EFFECT OF FREE MATERNITY SERVICES ON MATERNAL NEAR-MISS MORBIDITY AMONG WOMEN DELIVERING AT EMBU COUNTY REFERRAL HOSPITAL – A QUASI EXPERIMENTAL STUDY.

A thesis in partial fulfillment of the requirements for the degree of Master of Medicine in Obstetrics and Gynecology, University of Nairobi.

Dr. Winnie K. Mwebia,

Registrar,

Department of Obstetrics and Gynecology,

Registration Number: H58/75424/2014.

DECLARATION

I declare that this is an original write up. It does not duplicate any previously written or published material, to the best of my knowledge. Where reference was made from other sources, the source literature has been cited. This is a product of my own work, done with the guidance of my supervisors.

Candidate:

Sign	Date
•	

Dr. Winnie Mwebia

MBchB.

This proposal is presented with our approval as the university supervisors:

1st Supervisor:

Sian	Date
- 3	

Dr. Francis X. Odawa

MBChB, MMED (Obs/Gyn).

2nd Supervisor:

Sign_____Date____

Prof. MuiaNdavi

MBchB, MMED(Obs/Gyn), Msc, Epidemiology (London), FHBR (Harvard), DLSHTM (London).

CERTIFICATE OF AUTHENTICITY

This is to certify that this dissertation is the original work of Dr. Winnie Mwebia, Master of Medicine student in the Department of Obstetrics and Gynecology, Registration Number H58/75424/2014 University of Nairobi (2014 – 2018). The research was carried out at the Embu County Referral Hospital Maternity Unit under supervision of the department of Obstetrics and Gynecology, School of Medicine, College of Health Sciences, University of Nairobi. It has not been presented in any other university for award of degree.

Signature

Date

Professor Omondi Ogutu Associate Professor of Obstetrics and Gynaecology Consultant Obstetrician and Gynaecologist Chairman Department of Obstetrics and Gynaecology University of Nairobi

ACKNOWLEDGEMENT

I am grateful to God for enabling me to complete this work.

I appreciate the guidance and mentorship of my very dedicated supervisors; Dr. F.X Odawa and Prof. NdaviMuiaas I worked to design and complete the study.

I am also very grateful to the faculty members of the Department of Obstetrics and Gynecology with special gratitude to the research team led by Professor MuiaNdaviand Dr. Osoti for the constant lessons on research. You help me understand what research is all about and equipped me well to conduct this research.

Special thanks to my friend and statistician Mr. Justus Kilonzi for helping me design my study and analyze the data.

Lastly, I would like to thank the management of Embu county referral hospital for allowingme to use the facility as the study site. We are also grateful to the women whose records were reviewed.

DEDICATION

I dedicate this work to my family: My loving husband Dr. NgureNyaga and our two sons Victor Nyaga and Jeremy Gitonga. You remained very patient with me as I worked days on end to complete this work. Without your love and support, I would not have made it this far.

Special dedication to all mothers, who risked their lives to bring life.

DECLARATION	ii
CERTIFICATE OF AUTHENTICITY	iii
ACKNOWLEDGEMENT	iv
DEDICATION	v
LIST OF FIGURES AND TABLES	
LIST OF ABBREVIATIONS	ix
DEFINITION OF TERMS	x
ABSTRACT	xi
CHAPTER ONE	1
1.1 STUDY BACKGROUND	1
1.2 LITERATURE REVIEW	2
1.3 CONCEPTUAL FRAMEWORK	
1.4 RATIONALE	11
1.5 NULL HYPOTHESIS	13
1.6 RESEARCH QUESTION	13
1.7 STUDY OBJECTIVES	13
CHAPTER TWO	14
RESEARCH METHODOLOGY	14
2.1 STUDY DESIGN	14
2.2 STUDY SETTING	14
2.3 STUDY POPULATION	15
2.4 SAMPLE SIZE CALCULATION AND SAMPLING PROCEDURES	15
2.5 INCLUSION CRITERIA	16
2.7 DATA VARIABLES	19
2.8 DATA ANALYSIS	20
2.9 STUDY LIMITATIONS	21
2.10 ETHICS APPROVAL	21
2.11 DATA DISSEMINATION	21
CHAPTER THREE	22
RESULTS	22
3.1 STUDY FLOW	22
3.2 INCIDENCE OF PTLCS AND MNMS	23

3.3 CAUSES OF PTLCS AND MNMS	24
3.4 USE OF CRITICAL INTERVENTIONS	
3.5 MNM INDICATORS	
CHAPTER FOUR	27
DISCUSSION	27
4.1 CAUSES OF PTLCS AND MNMS	
4.2 USE OF CRITICAL INTERVENTIONS	
4.3 MNM INDICATORS	
4.3.1 Overall MNM indicators	
4.3.2 Hospital Access Indicators	31
4.3.3 Intra-hospital Care Indicators	31
CHAPTER FIVE	
CONCLUSIONS AND RECOMMENDATIONS	
5.1 CONCLUSIONS	32
5.2 RECOMMENDATIONS	
REFERENCES	34
APPENDIX	
A DATA COLLECTION FORM	
B KNH-UON ERC APPROVAL LETTER	Error! Bookmark not defined.

LIST OF FIGURES AND TABLES

Table 1: WHO Maternal Near Miss Indicators	6
Table 2: WHO Organ Dysfunction System for Identification of Maternal Near Misses	7
Table 3: Incidence of PTLCs and MNMs	23
Table 4: Dysfunctional Organ System	24
Table 5: Causes of PTLCs and MNMs	25
Table 6: Use of Critical Interventions	26
Table 7: MNM Indicators	27
Figure 1: Conceptual Framework	11
Figure 2: Maternal Near Miss Screening Process	17
Figure 3: Data Variables	20
Figure 4: Study Flow	

LIST OF ABBREVIATIONS

ANC	Antenatal Clinic
ARF	Acute Renal Failure
AKI	Acute Kidney Injury
CPR	Cardiopulmonary Resuscitation
Cr	Creatinine
C/S	Caesarean Section
DHIS	District Health Information System
ECRH	Embu County Referral Hospital
MMR	Maternal Mortality Ratio
PNC	Postnatal Clinic
SMI	Safe Motherhood Initiative
FiO ₂	Fraction of inhaled oxygen
FMS	Free Maternity Services
HELLP	Hemolysis Elevated Liver Enzymes Low Platelets
HIV/AIDs	Human Immunodeficiency Virus/ Acquired Immunodeficiency Deficiency
	Syndrome
ICU	Intensive Care Unit
KDHS	Kenya Demographic Health Survey
KNH	Kenyatta National Hospital
LBs	Live Births
LMICs	Low and Middle-Income Countries
LTCs	Life Threatening Conditions
МСН	Maternal and Child Health
MD	Maternal Death
MM	Maternal Mortality
MNM	Maternal Near Miss
MNMR	Maternal Near Miss Ratio
МОН	Ministry of Health
MTRH	Moi Teaching and Referral Hospital
O 2	Oxygen
PaO ₂	Partial Pressure of Oxygen
PTLCs	Potentially Life-Threatening Conditions
RR	Respiratory Rate
SAMM	Severe Acute Maternal Morbidity
SMO	Severe Maternal Outcome
SMOR	Severe Maternal Outcome Ratio
UI	Uncertainty Interval
WHO	World Health Organization

DEFINITION OF TERMS

- 1. **Critical Interventions:** Those interventions that are required in the management of PTLCs and LTCs. In the WHO near miss approach, the following are considered to be critical interventions: blood transfusion, interventional radiology, laparotomy (including hysterectomy but excluding C/S).
- 2. Eclampsia: Generalized fits in a patient without previous history of epilepsy. Includes coma in pre-eclampsia
- 3. Live Birth: Birth of an offspring which breathes or shows evidence of life.
- 4. **Maternal Death:** Death of a pregnant woman while pregnant or within 42 days of termination of pregnancy or from its management but not from accidental or incidental causes.
- 5. **Maternal Near Miss:** A woman who nearly died but survived a complication that occurred during pregnancy childbirth or within 42 days of pregnancy termination
- 6. **Potentially Life-Threatening Conditions:** also known as "severe maternal complications" a category of clinical conditions and diseases that threaten the life of a woman during pregnancy, labor and after pregnancy termination. Five conditions are included in the WHO near miss approach: Severe PPH, Severe Pre-eclampsia, Eclampsia, Severe systemic infection/sepsis, Uterine rupture.
- 7. Severe Maternal Outcomes also known as "Life Threatening Conditions" refer to those conditions with evidence of organ dysfunction, either as maternal near misses or maternal deaths
- 8. **Severe PPH:** Genital bleeding after delivery with at least one of: Perceived abnormal bleeding (1000ml) of more or any bleeding with hypotension or blood transfusion.
- Severe pre-eclampsia: Persistent systolic blood pressure of 110 mmHg; Proteinuria of 5g or more in 24hrs; Oliguria of <400ml in 24 hrs; HELLP Syndrome: Pulmonary edema
- 10. Severe systemic infection /sepsis: Presence of fever (body temperature >38° C), a confirmed or suspected infection e.g. chorioamnionitis, endometritis, pneumonia) and at least one of the following: heart rate >90, respiratory rate >20, leucopenia wbcs< 4000, leukocytosis (wbcs>12000)
- 11. Uterine rupture: Rupture of uterus confirmed by laparotomy.

ABSTRACT

Background:

Healthcare cost is a major barrier to access of essential maternal services in the developing world. On 1st June 2013, Kenya introduced Free Maternity Services (FMS) in an effort to promote access and improve maternal outcomes. Subsequently, service utilization increased resulting in pressure on existing resources- a potential compromise to the quality of care offered. The World Health Organization (WHO) maternal near miss (MNM) tool was used to evaluate maternal outcomes under FMS in a county referral hospital in Kenya.

Objective:

The broad objective was to evaluate the effect of free maternity services on maternal near miss morbidity at Embu County Referral Hospital. The specific objectives were to; determine the incidence of maternal near miss, compare the causes of Potentially-Life Threatening conditions and Near Misses and lastly to compare the MNM indicators before and after FMS.

Methods:

Study design: Retrospective quasi experimental (pre-post type).

Treatment group: Records of 186 women with near miss morbidity after introduction of FMS. Post-period was June 2014 to May 2016.

Comparison group: Records of 185 women with near miss morbidity before introduction of FMS. Pre-period was October 2010 to May 2013.

Setting: Embu county referral hospital in Eastern Kenya.

Study population: Women offered maternity services at Embu county referral hospital between Oct 2010 to May 2016.

Data collection and analysis: Data abstraction form was adopted from the WHO Maternal Near-Miss tool. Analysis used SPSS version 24. Pierson Chi-square test of statistical significance was applied (p value <0.05).

Results:

The incidence of MNM was 2.2% and 2.5% in the pre and post periods respectively. The commonest cause of maternal near miss in both study periods was severe postpartum hemorrhage (PPH) and severe preeclampsia. Severe PPH increased (91.0% vs 80.0% p-value 0.005), while that of severe preeclampsia reduced in the post-period (6.5% vs 13.0% p-value 0.029). Anemia was the biggest contributory cause of near misses but reduced in the post-period (30.1% vs 43.8% p-value 0.020). Use of blood products increased in the post-period (68.2% vs 78.5% p-value 0.000). Maternal near miss ratio, which is a measure of the amount of resources needed in a facility, increased in the in the post-period (from 22.7/1000 to 26.3 /1000 live births). The proportion of severe maternal outcomes within 12 hours of admission(SMO12) increased from 66% to 69% after FMS.

Conclusion:

Introduction of free maternity services had mixed effect on maternal near miss morbidity at Embu county referral hospital in Kenya. MNM cases due to severe preeclampsia and anemia reduced significantly while those due to severe PPH increased. The need for blood transfusion also increased, and this mirrored the increase seen in severe PPH. The MNM indicators in this study suggest that the first and second delays in access did not improve as expected after removal of the cost barrier. In addition, these indicators showed that the resources required to manage severe complications of childbirth were suboptimal in the facility.

Recommendations:

To optimize obstetric care under the free maternity services program in Kenya, there is need to develop strategies for prevention and management of severe PPH. Secondly, national blood transfusion services need to be strengthened in order to match the increased demand for blood.Audit of the existing resources is also essential in order to identify specific areas that need to be enhanced. Also, other barriers of hospital access should be evaluated in order to reduce first and second delays.

CHAPTER ONE

1.1 STUDY BACKGROUND

Timely access to essential services for preventing and treating pregnancy-related complications, can reduce the high maternal morbidity and mortality in Sub-Saharan Africa (1)⁻ High cost of healthcare is one of the main barriers to access (2). In 2008-09 the maternal mortality ratio (MMR) in Kenya was 488/100,000 live births, way above the millennium development goal 5 target of 147/100000 live births (3). In June 2013, the Government implemented free maternity services in all public health facilities through a presidential decree. This was an effort to improve access to maternity care and ultimately reduce maternal mortality. Under FMS, all fees for antenatal care, deliveries and postnatal care up to six weeks were abolished. This extended to all delivery related complications(4).

Over time, uptake of maternity services increased. Two years after its implementation, the number of women receiving antenatal care and delivering in public health facilities increased by 50% and 26% respectively. This led to pressure on the existing resources, particularly human resource and hospital supplies, which were not immediately increased to match the increased utilization (5,6). This mismatch could potentially compromise the provision of timely emergency obstetric care(7).

Review of maternal near misses has been shown to be a good alternative to maternal death review in assessment of quality of care both at facility and health system level. The World Health Organization MNM tool provides a standard approach to assessment of quality of care. It enables comparability of findings over various periods and settings (8). A multinational study that utilized this tool found a global maternal near miss ratio (MNMR) of 8.3/1000 live births. Countries with high MMR had an equally high MNMR of 13.3/1000 live births – two to three times higher than countries with low MMR. In both high and low maternal mortality settings, coverage of essential interventions was similar except for the timeliness in which they were offered(1). This emphasized the need for overall improvement in quality of care and emergency obstetric services over and above universal coverage of life-saving interventions. Unpublished data show that the MNMR in Kenya is 42/1000 live births(9).

Kenya is divided into 47 counties, with a devolved healthcare system. We utilized the WHO near miss tool to compare the pattern of MNM morbidity among women delivering in a county referral hospital before and after introduction of the free maternity services policy in Kenya from 2010 to 2016. This would provide a comparative assessment of the quality of care between the two periods.

1.2 LITERATURE REVIEW

Maternal health improvement remains a key development agenda globally. Although some progress has been made in the reduction of maternal deaths, the numbers have remained high with the developing countries bearing the greatest burden(10). There was a 44% decline in MMR globally, from 532,000 MDs in 1990 to 303,000 MDs in 2015. The annual decline rate was however insufficient at 2.3%, which fell short of the 5.5% rate envisioned in the MDGs to reduce MMR by three-quarters by the year 2015. Sub-Saharan Africa had the highest number of MDs accounting for 66% of these deaths, which was partly explained by the HIV/AIDs epidemic in the continent. In this review, Kenya was among the 18 countries in this region, with "very high" MMR estimated at 510 (UI 344 - 754/ 100000 LBs). These findings underscored the need for targeted efforts towards improving access to quality maternal health care, as well as primary prevention of unintended pregnancies through family planning(11).

The Kenya Demographic Health Survey (KDHS) of 2009 reported an average MMR of 488/100000 LBs(3). This MMR was more than three times higher than the 147/100000 live births that was the MDG5 goal for the country. An earlier review of maternal deaths at Kenyatta National Hospital (KNH) from 1995 to 1999 and found an unacceptably high average MMR of 921.5 / 100000 LBs. Among the factors identified as contributory to the high MMR was inability to attend meaningful antenatal care and birth order. Lack of ANC attendance was similarly reported by as a risk factor for maternal death, in a study carried out at Moi Teaching and Referral Hospital (MTRH) between 2004 - 2011(12,13).

Most of maternal deaths (approximately 74%) can be avoided if women had timely access to the interventions aimed at preventing and treating pregnancy-related complications. These interventions include: antenatal care (ANC), for early recognition of complications in a mother during pregnancy; delivery by skilled birth attendants; postnatal care (PNC) to recognize and manage those complications arising from the postnatal period - which is the most vulnerable period for both mother and child and lastly, availability of emergency obstetric care services, to manage any major complication arising(14,15).For instance, only 62% of women in Kenya deliver under the care of skilled birth attendants and only 58% attend at least 4 of the WHO

recommended antenatal visits, both of which fall below the 90% targeted by the MDGs by the year 2015(17).

Delays in accessing these essential interventions contributes largely to the high maternal morbidity and mortality in Kenya and other developing countries. The three recognized delays are (I) delays in seeking health care, (II) delays in arrival at the health facility and (III) delays in the provision of healthcare services(16).

Cost is one of the main barriers of access in developing countries. This is more prominent among the poor households where there is limited cash flow and contributes to first and second delays(2) In an effort to reduce these delays, the Kenyan government instituted Free Maternity Services (FMS) in July 2013, with the overall aim of improving maternal and neonatal health in the country. The FMS policy was designed so as to address the barrier to utilization of maternity services due to inability to afford MCH services by a large pool of the population. Under the FMS program, the Kenyan government abolished fees for accessing maternal care in the public hospitals across the country. The services covered under FMS include ANC, Deliveries, PNC and complications of delivery including; ICU care, renal dialysis, and complicated medical diseases in pregnancy(4).

The FMS programme led to an increase in the utilization of the public maternity services. For instance, national statistics as reported on the DHIS 2 indicate that mothers attending ANC clinic for the 4th visit increased by 11% within the first year of implementation. The number of hospital deliveries also increased by 22% and 17% for

normal and caesarean deliveries respectively. This propelled the proportion of women in Kenya delivering under skilled birth attendants from 44% to 62%. There was also a significant decline in cases of obstructed labor from 3.2% to 1.6%. For the other direct complications of pregnancy, the decline noted was not statistically significant(5,17). Despite the increase in service utilization, it was noted that the resources; infrastructure, staff and commodities were not equally increased to cater for the rising demand. A report by the ministry of health on the status of the policy implementation, noted increased pressure on the existing resources and raised concerns over the quality of care provided. A national referralhospital reported a 26% increase of deliveries, 22% increase of Caesarean section and 50% increase of ANC attendance. The staff was inadequate, with 1 nurse taking care of 15 patients. Two referral hospitals reported an increase in maternal mortality due to a tendency to focus more time on the complicated referral cases, compromising the care of the booked uncomplicated patients(5)

This drawback is not unique to Kenya. Similar challenges have been encountered in other developing countries upon introduction of FMS(7). A study carried outin Ghana 3 years after the introduction of free delivery services found that the services were generally favorable especially to the poor by lifting the barrier of cost for access of hospital delivery services. However, the increase in service utilization did not result in improvement of the quality of care, which was overall poor. In order to realize the aim of improving maternal health in the country as intended by the policy, a recommendation was made to improve quality of clinical care(18). There was therefore a need to assess the quality of obstetric care as well as the maternal outcomes under the FMS

programmein Kenya. This assessment would help to identify the specific strengths and weaknesses of the programme so as to formulate interventions that will optimize maternal health in the country. The WHO maternal near miss tool is a standardized approach for assessment of the quality of obstetric care. It outlines the criteria for case definitions of maternal near miss/ severe morbidity as well as a set of indicators (*Table 1*) that can be used to compare various aspects of care. It allows a systematic process that is replicable and comparable over time and across settings(19)

Table 1: WHO Maternal Near Miss Indicators

In Product	Description	
Indicator	Description	
Overall Near-Miss	Indicators	
Maternal near- miss ratio (MNMR)	The number of MNM cases/ 1000 live births. This indicator gives an estimate of the amount of care and resources needed in a particular facility.	
Severe Maternal	The number of women with life-threatening conditions (MD+MNM)/ 1000 live	
Outcome Ratio (SMOR)	births. Similarly, this gives an estimate of the amount of care and resources needed in a facility.	
Maternal Near-	The number of MNM per 1 MD.	
Miss Mortality Ratio (MNM:1MD)	The higher the ratio, the more the women who survived as near misses rather than dying, hence indicate better quality of care.	
Mortality index (MI).	The number of MDs divided by the total number of women with LTCs expressed as a percentage.	
(((())))	A Higher index implies that more women with LTCs died, indicating poor quality of care.	
Hospital Access Indicators		

SMO12	This is the number of SMO cases developing within 12 hours of hospital stay.
SMO12/ All SMO	Proportion of SMO12 cases among all SMO cases.
cases	A high proportion indicate that women are arriving in hospital too late, hence a 1 st and 2 nd delay issue.
SMO12 Referrals	Proportion of SMO12 cases coming from other health facilities
	A high proportion indicate the health system contribution to 1 st and 2 nd delays.
SMO12 Mortality	Number of MDs occurring within 12 hours of admission among all SMOs.
Index	A higher index implies that more women died within 12 hours of admission, indicating a 1 st and 2 nd delay issue.

Intrahospital Care Indicators

Intrahospital SMO	The number of SMO cases occurring after 12 hours of admission
cases	
Intrahospital SMO	The number of SMO cases occurring after 12 hours of admission per 1000LB

rate	This indicates the level of intrahospital care. Higher rates imply poor hospital care (3 rd delay)
Intrahospital Mortality Index	Number of MDs occurring after 12 hrs of admission among all SMOs A higher index implies that more women died after 12 hrs of admission, indicating a 3 rd delay (poor quality of care)

MD- Maternal Death; **MNM-** Maternal Near Miss; **LTC-** Life threatening Condition; **SMO-** Severe Maternal Outcome; **WHO-** World Health Organization

A maternal near miss is defined as a woman who nearly died, but survived acomplication that occurred during pregnancy childbirth or within 42 days of pregnancy termination. Cases of MNM are identified using organ dysfunction system. This criterion is supplemented with clinical, lab and management-based markers of organ dysfunction that made it feasible for use, even in the low resource setting without high level amenities (20) *Table 2* outlines the organ dysfunction system as outlined in the WHO tool.

Dysfunctional System	Clinical Criteria	Laboratory Markers	Management - Based Proxies
Cardiovascular	-Shock -Cardiac arrest	-Ph<7.1 -Lactate>5	-Use of continuous vasoactive drugs - CPR
Respiratory	-Acute cyanosis -Gasping -RR >40 and <6 bpm	-O ₂ sat <90% for >/= 60 min -PaO ₂ /FiO ₂ <200 mmHg	-Intubation and ventilation not related to anesthesia
Renal	-Oliguria unresponsive to fluids and diuretics	-Cr >/= 300 umol/L and >3.5mg/dl	-Dialysis for AKI
Hematological/ Coagulation	-Failure to form clots	-Acute severe thrombocytopenia of < 50,000 platelets	- Transfusion of >5 units of blood/red cells
Hepatic	-Jaundice in the presence of preeclampsia	-Bilirubin >100 umol/L and 6.0 mg/dl	
Neurologic	-Loss of consciousness not medically induced lasting for >6hrs. -Stroke -Uncontrollable fit/ status epilepticus -Total paralysis		
Alternative Severity Proxy			-Hysterectomy following uncontrollable hemorrhage.

Table 2: WHO Organ Dysfunction System for Identification of Maternal Near Miss Cases

WHO- World Health Organization; CPR- Cardiopulmonary Resuscitation; PaO₂-Partial pressure of oxygen; FiO₂-Fraction of Inhaled oxygen; MMHg- millimeters of mercury; Cr- Creatinine; AKI- Acute Kidney Injury Overall, the MNM concept presents several advantages over maternal death reviews alone, in evaluating the quality of maternal care:With an increasing number of women delivering in hospitals, there is an increase in those women with high risk conditions which necessitate management measures of these potentially life threatening conditions to avoid mortalities(21). MNM studies can provide invaluable information on these measures and also allow comparison over time and across different facilities or counties. Secondly, MNM cases are more than those of maternal deaths, making studies easier with less data to handle. Also, qualitative data can be collected through interviewing the survivorson their experiences and this first-hand data which would greatly inform on the gaps in the service delivery cannot be collected from review of maternal deaths alone. Lastly, review of near misses isless threatening to the morale of participants as compared to MDs, as these cases are often interpreted as "great saves" (20,22).

Globally the MNM concept is gaining wider acceptance. Studies using this concept have been carried out in various countries, underscoring its role in the quality of care evaluation. Global maternal near miss ratio (MNMR) is8.3/1000 LBs. The ratio is higher in countries with high MMR than those with low MMR(23). In an audit carried out in a tertiary center in Manipal India, a very near miss mortality index was found (5.6:1) which indicated poor quality of care that was attributed to late referrals from the peripheral facilities. This prompted a recommendation to establish other tertiary centers within the regions that referred the most, thereby alleviating the second delay that was responsible for these poor outcomes(24). Similarly, a study done at a tertiary care facility in Ghana

found that majority of the mothers with Potentially life-threatening conditions (PLTCs) had been referred to the facility and that more than half of the severe maternal outcomes occurred within the first 12hrs of admission. This again emphasized the need to strengthen the referral systems and effective use of critical care with evidence based interventions to improve on maternal outcomes (25). A nation-wide study was carried out in Nigeriainvolving 42 tertiary hospitals across the nation. MNM ratio was 15.8/1000 LB with a SMOR of 26.7/1000 LB. WHO estimates that the prevalence of severe maternal outcomes is expected to be approximately 7.5/1000 LBs. The higher SMOR found in this study therefore indicate a suboptimal survival rate of women with PTLCs in the country. Three guarters of these patients had not attended ANC, with 91.8% arriving to hospital in critical condition. Also, majority of these patients had been referred from other facilities. This study emphasized on the need to strengthen the primary, secondary and private facilities in the country in order to promote accessibility and thereby reducing the 1st and 2nd delays noted to be the major contributors of poor maternal outcomes in this study⁽²⁶⁾

Published literature on MNM in Kenya was not found. Three unpublished studies of MNM found were all carried out in the country's largest referral hospital, KNH. The studies were carried out in 2002, 2009 and 2017 by *Murage et al*, *Owiti et al and Watau et al* respectively. In the 2002 and 2009 studies did not use the WHO MNM as it had not been defined then. The 2017 study used the WHO criteria, and found a MNMR of 51/1000 LBs and 42/1000 LBs before and after introduction of FMS.The lower MNMR

was still more than five times the global average, indicating need for more resources at the national referral hospital.

KNH is a national tertiary referral hospital in Kenya, which handles the most complex cases in the country. It is therefore not a true representative of the other public hospitals in the country. A county referral hospital, as chosen for this study would give a baseline assessment at the county level. A quasi-experimental study of the pre and post type was employed. This is an analytical design which would aid in establishing the effect of FMS on MNM and by proxy, on the quality of care provided under the FMS. Insights gained on the accomplishments and downfalls of the programmewill help to tailor the necessary interventions required to advance maternal health agenda in the country.

1.3 CONCEPTUAL FRAMEWORK

The conceptual framework of this study represents the relationship between the maternal complications, PTLCS and SMOs (MNM+MDs) and the changes expected in this relationship upon introduction of FMS. The outcomes in this relationship include:

- The proportion of women with maternal complications that result in PTLCs or non PTLCs.
- ii. The proportion of PTLCs that result in SMOs or non-SMOs
- iii. The proportion of SMOs that result in MNMs and MDs.

Since Embu County ReferralHospital lacks some of the services required in the management of severe maternal complications such as; dialysis, ICU facilities and transfusion of some blood components, another outcome of interest was the proportion

of women with PTLCs, SMOs, and MNMs who were referred to a higher facility for these critical interventions.

In this study, the effect of FMS on these variables was evaluated as a proxy to the quality of obstetric care offered under the policy.

This relationship in the context of FMS is summarized in figure 1 below.

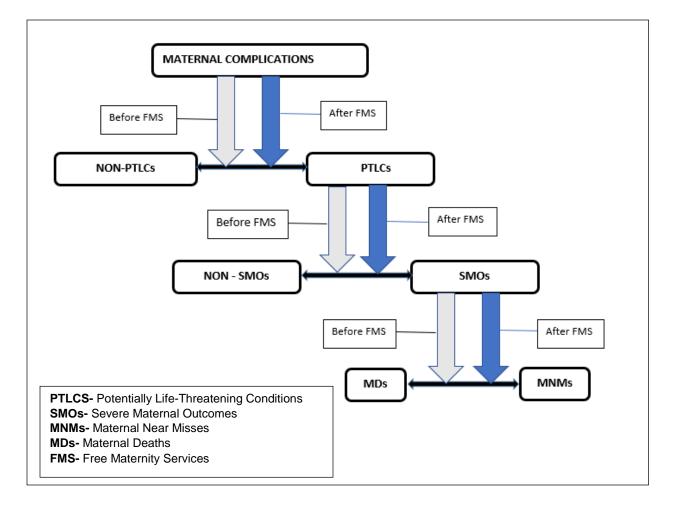


Figure 1: Conceptual Framework (The Effect of Free Maternity Services on Maternal Near Miss Morbidity)

1.4 RATIONALE

Maternal morbidity and mortality remain a high-priority issue globally as well as locally.

According to WHO, Kenya is among the Sub Saharan countries with "very high" MMR

and is listed among the 13 countries that contribute to 67% of global maternal deaths. Therefore, there was need for a comprehensive understanding of threats to maternal health in the country in order to improve on the maternal care.

The introduction of FMS in Kenya was aimed at increasing access to hospital deliveries under skilled care, therefore improving the quality of maternal health care and consequently reducing the birth-related complications as well as maternal deaths. For that reason, there was need to evaluate the quality of obstetric care offered under the FMS policy in order to establish whether the desired impact of the policy had been achieved. The MNM approach that was employed in this study is an ideal tool for the assessment of the quality of obstetric care.

Preliminary studies done after the introduction of the FMS showed an increase in the utilization of maternal services in the country which resulted in pressure on the existing resources. There was therefore the need for an objective assessment of the overall effect of the policy. This was achieved by comparing various aspects of MNM before and after the introduction of the policy. Ultimately with the insight gained by this comparison, interventions can be designed to bridge the gap between increased utilization of maternal health services and pressure on the available resources in order to advance maternal health in the country.

Data on MNM in Kenya is very scarce. This is despite MNM being a suitable approach for monitoring the implementation of critical interventions in maternal health care. This

study offered a baseline assessment of quality of obstetric care at a county referral hospital, using a standardized method proposed by the WHO for the quality of care assessment. The standardization of data allows for comparability within the same setting over time as well as across various settings. The study can therefore be scaled up to the districts and the entire health system in order to generate more information and establish trends in maternal morbidity, which shall be useful in implementing other critical interventions in maternal health care.

1.5 NULL HYPOTHESIS

FMS policy has not had any effect on MNM morbidity, among women who delivered in Embu County referral Hospital 2 years after and 2 years before the policy introduction.

1.6RESEARCH QUESTION

What is the Effect of Free Maternal Services (FMS) Policy on MNM morbidity, among women who delivered in Embu County Referral Hospital 2 years after and 2 years before the policy introduction?

1.7 STUDY OBJECTIVES

Broad Objective:

To determine the effect of FMS policy on MNM morbidity among women who delivered at Embu County Referral Hospital, 2 years after and 2 years before the FMS policy introduction.

Specific Objectives:

Among women who delivered in Embu County referral Hospital 2 years before and 2 years after the policy introduction:

- 1. To evaluate the incidence of Maternal Near Miss.
- To Compare the causes of Potentially Life-Threatening Conditions (PTLCs) and MNMs
- 3. To Compare the Maternal Near Miss Indicators.

CHAPTER TWO

RESEARCH METHODOLOGY

2.1 STUDY DESIGN

A retrospective quasi-experimental study of the pre- and post- design using patient files. Treatment group were records of 186 women who had any near miss morbidity after the introduction of free maternity services. Comparison group were records of 185 women who had any near miss morbidity before the introduction of free maternity services. The pre-period was between October 2010 to May 2013 and the post-period between June 2014 to May 2016.

2.2 STUDY SETTING

Embu County Referral Hospital in the eastern region of Kenya. It is the largest hospital in the region, whose catchment area extends to the neighboring four counties. The maternity unit offers 24-hour comprehensive obstetric care. During the study period, there was one antenatal, one labor and two postnatal wards. There was one consistent maternity theatre available 24 hours a day with a second emergency theatre availed on request. Staffing remained consistent during the study period- two Obstetricians, three Medical Officers, three Medical officer interns, three Clinical officer interns and 15 approximately midwives. Deliveries conducted annually were about 3500 in the preperiod and 4800 in the post period. The hospital also houses the regional blood bank. There were no critical care or dialysis services, therefore patients who required them were referred to tertiary facilities. Women with early complications of pregnancy and readmissions with postpartum complications were admitted to the acute gynecology ward, whose services were not covered under FMS.

2.3 STUDY POPULATION

Women offered maternity services at Embu County Referral Hospital between 1st Oct 2010 to 31st May 2016.

2.4SAMPLE SIZE CALCULATION AND SAMPLING PROCEDURES

Using the Fox et al formulafor inferential studies where chi-square test of significance is used(27).

 $N = k \times \underline{P_1(1 - P_1) + P_2(1 - P_2)}$

 $(P_1 - P_2)^2$

• k = This is a constant which is dependent on the value of α and β used.

=7.9 (when α = 0.05; β = 0.2)

- Statistical significance of 5% was used (α=0.05)
- Statistical power of 80% was used (β=0.2)

- P₁ = Proportion of SMOs on standard care (before FMS) = 4.7% (Owiti 2009)
- P₂ = Proportion of SMOs with good quality of care (After FMS) = 0.75% (WHO 2009)

The calculated sample size was 172 records of women with maternal near misses, with a contingency of 10% added to compensate for incomplete records, giving a total of 189. Random sampling of months without replacement was done for each period. In the pre-period and post periods, 185 and 186 records were abstracted respectively.

2.5INCLUSION CRITERIA

Women who met the World Health Organization maternal near miss criteria were included in the study(as the admission diagnosis or developed the condition during their hospital stay). Two steps were employed in case identification.

1st step involved identification of women with PLTCs; those with severe maternal complications and those undergoing critical interventions (*Figure 2*). The 2nd step identified the near misses (those with organ dysfunction) using clinical, lab and management proxies of organ dysfunction (*Table 2*).

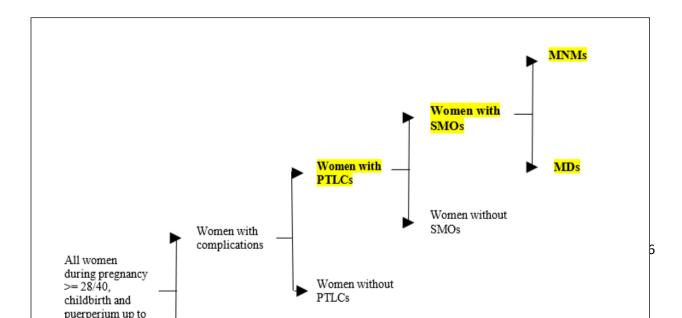


Figure 2: Maternal Near Miss Screening Process

Women with Potentially Life -Threatening Conditions were those with:

- a. Severe Maternal Complications:
 - Severe PPH
 - Severe pre-eclampsia
 - Eclampsia
 - Sepsis and severe systemic infection
 - Ruptured uterus
- b. Women undergoing critical interventions
 - Referrals out for ICU care*
 - Laparotomy (Includes hysterectomy and excludes C/S)
 - Use of blood products

Women with maternal near misses are those who suffered organ dysfunction(*Table 2*) but survived death.

Contextual modifications made to the WHO criteria were: a) lower threshold of transfusion to two units – this was found to have a higher specificity for maternal near miss cases in the low resource setting where blood availability is limited(28) and; b) since the facility did not have a critical care and renal dialysis units, women who needed these services and were referred out were considered to have potentially life-threatening conditions. Women with gestation below the viability threshold of 28 weeks were excluded. This is because these patients were admitted to the acute gynecology ward, whose services are outside the scope of free maternity care. Also excluded were

records of women who received care between July 2013 to May 2014, which was considered the period of transition.

Additional data to be collected was: Maternal deaths, when the SMO occurred as 12 hours before or after hospital admission. Data of time of occurrence of the SMO helpedto evaluate the role of 1st and 2nd delays as well as the intra hospital care (3rd delay). Total number of deliveries and live births were also noted for each study period. Of note is that most records of maternal deaths were missing and therefore not included in the analysis.

2.6DATA COLLECTION AND DATA MANAGEMENT

- Four research assistants were thoroughly trained on the study protocol for data collection.
- Data from the sampled files of those women fulfilling the inclusion criteria were entered into pre-structured data collection forms.
- The names of the patients were not entered in the data collection forms for confidentiality, instead code numbers were issued for each entry and key code.
 After the initial entry of data, the principal investigator counter-checked proper data entry, for every 5 entries.
- A database was then constituted in excel, whereby data from each form was enteredby the principal investigator. Data cleaning was then done by for errors such as duplication of forms. The data was then coded and transferred to SPSS software version 24 for analysis.
- The database was protected using an encrypted password that was accessible to the principal investigator and the statistician only.

2.7DATA VARIABLES

The data variables collected in this study are as shown in Figure 3 below.

Objective 1: (Establish Prevalence of MNMs)					
Independent variable:	Free Maternity Services				
Dependent variables:	Number of live births Numbers of maternal deaths Number of near misses				
Objective 2: (Evaluate Causes of PTLCs and MNMs)					
Independent variable:	Free Maternity services				
Dependent variables:	Severe maternal complications Use of critical interventions* Contributory causes				
Objective 3: (MNM Indicators)					
Independent variables:	Free maternity Services				
Dependent variables:	Overall MNM indicators Hospital access indicators Intrahospital care indicators Referrals out				
*For those not available at the interventions will be included.	facility, files of patient referred elsewhere for these				

Figure 3: Data Variables

2.10DATA ANALYSIS

Descriptive statistics in form of percentages were used to summarize the data values for the study variables. Comparative statistics were used to establish the significance of any differences in the variables after and before introduction of FMS. Chi-square test was used with p-value <0.05 considered significant. The analysis was done using the SPSS computer software version 24.

2.11STUDY LIMITATIONS

The limitations encountered in this study were:

- 1. Missing data. Being a retrospective study, some files as well as information from files was missed. We however increased the sample size required for the study from 172 to 185 (pre-period) and 186 (post-period)to minimize the effect of missing data. We also excluded analysis involving maternal deaths as most MD files were missing thereby reducing the risk of information bias.
- 2. The study did not capture near misses from early pregnancy complications as well as late onset sepsis. This is because these cases are normally managed in the acute gynecology ward, whose services were not covered under free maternity services. We therefore recommend a follow up study that include these complications.

2.12ETHICS APPROVAL

Ethics and administrative approvals were obtained from the Kenyatta National Hospital/University of Nairobi- Ethics Review Committee (P566/08/2016) and Embu County referral hospital respectively.

2.13DATA DISSEMINATION

The findings of this study will be shared through meetings and availing copies of the findings to the following: Embu level V Hospital staff and management, Ministry of Health- both national and the Embu County, KNH/UON ERC, KNH/UON Department of Obstetrics and Gynecology. In addition, a manuscript and a policy briefhave been preparedforpublishing ina peer-reviewed journal.

CHAPTER THREE

RESULTS

3.1 STUDY FLOW

A total of 15774 files were reviewed- 8441 in the pre- period and 7317 in the postperiod. In the pre- period, 19 files were excluded (gestation <28) leaving a total of **8422** files for screening. Of these,**8166** of these were live births. In the post- period, a total of 7333 files were reviewed out of which 16 files were excluded (gestation< 28 weeks) leaving a total of **7317**files.**7070** of these were live births.

In the pre- period the proportion of PTLCs was 5.2% (**435/8422**). Out of these, there were 2 MDs and **185** MNMs. Some of the MD files for this period were missing and therefore no further analysis involving MDs. In the post- period the proportion of PTLCs was 6.6% (**481/7317**). Out of these, 4 were MDs and **186** MNMs. Again, some of the MD files were missing and therefore no further analysis on MDs done (*Figure 4*).

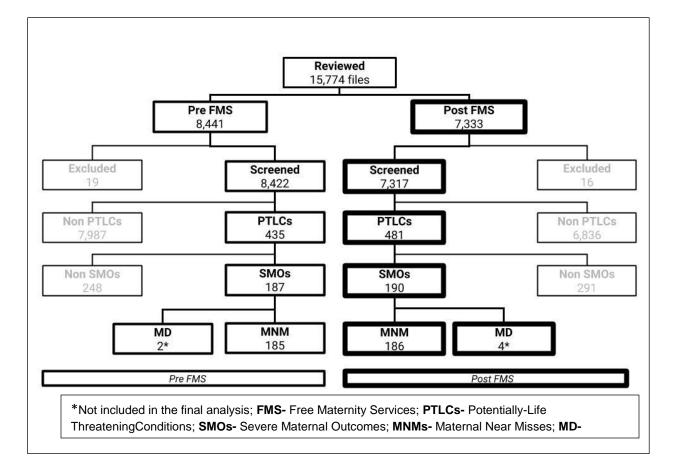


Figure 4: Study Flow of Records of Women with Maternal Near Miss Morbidity at Embu County Referral Hospital Pre (Oct 2010 – June 2013) and Post (June 2014 – May 2016) Introduction of Free Maternity Services

3.2 INCIDENCE OF PTLCS AND MNMS

The overall incidence of incidence of PTLCs was 5.1%. The incidence was lower in the pre-period and 5.2%, compared with the post period at 6.6%. For the near misses, the overall incidence was 2.4%. Similarly, the incidence was lower in the pre-period compared to the post-period, at 2.2% and 2.5% respectively *(Table 3).*

Hematologic dysfunction accounted for most of the MNM cases (89.9%), with no significant differences between the two study periods (93.6% Pre vs 86.3% Post; p-value 0.296). The second commonest organ dysfunction was cardiovascular system (16.2%) and the least common was hepatic dysfunction (0.5%).

Table 3: Incidence of PTLCs and MNMs at Embu County Referral Hospital Pre (Oct 2010-
June 2013) and Post (June 2014-May 2016) Introduction of Free Maternity Services

	Overall	Pre-Period	Post-Period	
	N=15739	N=8422	N=7317	
	n (%)	n (%)	n (%)	
PTLCs	916 (5.1)	435 (5.2)	481 (6.6)	
MNMs	371 (2.4)	185 (2.2)	186 (2.5)	

PTLCs- Potentially Life-Threatening Conditions; MNMs-Maternal Near Misses

Multiple organ dysfunction accounted for 17.2% of all women with organ dysfunction;

15.5% in the pre-period and 18.9% in the post-period(*Table 4*)

 Table 4:Dysfunctional Organ System Among Women with Severe Maternal Outcomes at Embu

 County Referral Hospital Pre (Oct 2010-June 2013) and Post (June 2014-May 2016) Introduction of

 Free Maternity Services

	Overall N= 377		Pre-P N= 18		Post-F N= 190		P-value*
Dysfunctional Organ System	n	(%)	n	(%)	n	(%)	
Hematologic	339	(89.9)	175	(93.6)	164	(86.3)	0.296
Cardiovascular	61	(16.2)	26	(13.9)	35	(18.4)	0.314
Respiratory	13	(3.4)	8	(4.3)	5	(2.6)	0.532
Uterine	11	(2.9)	5	(2.7)	6	(3.2)	0.838
Renal	9	(2.4)	1	(0.5)	8	(4.2)	0.052
Neurologic	7	(1.9)	1	(0.5)	6	(3.2)	0.139
Hepatic	2	(0.5)	0	(0)	2	(1.1)	0.360
Multiple Organ	65	(17.2)	29	(15.5)	36	(18.9)	

*X² Pierson Chi-square test of significance

3.3 CAUSES OF PTLCS AND MNMS

The leading cause of both PTLCs and MNMs in both periods wassevere PPH(*Table 5*). In the pre- period, severe PPH contributed to 60.7% of PTLCs and the proportion significantly increased after introduction of FMS (60.7% vs 71.1%; p-value 0.003). Similarly, among MNMs the proportion of women with severe PPH significantly increased in the post- period (80.0% vs 91.0% p-value 0.005). Severe preeclampsia was the second commonest cause of both PTLCs and MNMs in this period. The proportion of women with severe preeclampsia reduced significantly in the post-period: PTLCs 31.0% vs 23.9% p-value 0.002 and MNMs 13.0% vs 6.5% p-value 0.029.

	PTLCs				MNMs		
	Pre- Period N=435	Post-Period N=481	P-value*	Pre-Period N=185	Post-period N=186	P-value*	
Cause	n (%)	n (%)		n (%)	n (%)		
Direct Causes							
Severe PPH Severe Preeclampsia Ruptured Uterus Eclampsia Severe sepsis	264 (60.7) 135 (31.0) 24 (5.5) 22 (5.0) 8(1.8)	342 (71.1) 115 (23.9) 24 (5.0) 16 (3.3) 1 (0.2)	0.003 0.002 0.551 0.423 0.043	148 (80) 24 (13) 15 (8.1) 8 (4.3) 4 (2.2)	170 (91.0) 12 (6.5) 18 (9.7) 4 (2.2) 0 (0.0)	0.005 0.029 0.523 0.523 N/A	
Contributory Causes							
Anemia Previous C/S Obstructed labor HIV/AIDS	135 (28.1) 123 (25.6) 31 (6.9) 16 (3.3)	154 (35.4) 117 (26.9) 17 (3.9) 16 (3.7)	0.022 0.649 0.085 0.772	81 (43.8) 64 (34.6) 10 (5.4) 7 (3.8)	56 (30.1) 64 (33.4) 12 (6.5) 8 (4.3)	0.017 0.970 0.670 0.800	

 Table 5: Causes of PTLCs and MNMs at Embu County Referral Hospital Pre (Oct 2010-June 2013) and Post (June 2014-May 2016) Introduction of Free Maternity Services

*X² Pierson Chi-square test of significance;**PTLCs-** Potentially- Life Threatening Conditions; **MNMs-** Maternal Near Misses; **PPH-** Post Partum Hemorrhage;**C/S-** Caesarean Section; **NA-**Not applicable

Cases of ruptured uterus among the MNMs increased in the post- period (8.1% vs 9.7%) while those of eclampsiareduced (4.3% vs 2.2%), but these differences were statistically insignificant (p-value for both0.523) For severe sepsis, there was a reduction in the post-period, and this was significant among the PTLCs (1.8% vs 0.2% p-value 0.043). There were no cases of severe sepsis among the MNMs in the post-period.

Among the contributory causes of MNMs, anemia was the leading contributor in both periods. However, there was a significant decrease in anemia cases after introduction of

FMS (43.8% vs 30.1%; p-value 0.017). Previous C/S cases reduced (34.6% vs 33.4%) but Obstructed labor (5.4% vs 6.5%) and HIV cases increased after FMS (3.8% vs

4.3%). These differences were however not statistically significant (p-value 0.970, 0.670 and 0.800 respectively).

3.4 USE OF CRITICAL INTERVENTIONS

As shown on table 6, there was an increase in use of blood products (68.2% in preperiod vs 78.5% in post-period; p-value 0.000) among the PTLCs. Laparotomy for ruptured uterus was also increased the post- period (4.8% vs 4.1%) but this difference was statistically insignificant (p-value 0.899). The proportion of women referred out for various critical interventions reduced in the post- period (0.8% vs 1.2%). This difference was however not statistically significant (p-value 0.058)

Intervention	Pre- Period N= 435	Post-Period N= 481	P-value*	
	n (%)	n (%)		
Use of blood products	296 (68.2)	375 (78.5)	0.000	
Laparotomy	18 (4.1)	18 (4.8)	0.899	
Referrals out	5 (1.2)	4 (0.8)	0.0582	

 Table 6: Use of Critical Interventions at Embu County Referral Hospital Pre (Oct 2010-June 2013)

 and Post (June 2014-May 2016) Introduction of Free Maternity Services

*X² Pierson Chi-square test of significance

3.5 MNM INDICATORS

Severe Maternal Outcome ratio (SMOR) was higher in the Post- period at 26.90/1000 LBs vs 22.90/1000 live births. Maternal Near Miss ratio (MNMR) also increased in the post-periodfrom 22.70 /1000 to 26.30/ 1000 live births (LBs). Maternal Near Miss: Maternal Death ratio and the mortality index (MI) were not calculated in this study, as some of the maternal death (MD) records were missing hence a potential for bias. On

the hospital access indicators, the proportion of Severe Maternal Outcomes within 12 hours of hospital admission (SMO12) were similar in both periods; 0.66 in pre-period vs 0.69 in post-period. The proportion of SMOs coming from other facilities decreased after FMS (36.3% vs 27.5%), but this finding was statistically insignificant (p-value 0.131). On intra-hospital care indicators, the Intra-hospital SMOs reduced in the post-period (35.0% vs 31.0%). The intra-hospital SMO rate was8.20/1000 LBs in the pre- period and 8.35/1000 LBs in the post-period with a p-value of 0.792. *(Table 7)*.

 Table 7: MNM Indicators at Embu County Referral Hospital Pre (Oct 2010-June 2013) and Post

 (June 2014-May 2016) Introduction of Free Maternity Services

Indicator	Pre- Period	Post- Period	P-Value*
Overall MNM Indicators Severe Maternal Outcome Ratio (SMOR - per 1000 LBs)	22.9	26.9	
Maternal Near Miss ratio (MNMR- per 1000 LBs)	22.7	26.3	
Hospital Access Indicators SMOs within 12 hrs of hospital stay (SMO12)	124	131	
Proportion of SMO12 among all SMOs	0.66	0.69	
(SMO12/All SMOs) Proportion of SMOs coming from other facilities (%SMO12)	36.3	27.5	0.131
Intrahospital Care indicators Intrahospital SMO cases (%)	35.1	31.0	0.792
Intrahospital SMO rate (per 1000LBs)	8.20	8.35	

MNM- Maternal Near Miss; **SMOR-** Severe Maternal Outcome Ratio; **LBs-** Live Births; **SMO-**Severe Maternal Outcome; *X² Pierson Chi-square test of significance

CHAPTER FOUR

DISCUSSION

The incidence of PTLCs in both periods are similar to those found in MNM studies of developing countries (5.9% - 10.3%) but much higher than those found in Malaysia (1.8%) which is a developed country(24,29,30). This likely reflects a similarity in the

quality of obstetric care based on the resource availability. Similarly, the MNM infound in our study (2.2% and 2.5% in the pre and post- periods respectively) are within the range found in most studies across the globe (0.4% - 3.3%). It was however much higher than the 0.8% global average(21). This implies that the quality of obstetric care at the ECRH is below average with need for improvement.

4.1 CAUSES OF PTLCS AND MNMS

Severe PPH was the main cause of PTLCs and MNMs in both periods, comparable to global data(1). Studies within low resource settings vary- in Uganda and Ethiopia, hypertensive diseases were the main contributors while in Rwanda hemorrhage was the leading cause(31–33). Data from the Confidential Enquiry into Maternal Deaths (CEMD) in Kenya found PPH to be the leading cause of maternal death (39.7%), which correlates to our study finding(34). Compared to the CEMD, the proportion found in our study (80.0% and 91.0%) was much higher. This was attributed to the fact that our study did not include complications of early pregnancy as they were not covered under FMS, therefore we had a narrower range of complications. This was a limitation for this study but the exclusion reduced information bias. The increase noted after introduction of free maternity services can be attributed to: i) The increase in number of women delivering at the facility may have overwhelmed the staff, compromising intrapartum and immediate post-partum care. A study done at Nakuru county referral hospital in Kenya found staff shortage to be a challenge faced after FMS introduction leading to a compromise in quality of care offered (6). ii) Women with severe PPH who would otherwise have delivered at home or in lower level facilities accessed care at the county referral hospital after removal of the cost barrier. Most studies done on access of services after removal of user fees confirm increase in access to hospital deliveries(7).

The reduced proportion of women with preeclampsia and anemia observed after introduction of free maternity services was attributed to an increase in ANC attendance, as was documented in various studies carried out in the country after free maternity services(5,6). Blood pressure monitoring is a preventive intervention during ANC visits. This aids in early diagnosis of preeclampsia and referral for management before evolving into severe disease. Iron/folate supplementation, also done during ANC visit, is a well -known strategy for reducing anemia in pregnancy (35). This underscores the need to strengthen ANC services in the country, in order to sustain the benefits of improved uptake as seen in this study.

No cases of severe sepsis were found in the post-period. This is most likely because in this period women got discharged promptly postpartum due to the crowding in the wards. In case of readmission, it was to the acute gynecology ward which wasn't covered under FMS. We therefore recommend a follow up study looking into cases of severe sepsis.

The proportion of women with obstructed labor increased almost two-fold after FMSamong the PTLCs and similarly an increase was seen among the MNMs, although the increase was marginal. For both, the increase was not statistically significant. The doubling could also be an indication of stretched resources in the period after FMS introduction and therefore poor labor management.

29

4.2 USE OF CRITICAL INTERVENTIONS

The proportion of women who were transfused increased in the post-period (78.5% vs 68.2%), which mirrored the increase in seen in cases of severe PPH. In Kenya blood shortage contributes to one third of maternal deaths due to hemorrhage(34). This underscores the need to ensure adequate blood supplies in maternity units in order to optimize management of women with hemorrhage. Some of the challenges faced in adequate blood provision in Sub-Saharan Africa include poor set-up of blood centers, transport and laboratory systems as well as shortage of voluntary donors(36).

4.3 MNM INDICATORS

4.3.1 Overall MNM indicators

The study found an increase in both MNMR(from 22.7/1000 to 26.3 /1000 LBs) and SMOR (from 22.90/1000 to 26.90/1000 LBs) in the post-period. According to WHO, both indices estimate the amount of care/resources needed to manage maternal complications (8). This confirms the need for increase in resources in the era of FMS. A systematic review found that an increase in supplies and human resource is required to match the increase in service utilization after user fee abolishment in low resource settings (7). Human resource optimization is particularly emphasized for maternal health promotion in these settings (37). The recent CEMD in Kenya found that health-care worker related factors contribute to three quarters of maternal deaths in Kenya (34). This therefore highlights an urgent need to audit human resource in the maternity unit; skills, training, numbers, support structures, motivation and attitude. This will inform the specific aspects that need to be optimized in the setting of free maternity services.

30

4.3.2 Hospital Access Indicators

SMO12 refers to the proportion of SMOs that occurred within 12 hrs of hospital admission, with an underlying assumption that they represent the 1st and 2nd delay. The slight increase noted in our study in the post-period (69% from 66%) is contrary to the expectation that the elimination of user fees under the FMS would lead to a reduction in the 1st and 2nd delays. This could be due to other barriers of access that might not have been addressed by user fee elimination. A study carried out in Kenya on implementation of FMS noted that high cost of transportation along with perceived poor quality of services (especially in the smaller facilities like the health centers and dispensaries which are nearer to them) was a barrier to access(38). In this regard, there is need to further evaluate these barriers and devise solutions so as to realize the full benefits of FMS.

4.3.3 Intra-hospital Care Indicators

Intra-hospital SMOs, intra-hospital SMO rate and SMOs referred outare proxies for intra-hospital quality of care. Our study found no significant changes in the three indicators implying that the overall intra-hospital care did not change with the introduction of FMS. As much as user fee abolition has the potential to improve the quality of care, evidence shows that this is rarely achieved. This is because other complimentary interventions such as resource optimization to match the increased utilization are usually neglected, like in the Kenyan case(39). A comprehensive approach should therefore be taken on the implementation of FMS in order to achieve improvement in quality of hospital care.

31

CHAPTER FIVE

CONCLUSIONS AND RECOMMENDATIONS

5.1 CONCLUSIONS

This study found that introduction of free maternity services had mixed effect on maternal near miss morbidity at Embu county referral hospital in Kenya. Gains were made in reduction of severe preeclampsia and anemia cases and this underscores the benefits of improved access to antenatal care. The major loss identified was an increase in cases of severe PPH, which is known to be the main cause of maternal mortality globally and locally. The need for blood transfusion also increased, which mirrored the increase seen in severe PPH.

The MNM indicators in this study suggest that the first and second delays in access did not improve as expected, after removal of the cost barrier. In addition, these indicators showed that the resources required to manage severe complications of childbirth were suboptimal in the facility.

5.2 RECOMMENDATIONS

- There is need to support the ANC clinics and services further so as to sustain the reduction in preeclampsia and anemia in pregnancy. Prevention and early management of these two conditions should be emphasized because as much there was a significant decline was noted, they are still significant causes of maternal near miss morbidity at the facility.
- 2. There should be focused efforts on prevention and management of PPHin order to reduce morbidity due to severe PPH, whose contribution to maternal near miss

morbidity was noted to have a significant increase after introduction of FMS in the country.

- 3. Studies on effect of free maternity services on maternal sepsis and severe morbidity arising from complications of early pregnancy should be carried out. Our study did not inform on these complications, which are significant contributor of maternal near miss morbidity globally.
- 4. To meet the increased demand for blood products, the national blood transfusion services should be audited for existing gaps that require support so as to optimize care of women with maternal near miss morbidities.
- At the policy- making level, there is need to evaluate and address other barriers of hospital access other than cost so as to optimize access and utilization of the free maternity services.
- 6. Various resources at the facilities offering FMS should be audited to aid in identification of specific gaps in the existing resources. This will facilitate optimization of these resources so as to improve the overall quality of care.

REFERENCES

- 1. Souza JP, Gülmezoglu AM, Vogel J, Carroli G, Lumbiganon P, Qureshi Z, et al. Moving beyond essential interventions for reduction of maternal mortality (the WHO Multicountry Survey on Maternal and Newborn Health): A cross-sectional study. Vol. 381, The Lancet. 2013. p. 1747–55.
- 2. Kyei-Nimakoh M, Carolan-Olah M, McCann T V. Access barriers to obstetric care at health facilities in sub-Saharan Africa-a systematic review. Syst Rev. 2017;6(1):1–16.
- 3. Kenya National Bureau of Statistics (KNBS); ORC Macro. Kenya Demographic and Health Survey 2008-09. Heal (San Fr. 2010;1–314.
- 4. United States Agency for international Development. Maternal & Newborn Health Care in Kenya. 2013;90. Available from: http://www.healthpolicyproject.com/ns/docs/MaternalNewbornHealthCare _Kenya_oct2013.pdf
- 5. Health MOF. Ministry of Health Status of Implementation of Free Maternity Services (Fms) Program in the Devolved Health System in Kenya. 2015;
- 6. Wamalwa EW. Implementation challenges of free maternity services policy in kenya: The health workers' perspective. Pan Afr Med J. 2015;22:1–5.
- 7. Hatt LE, Makinen M, Madhavan S, Conlon CM. Effects of user fee exemptions on the provision and use of maternal health services: A review of literature. J Heal Popul Nutr. 2013;31(4 SUPPL.2).
- 8. World Health Organization. The WHO near-miss approach for maternal health. 2011;29. Available from: http://apps.who.int/iris/bitstream/10665/44692/1/9789241502221_eng.pdf
- 9. The pattern of severe maternal and neonatal outcomes at Kenyatta National Hospital, after and before the introduction of Free Maternity Services. A Quasi-Experimental Study. A thesis submitted in partial fulfillment of the requirements for the degree o. 2013;
- 10. World Bank. Over 99 percent of maternal deaths occur in developing countries [Internet]. World Bank. 2012. Available from: http://data.worldbank.org/news/over-99-percent-of-maternal-deaths-occur-in-developing-countries
- 11. Group WB. Trends in Maternal Mortality: 1990 to 2015. 2015;
- 12. J.B.O.OYIEKE SO and CSK. MILLENNIUM DEVELOPMENT GOAL 5: A REVIEW OF MATERNAL MORTALITY AT THE KENYATTA NATIONAL HOSPITAL, NAIROBI J.B.O. OYIEKE, S. OBORE and C.S. KIGONDU. East Afr Med J. 2006;83(1):4–9.
- 13. Yego F, D'Este C, Byles J, Williams JS, Nyongesa P. Risk factors for maternal mortality in a Tertiary Hospital in Kenya: a case control study. BMC Pregnancy Childbirth [Internet]. 2014;14:38. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=medl&AN=24447 854 http://sfx.scholarsportal.info/uhn?sid=OVID:medline&id=pmid:24447854&id=doi:10.1186/1471-2393-14-38&issn=1471-2393&isbn=&volume=14&issue=1&spage=38&pages=38&date=2014&
- 14. Wagstaff A, Claeson M, Hecht RM, Gottret P. Chapter 9 Millennium Development Goals for Health : What Will It Take to Accelerate Progress ? In: Health (San Francisco). 2003. p. 181–94.
- 15. THE MILLENNIUM DEVELOPMENT GOALS FOR HEALTH.
- 16. Thaddeus S, Maine D. Too far to walk: Maternal mortality in context. Soc Sci Med. 1994;38(8):1091–110.
- 17. KNBS. Key Indicators 2014 Kenya Demographic and Health Survey. 2015;

- Asante F, Chikwama C, Daniels A, Armar-Klemesu M. Evaluating the economic outcomes of the policy of fee exemption for maternal delivery care in ghana. Ghana Med J [Internet]. 2007 Sep [cited 2016 Apr 27];41(3):110–7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/18470328
- 19. Say L, Souza JP, Pattinson RC. Maternal near miss--towards a standard tool for monitoring quality of maternal health care. Best Pract Res Clin Obstet Gynaecol [Internet]. 2009;23(3):287–96. Available from: http://www.sciencedirect.com/science/article/pii/S152169340900008X
- 20. van den Akker T, Beltman J, Leyten J, Mwagomba B, Meguid T, Stekelenburg J, et al. The WHO Maternal Near Miss Approach: Consequences at Malawian District Level. Vol. 8, PLoS ONE. 2013.
- 21. Sanjeev K. Gupta DKPRTRGAKSRSRPLAPGCL. Impact of Janani Suraksha Yojana on Institutional Delivery Rate and Maternal Morbidity and Mortality: An Observational Study in India. J Health Popul Nutr. 2012;30(4):464.
- 22. Souza JP, Cecatti JG, Parpinelli MA, Serruya SJ, Amaral E. Appropriate criteria for identification of near-miss maternal morbidity in tertiary care facilities: a cross sectional study. BMC Pregnancy Childbirth. 2007;7:20.
- 23. Souza JP, G??Imezoglu AM, Vogel J, Carroli G, Lumbiganon P, Qureshi Z, et al. Moving beyond essential interventions for reduction of maternal mortality (the WHO Multicountry Survey on Maternal and Newborn Health): A cross-sectional study. Vol. 381, The Lancet. 2013. p. 1747–55.
- 24. Ps R, Verma S, Rai L, Kumar P, Pai M V., Shetty J. "near miss" obstetric events and maternal deaths in a tertiary care hospital: An audit. J Pregnancy. 2013;2013.
- 25. Tunçalp Ö, Hindin MJ, Adu-Bonsaffoh K, Adanu RM. Assessment of maternal near-miss and quality of care in a hospital-based study in Accra, Ghana. Int J Gynecol Obstet [Internet]. 2013;123(1):58–63. Available from: http://dx.doi.org/10.1016/j.ijgo.2013.06.003
- 26. Oladapo O, Adetoro O, Ekele B, Chama C, Etuk S, Aboyeji A, et al. When getting there is not enough: a nationwide cross-sectional study of 998 maternal deaths and 1451 near-misses in public tertiary hospitals in a low-income country. BJOG An Int J Obstet Gynaecol [Internet]. 2015;n/a-n/a. Available from: http://doi.wiley.com/10.1111/1471-0528.13450
- 27. Fox N, Hunn A. Sampling and Sample Size Calculation. NIHR RDS East Midlands. 2009;1(1):1–4.
- 28. Nelissen E, Mduma E, Broerse J, Ersdal H, Evjen-Olsen B, van Roosmalen J, et al. Applicability of the WHO Maternal Near Miss Criteria in a Low-Resource Setting. PLoS One. 2013;8(4).
- 29. Norhayati MN, Nik Hazlina NH, Sulaiman Z, Azman MY. Severe maternal morbidity and near misses in tertiary hospitals, Kelantan, Malaysia: A cross-sectional study. BMC Public Health [Internet]. 2016;16(1):1–13. Available from: http://dx.doi.org/10.1186/s12889-016-2895-2
- Madeiro AP, Rufino AC, Lacerda érica Z, Brasil LG. Incidence and determinants of severe maternal morbidity: A transversal study in a referral hospital in Teresina, Piaui, Brazil. BMC Pregnancy Childbirth [Internet]. 2015;15(1):1–9. Available from: http://dx.doi.org/10.1186/s12884-015-0648-3
- 31. Kalisa R, Rulisa S, van den Akker T, van Roosmalen J. Maternal Near Miss and quality of care in a rural Rwandan hospital. BMC Pregnancy Childbirth [Internet]. 2016;16(1):1–8. Available from: http://dx.doi.org/10.1186/s12884-016-1119-1
- 32. Nakimuli A, Nakubulwa S, Kakaire O, Osinde MO, Mbalinda SN, Nabirye RC, et al. Maternal near misses from two referral hospitals in Uganda: A prospective cohort study on incidence, determinants and prognostic factors. BMC Pregnancy Childbirth [Internet]. 2016;16(1):1–10. Available from: http://dx.doi.org/10.1186/s12884-016-0811-5
- 33. Liyew EF, Yalew AW, Afework MF, Essén B. Incidence and causes of maternal near-miss in

selected hospitals of Addis Ababa, Ethiopia. PLoS One. 2017;12(6).

- 34. Ministry of Health Kenya. Saving Mothers ' Lives Confidential Inquiry into Maternal. 2017;
- 35. World Health Organization (WHO). WHO recommendations on antenatal care for a positive pregnancy experience WHO Library Cataloguing-in-Publication Data WHO recommendations on antenatal care for a positive pregnancy experience. World Heal Organ. 2016;10(January):176.
- 36. Kimani D, Mwangi J, Mwangi M, Bunnell R, Kellogg TA, Oluoch T, et al. Blood donors in Kenya: A comparison of voluntary and family replacement donors based on a population-based survey. Vox Sang. 2011;
- 37. Lassi ZS, Musavi NB, Maliqi B, Mansoor N, de Francisco A, Toure K, et al. Systematic review on human resources for health interventions to improve maternal health outcomes: Evidence from low- and middle-income countries. Hum Resour Health [Internet]. 2016;14(1). Available from: http://dx.doi.org/10.1186/s12960-016-0106-y
- 38. MWANGI, JONAH M. Effect of the Free Maternity Programme on the Access. 2017; Unpublished manuscript, United States International University Africa, Nairobi Kenya.Retrieved from http://erepo.usiu.ac.ke/handle/11732/17/broswe?value=Mwangi%2C+Dr.+Jonah+M.&type=author
- 39. Tama E, Molyneux T, Waweru E, Tsofa B, Barasa E. Examining the Implementation of the free maternity services in Kenya: a mixed methods process evaluation. Int J Health policy Manag. 2018;7(7):603-613. doi:10.15171/ijhpm.2017.135

APPENDIX

A DATA COLLECTION FORM

World Health Organization

Screening Questions

In questions 1 to 4 please specify:

0= The condition was not present during the hospital stay.

1= The condition was present at arrival or within 12hrs of hospital arrival.

2= The condition developed after 12hrs of hospital arrival.

3= Information not available/ unknown or not applicable.

1. Severe Complications/ Potentially Life-Threatening Conditions

□ A0 Severe PPH

- □ A1 Severe Preeclampsia
- 🗆 A2 Eclampsia
- □ A3 Sepsis/Severe systemic infection
- □ A4 Ruptured uterus

2. Critical Interventions or Referrals out.

□ B0 Use of blood products (includes any blood transfusion)

🗆 B1 Laparotomy

□ B2 Referrals out

3. Organ Dysfunction (Life Threatening Conditions)

C0 Cardiovascular dysfunction

(Shock, use of continuous vasoactive drugs, cardiac arrest, CPR, sever hypo perfusion; lactate >5mmol/L or >45mg/ dL, severe acidosis; Ph ,7.1

C1 Respiratory Dysfunction

(Acute cyanosis, gasping, severe tachypnea(RR>40 bpm), severe bradypnea (RR <6 bpm), severe hypoxemia (PaO₂/FiO₂ <200, O₂ saturation (<90% for RR \geq 60min), intubation or ventilation not related to anesthesia.

C2 Renal Dysfunction

(Oliguria non-responsive to fluids or diuretics, dialysis for ARF or severe azotemia; Creatinine ≥300umol/ml or

World Health Organization

4.Maternal Deaths

D0 Death during pregnancy, delivery or within 42 days of pregnancy termination.

□ D1 Death after 42 days of pregnancy termination

NB: If you answered "1" or "2" in any of the questions 1-4, please go to question 5. If you answered "0" to all the questions, do not answer further questions. The woman is not eligible. From question 5, if any information is not available, unknown or not applicable, fill with "5"

E1

5. Date of hospital admission E0

d	d	Μ	m	у	у	у	У

6. Date of delivery

d	d	Μ	m	У	У	У	У

7. Date of discharge or death E2

d	d	Μ	m	У	У	У	У

8. Final Mode of delivery E3

1= Vaginal delivery 4= Died/discharged still pregnant

2= Caesarean section 5= Unknown/ other

3= Laparotomy for ruptured uterus

9. Best estimate of gestational age in competed weeks E4

10. Neonatal vital status (0= Alive 1=Dead)

🗆 E5 At birth

E6 At discharge or at 7days if still in hospital

11. Underlying Causes of Death/Near Miss

- □ F0 Obstetric Hemorrhage
- □ F1 Hypertensive Disorders
- □ F2 Pregnancy-related infection

≥3.5mg/DI)

C3 Coagulation/ Hematologic Dysfunction

(Failure to form clots or massive transfusion of RBCs ≥5 units or severe acute thrombocytopenia; Platelet count of <50,000 /ml)

C4 Hepatic Dysfunction

(Jaundice in preeclampsia, severe acute hyperbilirubinemia; bilirubin >1000 umol/L or >6.0mg/Dl)

□C5 Neurologic Dysfunction

(Prolonged unconsciousness, coma lasting >12hrs, stroke, status epilepticus, uncontrollable fits, total paralysis)

□ C6 Uterine Dysfunction/Hysterectomy

Hemorrhage or infection leading to hysterectomy.

□ F3 Obstructed Labor

□ F4 Other Obstetric disease/complication

12. Contributory/ Associated Conditions

🗆 G0 Anemia

□ G1 HIV Infection

□ G2 Previous C/S

G3 Cardiac disease

G4 Obstructed Labor

□ G5 Other