REPUBLIC OF KENYA

MINISTRY OF HEALTH

Incidence and Cost of Maternal Near-Miss in Kenya

Key Findings from a National Survey

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Acknowledgments

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APHRC African Population and Health Research Center

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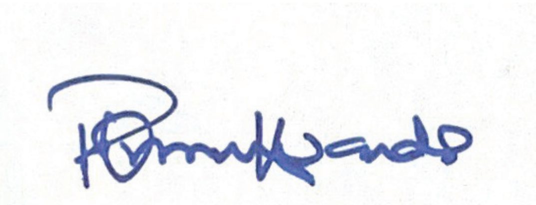
Foreword

Reducing the level of premature maternal deaths (mortality) globally by 2030 to less than 70 per 100,000 live births is the target of Sustainable Development Goal (SDG) 3.1. Currently, the maternal mortality ratio in Kenya remains relatively high despite decades of investment and commitments by the government. Moreover, accurate data to provide the basis for more targeted interventions and to monitor progress on this particular SDG target are hard to come by. The current study by APHRC is therefore very timely since it presents national level estimates on the incidence of maternal near-miss (MNM), the clinical management of pregnancy-related complications and the direct financial costs of managing such complications. This report highlights critical gaps in the quality of maternal healthcare to guide programming towards improving maternal outcomes.

Study findings show that the national annual incidence of maternal near-miss was estimated at 7.2 per 1,000 live births and the intra-hospital maternal mortality ratio was 36.2 per 100,000 live births. Majority of MNM cases were caused by postpartum hemorrhage and pre-eclampsia. Evidence shows that while the quality of care was largely optimal, a significant proportion of women could not obtain the required care for the complications they suffered. Findings also demonstrated that the direct financial burden of treating near-misses was high, with wide variations across regions in Kenya. Most patients made out–of-pocket (OOP) payments for costs incurred during care and a substantial proportion of patients benefitted from medical fee exemption or waivers.

Based on these findings, this study offers guidance on strategic opportunities available at health system, health facility and community levels to address the gaps identified and strengthen maternal healthcare. These include improving the health system's capacity to provide care for emergency obstetric care, introducing facility audits of near-miss events, as well as community-level research and interventions to eliminate barriers to care and assessing the efficacy of the free maternal health services policy in Kenya.



Dr. Patrick Amoth

Ag. Director General for Health

Ministry of Health

List of Acronyms

ANC	Antenatal Care
APHRC	African Population and Health Research Center
CoG	Council of Governors, Kenya
DMS	Directorate of Medical Services
EmOC	Emergency Obstetric Care
FHOK	Family Health Options Kenya
HMIS	Health Management Information System
ICD-10	International Classification of Diseases
IMUA	Incidence and complications of unsafe abortion
KEMRI SERU	Kenya Medical Research Institute Scientific and Ethics Review Unit
KHSSP	Kenya Health Sector Strategic and Investment Plan
LMICs	Low- and Middle-Income Countries
MD	Maternal Death
MMR	Maternal Mortality Ratio
MNM	Maternal Near-Miss
MoH	Ministry of Health, Kenya
MSK	Marie Stopes, Kenya
NACOSTI	National Commission for Science, Technology and Innovation
OOP	Out-of-Pocket
PAC	Post-abortion care
PLTCs	Potentially Life Threatening Conditions
SDG	Sustainable Development Goals
SMOs	Severe Maternal Outcomes
UHC	Universal Health Coverage
UoN/KNH ERC	University of Nairobi/Kenyatta National Hospital Ethics Review Committee
WHO	World Health Organization

Study definitions

Potentially life-threatening condition (PLTC): These are an extensive category of clinical conditions, including diseases that can threaten a woman's life during pregnancy and labour and after termination of pregnancy.1 We utilized all the conditions and interventions included in the WHO data collection tool,2 and included additional criteria to ensure we incorporated all possible severe obstetric cases in the Kenyan context including septic abortion, prolonged obstructed labour, and uterine evacuation.

Maternal near-miss (MNM): A woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy. We utilized the WHO maternal near-miss surveillance and assessment tool1 and adapted it to include additional variables for clinical, laboratory and management-based criteria within each organ system category. These additions to the tool were based on work on validating the WHO approach in other LMICs3 and based on feedback from our Kenyan collaborators about criteria commonly used in Kenyan referral hospitals that could also identify near-misses. The Kenya-adapted near-miss criteria is shown in Appendix Table 4 in comparison with the WHO maternal near-miss criteria.

Maternal death (MD): The death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and the site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes (according to the tenth International Classification of Diseases [ICD-10].4)

Severe maternal outcome (SMO): A life threatening condition (i.e. organ dysfunction) including all maternal near-miss cases and maternal deaths.

Underlying cause of death: The disease or condition that initiated the morbid chain of events leading to death or the circumstances of the accident or violence that produced a fatal injury.

Live Birth (LB): Birth of an offspring, which breathes or shows evidence of life.

Severe maternal outcome ratio (SMOR): The number of women with life-threatening conditions (i.e. maternal death and near-misses) per 1000 live births. This indicator gives an estimate of the amount of care and resources that would be needed in an area or facility [SMOR = (MNM + MD)/ LB].

Maternal near-miss ratio (MNMR): the number of maternal near-miss cases per 1,000 live births (MNMR = MNM/LB). Similar to the SMOR, this indicator gives an estimation of the amount of care and resources that would be needed in an area or facility.

Intra-hospital MMR: The number of maternal death that occurred in the hospital per 100,000 live births.

Mortality index (MI): The number of maternal deaths divided by the number of women with life-threatening conditions (i.e. maternal near-misses plus maternal deaths) expressed as a percentage [MI=MD/ (MNM+MD)]. The higher the index, the more the women with life-threatening conditions who die (indicative of low quality of comprehensive emergency care), whereas the lower the index the fewer women with life-threatening conditions who die (better quality of care).

Executive Summary

Despite efforts by the Kenyan government to improve maternal health in the last two decades, there has been little progress as measured by the rate of decline in maternal mortality ratio (MMR). Deficiencies in quality of care in terms of facility infrastructure, care processes and outcomes, contribute significantly to maternal deaths. Whereas maternal mortality has long been used to assess the quality of maternal health at national, community and facility levels, the rarity of its occurrence excludes a large proportion of women who suffer varying degrees of morbidity during and immediately after pregnancy. Thus, maternal near-miss (MNM), defined by the World Health Organization (WHO) as "a woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy", has been used more frequently as a standardized outcome to evaluate and improve the quality of obstetric care.

In view of the limited scope of using MMR as a tracking indicator for continued investments and interventions in maternal health, it is important to have nationally representative data on the incidence of, and financial burden of MNM on Kenyan women and their households. This will enable policy makers to better evaluate the healthcare system as well as identify and implement interventions to achieve national targets. We therefore conducted a nationally representative study to describe the incidence and the underlying causes of MNM, the quality of obstetric care and the cost of treating near-miss events in the country. The data was collected from February to May 2018 from 54 referral hospitals in 27 counties, with each participating facility being observed for a period of three months. Women admitted with potentially life-threatening conditions (using World Health Organization criteria) in pregnancy, childbirth or puerperium were eligible for inclusion in the study. All cases of severe maternal outcome [SMO] (MNM cases and deaths) were prospectively identified, and after consent, included in the study. Data were collected on clinical and obstetric history at admission, demographic characteristics, and overall financial costs of treatment at the point of discharge.

The national annual incidence of MNM was estimated at 7.2 per 1,000 live births and the intra-hospital maternal mortality ratio was 36.2 per 100,000 live births. The major causes of SMOs were postpartum hemorrhage and pre-eclampsia. About one-quarter (23%) of women with severe preeclampsia never received magnesium sulfate and 33% of those for whom blood was requested did not get blood or blood products. Our analysis showed that the financial burden of treating a maternal near-miss case in Kenya is high, with a median cost of KES 7,135 (~US$ 71) (IQR; KES 50-271,068) compared to KES 2,690 (~US$ 27) (IQR; KES 50-68,293) for women with other potentially life-threatening conditions. Considerable regional variations (i.e. highest median near-miss costs seen in the Nairobi and Central regions as well as in Rift Valley. Underlying cause of complication also influenced costs as patients with pregnancy-related infections and those with medical and surgical complications reported the highest expenses. Findings showed that majority of patients made out-of-pocket (OOP) payments for costs incurred during care. However, close to one-third of the patients benefitted from medical fee exemption or waivers, implying the cost of care might have been partially borne by the health system.

While this study reports that Kenya has a relatively low incidence of MNM compared to other countries in the region, provision of essential emergency obstetric care (EmOC) interventions is suboptimal for many direct obstetric conditions. The timing of near-miss events and death highlight the delays women experience in accessing care and underscores the need for community-level interventions to reduce barriers impeding timely access to care. To strengthen facility level data on quality of care, there is a pressing need to consider introducing facility audits of near-miss events as part of routine monitoring to enable the management teams for facilities to identify key challenges to care and bottlenecks that prevent provision of high quality maternal care. The relatively high costs of care incurred by near-miss patients who mainly use OOP payments, may expose some families to catastrophic health expenditures. It is vital to further assess the efficacy of the free maternal health services policy, as well as the potential of raising limits of insurance coverage for pregnant women, to help offset costs to individuals and their households. Building on the existing attempts to implement the universal health coverage (UHC), these efforts should include comprehensive coverage of priority maternal healthcare needs and addressing the barriers, including cost, to timely and quality maternal healthcare services.

Background

Preventable maternal mortality remains highest in sub-Saharan Africa (SSA), including Kenya, where the maternal mortality ratio (MMR) is estimated at 362 maternal deaths per 100,000 live births [1]. The Kenyan government has increasingly invested in efforts to address maternal morbidities and deaths through a mix of interventions, with very limited improvements in MMR over the last two decades [2, 3]. Using MMR to track improvements in the quality of care provided by the health system is challenging because maternal deaths are rare events in communities and health facilities [4]. Yet, for every maternal death there remains a substantial number of women who suffer varying degrees of morbidity during and immediately after pregnancy.

Consequently, the maternal near-miss (MNM) approach was developed by the World Health Organization (WHO) as a standardized outcome to evaluate and improve the quality of obstetric care [5]. MNM refers to "a woman who nearly died but survived a complication that occurred during pregnancy, childbirth or within 42 days of termination of pregnancy" [6]. MNM is a valuable endpoint measure because the causes are similar to those of maternal mortality, and near-miss events are more common than maternal deaths, leaving open the potential for women to be interviewed [7]. By implication, near-miss studies have greater power to identify factors associated with adverse maternal outcomes, and provides an opportunity to generate recommendations to address the underlying causes at all levels of health delivery [8]. Several studies have affirmed the use of the MNM criteria in low-income settings [5, 7, 9, 10], and globally, there is increased recognition of the importance of using severe morbidity to evaluate progress towards improving health systems and obstetric outcomes [11].

Majority of the interventions the Kenyan government have taken to improve maternal outcomes have focused on increasing access and reducing the cost of care to women. For example, in the last 15 years, the 2006 care subsidy voucher program [12] and the free maternity care program in public facilities in 2013 have been promoted [2]. Although a recent study found an increase in utilization of maternal health services following the free maternity care program, there was no evidence of a corresponding significant decline in national MMR [13]. Further, while the policy of free maternity care theoretically covers antenatal visits, deliveries, and post-natal visits, in practice, it covers only deliveries. Some studies have suggested the existence of many informal or "unapproved" costs that contribute to delays in accessing care or discourage women from seeking skilled maternity care, especially in contexts where the majority of women are poor, uneducated and lack insurance coverage for medical care [14, 15]. The objective of our study was to describe the incidence and cause distribution of MNMs in Kenya, the clinical management of these complications and the direct financial cost to patients/their caregivers for treating maternal near-misses.

Data and methods

2.1 Study design, setting and population

We conducted a cross-sectional study within a nationally representative sample of public and private facilities in Kenya between February and May 2018. All level 5 and level 6 hospitals were eligible for participation. We also generated a simple random sample, stratified by region, of all level 4 hospitals. Selected facilities were then observed for a period of three months for data collection.

2.2 Sample size determination of hospitals

There are six levels of health care in the Kenyan public health system as per the 2014 Kenya Health Sector Strategic and Investment Plan (KHSSP): Level I) community units; Level II) dispensaries; Level III) health centers; Level IV) primary referral facilities; Level V) secondary referral facilities; and Level VI) tertiary referral facilities. Since MNM events are severe complications that may require surgery, we included all Level V and VI facilities which are designated to perform Caesarean sections and are more likely to handle MNM cases or severe complications. Level 4 facilities were the most likely to receive and to treat MNM cases as primary referral facilities, especially where there is no higher-level facility in the immediate region. The sample size for level 4 facilities was drawn using the incidence and complications of unsafe abortion (IMUA) study. The IMUA study had included a universe of 424 sub-county facilities, from which a total of 46 level 4 hospitals were selected to participate. Selected facilities that declined to participate, or that were non-functional at the time of the survey were replaced with similar-level facilities drawn from a replacement list generated before the study commenced. For cases of Level 5 and 6 facilities, no replacements were available because the sampling proportion was 100%. Fifty-four facilities participated in the study, with a response rate of 86% (Table 1).

All women of reproductive age admitted with a potentially life-threatening condition (PLTC), or as a MNM, or a maternal death (MD) that occurred in the participating facilities during pregnancy, delivery or within 42 days of delivery or termination of pregnancy were eligible for inclusion as well as those who developed these conditions during their hospital stay. Table 1 summarizes the sampling and the response rate by level of participating facilities. Maternal death was defined according to the International Classification of Diseases (ICD-10) [16]. Severe maternal outcomes (SMO) included all near-misses and maternal deaths (Appendix 1).

Table 1 **Sampling and response rate, by level of health facility, Kenya 2018**

	Facility level				Patient level			
Level of health facility	**Universe of health facilities**	**Sampling proportion**	**Response rate**	**Total study facilities**	**Total cases**	**Eligible cases**	**Response rate**	**Interviewed women**
Level 4	424	11%	89%	41	269	266	100%	256
Level 5*	16	94%	73%	11	314	311	99.4%	302
Level 6	2	100%	100%	2	144	141	99.3%	137
Total**	**442**	**14%**	**86%**	**54**	**727**	**718**	**99.6%**	**695**

Included all level 6, 5, and a sample of level 4 facilities, both public and private.
All MSK and FHOK facilities have been excluded from this component.
All estimates are unweighted
* Some of the private Level 5 facilities declined to participate
** For cost component - we had a total of 623 respondents (after excluding 17 maternal deaths, those who never consented and some of the women who were referred before being interviewed for the cost data)

2.3 Maternal Near-Miss Study

The maternal near-miss study had two separate but complementary aspects of data collection. The first involved a clinical survey of all women identified and treated with all forms of life-threatening complications in the sampled facilities. We used two criteria for defining maternal near-miss cases: the WHO operational definition, based on organ failure, and an adapted model for the Kenyan context (Appendix 1). The Kenyan adaptation was added to questions from the WHO MNM surveillance and assessment tool used to develop our data collection instrument [17]. These adaptations were selected based on previous studies attempting to validate the criteria of the WHO near-miss approach in other low- and middle-income countries (LMICs) and with input from the clinicians participating in the study [5, 18]. All near-miss indicators were defined according to the WHO near-miss manual [17], and these definitions can be found in Appendix 2. For some conditions within the WHO near-miss organ dysfunction categories (shock, abnormal liver enzymes, and massive blood transfusion), we collected detailed information on the clinical signs and symptoms used to diagnose each condition.

The second component of the study was an interview with the women to obtain information on their health seeking decision-making behaviors, their experiences with delays to seeking and receiving care, and the social and economic costs (e.g. medicines, hospital bills for consultation or any surgical procedures, diagnostic examinations such as laboratory tests and x-ray) and non- medical/indirect (e.g. transport, food, telephone expenses, and accommodation) incurred during the illness period. The interviews were conducted at the time of discharge, within the premises of the participating health facilities with the exact locations determined in consultation with facility management.

2.4 Data collection

The medical records extraction tool was pre-tested on case files of discharged obstetric patients at a sub-county hospital not included in the study to verify its appropriateness for the Kenyan context. Each participating facility designated one study clinician, among whom were clinical officers and nurses. The clinician research assistants were trained to conduct face-to-face interviews and extract data from medical records. Larger facilities with normally higher caseloads had two to three interviewers. All facility interviewers participated in a two-day training on the tool and other study procedures, and piloted the tool in a sub-county hospital in Nairobi. Each study clinician visited the obstetrics wards, delivery rooms, emergency rooms and intensive care units daily to identify eligible women. Each eligible woman admitted (except maternal deaths) was first approached by her health care provider who informed her about the study and solicited their participation. If she agreed and was in a stable condition, the facility interviewer further explained the study and obtained her written consent to participate. Consent included permission to interview her, her health care provider and to review her medical records. Upon receiving each informed consent to participate in the study, the study clinicians interviewed the woman's health care provider, reviewed her health records to extract information about her clinical condition using the study tool, and interviewed her to collect any information not recorded in her medical records. We also extracted individual level data for each woman who came in with a complication, died and had consented to participate in the study before death. Women who did not consent (either because they refused to participate or could not provide consent before death), and those who were dead on admission were recorded in the monthly caseloads and included in the intra-hospital MMR and mortality index, but their individual data was not extracted.

All patients who consented for the cost component were linked to a different set of trained fieldworkers at discharge who conducted interviews with them or with their caretakers about their experiences and costs of care. Data collected included both direct medical costs (e.g. medicines, hospital bills for consultation or any surgical interventions, diagnostic procedures such as laboratory tests and x-ray) and direct non-medical costs (e.g. transport, food, telephone expenses and accommodation) incurred during the index MNM event. Information on care seeking behaviors was also collected. Indirect costs such as lost earnings and waiting time; and intangible costs such as pain, inconvenience and anxiety, were not measured. Interviews were administered using a tablet-based questionnaire on SurveyCTO platform. The interviews were conducted within the health facilities in a private location determined in consultation with facility management. All interviews were then uploaded to a central server based at the African Population and Health Research Center (APHRC), Nairobi where the data was retrieved, cleaned and analyzed. We also conducted a facility audit to obtain data on the total number of deliveries, live births, gynaecological admissions, post-abortion care admissions, and maternal deaths occurring during each month of the study from each participating facility's Health Management Information System (HMIS).

2.5 Data analysis and management

Before clinical data entry, a medical doctor performed validity checks of questionnaires for clinical inconsistencies or missing data. Double data entry was done for 10% of data collection forms and inconsistency checks programmed in a statistical software to flag any potential errors. If errors were found, the study team followed up with the study clinicians to verify or obtain the correct information from the woman's medical records.

We conducted descriptive analysis of women's characteristics, underlying and contributory causes of severe morbidity, and the distribution of organ dysfunction, by type of SMO. National estimates of maternal near-miss were generated using the adapted Kenyan definition. The number of near-miss cases was annualized from the three-month study period and weighted for study design to obtain a national annual incidence of maternal near-miss for 2018. We estimated the SMO ratio, intra-hospital maternal mortality ratio, maternal near-miss ratio, and other maternal near-miss indicators at the national level and at the regional level. We also described the corresponding standards of care for each complication to assess the quality of care provided using the WHO near-miss guidelines. We compared the number of near-misses generated for each organ dysfunction category and their categorization using our adapted study criteria and the WHO criteria. We also examined the WHO approach of asking clinicians to select checkboxes to indicate a diagnosis of some near-miss conditions aligned with the WHO clinical definitions for these conditions. To do this we compared the selection of diagnoses using just the checkbox to a diagnosis generated in statistical software using the constellation of clinical signs and symptoms WHO requires to detect the condition diagnosed.

For the cost data, we conducted descriptive analysis to estimate the cost of treatment for maternal near-misses and other potential life threatening complications. To estimate the direct cost of care, median and interquartile ranges (IQR) were generated. Estimated cost of treatment was therefore described by regions, wealth index, demographic characteristics, and near-miss status and by underlying cause of near-miss condition. Data analysis was conducted using Stata Version 15.1.16 [19].

2.6 Ethical considerations

The Kenya Medical Research Institute (KEMRI) Scientific and Ethics Review Unit (SERU) reviewed and approved this study on December 20, 2017 (protocol ID: KEMRI/RES/7/3/1) following internal approval by the APHRC's ethic review committee. The African Population and Health Research Centre (APHRC) also obtained a research permit for this study from the National Commission for Science, Technology and Innovation (NACOSTI) on March 28, 2018 (Approval Ref: NACOSTI/P/18/46177/21949), and Guttmacher Institute institutional review board on September 26, 2016 (DHHS identifier IRB00002197). Prior to commencing data collection additional approvals were obtained from the Director of Medical Services (MoH) as well as from the respective Directors of Health in the selected counties and the Council of Governors (CoG). Additionally, individual written consent was obtained from each woman who participated in the study.

Findings

3.1 Incidence of Maternal Near-Miss

3.1.1 Characteristics of study population

Table 2 describes the demographic characteristics of patients with PLTCs and SMOs. Whilst the majority of women with self-limiting PLTCs, MNM, and maternal deaths were between ages 20 and 34; 8% of maternal near-miss cases and 14% of women with PLTCs were adolescents aged 15-19 years. The majority of patients with PLTCs, MNM and maternal deaths received antenatal care (77%, 66%, and 82%, respectively). Similarly, the majority of women with PLTCs (36%) and those who experienced near-miss (39%) had a history of four pregnancies or more. Almost two-thirds of near-miss women (65%) and less than one-third of maternal deaths (32%) experienced their severe obstetric complication before admission to the facility. Whilst approximately a quarter of MNM and maternal deaths delivered via caesarean section, 20% of near-miss cases had a laparotomy for ectopic pregnancy and 9% had a spontaneous or induced abortion. About a fifth of women who experienced a near-miss event also experienced a fetal death.

Table 2 **Characteristics of women with potentially life-threatening conditions, maternal near-miss events, and maternal death, Kenya 2018**

Characteristics of respondents [a]	Potentially life- threatening conditions (PLTCs)[b]	Maternal Near-Miss (MNM)	Maternal Death (MD)[c]
	N (%)	N (%)	N (%)
Age			
15-19	269 (14%)	105 (8%)	-
20-24	436 (22%)	367 (29%)	3 (7%)
25-29	465 (24%)	359 (28%)	18 (43%)
30-34	458 (23%)	252 (20%)	15 (35%)
35+	344 (17%)	195 (15%)	6 (14%)
Number of pregnancies			
1	471 (24%)	375 (29%)	13 (31%)
2	391 (20%)	201 (16%)	14 (33%)
3	402 (20%)	203 (16%)	5 (12%)
4+	708 (36%)	500 (39%)	10 (24%)
Received any professional antenatal care[d]			
	1478 (77%)	840 (66%)	32 (82%)
Estimated Gestational Age			
First Trimester	272 (16%)	244 (25%)	-
Second Trimester	177 (11%)	102 (10%)	1 (3%)
Third Trimester	1228 (73%)	643 (65%)	37 (97%)
Timing of severe obstetric complication			
Before admission	1266 (66%)	813 (65%)	11(32%)
During admission	647 (34%)	442 (35%)	23 (68%)
Final mode of delivery			
Vaginal delivery	460 (24%)	513 (40%)	30 (77%)
Caesarean Section	873 (45%)	334 (26%)	9 (23%)
Abortion (spontaneous or induced)	281 (14%)	109 (9%)	-

Laparotomy for ectopic pregnancy	179 (9%)	256 (20%)	-
Discharged/or referred	151 (8%)	64 (5%)	-
Fetal outcome at birth			
Alive	1119 (90%)	656 (78%)	38 (97%)
Dead	122 (10%)	186 (22%)	1 (3%)
Total	**1972 (100%)**	**1279 (100%)**	**42 (100%)**

All estimates are weighted from the three-month study period and include only patients who consented to be interviewed

PLTCs: Professional ANC care—12; Estimated EGA—60; Timing of SMO—18; Final mode of delivery—4; Fetal outcome at birth—115. MNM: Professional ANC care—6; Estimated EGA—96; Timing of SMO—9; Final mode of delivery—2; Fetal outcome at birth—108.

[a] Unweighted missing cases for each characteristic variable.

[b] PLTCs does not include patients who were classified as a MNM or MD.

[c] Patients who did not consent and were a maternal death were not included in the maternal death total in this table, but are included in the incidence calculations.

[d] Skilled provider includes-obstetrician/gynaecologist, medical officer, clinical officer, nurse or midwife.

3.1.2 Primary outcome estimates

During the period of data collection, there were 36,162 live births, 318 women with potentially life threatening complications (PLTCs) who did not experience a near-miss event or die and 377 cases with a severe maternal outcome (SMO) (360 near-misses and 17 maternal deaths).

At the national level, we estimated an annual intra-hospital maternal mortality ratio of 36.2 per 100,000 live births (0.04%), a maternal near-miss ratio of 7.2 per 1,000 live births (0.7%), and a SMO ratio of 7.6 per 1,000 live births in 2018 (0.8%). We also estimated that there were 20 MNM for each maternal death in hospitals, and a national mortality index in hospitals of 4.8%. Although most SMOs occurred before admission to a hospital (64%), and the majority of these cases were referred from other facilities (~60%), 36% of SMOs occurred whilst women were admitted (Table 3).

Table 3 **Estimated annual incidence of maternal near-miss and other severe maternal outcome indicators in Kenya in 2018**

Annual number of facility caseloads	National
Total number of facility live births	708,459
Total number of facility deliveries	726,158
Annual number of severe maternal outcomes	
Number of maternal near-miss cases	5,116
Number of maternal deaths	256
Overall Maternal Near-Miss Indicators	
Severe maternal outcome ratio (per 1,000 live births)	7.6 (4.9 - 10.2)
Maternal near-miss incidence ratio (per 1,000 live births)	7.2 (4.6 - 9.9)
Intra-hospital maternal mortality ratio (per 100,000 live births)	36.2 (13.3 - 59.0)
Mortality Index (MI)*	4.8%
Maternal near-miss: maternal death ratio	20.0
Hospital Access Indicators	**N (%)**
Severe maternal outcome occurred before admission in hospital	824 (64%)
Severe maternal outcome occurred during stay in hospital	465 (36%)
Severe maternal outcome occurred before admission, referred from other facilities	480 (58%)
Mortality index: SMO occurred before admission	1.6%

Severe maternal outcome ratio (SMOR): The number of patients with life-threatening conditions (i.e. maternal death and near-misses) per 1,000 live births· [SMOR = (MNM + MD)/LB].

Maternal near-miss ratio (MNMR): The number of maternal near-miss cases per 1,000 live births (MNMR = MNM/LB).

Intra-hospital MMR: The number of maternal death that occurred in the hospital per 100,000 live births.

Mortality index (MI): The number of maternal deaths divided by the number of patients with life-threatening conditions (i.e. maternal near-misses plus maternal deaths) expressed as a percentage [MI = MD/ (MNM + MD)].

Maternal near-miss mortality ratio (MNM: 1 MD): The ratio between maternal near-miss cases and maternal deaths.

3.1.3 Organ dysfunction in near-miss cases and causes of severe maternal outcomes

Amongst near-misses, hematologic (36%) and cardiovascular dysfunction (27%) were the most prevalent organ dysfunctions whilst respiratory (93%) and cardiovascular (83%) dysfunction was the most common amongst maternal deaths. Obstetric hemorrhage and hypertensive disorders were the most common underlying causes of SMOs. About a fifth of all maternal deaths were due to hypertensive disorders and pregnancies with abortive outcomes contributed to 12% of deaths and 9% of near-misses. The contribution of other obstetric complications to MNM (28%) was substantially more than their contribution to maternal deaths (2%). Previous caesarean section (16%) was the biggest contributory cause to MNM followed by anemia (8%). The mortality index was highest for respiratory dysfunction (13%) and lowest for renal, uterine, and hepatic dysfunctions (1%, 1% and 2% respectively) (Table 4).

Table 4 **Distribution of organ dysfunction, underlying causes and contributory conditions among maternal near-miss cases and maternal deaths, Kenya 2018**

Organ dysfunction	Potentially life-threatening conditions (N = 1972)	Maternal Near-Miss (N = 1279)	Maternal deaths** (N = 42)	Mortality index
	N (%)	N (%)	N (%)	%
Cardiovascular	n/a	342 (27%)	35 (83%)	9%
Respiratory	n/a	255 (20%)	39 (93%)	13%
Renal	n/a	316 (25%)	2 (5%)	1%
Hematologic	n/a	457 (36%)	21 (50%)	4%
Hepatic	n/a	142 (11%)	3 (7%)	2%
Neurologic	n/a	219 (17%)	14 (34%)	6%
Uterine *	n/a	292 (23%)	2 (5%)	1%
Underlying causes				
Pregnancy with abortive outcome	291 (15%)	112 (9%)	5 (12%)	4%
Obstetric hemorrhage	1181 (60%)	686 (54%)	24 (57%)	3%
Hypertensive disorders	442 (22%)	327 (26%)	9 (21%)	3%
Pregnancy-related infections	117 (6%)	75 (6%)	2 (5%)	3%
Other obstetric disease or complications	783 (40%)	354 (28%)	1 (2%)	0%
Medical/Surgical/Mental disease or complications	2 (0%)	45 (4%)	2 (5%)	4%
Contributory causes/associated conditions				
Anemia	234 (15%)	103 (8%)	1 (2%)	1%
HIV infection****	115 (6%)	31 (3%)	1 (4%)	3%
Previous caesarean section	312 (16%)	204 (16%)	1 (2%)	0%
Prolonged obstructed labor	552 (28%)	46 (4%)	1 (2%)	2%

* Includes paralytic ileus (absent bowel sounds in a gaseous distended abdomen), PTE (pulmonary thromboembolism) showing the above respiratory symptoms and signs, hysterectomy following infection or hemorrhage, and laparotomy

** Women who died who did not consent were not included in this MD total, but are included in the incidence calculations.

*** All cases are weighted

**** 5 women who died have missing HIV status so the denominator used to estimate proportion is smaller than for other contributory causes

3.1.4 Quality of definitive clinical care provided for major obstetric conditions

Table 5 shows the standards and processes of care provided for each of the major direct obstetric complications. Seventy-seven percent of women with pre-eclampsia/eclampsia received magnesium sulfate, while 93% with postpartum hemorrhage (PPH) received oxytocin or ergometrine. Although blood was requested for 84% of women with antepartum hemorrhage (APH), only 55% of them received blood transfusions. Almost all women who went through caesarean section and those with severe infection or sepsis received parenteral antibiotics for prophylaxis and as treatment respectively (98% and 99%). For the 74% with ruptured uteruses, 44% of them had a laparotomy after staying in the facility for 3 hours while 53% of them had an SMO.

Table 5 **Process and outcome indicators for selected obstetric complications, Kenya 2018**

Interventions, by selected obstetric complications	**Number and percentage of women**	
	N	**%**
Antepartum hemorrhage (APH)[#]		
Women with APH	226	7
Requested blood	191	84
Blood given (out of those with blood requested)	109	67
IV fluids given	224	99
Cases with SMO [a]	96	43
Mortality [b]	-	-
Postpartum hemorrhage (PPH)		
Women with PPH	1755	53
Oxytocin, Ergometrine, Oxytocin/Ergometrine	1597	93
Misoprostol	740	45
Other uterotonic	57	4
Tranexamic acid	450	27
Removal of retained products	704	43
Balloon or condom tamponade	97	6
Artery ligation	32	2
Hysterectomy	70	4
Uterine packing, Uterine massage	821	50
Repair of tears	338	21
Cases with SMO	670	38
Mortality	24	1
Severe pre-eclampsia/eclampsia		
Women with severe pre-eclampsia/eclampsia	778	24
Magnesium sulfate	580	77
Other anticonvulsant	116	16

Cases with SMO	137	67
Mortality	9	1
Severe infections/sepsis		
Women with sepsis/severe infections	194	6
Parenteral antibiotics	192	99
Cases with SMO	77	40
Mortality	2	1
Caesarean section related complications		
Women undergoing caesarean	1216	37
Prophylactic antibiotic	1181	98
Cases with SMO	343	28
Mortality	9	1
Ruptured uterus#		
Women with ruptured uterus	74	2
Laparotomy 3 hours of hospital stay	33	44
Cases with SMO	53	71

All estimates are weighted from the three-month study period and include only patients who consented to be interviewed.

Obstetric complications are not mutually exclusive; a patient can have more than one type of complication.

[a] SMO = severe maternal outcome includes maternal near-miss and maternal death.

[b] Patients who did not consent and were a maternal death (unweighted n = 7) were not included in the maternal death total in this table, but are included in the incidence calculations.

3.1.5 Near-miss indicators by regions

Table 6 describes the near-miss indicators by region. The MNM ratio and SMO ratio ranged from 4.3 per 1,000 live births (0.4%) and 5.1 per 1,000 live births (0.5%) respectively in the Eastern region to 9.4 per 1000 live births (1%) and 9.7 per 1000 live births (1%) respectively in the Rift Valley. Mortality indices varied greatly across regions from 0.6% in Nyanza and Western regions to 15.6% in the Eastern region. Similarly, the intra-hospital mortality ratio was highest for hospitals in the Eastern region. Rift Valley recorded the highest number of SMOs occurring before admission to a hospital whilst Nyanza and Western had the highest number of SMOs occurring during their hospital stay.

3.1.6 Comparing case yield from WHO near-miss criteria and the Kenyan adaptation

Using the WHO criteria identified 250 near-miss cases while the Kenya-adapted criteria identified 360 cases - about 1.4 times more. Appendix 4 shows the number of events in each subcategory of the organ/system. Using the Kenyan criteria for transfusion of two or greater units of blood and blood products in cases of severe anemia in pregnancy, we identified 60 near-miss cases compared with 42 using the WHO criteria of five or more units of blood. However, all the women missed within the WHO transfusion criteria would have been identified as near-misses by the other WHO criteria. We explored which criteria within the Kenyan adaptation identified over 5% of additional MNM cases that would have been missed using the WHO criteria. They include our definition of shock and undergoing a laparotomy other than a caesarean section.

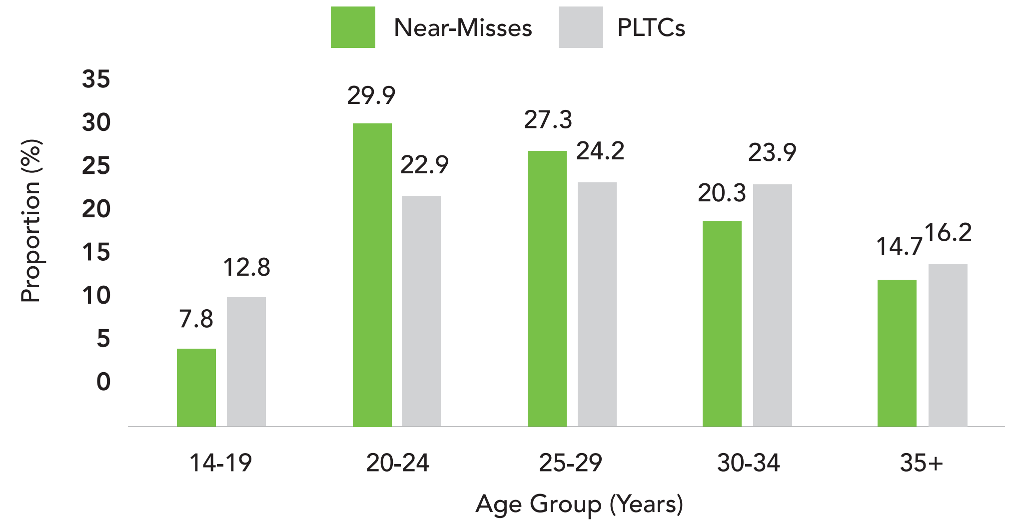
3.2 Financial Cost of Maternal Near-Miss

Of the 695 patients included in the clinical study, a total of 623 consented and were interviewed for the cost of near-miss component. The 72 patients not interviewed included 17 deaths, 23 non-consents, 13 discharged without the knowledge of the providers while 19 were referred to other health facilities.

3.2.1 Sociodemographic characteristics of the women

Over half of the near-misses (57.2%) and about 47% of patients with PLTCs were aged between 20-29 years. About one in ten near-miss patients (7.8%) were teenagers whereas slightly more than one third were above 30 years. Except for patients of ages 20-29; near–miss patients were a slight minority in all the other age-groups (Figure 1). Considering regions of residence for patients, the majority (32.5%) near-miss cases were in the Rift Valley region while close to three in five (59.5%) of those with PLTCs were in the Nyanza and Western regions. The region with the least number of near-misses and PLTCs was the Eastern (6.9% of near-miss cases and 6.2% of PLTCs). In Eastern (54.9%), Nairobi and Central (36.5%), as well as Nyanza and Western (30.1%) regions, the majority of near-miss patients were aged 20-24 years. It was only in the Rift Valley region where near-miss patients aged 30-34 years were the majority.

Figure 1 **Age distribution of patients**



The vast majority of women in both cases had received some formal education at various education levels including primary (36.6%), secondary (37.9%) and tertiary 16.5%. Majority of the patients were protestants (64.3%) followed by Catholics (25%). Approximately two-thirds of the near-misses were unemployed (62.4%) or resided in rural settings (65.6%) (Table 6). Similarly, the majority of patients were married (77.5%). Whereas a slight majority of patients who were married had PLTCs, for those never married (20.3%) and divorced (4.9%)

Table 6 **Socio-demographic characteristics of women with pregnancy and birth related complications (all weighted)**

Characteristic	Near-Miss (N=1180)	PLTCs (N=1845)	All cases (N=3025)
	N (%)	N (%)	N (%)
Age group			
15-19	92 (7.8)	236 (12.8)	328 (10.8)
20-24	353 (29.9)	423 (22.9)	776 (25.7)
25-29	322 (27.3)	447 (24.2)	769 (25.4)
30-34	240 (20.3)	441 (23.9)	681 (22.5)
35+	173 (14.7)	298 (16.2)	471 (15.6)
Education levels			
Primary	387 (32.9)	721 (39.1)	1108 (36.6)

Secondary	467 (39.6)	680 (36.9)	1147 (37.9)
Tertiary	181 (15.3)	318 (17.2)	499 (16.5)
No education	144 (12.2)	126 (6.8)	270 (8.9)
Occupation			
Employed	444 (37.6)	674 (36.5)	1118 (37.0)
Unemployed	736 (62.4)	1171 (63.5)	1907 (63.0)
Place of Residence			
Rural	774 (65.6)	1331 (72.1)	2105 (69.6)
Urban	406 (34.4)	514 (27.9)	920 (30.4)
Religion			
Catholic	373 (31.6)	382 (20.7)	755 (25.0)
Protestant	695 (58.9)	1249 (67.7)	1944 (64.3)
Muslim	112 (9.5)	214 (11.6)	326 (10.8)
Marital status			
Married	882 (74.7)	1463 (79.3)	2345 (77.5)
Divorced/Widowed	58 (4.9)	88 (4.8)	146 (4.8)
Never married	240 (20.3)	294 (15.9)	534 (17.7)
Regions			
Coast and N. Eastern	112 (9.5)	196 (10.6)	308 (10.2)
Eastern	82 (6.9)	114 (6.2)	196 (6.5)
Nairobi and Central	300 (25.4)	168 (9.1)	468 (15.5)
Nyanza and Western	302 (25.6)	1097 (59.5)	1399 (46.2)
Rift Valley	384 (32.5)	270 (14.6)	654 (21.6)
All estimates have been weighted			

3.2.2 Reproductive history of women

Three in four patients (76.8%) with pregnancy or childbirth related complications reported having ever given birth, while slightly more than a quarter (27.6%) of near-miss patients had no history of childbirth before this pregnancy.

Thirty-eight percent of all patients reported between one and two previous live births with a majority of patients with near-misses (35.8%) being in the same group (1-2 live births). Also, a higher proportion of patients reported between one and two living children (50.2%), with the proportions appearing even across all categories and across near-miss and PLTC patients (Table 7). Notably, 32% of all patients had indicated that their pregnancies were unintended, with about a similar proportion experiencing near miss events. Considering wantedness of the current pregnancy, in general, more than half the patients wanted their pregnancies. However, close to four in ten near-miss patients (39.2%) wanted later or never wanted their pregnancies at all. Meanwhile, about 62% of all patients were not using any contraceptive method to prevent the current pregnancy, and among these were - 67% of patients who suffered near miss complications. For those on a form of contraception, just one in five (22%) were on long term methods compared to one in five (13%) for short term methods. Few patients reported any previous induced abortion – 5.8% for all women and 3% for patients with maternal near-miss complications. However, about a third of the women reported that they have had previous unintended pregnancies and considering that this proportion is not too distant from those who considered the index pregnancy as unintended may actually suggest to the contrary that a good number might had prior abortion attempts.

Table 7 Selected reproductive characteristics of patients

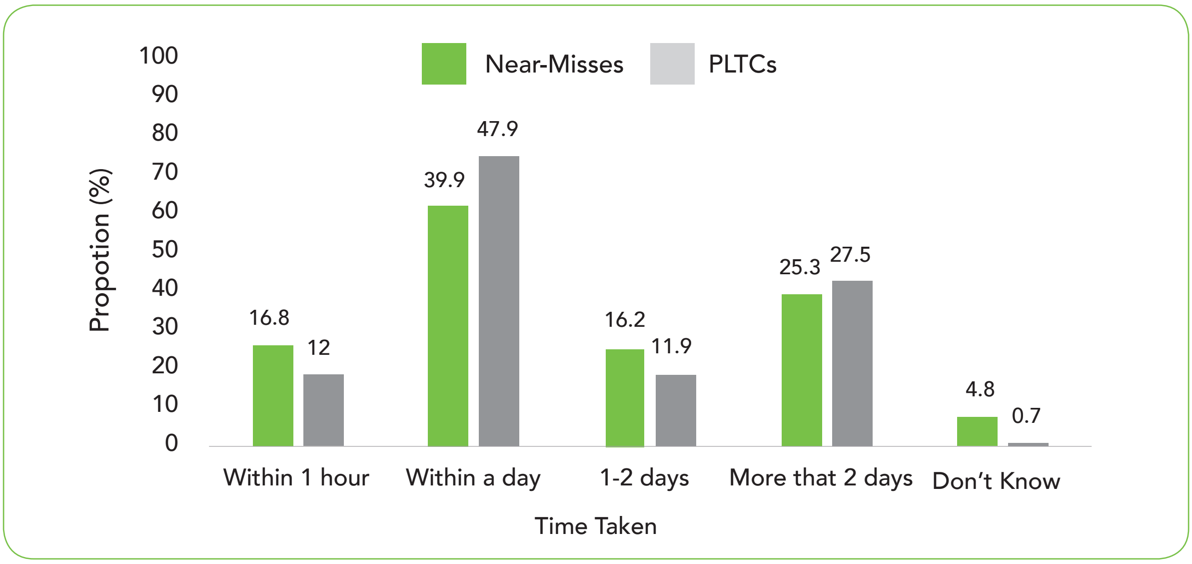
Characteristic	Near-Miss (n = 1180)	PLTC (n = 1845)	All cases (n = 3025)
Live births			
1-2	422 (35.8)	736 (39.9)	1158 (38.3)
3-4	244 (20.7)	467 (25.3)	711 (23.5)
5 and above	188 (15.9)	267 (14.5)	455 (15.0)
None	326 (27.6)	375 (20.3)	701 (23.2)
Living children*			
1-2	415 (48.6)	752 (51.2)	1167 (50.2)
3-4	279 (32.7)	473 (32.2)	752 (32.4)
5 and above	139 (16.3)	216 (14.7)	355 (15.3)
None	21 (2.5)	29 (2.0)	50 (2.2)
Pregnancy Wantedness			
Wanted then	716 (60.7)	991 (53.7)	1707 (56.4)
Wanted later	290 (24.6	502 (27.2)	792 (26.2)
Not wanted at all	172 (14.6)	352 (19.1)	524 (17.3)
Don't know	2 (0.2)	0 (0.0)	2 (0.1)
Type of contraceptive			
No contraceptive	802 (68.0)	1113 (60.3)	1915 (63.3)
Short acting contraceptives	116 (9.8)	281 (15.2)	397 (13.2)
Long acting reversible contraceptives	227 (19.3)	439 (23.8)	666 (22.0)
Traditional	**35 (3.0)**	**12 (0.7)**	**47 (1.5)**

All estimates have been weighted
*For those who have ever had a live birth

3.2.3 Relationship between delays and maternal near-miss complications

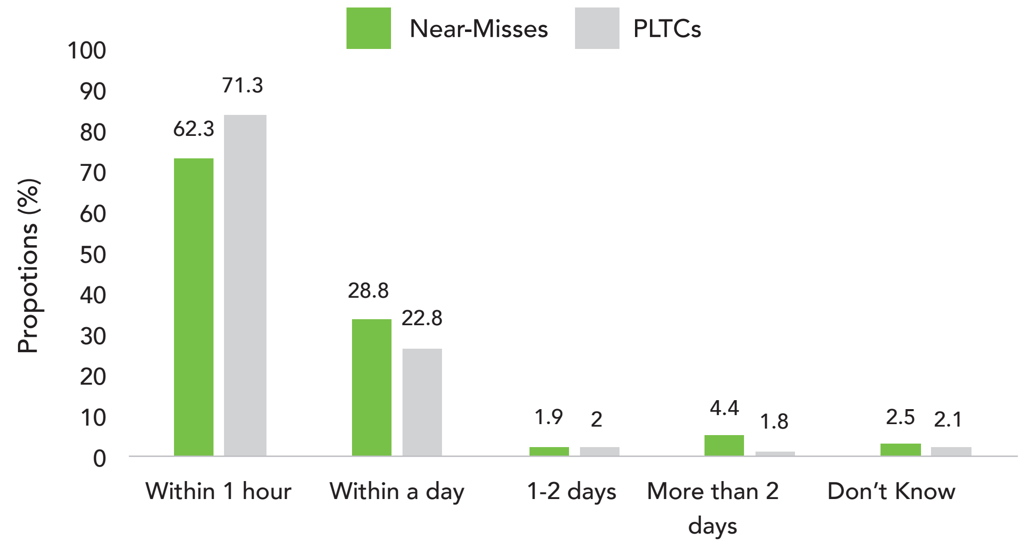
In this section, we report on three common delays – of deciding to seek care, arriving at the health facility, and in obtaining required care after arrival at the facility. Majority of patients (44%) realized that they needed to seek care within a day (less than 24 hours). Approximately eight in ten (78%) of women with MNM reported delays ranging from an hour to more than 48 hours (2 days) from the onset of complications to deciding to seek care (Figure 2).

Figure 2 Delays in seeking care



After deciding to seek care, the majority of patients (67.8%) arrived at the facility within an hour. However, more than one in three of near-miss patients (35.1%) reported delays ranging from two hours to more than two days to reach health facilities (Figure 3).

Figure 3 **Time taken to arrive at the facility**



Surprisingly, over 82% reported waiting for between two to five days to receive definitive care once at the facility. Considering near-miss patients only, the majority of them (83.1%) experienced delays of at least two days upwards from the moment they got to the health facility and were seen by a health provider to the time they received definitive care for complications they suffered e.g. surgery for a ruptured uterus or uterotonics for PPH (Table 8).

Table 8 **Patient delays in seeking health care**

Characteristic	Near Miss (N = 1180)	PLTC (N = 1845)	All cases (N= 3025)
Delays in seeking care			
Within 1 hour	198 (16.8)	222 (12.0)	420 (13.9)
Less than a day (<24 hours)	436 (36.9)	883 (47.9)	1319 (43.6)
1-2 days	191 (16.2)	220 (11.9)	411 (13.6)
More than 2 days	298 (25.3)	508 (27.5)	806 (26.6)
Don't know	57 (4.8)	12 (0.7)	69 (2.3)
Arriving at the health facility			
Within 1 hour	735 (62.3)	1316 (71.3)	2051 (67.8)
Less than a day (<24 hours)	340 (28.8)	421 (22.8)	761 (25.2)
1-2 days	23 (1.9)	37 (2.0)	60 (2.0)
More than 2 days	52 (4.4)	33 (1.8)	85 (2.8)
Don't know	30 (2.5)	38 (2.1)	68 (2.2)
Obtaining definitive care after arrival at the facility**			
Within 1 hour	57 (4.8)	166 (9.0)	223 (7.4)
Within a day	38 (3.2)	20 (1.1)	58 (1.9)
1-2 days	34 (2.9)	105 (5.7)	139 (4.6)
More than 2 days	981 (83.1)	1511 (81.9)	2492 (82.4)
Don't know	70 (5.9)	43 (2.3)	113 (3.7)

Number of other facilities visited			
None	554 (46.9)	1160 (62.9)	1714 (56.7)
1-2	620 (52.5)	662 (35.9)	1282 (42.4)
3 and above	6 (0.5)	23 (1.2)	29 (1.0)

All estimates have been weighted

**This includes the total time it took to be attended to after arriving at the facility, and the waiting time to receive the definitive care for complications suffered, e.g. surgery for a ruptured uterus or uterotonics for PPH

3.2.4 Direct financial cost of treating maternal near-misses

In this section, we estimate the financial costs incurred by the patients in the process of seeking care for their pregnancy- and childbirth-related complications. These costs include those incurred for direct medical care (such as consultation, laboratory and drugs), as well as the non-medical costs (comprising transportation, food, and accommodation) during the care-seeking period. Considering total financial costs expended by patients during care, the majority with pregnancy and childbirth-related complications spent at most KES 1000 for their care (38%), while 32% and 30% spent between KES 1001-5000 and above KES 5000 respectively (approximately between $10-50 and over $50 respectively). Forty percent of near-miss patients spent above KES 5000 for care compared to just 25% of PLTCs. Disaggregated by medical[1] and non-medical costs[2], in both cases the majority of patients (>60%) spent KES 1000 or less during care (Table not shown).

The total median cost of treatment for a near-miss event was KES 12,060 (IQR; 330-271,068) compared to KES 6720 (IQR; 400-68,293) for PLTCs. A significant share of the total costs of treating near-misses was attributed to direct costs of medical care (e.g. medicines, laboratory tests, x-rays etc.), with a median cost of KES 4350 (IQR; 100-161,434) compared to non-medical costs (e.g., transport and food) that was at KES 2500 (IQR; 50-40,900) (Table 9).

Table 9 **Median costs of treating near-misses and other obstetric complications**

Cost	Group	Number of responses	Min	Max	Median	IQR
Non-Medical Costs	Near-Miss	231	30	177,250	2,500	50-40,900
	PLTCs	183	20	41,200	1,500	50-18,350
	All cases	414	20	177,250	2,100	40-41,200
Medical Costs	Near-Miss	231	20	322,959	4,350	100-161,434
	PLTCs	183	10	127,734	2,820	50-49,500
	All cases	414	10	322,959	3,585	50-161,434
Total costs incurred	Near-Miss	231	120	521,800	12,060	330-271,068
	PLTCs	183	130	136,284	6,720	400-68,293
	All cases	414	130	521,800	8,712	280-271,068

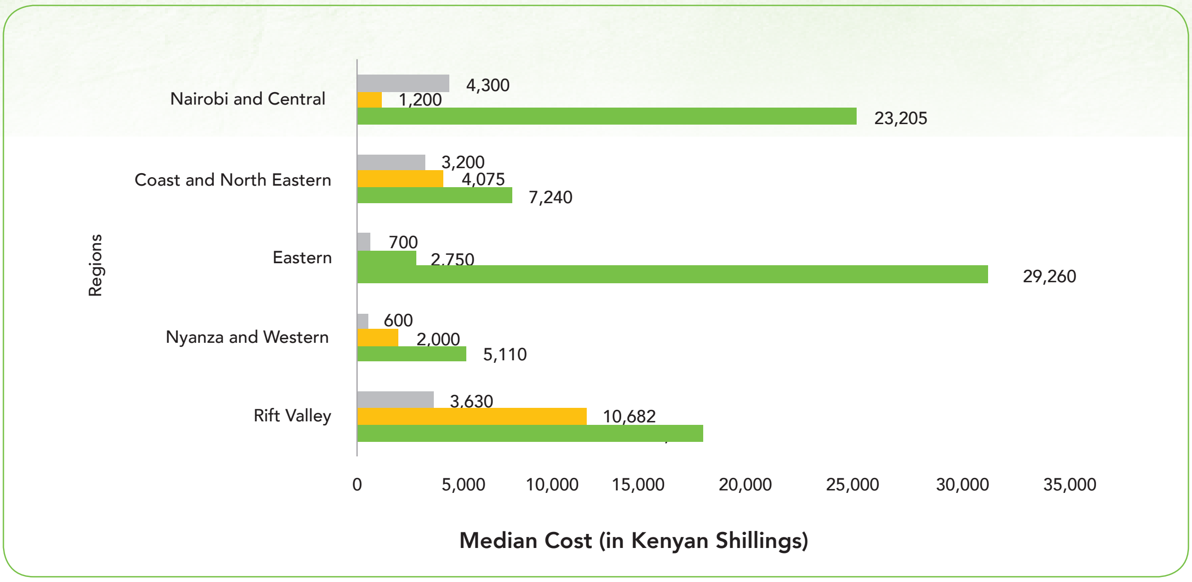
3.2.5 Regional variations in the cost of treating MNM

Our analysis reveals considerable regional disparities in the cost of treating near-miss episodes with the highest total median costs reported in Eastern (KES 29,260), Nairobi and Central (KES 23,205), and Rift Valley (KES 16,110) regions. The least costs for treating near-miss patients were in Nyanza and Western region (KES 5,110) (Figure 4).

[1]We define medical cost as all financial expenditure on medical care and consumables during the period of MNM care seeking.

[2]Non-medical costs comprised transportation, food, accommodation spending during the care seeking period. It does not include costs associated with lost wages.

Figure 4 **Median costs for treating near-misses by regions in Kenya**



Considering all cases (not just the near-misses), the highest total median cost of treatment were reported in Rift Valley KES 13,114 (IQR; 700-235,133) and Coast and North Eastern KES 7,545 (IQR; 1,600-36,900) regions. The lowest median costs were reported in Eastern KES 3,250 (IQR; 640-22,500) and Nyanza and Western KES 4,620 (IQR; 350-67,000) regions (Table 10).

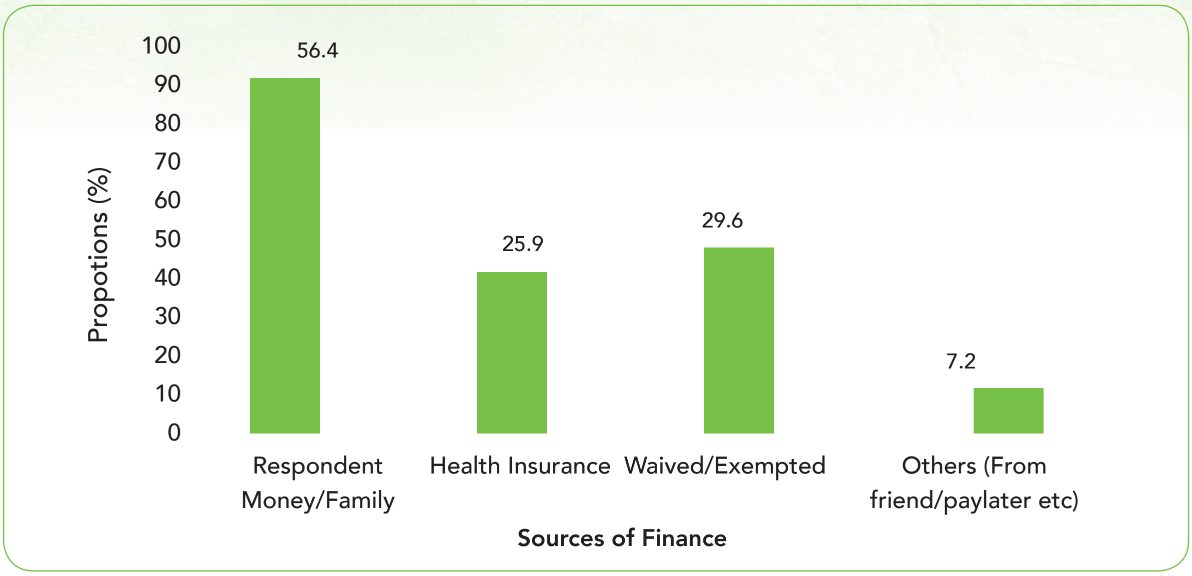
Table 10 **Regional variations in the costs of treating near-misses and other obstetric complications**

Region	Categories of cost	Min	Max	Median	IQR
Nairobi and Central (N=60)	Total Costs	410	521,800	5,230	1,200-105,555
	Medical Costs	10	20,950	1,100	100-9,600
	Non-Medical Costs	50	63,100	3,000	50-18,800
Coast and North Eastern (N=36)	Total Costs	1,200	148,583	7,545	1,600-36,900
	Medical Costs	200	37,250	4,075	1,000-17,200
	Non-Medical Costs	50	14,500	2,300	200-9,900
Eastern (N=29)	Total Costs	200	75,260	3,250	640-22,500
	Medical Costs	80	19,000	1,570	490-17,000
	Non-Medical Costs	30	11,450	1,000	150-3,800
Nyanza and Western (N=129)	Total Costs	120	90,700	4,620	350-67,000
	Medical Costs	20	49,500	1,830	150-34,600
	Non-Medical Costs	20	41,200	700	50-29,750
Rift Valley (N=160)	Total Costs	520	341,659	13,114	700-235,133
	Medical Costs	50	322,959	9,402	200-161,434
	Non-Medical Costs	100	177,250	2,700	150-26320

3.2.6 Source of healthcare finances

The main sources of financing for majority of patients (both near-misses and PLTCs), was personal finances and savings (56%). Close to one third (29.6%) of patients had their medical bills waived or exempted by the health facility and thus absorbed by the health system. Further, only one quarter (25.9%) of patients had their costs covered by their health insurance package (Figure 5).

Figure 5 **Sources of finances for patients with near-misses and other obstetrics complications**



Discussion

To our knowledge, this is the first nationally representative study describing the incidence, causes and cost of maternal near-miss in Kenya. We collected data prospectively and utilized all the standardized criteria in the WHO near-miss tool, whilst adapting for local context, which allowed us to compare case yield from both criteria.

Our study shows that the burden of maternal near-miss (0.7%) and SMO (0.8%) recorded was almost similar to the estimates reported for Kenya from 20 hospitals within the 2013 WHO multi-country survey (0.4% and 0.7% respectively) [20] but lower than what has been reported in other countries in the SSA region such as in Nigeria (1.6% and 2.7%) [21]. The figures are also lower than estimates of near-miss for other high MMR countries in Africa within the 2013 WHO multi-country survey [20], and much lower than estimates reported in more recent smaller facility-based studies in Africa. The intra-hospital MMR (36.2 per 100,000 live births) estimated in our study is also much lower than the Kenya estimate in the 2013 WHO multi-country study, which was 280 per 100,000 live births[20]. Additionally, the ratio of MNM to deaths in our study (20:1) is lower than the ratio reported in a recent study conducted in three counties in Western Kenya between 2014 and 2016 where there were 39 near-misses for every maternal death [22, 23].

Further, this study indicates a relatively low mortality index of 4.8%, with considerable differences between regions in Kenya. This figure was much lower than the mortality index of 41% in Nigeria which may be indicative of substantial differences in the quality of care provided for women at referral facilities in both settings [21]. A mortality index below 20% and case fatality rates for direct obstetric complications of less than 1% are considered indicative of health systems that are managing severe cases optimally. Although Kenya's indicators fall within the range of optimal care and comparatively lower than in other African countries [24], over one-third of near-misses occurred during admission. This may be an indication of delays in receiving appropriate treatment in hospitals. There were also gaps in the coverage of evidence-based interventions for some conditions including –- the receipt of blood transfusion services for APH, prompt surgical intervention for uterine rupture, and magnesium sulfate for severe pre-eclampsia and eclampsia. All these services are core components and process indicators of comprehensive EmOC, which are key to managing the commonest causes of maternal mortality at referral level hospitals. While obstetric hemorrhage and hypertensive disorders of pregnancy were the commonest causes of mortality, fatality was similar across all major underlying causes of SMOs. After hemorrhage and hypertensive disorders, abortive outcomes were the commonest cause of death.

Furthermore, our study findings suggest that the financial burden arising from MNM events in Kenya is high. Generally, the direct cost of treating MNM was higher compared to PLTCs, and vary considerably across the regions. Specifically, the median expenditure for treating a case of MNM was KES 12,060 (US$ 121), whereas the median expenditure for all cases (MNM and PLTC) was KES 8,712 (US$ 88). These costs were quite high given the median monthly wage of US$ 69 (KES 6900) in Kenya in 2018 [25]. This figure is also higher than that seen in Ghana for treatment of maternal complications, where the median expenditure to patients/households was US$32.03 (~KES 3200) [26]. This disparity could be possibly explained by the fact that our current study focused on more severe maternal complications i.e. the near-misses, which may require longer hospital stays, more sophisticated treatment procedures provided by higher cadre of health care providers, hence higher costs of care. Further the payment for care involved out-of-pocket expenditure for majority of the women in this study and exceeds the monthly median household income. In Kenya, economically vulnerable women who experience near-miss events risk potential catastrophic expenditures with severe disruption of household finances in the short- to long-term [27]. While there have been efforts by the Kenyan Ministry of Health to reduce the costs of healthcare to individual women and their households (such as the removal of delivery fees) [2], our study shows that women with near-miss events continue to pay substantially high amounts of money for health care, even in public health facilities. Fear of such costs may deter women or their social networks from utilizing emergency obstetric services altogether in future complicated pregnancies [15, 28] or result in delays in accessing services, which can increase the severity of complications.

Conclusions and Recommendations

In this report, we provide new evidence on incidence of maternal near-miss, its causes and the individual level costs incurred for treatment. Although Kenya has a relatively low incidence of maternal near-miss, coverage of essential EmOC interventions is suboptimal for many direct obstetric conditions. To address the gaps identified in maternal health care, there is need for strategic investment and research aimed at:

1. Improving the health system's capacity to provide care for emergency obstetric care.
2. Timing of near-miss events and death highlights the delays women experience in accessing care and emphasizes the need for community-level research and interventions that identifies and reduces or eliminates barriers to care.
3. Strengthening the referral systems and to facilitate availability of essential EmOC interventions particularly blood transfusions, surgical services, oxytocin, and magnesium sulfate.
4. Introduction of facility audits of near-miss events (in addition to maternal deaths) as part of routine monitoring. This will enable health facilities identify institutional bottlenecks to providing high quality maternal care and to implement strategies to tackle the challenges identified.
5. This study affirms that there are high financial costs incurred by women who experience MNM events. There is need to further assess the efficacy of the free maternal health services policy in Kenya
6. Explore the potential of raising limits of insurance coverage for pregnant women, to help offset costs to individuals and their households.
7. Build on the existing attempts to implement the universal health coverage (UHC) that comprehensively covers maternal health care needs and address the barriers, including cost, to timely and quality maternal health care services.

Study Limitations

The study had a relatively short duration, which may not have accounted for seasonal trends in hospital admissions. Also, the study was conducted right after a national nurses' and doctors' strike across Kenya [29] which most likely resulted in lower-than-typical caseloads and more maternal deaths outside of public hospitals around data collection [30, 31]. Additionally, despite our efforts to ensure high quality data collection, it is possible that we missed or misclassified cases. Furthermore, because of the need to obtain consent from women or their families before extracting clinical data, we had a higher proportion of maternal deaths than near-misses from whom we could not obtain consent [32]. Thus, our sample includes a higher proportion of eligible near-misses than maternal deaths.

In estimating the cost of near-misses, we did not collect indirect costs incurred during treatment, which may have included the value of relatives' time spent travelling to the hospital and waiting time before treatment is offered. This is in spite of the fact that indirect costs have been shown to contribute significantly to overall costs of health care [33]. Also, lost productivity to the household due to possible long-term morbidity suffered by women as a result of the near-miss event was not explored in this study. Despite these limitations, our study provides estimates of the direct cost of care for MNM in Kenya. We attempted to capture all direct costs of care incurred during the treatment process, including referrals and care received before arriving at the facility of discharge.

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Appendices

Appendix 1: Identifying criteria for maternal near-miss

World Health Organization (2011) criteria	Nelissen et al. (2013) criteria
Clinical criteria	
Acute cyanosis	Acute cyanosis
Gasping	Gasping
Respiratory rate >40 or <6/min	Respiratory rate >40 or <6/min
Shock	Shock
Oliguria non responsive to fluids or diuretics	Oliguria non responsive to fluids or Diuretics
Failure to form clots	Failure to form clots
Loss of consciousness lasting >12hrs	Loss of consciousness lasting >12hrs
Cardiac arrest	Cardiac arrest
Stroke	Stroke
Uncontrollable fit/total paralysis	Uncontrollable fit/total paralysis
Jaundice in the presence of pre-eclampsia	Jaundice in the presence of pre-eclampsia
Laboratory-based criteria	
Oxygen saturation <90% for ≥60 minutes	Oxygen saturation <90% for ≥60 minutes
PaO_2/FiO_2<200 mmHg	
Creatinine ≥300μmol/l or ≥3.5 mg/dL	
Bilirubin>100 mmol/l or > 6,0 mg/dl	
pH <7.1	
Lactate >5	
Acute thrombocytopenia (<50 000 platelets)	Acute thrombocytopenia (<50 000 platelets)
Loss of consciousness and the presence of glucose and ketoacids in urine	
Management-based criteria	
	Admission to intensive care unit
Use of continuous vasoactive drugs	
Hysterectomy following infection or hemorrhage	Hysterectomy following infection or Hemorrhage
Transfusion of ≥5 units of blood	Transfusion of ≥2 unit of blood
Intubation and ventilation for ≥60 minutes not related to anesthesia	Intubation and ventilation for ≥60 minutes not related to anesthesia
Dialysis for acute renal failure	
Cardio-pulmonary resuscitation	Cardio-pulmonary resuscitation
Severe maternal complications	
	Eclampsia
	Sepsis or severe systemic infection
	Uterine rupture

Appendix 2: Estimated annual incidence of maternal near-miss and other severe maternal outcome indicators in Kenya, by regions in 2018

	National	Nairobi & Central	Eastern	Eastern	Nyanza & Western	Rift Valley
Annual Number of Facility Caseloads						
Total number of facility live births	708,459	196,189	57,247	101,044	168,523	185,455
Total number of facility deliveries	726,158	198,966	62,049	100,770	174,428	189,946
Annual Number of Severe Maternal Outcomes						
Number of maternal near-miss cases	5,116	1,199	467	437	1,264	1,749
Number of maternal deaths	256	100	16	81		51
Overall Maternal Near-Miss Indicators						
Severe maternal outcome (SMO) ratio (per 1,000 live births)	7.6 (4.9 to 10.2)	6.6 (0.8 to 12.5)	8.4 (3.0 to 13.9)	5.1 (2.9 to 7.3)	7.6 (3.1 to 12.0)	9.7 (3.3 to 16.1)
Maternal near-miss incidence ratio (per 1,000 live births)	7.2 (4.6 to 9.9)	6.1 (0.3 to 11.9)	8.2 (2.7 to 13.6)	4.3 (2.3 to 6.4)	7.5 (3.1 to 11.9)	9.4 (3.2 to 15.6)
Intra-hospital maternal mortality ratio (per 100,000 live births) (13.3 to 59.0)	36.2 (13.3 to 59.0)	51.0 (-16.1,118.1)	27.9 (22.5 to 33.4)	80.2 (-0.6, 161.0)	4.7 (3.8 to 5.7)	27.6 (-18.8, 74.0)
Mortality Index (MI)*	4.8%	7.7%	3.3%	15.6%	0.6%	2.8%
Maternal near-miss: maternal death ratio	20.0	12.0	29.2	5.4	158.1	34.2
Hospital Access Indicators	**%**	**%**	**%**	**%**	**%**	**%**
Severe maternal outcome occurred before admission in hospital	64%	70%	70%	55%	45%	73%
Severe maternal outcome occurred during stay in hospital	36%	30%	30%	45%	55%	27%
Severe maternal outcome occurred before admission, referred from other facilities	58%	59%	31%	39%	63%	66%
Mortality index: SMO occurred before admission	1.6%	4%	1.2%	1.7%	1.4%	0.3%

* Mortality index is calculated as: maternal deaths / (maternal near-miss + maternal deaths)

** All cases are weighted

Appendix 3: Utilization of the WHO Near Miss Criteria adapted for Kenyan context

WHO Near Miss Criteria, by organ dysfunction criteria		WHO criteria*		Kenya criteria N	Kenya-adapted criteria*		Women classified as MNM solely on the basis of criteria from Kenya adaptation	
		N	%		N	%	N	%
MNM Total		**250**	**36%**		**360**	**52%**	**133**	**30%**
Cardiovascular								
Clinical Criteria	Shock	94	14%	Shock**	109	16%	44	10%
	Cardiac arrest	5	1%	Cardiac arrest	5	1%		
				Severe anaemia (standalone < 4 Hb)	27	4%	9	2%
Laboratory markers	Severe acidosis (pH < 7.1)	6	1%	Severe acidosis (pH < 7.1)	6	1%		
	Severe hypofusion (Lactate > 5 mEq/mL)	1	0%	Severe hypofusion (Lactate > 5 mEq/mL)	1	0%		
Management based proxies	Use of continuous vasoactive drugs	12	2%	Use of continuous vasoactive drugs	12	2%		
	Cardio-pulmonary resuscitation	15	2%	Cardio-pulmonary resuscitation	15	2%		
Respiratory								
Clinical Criteria	Acute cyanosis	18	3%	Acute cyanosis	18	3%		
	Gasping	63	9%	Gasping	63	9%		
	Severe tachypnea (respiratory rate >40 breaths per min)	35	5%	Severe tachypnea (respiratory rate >40 breaths per min)	35	5%		
Laboratory markers	Oxygen saturation <90% for >=60 minutes)	44	6%	Oxygen saturation <90% for >=60 minutes	44	6%		
	PaO2/FiO2<200 mmHg	4	1%	PaO2/FiO2<200 mmHg	4	1%		
Management based proxies	Intubation and ventilation >60 mins not related to anaesthesia	11	2%	Intubation and ventilation >60 mins not related to anaesthesia	11	2%		
				Oxygen by mask or nasal tubes	64	9%	10	2%
Renal								
Clinical Criteria	Oliguria non-responsive to fluids or diuretics	44	6%	Oliguria non-responsive to fluids or diuretics	44	6%		
				Central oedema (puffy face, etc)	81	12%	22	5%

Laboratory markers	Severe acute azotaemia (Creatinine ≥300μmol/l or ≥3.5 mg/dL)	32	5%	Severe acute azotaemia (Creatinine ≥300μmol/l or ≥3.5 mg/dL)	32	5%		
				Serum urea >8mmol	37	5%	7	2%
				75% decrease in GFR calculated from 75mL/min per 1.73mm2	6	1%	0	0%
Management based proxies	Dialysis for acute renal failure	15	2%	Dialysis for acute renal failure	15	2%		
Coagulation/hematologic dysfunction								
Clinical Criteria	Failure to form clots	11	2%	Failure to form clots***	11	2%		
				Tendency to bleed	38	5%	13	3%
Laboratory markers	Severe thrombocytopenia (<50,000 platelets/ ml)	15	2%	Severe thrombocytopenia (<50,000 platelets/ ml)	15	2%		
				Abnormal liver function tests	21	3%	8	2%
Management based proxies	Transfusion of >= 5 units of blood	42	6%	Transfusion of >= 2 units of blood & HB level < 7	60	9%		
Hepatic dysfunction								
Clinical Criteria	Jaundice in the presence of pre-eclampsia	9	1%	Jaundice in the presence of pre-eclampsia	9	1%		
				Jaundice in the presence of sepsis	9	1%	1	0%
				Tender enlarged liver in PET	7	1%	4	1%
				Abnormal liver enzymes (AST <5 or >48 IU/L; ALT <7 or >55 IU/L)	32	5%	13	3%
				Abnormal liver enzymes with associated impaired consciousness	19	3%	5	1%
Laboratory markers	Severe acute hyperbilirubinemia (Bilirubin > 100μmol/l or >6 mg/dL)	16	2%	Severe acute hyperbilirubinemia (Bilirubin > 100μmol/l or >6 mg/dL)	16	2%		

Management based proxies				Admission for critical care	14	2%	1	0%
Neurologic dysfunction								
Clinical Criteria	Prolonged unconsciousness (lasting ≥ 12 hours)	39	6%	Prolonged unconsciousness (lasting ≥ 12 hours)	39	6%		
	Stroke	2	0%	Stroke	2	0%		
	Uncontrollable fits/ status epilepticus	33	5%	Uncontrollable convulsions	33	5%		
	Total paralysis	0	0%	Total paralysis	0	0%		
Laboratory markers				EEG	8	1%	3	1%
				CT Scan	15	2%	2	0%
Management based proxies				Critical care	18	3%	2	0%
Uterine dysfunction								
Clinical Criteria				Paralytic ileus (Absent bowel sounds in a gaseous distended abdomen)	7	1%	1	0%
				PTE (pulmonary thromboembolism) showing the above respiratory symptoms and signs	3	0%	0	0%
Management based proxies	Hysterectomy following infection or haemorrhage	19	3%	Hysterectomy following infection or haemorrhage	19	3%		
				Laparotomy	45	6%	30	7%
Incidence calculations****								
Maternal near-miss incidence ratio (per 1,000 live births)		4.7			7.6			
Severe maternal outcome ratio (per 1,000 live births)		4.9			7.9			

* Women can have multiple criteria

** Shock in WHO was defined based on clinicians simply selecting a woman as shock based on the training definition of persistent systolic blood pressure

≤80mm Hg alone or persistent systolic blood pressure ≤90mm Hg with a pulse rate at least 120 bpm, and requiring administration of any IV fluids and/or cold extremities, blurred vision. WHO in the Kenya adapted criteria was defined by using both clinicians assessment and an algorithm in statistical software to identify women with all the criteria for shock who were missed by clinicians.

*** Failure to form clots defined as the absence of clotting from IV site >7 minutes

**** Incidence is calculated using weighted cases and live births

***** All cases are weighted

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