livebirths. This was calculated as follows:  $\frac{\text{total number with SMO}}{\text{Total number of live births}} \times 1000$ ; therefore  $\frac{297}{3033} \times 1000$  in an SMOR of 9.8 per 1000 live births.

The maternal near-miss ratio (MNMR), refers to the number of mothers with near miss per 1000 live births. This was calculated as follows:  $\frac{\text{total number of near-miss cases}}{\text{total number of live births}} \times 1000$ ; therefore  $\frac{291}{3033} \times 1000$  giving a MNMR of 9.5 per 1000 live births.

The maternal near miss mortality ratio, which is the ratio of maternal near miss to maternal death (MNM:MD) was calculated as follows:  $\frac{291}{6}$  and found to be 48.5, meaning that for every one patient who died, around 48 patients had a near-miss. The higher the maternal near miss to mortality ratio, the more likely a very sick mother is likely to survive and also may point to better quality healthcare. A maternal near miss mortality ratio that trends downwards towards 1 means as many sick mothers die as those who survive.

The mortality index refers to the number of maternal deaths expressed as a percentage of all patients with SMO (maternal near miss + maternal mortality). Lower percentages mean a smaller number of critically ill patients die, while on the contrary, higher percentages mean a larger percentage of critically ill patients die. It is a pointer of the quality of health care. This was calculated as follows:  $\frac{\text{total maternal deaths}}{\text{total patients with SMO}} \times 100$  ;

therefore,  $\frac{6}{297} \times 100$ , giving a mortality index of 2%. While as the WHO does not set a limit as what a good or acceptable mortality index is, mortality index is used by individual facilities to track their progress in terms of SMO outcomes over time, where decreasing percentages indicate improvement in patient care.

**Table 7: Occurrence of SMO by demographic and obstetric characteristics and antenatal care attendance**

Variable	Category	SMO		p-value
		No	Yes	
Age	≤19	237(94.8%)	13 (5.2%)	0.033 <sup>c</sup>
	20 -34	2449(91.2%)	237(8.8%)	
	≥ 35	240(86.6%)	37(13.4%)	
Marital status	Married	2269(90.5%)	237(9.5%)	0.849 <sup>f</sup>
	Never married	611(91.5%)	57(8.5%)	
	Divorced	28(90.3%)	3(9.7%)	
	Widowed	8(100%)	0	
Highest Level of education reached	Primary or below	716(88.7%)	91(11.3%)	0.018 <sup>f</sup>
	Secondary	1300(92%)	113(8%)	
	Tertiary	890(89.6%)	103(10.4%)	
Parity	0	1317(91.1%)	129(8.9%)	0.737 <sup>c</sup>
	1	751(90.5%)	79(9.5%)	
	2 – 4	778(90.8%)	79(9.2%)	
	≥5	70(87.5%)	10(12.5%)	
Delivery mode in previous pregnancies	All SVD	1326(91.8%)	117(8.2%)	<0.001 <sup>c</sup>
	Previous CS	208(83.2%)	42(16.8%)	
Delivery mode in index pregnancy	SVD	2136(93.1%)	158(6.9%)	<0.001 <sup>c</sup>
	C/S	681(84.8%)	122(15.2%)	
Timing of admission	28-36 weeks	388(83.1%)	79(16.9%)	<0.001 <sup>c</sup>
	37-42 weeks	2429(92.8%)	192(7.2%)	
	>42 weeks	88(92.1%)	7(7.9%)	
	Postnatal	17(58.6%)	12(41.4%)	
Admission mode	From home	2858(91.5%)	267(8.5%)	<0.001 <sup>c</sup>
	Referral	58(65.9%)	30(34.1%)	
ANC attendance	No	25(78.1%)	7(21.9%)	0.021 <sup>f</sup>
	Yes	2888(91.1%)	282(8.9%)	
ANC Hemoglobin	≥11	2314(91.6%)	212(8.4%)	0.013 <sup>c</sup>
	<11	576(88.5%)	75(11.5%)	
HIV status	Negative	2828(91.1%)	278(8.9%)	0.301 <sup>c</sup>
	Positive	64(87.7%)	9(12.3%)	

<sup>c</sup> Chi Square

<sup>f</sup> Fisher Exact test

Among patients who were aged 19 years and below, 5.2% of them developed SMO, while as, among women aged 40 years and above a greater proportion (13.4%)

developed SMO. Age was significantly associated with the occurrence of severe maternal outcome. ( $p=0.033$ ) There was a significant difference ( $p>0.001$ ) between the proportion of mothers who got SMO and had previous deliveries who delivered via caesarean section and those who delivered via SVD (16.8% versus 8.2%). In addition, among women who delivered via SVD in the current pregnancy, 6.9% of them got SMO compared to 15.2% of the women who delivered via caesarean section and this difference was significant statistically. ( $p<0.001$ ) Among mothers admitted at 37 weeks gestation or more, 7.2% got SMO, compared to 41.4% of those admitted in the postpartum period, and this difference was statistically significant ( $p<0.001$ ). Likewise, the differences between patients who came in as referrals and those from home, those who attended antenatal care and those who did not and those who had antenatal hemoglobin of less than or above 11mg/dl were all statistically significant ( $p<0.05$ )

Marital status, parity and HIV status were not significantly associated with severe maternal outcome. This is summarized in Table 7.

**Table 8: Predictors of Severe Maternal Outcomes**

Variable	Category	SMO		aOR	95% CI	p-value
		No n(%)	Yes n(%)			
Age	20 -34	2449(91.2)	237(8.8)	Ref		
	≤19	237(94.8)	13 (5.2)	0.44	0.22-0.87	0.019
	≥ 35	240(86.6)	37(13.4)	1.56	1.05-2.32	0.027
Highest Level of education reached	Tertiary	890(89.6)	103(10.4)	Ref		
	Primary and below	716(88.7)	91(11.3)	1.11	0.97-2.18	0.718
	Secondary	1300(92)	113(8)	0.80	0.58-1.06	0.119
Delivery mode index pregnancy	SVD	2136(93.1)	158(6.9)	Ref		
	C/S	681(84.8)	122(15.2)	2.19	1.68 – 2.85	<0.001
Delivery mode in previous pregnancies	All SVD	1326(91.8)	117(8.2)	Ref	1.52-2.91	<0.001
	Previous CS	208(83.2)	42(16.8)	2.09		
Maternal period of admission	37-42 weeks gestation	2429(92.8)	193(7.2)	Ref		
	28-36 weeks gestation	388(83.1)	79(16.9)	2.81	2.08-3.80	<0.001
	>42 weeks gestation	88(92.1)	7(7.8)	0.96	0.53-1.24	0.463
	Postnatal	17(58.6)	12(41.4)	51.38	10.30-256.39	<0.001
Admission mode	From home	2858(91.5)	267(8.5)	Ref		
	Referral	58(65.9)	30(34.1)	3.43	1.94 – 6.05	<0.001
ANC Hemoglobin	≥11	2314(91.6)	212(8.4)	Ref		
	<11	576(88.5)	75(11.5)	1.36	1.00 – 1.83	0.047
ANC care	Yes	2889(91.1)	282(8.9)	Ref		
	No	25(78.1)	7(21.7)	2.54	1.36-4.32	<0.001

From table 8, patients aged 35 years or older had a 56% more chance of sustaining SMO compared to those aged 20 to 34 years, keeping education level, mode of delivery of the index pregnancy, timing of admission, mode of admission and ANC hemoglobin constant. On the contrary, patients aged 19 years and below were found to have a 56%

less chance of getting SMO compared to those aged 20 to 34 years. This cohort of patients were also significantly lower in number among all the patients screened.

Patients who had only primary school education or lower had an increased 10% chance of sustaining SMO holding all other factors constant, though this was not statistically significant. Likewise, having achieved secondary education was associated with a 20% less risk of sustaining SMO, although this was also not statistically significant.

Patients who were delivered via caesarean section in the index pregnancy were 2.2 times more likely to develop SMO compared to those who delivered via vertex delivery holding all other variables constant. Patients who had any of their previous delivery via caesarean section were also twice as likely to develop SMO compared to those without caesarean section delivery in their previous pregnancies.

Patients who were admitted at between 28 to 36 weeks gestation had a 2.8 times likely risk of developing SMO compared to those who delivered at 37 to 42 weeks and this association was statistically significant ( $p < 0.001$ ) Likewise, patients who were admitted in the postnatal period had a 51 times risk of developing SMO compared to those admitted at 37 to 42 weeks, keeping all other variables constant. In addition, patients who came in as referrals had a 3.4-fold risk of having SMO compared to those from home, holding all other factors constant, and this was statistically significant. ( $p < 0.001$ ) Patients who had an antenatal haemoglobin of less than 11 had a 36% chance of having SMO, keeping all other variables constant. This also had statistical significance ( $p = 0.047$ ).

Holding all other factors constant, failure to attend antenatal care was associated with a two and a half increased risk of getting SMO and this was statistically significant. ( $p < 0.001$ )



The factors that were significantly associated with increased likelihood of getting SMO were age over 35 years, delivery by caesarean section in the index pregnancy, delivering via caesarean section in a previous pregnancy, admission at gestation between 28 to 36 weeks, coming to the hospital as a referral and antenatal hemoglobin of less than 11.

**Table 9: Predictive ability of MOEWS for near miss and maternal mortality**

	SMO	NO SMO	Total	
<b>MOEWS TRIGGER</b>	228	146	374	<b>Sn = 76.77</b>
<b>NO MOEWS TRIGGER</b>	69	2770	2839	<b>Sp = 94.99</b>
<b>Total</b>	297	2916	3213	<b>PPV = 60.96</b>
				<b>NPV = 97.57</b>

Sn = Sensitivity

Sp = Specificity

PPV = positive predictive value

NPV = Negative predictive value

From the results shown in Table 9, the sensitivity of the MOEWS chart was found to be 76.8%. This means that there is a 77% probability that the MOEWS will be positive (trigger) for any patient who would eventually develop a severe outcome. On the contrary, 23% of the time, there will be no MOEWS trigger for patients who develop SMO.

The specificity of the MOEWS tool for SMO was found to be 94.9%; that is, there is approximately a 95% chance that there will be no MOEWS trigger for patients who do not develop SMO. Conversely, there is a likelihood of 5% that the MOEWS chart will trigger in absence of SMO.

The positive predictive value of the MOEWS chart was found to be 60.9%. It follows that if the MOEWS chart triggers as positive, there is a 61% probability that the woman will have SMO.

Lastly the negative predictive value of the chart was found to be 97.5%. This means that if the MOEWS chart is negative (no trigger) there is 97% probability that the patient will not suffer SMO.

**Table 10: Association of red trigger, yellow trigger and no trigger with the occurrence of SMO**

Variable	Category	SMO		Total
		No	Yes	
Heart rate	None	2,900 (92.9%)	225 (7.1%)	<0.001 <sup>f</sup>
	Yellow trigger	12 (30.0%)	28 (70.0%)	
	Red trigger	8 (15.4%)	44 (84.6%)	
Respiratory rate	None	2,907 (91.8%)	263 (8.2%)	<0.001 <sup>f</sup>
	Yellow trigger	8 (38.1%)	13 (61.9%)	
	Red trigger	5 (19.2%)	21 (80.8%)	
Temperature	None	2,912 (90.9%)	295 (9.1%)	0.230 <sup>f</sup>
	Yellow trigger	6 (85.7%)	1 (14.3%)	
	Red trigger	2 (66.7%)	1 (33.3%)	
SPO2	None	2,918 (91.2%)	287 (8.8%)	<0.001 <sup>f</sup>
	Yellow trigger	1 (20.0%)	4 (80.0%)	
	Red trigger	1 (14.3%)	6 (85.7%)	
Systolic blood pressure	None	2,900 (94.3%)	179 (5.7%)	<0.001 <sup>c</sup>
	Yellow trigger	13 (22.0%)	46 (78.0%)	
	Red trigger	7 (8.9%)	72 (91.1%)	
Diastolic blood pressure	None	2,905 (94.7%)	169 (5.3%)	<0.001 <sup>f</sup>
	Yellow trigger	6 (12.2%)	43 (87.8%)	
	Red trigger	9 (9.3%)	88 (90.7%)	

A significantly greater proportion of patients with red triggers compared to yellow triggers and those without any trigger at bivariate level were associated with occurrence of SMO for heart rate, respiratory rate, SPO2, systolic blood pressure and diastolic blood pressure. ( $p < 0.01$ ). Likewise, a greater proportion of patients with red triggers for temperature had SMO compared to yellow triggers or no triggers but this was not statistically significant. This information is summarized in Table 10.

**Table 11: Individual vital sign triggers on the MOEWS chart and their association with occurrence of SMO**

Variable	Category	aOR	p-value	95% CI
Heart rate	None	1		
	Yellow/red trigger	30.615	<0.001	15.523 – 60.380
Respiratory rate	None	1		
	Yellow/red trigger	3.363	0.040	1.055 – 10.718
Temperature	None	1		
	Yellow/red trigger	0.126	0.116	0.009 – 1.670
SPO2	None	1		
	Yellow/red trigger	13.488	0.063	0.867 – 209.757
Systolic blood pressure	None	1		
	Yellow/red trigger	12.8001	<0.001	6.262 – 26.169
Diastolic blood pressure	None	1		
	Yellow/red trigger	45.803	<0.001	22.949 – 91.413

From the Table 11, heart rate, respiratory rate, systolic blood pressure and diastolic blood pressure were the individual vital signs that were independently associated with occurrence of severe maternal outcome. When a patient triggered the MOEWS chart for heart rate, there was a 30 times more likelihood of having SMO as compared to a patient who did not. Likewise, a trigger for respiratory rate was associated with a three-time increased likelihood of developing SMO. Triggers for systolic blood pressure and diastolic blood pressure were associated with 12 times and 45 times risk of developing SMO respectively.

**Table 12: Association between severe maternal outcomes and fetal outcomes**

Variable	Category	SMO		p-value
		No	Yes	
Fetus outcome	Live birth	2776 (91.5%)	257(8.5%)	<0.001 <sup>c</sup>
	Fresh still birth	24 (63.2%)	14 (36.8%)	
	Macerated still birth	35 (89.7%)	4 (10.3%)	
5 minutes APGAR score	≤3	9(81.8%)	2(18.2%)	0.013 <sup>f</sup>
	4 – 7	115(85.2%)	20(14.8%)	
	8 – 10	2646(91.8%)	236(8.2%)	
10 minutes APGAR score	≤3	7(87.5%)	1(12.5%)	0.011 <sup>f</sup>
	4 – 7	51(80.9%)	12(19.1%)	
	8 – 10	2712(91.7%)	244(8.3%)	
Birth weight	<2500	306(79.3%)	80(20.7%)	<0.001 <sup>c</sup>
	≥2500	2515(92.8%)	195(7.2%)	
Baby admitted to Newborn unit	No	2639(92.1%)	227(7.9%)	<0.001 <sup>c</sup>
	Yes	135(77.6%)	39(22.4%)	

<sup>c</sup> Chi Square

<sup>f</sup> Fisher Exact test

From Table 11, among patients who delivered live births, only 8.5% developed SMO. This was in contrast to an SMO rate of 36.8% among patients who delivered fresh still births, and 10.3% in those that macerated still births. The difference between the groups was statistically significant.

Additionally, 18.2% of mothers who had SMO delivered babies with apgar score of 3 or less at 5 minutes. This was in contrast to 14.1% of mothers with SMO who delivered babies with apgar score of between 4 and 7. In contrast, 8.2% of mothers with SMO delivered babies with apgar score greater than 8 at 5 minutes. The difference between the groups was statistically significant.

Among mothers who had delivered babies with weight less than 2500 grams, 20.7% of them had SMO. On the other hand, mothers who delivered babies weighing 2500 grams or more, 7.2% of them had SMO. There was a statistically significant difference between the two groups. ( $p < 0.001$ )

Among mothers with SMO, 22.4% of them had their neonates admitted to the newborn unit. This is in contrast to only 7.9% of babies born to mothers who did not suffer SMO. This difference in likelihood of admission to the newborn unit was statistically significant.

## CHAPTER FIVE

### 5.0 DISCUSSION

#### 5.1 Severe Maternal Outcome indicators at MTRH, Eldoret

From our study, 98% of the patients who had SMO got maternal near miss while 2% died. We also found out that the maternal severe outcome ratio (SMOR) and maternal near miss ratios (MNMR) were 9.8 and 9.5 per 1000 live births respectively. Our results tally with the findings of a study assessing maternal near miss at MTRH that found a SMOR of 11.4 and a MNMR of 10.4 per 1000 live births. (Ndingori et al., 2018) The results of our study are also in keeping with a nationwide study that assessed the incidence of near miss among 35 referral hospitals in Kenya and found a MNM ratio of 7.2 per 1000 live births. The region specific MNM ratio for the Rift Valley region, in which MTRH is located, was found to be 9.7 per 1000 live births. (Owolabi et al., 2020) Similarly, in Zimbabwe, the SMOR was found to be 10.4 per 1000 live births, with MNMR of 9.3 per 1000 live births similar to our study (Chikadaya et al., 2018) This was in contrast with a large study done in Ethiopia that found the crude maternal near miss incidence ratio to be higher at 20.8 per 1000 births. Our study was also slightly different to findings of a large global meta-analysis of MNM studies that found a pooled global MNM ratio of 14 per 1000 live births, with a MNM ratio of 24 per 1000 births in low to middle income countries, in which Kenya was included. (Firoz, Trigo Romero, Leung, Souza, & Tunçalp, 2022) The difference was likely due to quality of obstetric care among the different countries, as well as the inclusion of laboratory-based criteria in the definition of MNM in some studies, which may have overestimated the MNM ratio compared to our study.

The maternal near miss mortality ratio from our study was found to be 48 near misses for each mortality that occurred (48:1). This was slightly better compared to a nationwide survey done among 35 referral hospitals in the country that found a ratio of 20:1. (Owolabi et al., 2020). This difference is likely due to the difference in the quality of maternal services and facilities in the different hospitals, as some of the facilities studied are Level 5 county referral hospitals compared to MTRH, which is a level 6 national referral hospital. Elsewhere in Zimbabwe, the near miss mortality ratio in a large hospital was found to be 8.5:1, (Chikadaya et al., 2018), showing that less mothers were likely to survive in case they were diagnosed with SMO compared to our study. Khan and colleagues in their study found that the outcomes were even worse in a tertiary hospital in India, with a ratio of 5:1. (Khan et al., 2017). The difference is likely due to the large disparities in the quality of provision of maternal health care services or other factors outlined in the three-delay model that may impact how patients receive maternal health care services.

From our study, we found that the mortality index was 2%, meaning of all mothers with SMO, 2% died while 98% had near miss. This is slightly lower than a nationwide mortality index of 4.8% among 35 major hospitals in Kenya. (Owolabi, 2020). This is also lower by than a study done in Ethiopia that showed a mortality index of 7.4% (Yesmane, 2020). The lower the percentage, the less likely that a sick mother is likely to die from severe illness and may point towards better care. While WHO does not specifically set a threshold of what should be low or high mortality index, the mortality index may also be used to audit the progress of quality of services over time, with reducing numbers a pointer at improved maternal health care.

From our study, the intra-hospital mortality rate established was 197 per 100,000 live births. Similarly, in a study that assessed the mortality rate in lower middle income



countries, Kenya included, the ratio was found to be 163 per 100,000 live births. (Heitkamp, 2021) This is also in keeping with an intra-hospital rate of 192 per 100,000 live births in another similar sized hospital and study in India. (Sharma et al., 2020) In contrast the maternal mortality ratio in two large referral hospitals in Zimbabwe was found to be 111 per 100,000 live births. (Chikadaya et al., 2018) The intra-hospital maternal mortality ratio in a number of sampled referral hospitals in Kenya was found to be 36 per 100,000 live births. (Owolabi et al., 2020) The difference in the rate was likely due to the inclusion of referral hospitals with less numbers of referrals with severe disease, and that MTRH may serve a larger population than some of the hospitals sampled.

## **5.2 Sociodemographic characteristics and occurrence of SMO**

From the study we found that, in terms of SMO occurrence by age group, the majority of mothers with SMO were aged 20 to 34 years at 82.5%. Majority of patients with SMO had attained secondary school education. The sociodemographic factors associated with severe maternal outcome at bivariate level were age at admission and the level of education. At multivariate level, only age above 35 years was associated with an increased risk of patients suffering SMO, with these mothers having a 50% greater chance of suffering SMO with all other factors kept constant

These findings are similar to those of a study done in Kenya in which it was found out that majority of patients with SMO were aged 20 to 34 years at 74%, followed by those above 35 years at 16% while those less than 19 years were at 11%. (Juma et al., 2021) These results are also in keeping with a similar study done in Tigray region of Ethiopia, in which 77% of mothers with SMO were aged between 20 and 34 years. (Teka, Yemane, Berhe Zelelow, Tadesse, & Hagos, 2022) Similarly, a study done in India that assessed maternal near miss in a rural tertiary care facility found that SMO

majorly affected the age group 20-35 years at around 84%, followed by those above 35 years at 9%.(Verma, Kanti, Vishwakarma, Gupta, & Shree, 2020) On the contrary, in a study done in Ethiopia, the majority of patients were the extremes of age with 39% being less than 19 years while 38% were aged 35 years and above. (Mekango, Alemayehu, Gebregergs, Medhanyie, & Goba, 2017) This difference could be attributed to different cultural and demographic characteristics in this population with teenagers making up the majority of patients seeking care, and teenagers are likely to have various obstetric complications that could predispose them to SMO.

Similar to our study, a study conducted in Ethiopia showed that women aged 35 years and above had a 74% increased risk of SMO compared to women aged 20 to 34 years. (Teshome et al, 2022) Likewise, it was found that increasing maternal age was associated with increase in SMO, with mothers above 35 years having a 25% increased chance of SMO in one study in Brazil (Oliveira, 2015) The increased risk of maternal morbidity and mortality at this extreme of age is likely due to the increased risk of other medical conditions such as diabetes mellitus and hypertensive disease which may put these mothers at increased risk of adverse pregnancy outcomes.

### **5.3 Obstetric characteristics and the occurrence of SMO**

From our study, among patients with SMO, majority had between two to four previous deliveries, while 43 % were primigravid. The obstetric factors associated with severe maternal outcome at bivariate level were delivery via CS in any previous delivery, delivery via CS in the index pregnancy, the timing of admission, patient mode of admission (whether from home or as a referral), attendance of antenatal care and antenatal haemoglobin. At multivariate level, the obstetric factors associated with SMO were being delivered by CS in a previous pregnancy and delivery via CS in the index pregnancy, which both increased the risk of SMO two-fold. Admission in the period of

28 to 36 weeks or in the postnatal period, were also associated with increased rates of SMO, with the latter increasing the risk 51-fold. Likewise, being brought in as a referral and antenatal hemoglobin of less than 11 were associated with SMO as was failure to receive antenatal care.

A study done in Rural India found that majority of patients with SMO were multiparous at 55% while the SMO rate among primiparous patients was 44%, which was similar to findings in our study. (Verma et al., 2020) Likewise, another study in India also showed that 46% of patients who suffered SMO were primigravid, while 54% of patients were multiparous. (Mansuri et al., 2019) This is in contrast to a study done in India that showed that primigravid patients were highest among patients with SMO at 60%. (Gupta et al., 2018). Another study also showed that SMO was more prevalent among primigravid patients at 60%, compared to 40% in multigravid patients. (Sharma et al., 2020) In a study done in Brazil, the rates of SMO were also higher among primigravid patients at 53%. (Lima, Carvalho, Feitosa, & Nunes, 2017) This difference could be explained by different demographic characteristics of the population seeking healthcare at MTRH and the other countries, with more likely younger patients seeking delivery services in the other countries. For instance, the average age at delivery in India is 20 years (World Bank, 2016) compared to 26 years in our study.

From our study, we found a statistically significant difference in the occurrence of SMO between patients who attended antenatal care versus those who did not, with non-attendance conferring a two times risk of SMO. In a study done at MTRH, Eldoret, attendance of antenatal care was likewise found to be significantly protective from occurrence of SMO. (Ndingori et al., 2018) In a different study done in Ethiopia, failure to attend ANC was also associated with a nine times increased risk of developing SMO. (Liyew et al., 2018) Likewise, in another study done in Brazil, having an ANC

attendance of less than 6 visits was associated with a two times elevated risk of developing SMO. (De Lima et al., 2019) Failure to attend ANC is likely to lead to failure of recognition of conditions that may affect fetal and maternal outcomes such as hypertensive disease, diabetes mellitus in pregnancy or anaemia among others and increase the risk of a mother suffering SMO.

From our study, 43.3% of babies born to mothers with SMO were likely to be delivered via caesarean section. It was also established that delivery via caesarean section is significantly associated with development of SMO. Our findings are similar to a study looking at the SMO rates among major tertiary hospital in Kenya, it was discovered that 45% of all mothers who had SMO eventually had been delivered via caesarean section. (Owolabi et al., 2020) Similarly in Ethiopia, it was found out that 50% of patients with SMO were delivered via caesarean section. (Mekango et al., 2017) In a study done in Ethiopia, being delivered via caesarean section in the index pregnancy was associated a 3-fold increase in SMO risk. (Teshome et al., 2022) The findings are also in keeping with another study done in Brazil to assess fetal and maternal outcomes it was found that delivery via caesarean section was associated with double the risk SMO compared to vaginal delivery. (De Lima et al., 2019) Delivery via caesarean section is likely to be done to mothers with other comorbidities due to fetal or maternal conditions, who already have an increased risk of SMO. The procedure itself is also associated with higher likelihood of morbidity and mortality such as postpartum bleeding and infections.

From our study, having had a previous caesarean delivery was associated with a two-fold increased risk of developing SMO. In a study looking at SMO rates in major referral hospitals in Kenya, previous delivery via caesarean section was associated with a four times increased risk of SMO compared to those patients without previous

caesarean delivery. (Owolabi et al., 2020) Elsewhere, a study done in Ethiopia looking at the predictors of near miss found that women who had prior history of delivery via caesarean section had 7 times higher risk of maternal near miss than those without any caesarean delivery. (Kasahun, Wako 2018) This is similar to a study done in a number of public hospitals in Ethiopia, that showed a three-fold increase in risk of SMO among patients who had previous caesarean section delivery. (Dessalegn et al., 2020) Similarly, a three-fold increase in SMO risk was demonstrated among women with previous caesarean section in another study done in Ethiopia (Habte, 2020) The likely cause for the increased risk is that women who have previous caesarean section are at increased risk of having repeat caesarean sections, have an increased risk of uterine rupture and antepartum haemorrhage due to a low lying placenta.

We found out that patients admitted between 28 to 37 weeks gestation had a two-fold increase in the risk of getting SMO, while admission in the postpartum period was associated with a 50 times greater risk of getting SMO. A study in Brazil showed a three-fold risk of SMO in mothers admitted before term. (Zanette, 2015). This is likely because certain conditions such as hypertensive disease in pregnancy may have earlier onset before term and may cause healthworker interventions such as delivery via caesarean section which may increase the risk of SMO. While not as high as in our study, a significant two times elevation in SMO risk was noted among patients in the postpartum period in a study done in Quebec, Canada (Ukah, 2021) The increased risk in the postpartum period is likely due to the manifestation of various complications of the conditions that occur during labour and childbirth in the postpartum period, such as eclampsia and postpartum haemorrhage.

From our study, coming in to the facility as a referral conferred a four times risk of suffering SMO. This was similar to a study done in Ethiopia that showed a four times

higher risk of SMO in patients who were brought in as referrals. (Teshonne, 2022) In another study done in Ethiopia, women who had been referred from another facility compared to those who came from home had seven times higher risk of developing maternal near miss. (Kasahun & Wako, 2018) Patients who come in as referrals are likely to have visited a lower-level health facility where maternal health care services are not available and are likely to experience delays in decision-making and transportation that may impact negatively on their outcomes.

From this study it was found that antenatal anaemia (haemoglobin less than 11mg/dl) during the antenatal care was significantly associated with SMO. This was a similar finding to a study done in Ethiopia that showed a four times increased risk SMO rate with antenatal hemoglobin of less than 11. (Liyew et al., 2018a) In another study in the same country, maternal anaemia was also found to be the leading contributor to maternal near miss. (Liyew et al., 2017) Similar findings were also demonstrated in India where antenatal anaemia was an independent risk factor for development of SMM among mothers. (Tabassum et al., 2017) Anaemia during pregnancy and delivery is likely to lead to complications such as postpartum haemorrhage which is a direct cause of severe maternal morbidity and mortality.

#### **5.4 Leading causes of morbidity and mortality in patients with SMO**

From our study we found that the leading cause of SMO was severe preeclampsia at 55.2%, followed by postpartum hemorrhage at 13.1%, sepsis at 6%, with both eclampsia and ruptured uterus causing 1.7% of all SMO causes. Also, among all cases with SMO, 92% of patients with SMO had the 5 life threatening conditions described by WHO.

This compares favourably to a study done in Tigre Ethiopia, in which the leading causes of maternal near miss were the three major diagnoses of pre eclampsia at 44%, obstetric hemorrhage at 24% and sepsis at 18%. (Teka et al., 2022) Likewise, in a study done in Brazil, it was found that 85% of patients with maternal near miss had a life threatening condition. It was found that the leading causes of maternal near miss were hypertensive disease in pregnancy (67%), hemorrhage at 42% and sepsis at 12%. ( De Lima et al., 2019) A similar study in Ghana that used only clinical criteria and the five life threatening conditions assessing SMO among three referral tertiary hospitals found that the leading cause of maternal near miss was preeclampsia/eclampsia at 41%, followed by hemorrhage at 12%, sepsis at 11% and ruptured uterus at 4 (Oppong et al., 2019)

Conversely, in a study done in India, postpartum haemorrhage was found to be the most common cause of maternal near miss at 63%, with hypertensive disease in pregnancy contributing to 20% of deaths. (Kulkarni et al., 2017) Similarly, in another study in a tertiary hospital in India, postpartum haemorrhage caused around 40% of SMO cases and was the leading contributor. Preeclampsia and eclampsia followed at 24% and sepsis at 13%.(Gupta et al., 2018) Elsewhere in Zimbabwe, obstetric hemorrhage was also the leading cause of SMO at 35% with hypertensive diseases (preeclampsia and eclampsia) second. (Chikadaya et al., 2018) Postpartum haemorrhage was also found to be the leading cause of severe maternal outcome in a large survey of referral hospitals in Kenya at 54%, with hypertensive disease at 26% and sepsis at 6%. (Owolabi et al., 2020) In a large analysis of studies assessing severe maternal outcome, it was found out that severe maternal haemorrhage was the leading cause of adverse maternal outcomes in lower middle-income countries like Kenya while as, hypertensive diseases including preeclampsia and eclampsia was the leading cause in upper middle income countries.

(Heitkamp et al., 2021) The difference in causes observed between our study and those observed in other centres or countries would be differences in the robustness of the different healthcare systems in preventing and managing obstetric haemorrhage, and that MTRH being a referral facility is likely to handle more severe cases of hypertensive disease.

### **5.5 Predictive ability of MOEWS for determining SMO**

From the findings in our study, the sensitivity of the MOEWS chart was found to be 77%, specificity of 95%, positive predictive value of 61% and negative predictive value of 98%.

Comparing our findings to a study done in India to evaluate the validity of the MOEWS tool in predicting morbidity and mortality in postpartum patients, the MOEWS tool was found to be 89% sensitive, 79% specific, had a positive predictive value of 39% and negative predictive value of 98%. The parameters of validity for this study might be different due to the difference in definition of maternal near miss in which management based criteria was not used. (S. Singh et al., 2012) In another study done in India, the MOEWS chart for the defined morbidity as per the study was found to be 86% sensitive, 85% specific, with PPV and NPV of 53% and 96% respectively. (A. Singh et al., 2016) In this study, the definition of SMO was the same as for our study and the results are comparable. Elsewhere, in another study done in Uganda for assessing the validity of the MOEWS chart, MOEWS was 81% sensitive, 76% specific with PPV 36% and NPV of 96%. There criteria used to assign near miss in this study was dependent on the diagnosis of the attending physician, and could have affected what was defined as near-miss, hence may have affected its validity (Otuu, Kizito, Daniel, & Peter, 2018) In a retrospective study done in the USA assessing ability of the MOEWS to predict admission to ICU, a near-miss predictor, the sensitivity was found to be 72%,



specificity 96%, PPV 95%, and NPV 77%. This is in line with the findings of our research. (Shields et al., 2016) In a large review of literature, it was found that the MOEWS identified had quite a wide range of ranges for sensitivity and specificity. The ranges defined were 72% to 97% for sensitivity and 67% to 98% for specificity. The ranges for and PPV were found to be 25% to 74%. (Umar et al., 2019) These ranges are in keeping with the findings of our study.

The MOEWS chart showed a relatively high sensitivity, though from this study it was likely to miss two out of every ten patients who get SMO. In addition, the MOEWS chart showed a high degree of specificity, and its use could be important in excluding the occurrence of severe maternal outcome among the patients it is employed on. However, its relatively low positive predictive value is likely to be associated with many false positive triggers and may eventually result in ‘alarm fatigue’, an eventual reluctance to respond to triggers, among health care workers. (Nair, Dockrell, & Colgain, 2018) The negative predictive value being high would support its usefulness in asserting that patients who do not trigger on the charts are actually unlikely to have any adverse outcomes.

### **5.6 Individual vital sign Triggers on the MOEWS chart and their association with SMO**

From our study, we found that the presence of a red trigger for any vital sign was significantly associated with the occurrence of SMO as compared to patients who had only one yellow trigger or no trigger at all. Our findings are in keeping with a study that assessed the association of red and yellow triggers with occurrence of SMO. Red triggers were associated with an eleven times increased risk for occurrence of SMO. Yellow triggers alone were not significantly associated with any severe maternal outcome. (Hannola et al., 2021) Red triggers are associated with a greater derangement

of vital sign values and this could point to more severe organ dysfunction, hence the increased association with occurrence of SMO

Additionally, we established that heart rate, respiratory rate, systolic blood pressure and diastolic blood pressure were the individual vital signs that were independently associated with occurrence of severe maternal outcome. Similarly, a study conducted in India showed an increased risk of severe maternal outcome when abnormal heart rate, systolic blood pressure and diastolic blood pressure triggered on the MOEWS chart. Temperature and oxygen saturation did not adversely affect the outcomes. (S. Singh, Mcglennan, England, & Simons, 2012) In the same way, it was found out in Finland that abnormal heart rate, systolic blood pressure and diastolic blood pressure were the vital signs that were directly associated with severe maternal outcome. (Hannola et al., 2021) On the contrary, in another study, the vital signs that were significantly associated with severe maternal morbidity and mortality were temperature, increased heart rate, systolic blood pressure and respiratory rate. (Ryan et al., 2017) In a study done in India, after adjusting for other factors, heart rate, systolic and diastolic blood pressures as well as temperature were all found to be statistically significant for SMO. (A. Singh, Guleria, Vaid, & Jain, 2016) The initial response to maternal deterioration from a patient is likely to be subtle changes in heart rate and respiratory rate to try to compensate for small alterations in cardiorespiratory system function, such as reduced circulating blood volumes. As the deficit becomes larger, such as above 30% loss of fluid volume, drops in blood pressure may be noted. The MOEWS chart may pick these early combinations of deterioration, usually appearing as Yellow Triggers. The MOEWS trigger for temperature in our study was likely affected by the early use of antibiotic and antipyretics in most patients presenting with fever as prescribed in most hospital protocols including MTRH, and this finding is

consistent with evaluation of the performance of MOEWS sepsis alone, which was found to be low due to early initiation of antibiotics. (Page, 2015)

### **5.7 Fetal outcomes among patients who suffered SMO**

From our study 97.5% of all patients gave birth to live infants. In addition, 7.2% of mothers with SMO delivered still births compared to only 2% of mothers without SMO. There was significant association between SMO and occurrence of still birth, reduction in 5 and 10 minute Apgar scores, preterm birth, low birth weight and admission to the newborn unit.

Our results compare favourably with a study done in Brazil that showed that of all infants born to mothers with SMO, 6.2% were still born. (Lima et al., 2017) Conversely, a study done in Ethiopia showed a high still birth rate of 21% among mothers with adverse maternal outcomes. (Mekango et al., 2017) This could be due to the difference in the standard of maternal and fetal care available between the two countries, with other studies reporting higher adverse maternal outcome rates in Ethiopia than in our study. (Yemane & Tiruneh, 2020) Another study done in Ethiopia recorded an eight-times higher neonatal still-birth rate in mothers who suffered SMO. (Aliyi, 2021)

In addition, we found out that a greater proportion of infants born to mothers without SMO recorded better Apgar scores at 5 and 10 minutes compared to those born to mothers who had SMO. This is similar to a study that found a significant lower Apgar score at 5 and 10 minutes among mothers who had adverse maternal outcomes. (Zanardi et al., 2018) Elsewhere, it was similarly found that mothers with SMO were five times likely to have babies with lower apgar scores at one, five and ten minutes. (Liyew, Yalew, Afework, & Essén, 2018b) However, this findings are conflicting with findings by Ndingori et al. (2022) that found no significant difference in Apgar scores between

babies born to mothers who have SMO and those without SMO. This difference could be because the study patients in our study were unmatched compared to this study.

We found out that a significant proportion of 30% of infants born to mothers with SMO were below 2500 grams birth weight compared to 10.9% born to mothers without SMO. This compares favorably to the findings of a study in Brazil that had 34% of babies born to mothers with SMO weighing less than 2500 grams. (Lima et al., 2017) Likewise in Ethiopia, a higher number of babies born to mothers with SMO weighing less than 2500 grams at 48%. (Mekango et al., 2017) In a different part of the same country, having a mother experience SMO was associated with an eight times increased risk of delivering an infant weighing less than 2500 grams. (Liyew et al., 2018b) This was also the finding in a study that showed significant association between severe maternal disease and giving birth to babies with weights of less than 2500 grams. (Zanardi et al., 2018)

Additionally, we found out that 43.3% of babies born to mothers with SMO were delivered via caesarean section compared to 24.2% of infants born to mothers without SMO. Similarly, in a different study, a greater proportion of babies born to mothers with SMO were delivered through caesarean section. However, this proportion of patients with SMO delivered via caesarean section was much higher at 78%. (Lima et al., 2017) The higher rates of caesarean section in the Brazilian study could generally be attributed to a higher caesarean section rate in Brazil of 56% (Rudey et al., 2020), which is just over double the general caesarean section rate found in our study of 24.3%. The indications for caesarean section in patients with SMO are likely due to acute maternal and fetal complications warranting prompt delivery, such as eclampsia, and fetal compromise due to acute antenatal haemorrhage. This may explain the higher rates of caesarean section delivery in mothers with SMO.

In addition, we discovered that 22.4% of mothers with SMO had their newborns admitted to the neonatal care unit compared to only 7.9% of mothers without SMO. A similar study in Ethiopia also found a four times increased risk of admission to neonatal intensive care for babies born to mothers with severe maternal outcome. (Liyew et al., 2018)

Severe maternal outcomes were associated with adverse fetal outcomes, as maternal morbidities such as hypertensive disease, diabetes or maternal collapse could increase the risk of preterm and low weight birth because of either spontaneous or iatrogenic-caused early delivery. Preterm birth is a leading driver of neonatal morbidity and mortality and is associated with neonatal unit admissions. (Basnet et al., 2022) Additionally, mothers with certain chronic conditions such as hypertensive diseases are more likely to have babies who have a diminished reserve to cope with extrauterine life as these babies may usually experience restricted fetal growth, poor lung maturity and respiratory distress syndrome soon after delivery. (Li, 2019)

### **5.8 Study strengths**

1. The end points of maternal near miss and mortality were well defined using the WHO Maternal near-miss criteria tool which has been validated in various studies with similar settings to MTRH.
2. The MOEWS chart used for the recording of vital signs has been validated in different studies albeit in different populations and settings from the one at MTRH.

### **5.9 Study Limitations**

1. Our study is hospital based and the findings may not be generalizable to the general population.

2. There was no standardized guideline for taking vital signs as the data was collected in retrospect, hence the technique of measurement may be a potential confounder to the measured vital signs.
3. The significance of vital sign changes occurring outside the twenty-four hour period before the outcomes of interest could not be established from the study. Likewise, outcomes that might have occurred after patient discharge could not be established. This can be mitigated by including a longer observation period for vital signs and a longer follow up period.

## CHAPTER SIX

### 6.0 CONCLUSIONS AND RECOMMENDATIONS

#### 6.1 Conclusions

The severe maternal outcome ratio and maternal near miss ratios were 9.8 and 9.5 per 1000 live births respectively and were comparable to other similar sized facilities worldwide.

The maternal near miss to mortality ratio was 48 and a mortality index of 2%, meaning among very sick mothers, one mother out of 48 died. This rate performed better when compared to similar-sized hospitals in the region.

The intrahospital maternal mortality ratio was found to be 197 per 100,000 live births, which is better compared to most hospitals in the region and is comparable to rates in higher middle income countries.

The patient demographic factor that was positively associated with adverse maternal outcomes were age above 35 years.

Obstetric factors associated with SMO included delivery via caesarean section in any previous pregnancy, delivery via caesarean section in the index admission, failure to attend antenatal care, patients having antenatal anaemia of less than 11g/dl, coming to MTRH as a referral patient and being admitted in the period of gestation between 28 to 37 weeks and in the postnatal period.

The most common conditions that were associated with SMO was severe pre eclampsia followed by postpartum haemorrhage.

The validity of MOEWS chart was found to be high for predicting severe maternal outcome, but had low PPV which could cause many false positives, comparable to findings of its validation in other centres.

The presence of a red trigger on the MOEWS chart for all vital sign measures except temperature was associated with SMO compared to a yellow trigger or no trigger.

The vital sign triggers that were that were independently associated with SMO on the MOEWS chart were heart rate, respiratory rate, systolic blood pressure and diastolic blood pressure.

Severe maternal outcome was associated with significantly associated with higher rates of still birth, higher rates of birth weight below 2500 grams, increased delivery by caesarean section and admission of neonates to the newborn care unit. (NBU)

## **6.2 Recommendations**

1. We recommend to all maternal health care providers the use of the MOEWS chart for tracking patient vitals on admission until discharge due to its relatively good performance at picking out patients at risk of SMO and also for its high discrimination for patients who are unlikely to suffer SMO if they do not trigger on the MOEWS chart.
2. We recommend to all maternal healthcare providers that MOEWS charts to be used specifically for all patients admitted to the facility at the gestations of 28 to 37 weeks and the postnatal period to be under MOEWS chart surveillance throughout due to their increased chance of getting SMO..
3. We recommend to the Directorate of Reproductive Health at MTRH and the Paediatrics department that the newborn unit be informed in advance to



anticipate need for admission for more specialized care for babies born to antenatal mothers who get SMO at any time.

4. We recommend to the hospital administration that a hospital protocol be designed to guide health worker responses to the various triggers on the MOEWS charts, including the personnel to take action and time durations to be taken to assess patients depending on the vital sign trigger.
5. We recommend to the Department of Reproductive Health, Moi University and the Directorate of Reproductive Health, MTRH and Ministry of Health that a prospective study be designed with a structured method of vital sign taking and assessment to determine the validity of MOEWS for assessing severe maternal outcomes at MTRH or similar setting within the country. This is with the aim of likely developing a MOEWS with better validity measures or policy on the use of MOEWS for monitoring vital signs for all mothers admitted to a health facility.

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## APPENDICES

### APPENDIX 1: DATA ABSTRACTION FORM DATA ABSTRACTION SHEET

#### VALIDATION OF A MODIFIED OBSTETRIC EARLY WARNING SYSTEM FOR PREDICTING SEVERE MATERNAL OUTCOME AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET

#### 1. PATIENT INFORMATION

IP. Number:

Initials:

Date of Admission: (dd/mm/yyyy)

Date of Discharge/Death (dd/mm/yyyy):

Length of hospital stay:  Less than 24 hours  
 More than 24 hours: (specify number  
of days)

Year of Birth:

Age at admission (years):

Marital status:

Never married

Married

Divorced

Widowed

Highest Level of education reached:

None

Pre-primary

Primary

Secondary

Tertiary

Parity:

Outcome of previous pregnancy:

Preterm live Birth

Term live birth

Still birth

Gestation on admission by LMP or ultrasound in weeks:

Mode of admission:  From Home

Referral

Time of decision to refer to MTRH:

Time of arrival at MTRH:

Total time of referral (Arrival time- Decision to refer time):

Did the the patient attend antenatal clinic?  Yes

No

Unknown

Antenatal profile:  
measured:

Haemoglobin levels (g/dl) first

Blood group (ABO and rhesus):

VDRL:

HIV status:

missing)  Not complete (all or one component

Place first admitted at MTRH:

Labour ward

Antenatal ward

Postnatal ward

ICU/HDU

Cardiac Unit

## 2. MATERNAL OUTCOMES

Did the patient suffer severe maternal outcome (SMO)  Yes

No

Type of SMO suffered  Maternal mortality

Maternal near miss

Diagnosis on admission:

Diagnosis at discharge/ death/ Postmortem:

Did patient suffer from a potentially life threatening condition (see below)?

Yes

No

Life-threatening illness condition:  Severe postpartum haemorrhage

Severe pre-eclampsia

Eclampsia

Sepsis/severe systemic infection

Ruptured uterus

Where did SMO occur?

At referring facility

At MTRH

## 3. CRITERIA FOR DETERMINING MATERNAL NEAR MISS

For patients who had maternal near-miss, which clinical or interventional based criteria qualified them as near-miss? Laboratory criteria, if present, may be included.

**Near Miss Based on clinical criteria (tick those present)**

- Acute cyanosis
- Gaspings
- Respiratory rate of more than 40 or less than 6 breaths per minute

Rate:

- Shock
- Oliguria



#### 4. MOEWS CHART

Source of vital sign data:

Patient admission notes:

Patient referral form:

Theatre/ post-anaesthesia care unit (PACU) notes

Daily observation charts

Daily ward round notes:

Did the MOEWS chart trigger for abnormal vital sign(s)?                      Yes

No

Which vital sign(s) triggered in the chart?

Heart rate trigger	Value:	Yellow trigger	Red
--------------------	--------	----------------	-----

Respiratory rate trigger	Value:	Yellow trigger	Red
--------------------------	--------	----------------	-----

Temperature trigger	Value:	Yellow trigger	Red
---------------------	--------	----------------	-----

SPO2 trigger	Value:	Yellow trigger	Red
--------------	--------	----------------	-----

Systolic blood pressure trigger	Value:	Yellow trigger	Red
---------------------------------	--------	----------------	-----

Diastolic blood pressure trigger	Value:	Yellow trigger	Red
----------------------------------	--------	----------------	-----

### 3. FETAL OUTCOMES

What was the outcome of the fetus at birth?

Live birth

Fresh still birth

Macerated still birth

What was the apgar score at; 5 minutes..... 10 minutes.....

Birth weight in grams:

Mode of delivery:  Spontaneous Vertex Delivery  Breech  
 extraction  Caesarean Section  
 Assisted vaginal delivery

For live births, was the baby admitted to the new born unit? Yes  
 No

When did SMO occur?

Before Delivery

After delivery

### Appendix 3: IREC approval



**MOI TEACHING AND REFERRAL HOSPITAL**  
P.O. BOX 3  
ELDORET  
Tel: 3347112/3

**INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)**



**MOI UNIVERSITY**  
COLLEGE OF HEALTH SCIENCES  
P.O. BOX 4805  
ELDORET  
Tel: 3347112/3  
26<sup>th</sup> November, 2020

Reference: IREC/2020/145  
**Approval Number: 0003711**

Dr. Daniel Pius Kioko,  
Moi University,  
School of Medicine,  
P.O. Box 4806-30100,  
**ELDORET-KENYA.**

Dear Dr. Kioko,

**VALIDATION OF A MODIFIED OBSTETRIC EARLY WARNING SYSTEM FOR PREDICTING SEVERE MATERNAL OUTCOME AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET**

This is to inform you that **MU/MTRH-IREC** has reviewed and approved your above research proposal. Your application approval number is **FAN: 0003711**. The approval period is **26<sup>th</sup> November, 2020 – 25<sup>th</sup> November, 2021**.

This approval is subject to compliance with the following requirements;

- i. Only approved documents including (informed consents, study instruments, MTA) will be used.
- ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by **MU/MTRH-IREC**.
- iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to **MU/MTRH-IREC** within 72 hours of notification.
- iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to **MU/MTRH-IREC** within 72 hours.
- v. Clearance for export of biological specimens must be obtained from relevant institutions.
- vi. 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.
- vii. Submission of an executive summary report within 90 days upon completion of the study to **MU/MTRH-IREC**.

Prior to commencing your study; you will be required to obtain a research license from the National Commission for Science, Technology and Innovation (NACOSTI); <https://oris.nacosti.go.ke> and other relevant clearances. Further, a written approval from the CEO-MTRH is mandatory for studies to be undertaken within the jurisdiction of Moi Teaching & Referral Hospital (MTRH), which includes 22 Counties in the Western half of Kenya.

Sincerely,  
  
**DR. S. NYABERA**  
DEPUTY-CHAIRMAN  
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE ELDORET

**INSTITUTIONAL RESEARCH & ETHICS COMMITTEE**

**25 NOV 2020**

**APPROVED**

**INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE ELDORET**

cc	CEO - MTRH	Dean - SOP
	Principal - CHS	Dean - SON
		Dean - SOM
		Dean - SOD

### Appendix 4: Hospital data collection approval



An ISO 9001:2015 Certified Hospital



## MOI TEACHING AND REFERRAL HOSPITAL

Telephone (+254)053-2033/710764  
 Mobile: 722-201277/0722-206795/1734-6004-61/0734-683361  
 Fax: 053-2061740  
 Email: [ceo@mtrh.go.ke](mailto:ceo@mtrh.go.ke)/[directore@fromtrh@gmail.com](mailto:directore@fromtrh@gmail.com)

Nandi Road  
 P.O. Box 3 - 30100  
 ELDORET, KENYA

Ref: ELD/MTRH/R&amp;P/10/2/V.2/2010

3<sup>rd</sup> December, 2020

Dr. Daniel Pius Kioko,  
 Moi University,  
 School of Medicine,  
 P.O. Box 4606-30100,  
 ELDORET-KENYA

**APPROVAL TO CONDUCT RESEARCH AT MTRH FOR STUDY TITLED: VALIDATION OF A MODIFIED OBSTETRIC EARLY WARNING SYSTEM FOR PREDICTING SEVERE MATERNAL OUTCOME AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET**

In order to conduct research within the jurisdiction of Moi Teaching and Referral Hospital (MTRH) which includes 22 counties in the Western half of Kenya. You are required to strictly adhere to the regulations stated below in order to safeguard the safety and well-being of staff and patients seen at MTRH involved research studies.

1. The study shall be under Moi Teaching and Referral Hospital regulation.
2. A copy of MU/MTRH-IREC approval shall be provided.
3. Studies dealing with collection, storage and transportation of Human Biological Material (HBM) will not be allowed to export the HBM outside the jurisdiction of MTRH.
4. For those tests which are unavailable locally the PI is tasked to ensure sourcing of equipment and subsequent training of staff to build their capacity.
5. No data collection will be allowed without an approved consent form(s) to participants to sign.
6. Take note that data collected must be treated with due confidentiality and anonymity.

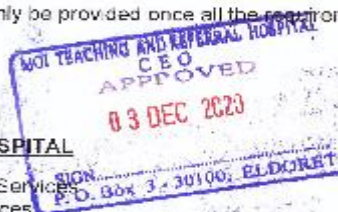
Permission to conduct research shall only be provided once all the requirements stated above have been met.

*(Signature)*  
 DR. WILSON K. ARDASA, MBS

CHIEF EXECUTIVE OFFICER

MOI TEACHING AND REFERRAL HOSPITAL

c.c. - Senior Director, Clinical Services  
 - Director of Nursing Services  
 - HOD, HRISM



All correspondence should be addressed to the Chief Executive Officer

Visit our Website: [www.mtrh.go.ke](http://www.mtrh.go.ke)

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